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Original Article

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We rely on transcutaneous bilirubin in fast paced NICU as compared to serum total bilirubin, a comparative study

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ABSTRACT

BACKGROUND & OBJECTIVE: Neonatal hyperbilirubinemia is common and requires timely detection to prevent bilirubin-induced neurological dysfunction. Serum total bilirubin (STB) is the diagnostic gold standard but is invasive and time-consuming, whereas transcutaneous bilirubin (TcB) offers a rapid, non-invasive screening alternative. To evaluate the correlation and agreement between TcB and STB in late preterm and term neonates and to assess the reliability of TcB as a NICU screening tool.
METHODOLOGY: This cross-sectional analytical study was conducted at the Neonatal ICU of the Combined Military Hospital Kharian, Pakistan, from June to August 2025. During this period, 159 jaundiced neonates (35–37 weeks of gestational age) were included. TcB values obtained with the Dräger JM-105 were compared with simultaneous STB measurements. To enhance analysis, data were stratified by gestational and postnatal age. Statistical tests included Shapiro–Wilk, Pearson/Spearman correlation, Intraclass Correlation Coefficient (ICC), and Bland–Altman analysis.
RESULTS: Mean TcB was 267.14 ± 77.84 µmol/L, and STB was 276.78 ± 80.12 µmol/L. Furthermore, all subgroups showed strong positive correlations ($r/\rho > 0.78$, $p < 0.01$), and ICC values ranged from 0.757 to 0.952. Additionally, Bland–Altman analysis showed a mean bias of –9.64 µmol/L, with limits of agreement from –49.1 to +29.8 µmol/L.
CONCLUSION: Taken together, these findings indicate that TcB demonstrates strong correlation and good agreement with STB, supporting its use as a reliable screening tool in resource-limited NICUs. Nonetheless, the consistent underestimation and wide limits of agreement observed suggest TcB should not be used as a stand-alone diagnostic test. Therefore, STB confirmation is recommended when values approach treatment thresholds.
KEYWORDS: Jaundice, Neonatal, Hyperbilirubinemia, Bilirubin.

INTRODUCTION

The medical condition known as Hyperbilirubinemia results in elevated bilirubin levels, leading to newborn jaundice, which manifests as yellow discolouration of the skin and eyes [1,2]. Jaundice stands as a primary medical concern for neonates, affecting 80% of preterm infants born before 37 weeks of gestational age and 60% of full-term babies born at or after 37 weeks during their first week of life. Dangerously high bilirubin levels require ongoing medical monitoring, as they may lead to kernicterus [2,3].

The sudden appearance of jaundice during the first 24 hours of life indicates that bilirubin has risen rapidly due of red blood cell breakdown, blood incompatibilities, certain metabolic disorders, or infections. The affected infant needs emergency medical tests followed by prompt treatment interventions. If newborn bilirubin levels surpass clinical thresholds, doctors might need to start phototherapy as well as exchange transfusion to ensure the swift reduction of toxic bilirubin in the blood [4,5]. The reliability of visual jaundice assessment depends on an observer's capabilities and is not a standardized methodology, while the results can be affected by multiple external factors, including lighting and the observer's judgment about skin tone or the color of clothing. As a result, it is not a reliable standalone method for assessing bilirubin levels in newborns [6,7].

Quantifying total bilirubin in serum serves as the diagnostic benchmark for severe hyperbilirubinemia, enabling healthcare providers to differentiate between infants who need treatment (10% of cases) and those who do not (90% of cases). The testing method of STB includes specific challenges [8]. Bilirubin levels vary naturally throughout

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the course of each day, making it difficult to find suitable measurement times in busy NICU settings. Repetitive blood sampling for bilirubin testing poses clinical challenges due to cost implications and pain for the newborn, which reduces parental monitoring and participation and, at times, leads to missed bilirubin assessments [9].

The testing method of Transcutaneous bilirubinometry (TCB) offers a widely accepted, economical solution that enables safe, painless bilirubin measurement while avoiding the risks of trauma and infection for newborns. TCB devices offer laboratory-level bilirubin screening through their fast, non-invasive testing and gives easy accessibility to trends of bilirubin at the bedside. Owing to its portability, it is useful in post-natal visits and outpatient follow-ups [10,11].

