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Diagnostic Accuracy of Transcutaneous Bilirubinometry Versus Serum Bilirubin Level

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ABSTRACT

Objective: To assess the diagnostic accuracy of transcutaneous bilirubinometry over serum bilirubin level in newborns with hyperbilirubinemia.

Methodology: This cross-sectional study was conducted at Department of Neonatology, Children Hospital, PIMS Islamabad for six months from 01-09-20 to 28-02-21, included 150 jaundiced neonates of any gender over six months. Exclusion criteria included pre-treated hyperbilirubinemia, very premature or low birth weight infants, congenital abnormalities, or infants of jaundiced mothers. Post ethical clearance and parental consent, neonates were evaluated using the MBJ-20 transcutaneous bilirubinometer, with results compared to serum bilirubin levels. The study identified true and false diagnostic outcomes based on a ≥12 mg/dL bilirubin threshold, signifying phototherapy initiation. Data analysis was performed with SPSS 26.0, calculating sensitivity, specificity, and accuracy, and determining diagnostic congruence through Pearson's correlation and ROC AUC, with a significance threshold at $p<0.05$.

Results: The mean serum bilirubin level and transcutaneous bilirubin levels were 14.28 ± 2.21 mg/dL and 14.52 ± 2.72 mg/dL respectively, with a mean difference of 0.24± 1.38 mg/dL ($t(149) = 2.141$, $p = .034$). This difference demonstrating a statistically significant overestimation compared to serum bilirubin levels. The correlation between transcutaneous and serum bilirubin levels was strong ($r = 0.864$, $p < 0.0001$). For the 12 mg/dL phototherapy threshold, the transcutaneous method showed high sensitivity (95.59%) and specificity (78.57%), with an overall test accuracy of 94%. The Area Under the Curve (AUC) for the receiver operating characteristic was 0.962, indicating high diagnostic precision.

Conclusion: Transcutaneous bilirubinometry is a low-cost, noninvasive, and accurate screening test for hyperbilirubinemia with a high sensitivity specificity and positive predictive value (PPV).

Keywords: Hyperbilirubinemia, Neonatal jaundice, Transcutaneous bilirubin, Transcutaneous bilirubinometer.

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Introduction

Hyperbilirubinemia is a common and benign disease in infants that occurs due to immature hepatic function, polycythemia, gastrointestinal immaturity, sepsis, etc. Early neonatal hyperbilirubinemia is a frequent occurrence. In the first few days of life, 50 % of term and 80 % of preterm neonates have serum bilirubin levels more than 5 mg/dl.[1] In infants, persistent hyperbilirubinemia can cause irreversible damage to the central nervous system, leading to kernicterus. Early detection is vital for avoiding the consequences of kernicterus, which include cerebral palsy, deafness, dental deformities, vision loss, and personality disorders.[2] Therefore, precise bilirubin level measurement and severity assessment is an important aspect of screening

and management. According to the NICE guidelines, all newborns with apparent jaundice should have their bilirubin levels checked. The American Academy of Pediatrics and the Canadian Academy of Pediatrics advocated for screening all newborns before discharge. [3,4]

The most reliable and extensively used diagnostic approach for measuring bilirubin levels is serum bilirubin (TSB), however it requires a needle prick, which is an expensive and time-consuming process. It can cause infections, be stressful and agonizing for the neonate, and not receive immediate results.[5] Yamanouchi and colleagues originally presented transcutaneous bilirubinometry in 1980 as a rapid, convenient, and non-invasive screening method for hyperbilirubinemia. TcB uses the principle of reflectance photometry and colorimetry. TcB devices estimate SB by directing light into the neonatal skin and measuring the intensity of specific wavelengths. [(6)] Several studies have documented that transcutaneous bilirubinometry has a good correlation and reliability also in preterm infants. [1,5,7]