The development of TCB technology over the last 35 years has resulted in smartphone-based diagnostic tools and photo threshold chart instruments, such as Bilistick BiliSpec BiliCam/BiliScan and Draeger's JM Instruments, as well as Philips BiliChek [12,13]. The analytic tools in these devices assess the yellowness of skin reflection to generate bilirubin estimation through color analysis [14].

Research shows that implementing the TCB screening process for newborns receiving NICU care and during outpatient check-ups and public health services leads to fewer blood tests and fewer cases of severe hyperbilirubinemia (≥20 mg/dL) [15]. Medical professionals require treating approximately one million global newborns who experience hyperbilirubinemia. The occurrence of kernicterus as a severe neurological consequence from untreated jaundice ranges from 2 to 42 cases throughout high-income countries per 100,000 live births. At Dr Soetomo General Hospital in Indonesia, researchers conducted a cohort study that showed that transcutaneous bilirubinometry (TCB) is an effective initial screening test for hyperbilirubinemia, especially among preterm newborns [16,17].

Also reduces the risk of exchange therapy. Although neonatal jaundice affects many infants, the accuracy of visual bilirubin assessment remains poorly studied. The accuracy and validity of improved transcutaneous bilirubin testing need to be evaluated in both term and preterm NICU patients operating in a fast-paced hospital environment [18,19]. This research aims to resolve discrepancies in the validity of transcutaneous bilirubinometry, which remains an unresolved issue in the current local context. Therefore, this study seeks to bridge problems in the local validity of TCB as a non-invasive option. The objective of the study was to evaluate the correlation and agreement between transcutaneous bilirubin (TcB) and serum total bilirubin (STB) in late preterm and term neonates and to determine whether TcB can be used reliably as a screening tool in NICU settings.

METHODOLOGY

This study was reviewed and approved by the Ethical Review Committee of the College of Physicians and Surgeons Pakistan (CPSP) (Ref No: CPSP/REU/PED-2022-052-7178). Permission to conduct the study was obtained from the Combined military hospital, Kharian, and all procedures adhered to the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from the parents or legal guardians of all participants. This cross-sectional study was conducted in the Department of Paediatrics, Combined Military Hospital, Kharian, over a period of three months from June to August 2025, after approval of the research article topic.

A sample size of 159 cases was collected using non-probability consecutive sampling, comparable to previously published study with strong correlation to TCB and STB [20]. TCB was measured using the Dräger JM-105 device. Late preterm neonates with gestational age (35–36+6 weeks) and term neonates with gestational age (37–37+6 weeks), aged 1–7 days of life, either gender. Preterm neonates with gestational age <35 weeks, term neonates with gestational age >38 weeks, presenting after the seventh day of life, undergoing phototherapy, or having received a blood transfusion were excluded. Additional exclusion criteria included sepsis, conjugated hyperbilirubinemia, blood group incompatibility, or any other acute illness.

The reference ranges for TCB and STB were based on NICE guidelines for neonatal jaundice. For 35–35+6 weeks: Day 1, 110–170 µmol/L; Day 2, 170–260 µmol/L; Day 3–7, 240–340 µmol/L. For 36–36+6 weeks: Day 1, 120–170 µmol/L; Day 2, 190–270 µmol/L; Day 3–7, 260–360 µmol/L. For 37–37+6 weeks: Day 1, 120–180 µmol/L; Day 2, 200–280 µmol/L; Day 3–7, 270–370 µmol/L. The study enrolled 159 eligible neonates from the NICU, inpatient wards, and outpatient department after ethical approval from the hospital committee. Informed consent was obtained from parents before data collection, which included neonate identification, age, gender, birth weight, gestational age, birth care and delivery method, and blood types of both mother and baby. All neonates in neonatology wards followed hospital-standard procedures to obtain blood for total bilirubin serum testing. TCB levels were measured from both the forehead and sternum sites before blood sampling. After testing, all information was recorded in the dedicated study Proforma.

The data were entered and analyzed through SPSS version 21. The Shapiro–Wilk test was applied to check the normality of the data. For quantitative variables, means ± SD were calculated. For comparison of preterm and term jaundiced neonates, a paired t-test or Wilcoxon signed-rank test was used as appropriate. Pearson's correlation coefficient was applied for normally distributed data, and Spearman's correlation coefficient for non-normal data. Agreement was assessed using the Intraclass Correlation Coefficient (ICC) and the Bland–Altman analysis. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 159 neonates born at 35, 36 and 37 weeks of gestation were included and stratified into nine subgroups based on gestational age and three postnatal age categories

(day 1, day 2 and beyond day 2 of life). Among 35-week neonates, 10 were assessed on day 1, 13 on day 2, and 25 beyond day 2 of life. In the 36-week gestational group, 9 neonates were evaluated on day 1, 9 on day 2 and the largest proportion, 35 neonates, beyond day 2. Similarly, among 37-week neonates, 9 were studied on day 1, 16 on day 2 and 33 beyond day 2 of life.

The mean transcutaneous bilirubin (TCB) level was 267.14 ± 77.84 µmol/L, whereas the mean serum total bilirubin (STB) level was 276.78 ± 80.12 µmol/L. Assessment of data distribution using the Shapiro–Wilk test showed that normality was maintained in the majority of gestational and postnatal age subgroups. However, significant departures from normal distribution were identified for STB values in neonates of 35 weeks' gestation on day of life (DOL) 2 and beyond DOL 2, for both TCB and STB in neonates of 36 weeks' gestation beyond DOL 2, for STB in neonates of 36 weeks' gestation on DOL 2, for STB in neonates of 37 weeks' gestation on DOL 1, and for both TCB and STB in neonates of 37 weeks' gestation beyond DOL 2. Parametric statistical tests were applied to normally distributed data, while non-parametric tests were used for non-normally distributed variables.

Table-I: Correlation Between TCB and STB.

Gestational Age and Day of Life	Number of Neonates	Correlation Method	Correlation Coefficient (r / ρ)	P-value
35 weeks, DOL1	10	Pearson	0.830	0.003
35 weeks, DOL2	13	Spearman	0.961	<0.001
35 weeks, >DOL2	25	Pearson	0.898	<0.001
36 weeks, DOL1	9	Pearson	0.955	<0.001
36 weeks, DOL2	9	Spearman	0.833	0.005
36 weeks, >DOL2	35	Spearman	0.947	<0.001
37 weeks, DOL1	9	Spearman	0.879	0.002
37 weeks, DOL2	16	Pearson	0.948	<0.001
37 weeks, >DOL2	33	Spearman	0.788	<0.001

Correlation Between TCB and STB

Correlation analysis demonstrated a strong positive association between TCB and STB across all subgroups. Pearson's or Spearman's correlation coefficients (depending on normality) are reported in Table I.

All correlations were highly statistically significant ($p < 0.01$); at the same time, most of them are very highly statistically significant ($p < 0.001$), with coefficients >0.78 across all subgroups, indicating a strong linear relationship between the two modalities.

Comparison and agreement between TCB and STB Values: Differences between TCB and STB values were assessed within each subgroup. Statistically significant differences between paired TCB and STB measurements were observed in six of the nine subgroups, while no statistically significant differences were identified in the remaining three subgroups. Agreement was assessed using the Intraclass Correlation Coefficient (ICC) with a two-way mixed-effects model for absolute agreement using the commonly accepted cut-offs from Koo & Li (2016). The overall ICC for the full dataset was ICC = 0.980, 95% CI: 0.972 to 0.986 and $p < 0.001$. Subgroup ICC values were also high, ranging from 0.757 to 0.952. The statistical comparison, ICC agreement and results are summarized below.

Table-II :Comparison and agreement between TCB and STB Values.

Gestation age (weeks)	Days of life	n	Mean TCB ± SD / Median (IQR)	Mean STB ± SD / Median (IQR)	Mean difference TCB- STB (95% Cl)	P-value	ICC (95% CI)
35	1	10	150.40 ±25.29	162.40 ±25.26	-12.00(-22.55, -1.45)	0.03	0.757 (0.184-0.937)
	2	13	222 (262.5-188.5)	230 (278.5-188)	-	0.196	0.943(0.823-0.982)
	>2	25	295.16±53.48	306.20±58.70	-11.04(-21.68, -0.39)	0.043	0.881(0.734-0.947)
36	1	9	142.89 ±26.64	155.67±31.36	-12.78(-20.37, -5.18)	0.005	0.865(0.073-0.974)
	2	9	188 (223.5-171)	188 (212-182.5)	-	0.405	0.931(0.740-0.984)
	>2	35	322 (369-270)	344 (278-378)	-	0.001	0.952(0.854-0.980)
37	1	9	181 (215-132.5)	190 (242-129.5)	-	0.767	0.855(0.507-0.965)
	2	16	259.06±35.61	268.56±36.88	-9.50(-15.79, -3.23)	0.006	0.919(0.627-0.976)
	>2	13	301 (380-282.5)	317 (389.5-281)	-	0.013	0.867(0.730-0.934)

There was good to excellent agreement between TCB and STB across all gestational ages and postnatal groups. Median (IQR) was used for non-normal data, and mean ± SD for normally distributed values.