This study aims to resolve discrepancies in the accuracy of transcutaneous bilirubinometry, an area with limited data in the local context. Existing literature exhibits conflicting evidence regarding non-invasive bilirubin assessment, particularly in diverse populations. [7,8] By comparing transcutaneous readings with serum bilirubin levels, this research seeks to validate the reliability of non-invasive methods within the local demographic. Outcomes will directly inform clinical practices, potentially reducing the reliance on invasive procedures for neonatal jaundice evaluation. Findings will contribute to the enhancement of our understanding and the refinement of guidelines for assessing hyperbilirubinemia in neonates

Methodology

It was a cross sectional study conducted at the Department of Neonatology, Children Hospital, PIMS Islamabad for six months from 01-09-20 to 28-02-21. A non-probability consecutive sampling technique was used for sampling. A sample size of 150 cases was calculated with 95% confidence level, percentage of Hyperbilirubinemia, i.e., 31.7%, the sensitivity of transcutaneous bilirubinometry, i.e., 78.3% with margin of error 13% and specificity of transcutaneous bilirubinometry, i.e., 94.2% with margin of error of 5%. [7]

Total 150 Neonates of either gender having clinical jaundice (Visible yellowish discoloration on the skin), were included in the study. Neonates who took treatment for Hyperbilirubinemia, gestational age of < 33 weeks, birth weight < 1500 gm, having major congenital malformations, and neonates of a jaundiced mother were excluded from the study. After institutional ethics committee approval, 150 neonates meeting inclusion criteria were enrolled, with parental informed consent secured. Demographic details were recorded. Bilirubin levels were determined using a MBJ-20 transcutaneous bilirubinometer, averaging three measurements for the final value. Blood samples were analyzed for serum bilirubin by the hospital laboratory. Data were assessed to confirm hyperbilirubinemia, using the established operational definition, All the neonates were treated treated as per hospital standard protocols. All data were documented in a Performa. Hyperbilirubinemia was defined transcutaneously as positive when bilirubin levels were ≥ 12 mg/dl, which aligned with the threshold for initiating phototherapy. Similarly, a serum bilirubin level of ≥ 12 mg/dl was used to indicate a positive diagnosis of hyperbilirubinemia.

Data analysis utilized SPSS 26.0, with descriptive statistics for variables including age and birth weight, and categorical variable frequencies like gender. A one sample t-test assessed methodological differences, while Pearson's coefficient measured correlation levels. Sensitivity, specificity, PPV, NPV, and accuracy were derived from a 2x2 contingency table. The diagnostic accuracy was quantified by ROC AUC analysis for the transcutaneous bilirubinometer, with statistical significance at $p < 0.05$.

Results

Among 150 neonates, there were males 53.3% (n=80), while females accounted for 46.7% (n=70). Neonates aged 4-7 days represented the largest age group at 53.3% (n=80). Average age at the time of presentation 4.47 ± 2.16 months and a gestational age at birth of 37.95 ± 2.26 weeks. The mean birth weight was recorded as 2782.49 ± 544.31 grams. The majority of neonates were term, with 72.7% (n=109) born at gestational ages of 37-40 weeks, and neonates with a birth weight over 2500 grams were predominant, comprising 78.7% (n=118) of the study population. Vaginal deliveries were the most frequent mode of birth, accounting for 70.7% (n=106) of cases. (Table I)

Serum bilirubin averaged 14.28 ± 2.21 mg/dL, while transcutaneous readings were slightly higher at 14.52 ± 2.72 mg/dL. The mean difference between the methods was 0.24 mg/dL (SD ± 1.38), with transcutaneous

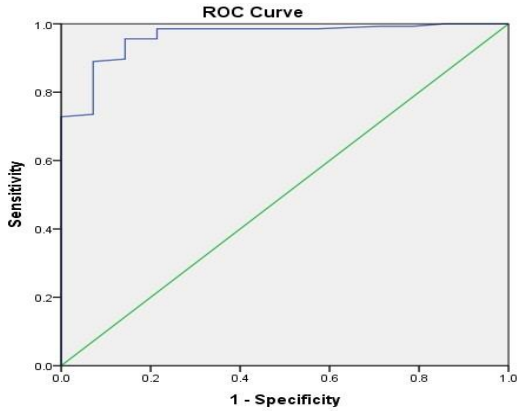
bilirubinometry showing a significant overestimation (t(149) = 2.141, p = .034; 95% CI, 0.0186 to 0.4628). Transcutaneous bilirubin and serum bilirubin had a Pearson Correlation coefficient (r) of 0.864 (p-value < 0.0001).