Bland–Altman analysis was generated for each subgroup to visualise the agreement between TCB and STB, demonstrating a mean bias of –9.64 µmol/L (95% CI –12.80 to –6.49; $p < 0.001$), as shown in Figure-I.

Figure-I: shows good agreement between TCB and STB with a small negative bias and no evidence of proportional bias across the range of bilirubin values.

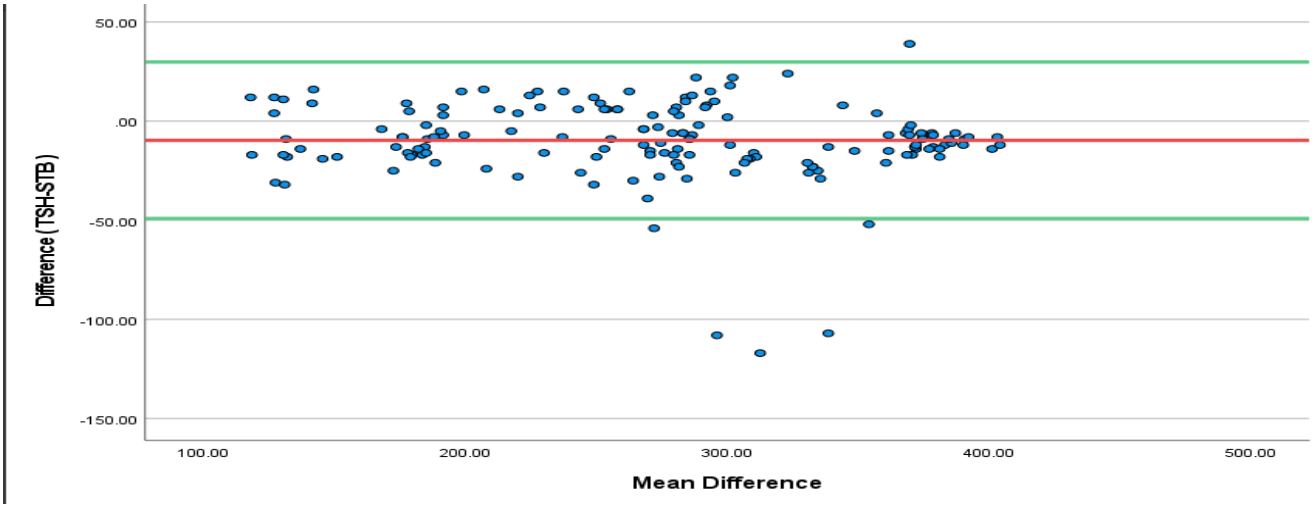

Table-III:Linear regression analysis between serum total bilirubin (STB) as independable variable and transcutaneous bilirubin (TCB) as dependable varibale.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
Constant	6.842	5.614		1.219	.225
STB	-.940	.019	-.968	48.260	.000

Simple linear regression analysis showed a linear relationship between serum total bilirubin and transcutaneous bilirubin measurements, with a regression slope of 0.940 ($p \leq 0.001$) and an intercept of 6.842 ($p=0.225$) . The coefficient of determination (R^2) was 0.937 (Table-III).

Analysis of proportional bias demonstrated a non-significant relationship between the difference in measurements and the mean bilirubin concentration (slope −0.012, $p = 0.372$) Table-IV.

Table-IV: Shows Regression of differences (TCB − STB) as dependent variable against mean bilirubin levels as independat variable.

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error			
Constant	-4.671	5.779		-0.808	.420
Mean	-.012	.014	-.071	-.895	.372

DISCUSSION

This study assessed the correlation, agreement, and systematic bias between transcutaneous bilirubin (TCB) and serum total bilirubin (STB) measurements in late preterm neonates born at 35–37 weeks of gestation, stratified by postnatal age. Our findings show a consistently strong positive correlation between TCB and STB across all gestational and postnatal age subgroups, with correlation coefficients exceeding 0.78 and reaching 0.96 [21]. These results suggest that TCB is a reliable predictor of STB levels in this population, consistent with multiple previous studies reporting strong correlations in both term and preterm infants [20,21].

Correlation and Agreement:

The overall ICC for the dataset was exceptionally high (0.980; 95% CI: 0.972–0.986), indicating excellent agreement between the two modalities. Subgroup analysis revealed that most ICC values fell into the "good" to "excellent" range, with the lowest agreement (ICC = 0.757) observed in 35-week infants on the first day of life. These findings are consistent with earlier research suggesting that agreement between TCB and STB improves with advancing postnatal age as skin maturity, perfusion, and bilirubin distribution stabilize.However, despite strong correlation and generally high ICC values, statistically significant differences between TCB and STB were observed in six of the nine subgroups. TCB systematically underestimated STB, particularly in DOL1 and >DOL2 groups, suggesting that while trends in bilirubin levels are well reflected by TCB, absolute values are lower. This is in agreement with prior studies reporting that TCB tends to underestimate STB in certain clinical contexts, possibly due to differences in skin thickness, melanin content, and the influence of dermal maturity on optical bilirubin measurement.

Bland–Altman Analysis and Clinical Implications:

Bland–Altman analysis revealed a mean bias of –9.64 µmol/L, confirming the tendency of TCB to yield lower values than STB. Although this mean difference was relatively small

compared to typical phototherapy thresholds, the limits of agreement (−49.1 to +29.8 μmol/L) were wide, indicating substantial individual variability. Importantly, the absence of proportional bias suggests that the underestimation was consistent across the bilirubin range, rather than varying with bilirubin severity [21].From a clinical perspective, this variability implies that while TCB is an effective screening tool for hyperbilirubinemia, it cannot completely replace STB measurement, particularly when bilirubin levels are near treatment thresholds. The strong correlation supports its utility for initial assessment and routine monitoring.

Influence of Gestational and Postnatal Age: Our results indicate that both gestational and postnatal age influence the performance of TCB. Agreement was generally weaker in earlier gestational ages and in the immediate postnatal period. This may reflect greater variability in skin maturity, hydration, and subcutaneous tissue composition in younger preterm infants, which can alter optical properties and affect transcutaneous readings [22,23].Additionally, the higher proportion of significant differences in the DOL1 and >DOL2 groups may be related to bilirubin kinetics, in which rapid rises or plateau phases may amplify discrepancies between modalities [24].

Comparison with Literature:

The present findings align with prior research indicating that TCB is a valid and non-invasive tool for hyperbilirubinemia screening in late preterm and term neonates. Studies by Engle et al , have similarly demonstrated strong correlation coefficients (>0.80) between TCB and STB, while cautioning against sole reliance on TCB in borderline cases [20,24]. Our observed bias and LoA are comparable to previous reports, further validating the reproducibility of these trends across populations .

Strengths and Limitations:

A major strength of this study is the stratification by both gestational and postnatal age, allowing a more nuanced understanding of TCB performance in late preterm infants. The use of multiple statistical approaches including correlation, ICC, and Bland–Altman analysis provides a robust assessment of both relative and absolute agreement. However, the study is limited by a modest sample size in some subgroups, particularly 35-week and 36-week infants on DOL1, which may limit statistical power and generalizability. Additionally, skin pigmentation and other individual factors affecting TCB accuracy were not specifically analyzed.

CONCLUSION

In summary, TCB demonstrates excellent correlation and good-to-excellent agreement with STB in late preterm neonates, although it consistently underestimates serum bilirubin values. While suitable for screening and follow-up monitoring, TCB cannot fully replace STB, especially when values are close to phototherapy thresholds. Clinical protocols should continue to incorporate confirmatory serum testing when management decisions depend on precise bilirubin measurement.

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Author Contributions:

Maryam: Substantial contributions to the conception and design of data for the work.
Talal Waqar : Interpretation of data for the work.
Muneeb Abid: Analysis of data for the work.
Muhammad Tayyab : Drafting the work.
Tehreem Fatima: Final approval of the version to be published.
Sidra ul Muntaha: Reviewing it critically for important intellectual content.

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