Table I: Clinical and demographical details. (n=150)		
Baseline characteristics	**Frequency**	**%**
Gender		
Female	60	46.7%
Male	80	53.3%
Gestational age (weeks)		
33-36 weeks	16	10.66 %
37-40 weeks	109	72.66 %
>40 weeks	25	16.6 %
Postnatal age at the time of presentation		
Up to 3 days	52	(34.7%)
4-7 days	80	(53.3%)
More than 7 days	18	(12%)
Birth weight		
≤ 2.5 kilogram	32	21.3 %
> 2.5 kilogram	118	78.66 %
Mode of delivery		
Spontaneous vaginal delivery	106	70.6 %
C-section	44	29.33 %

Using a 12 mg/dL threshold for phototherapy in 150 neonates, the transcutaneous bilirubinometer yielded 130 true positives and 11 true negatives for bilirubin levels, with 3 false positives and 6 false negatives. According to the 2x2 table, the calculated sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were 95.59%, 78.57%, 97.74%, 64.71%, and 94.00%, respectively. (Table II) The AUC was 0.962, indicating a high level of overall accuracy. At lower cutoff levels, sensitivity was consistently high, reaching 100% at a cutoff of 7.75 mg/dL with improving specificity. Beyond a cutoff of 12.25 mg/dL, there was a decrease in sensitivity, suggesting the increasing possibility of missed cases requiring phototherapy. (Graph 1)

Table II: Diagnostic Performance of Transcutaneous Bilirubinometry in Neonates for detecting hyperbilirubinemia.

	Results	**95 % CI**
Sensitivity	95.59%	90.64% to 98.36%
Specificity	78.57%	49.20% to 95.34%
Positive Likelihood Ratio	4.46	1.63 to 12.17
Negative Likelihood Ratio	0.06	0.02 to 0.13
Positive Predictive Value	97.74%	94.08% to 99.16%
Negative Predictive Value	64.71%	44.46% to 80.77%
Accuracy	94.00%	88.92% to 97.22%



Graph 1. ROC Curve Analysis of Transcutaneous Bilirubinometer Accuracy in Neonatal Hyperbilirubinemia Detection.

Discussion

In the present investigation, the principal objective was to evaluate the accuracy and reliability of transcutaneous bilirubinometry (TcB) in detecting hyperbilirubinemia in neonates, facilitating early intervention. The mean serum bilirubin level was recorded at 14.28 mg/dL, marginally lower than transcutaneous readings, which averaged 14.52 mg/dL. The findings of this study elucidate a robust correlation between TcB and serum bilirubin levels, substantiated by a statistically significant Pearson Correlation coefficient of 0.864 ($p < 0.001$). The high sensitivity and specificity rates—95.59% and 78.57%, respectively—underscore the utility of TcB as a preliminary screening tool. Notably, the area under the receiver operating characteristic curve (AUC) of 0.962 denotes a high level of overall diagnostic accuracy of the transcutaneous bilirubinometer, reflecting its effectiveness as a screening tool for hyperbilirubinemia in neonates. The diagnostic sensitivity was consistent and peaked at lower cutoff levels, reaching 100% sensitivity at a threshold of 7.75 mg/dL, which supports the use of transcutaneous bilirubinometry for early detection. However, specificity showed improvement as the cutoff levels decreased, indicating a trade-off between sensitivity and specificity at various thresholds.

Chokemungmeepisarn et al. (2020) reported a strong correlation (r=0.84) between TcB and TSB, mirroring the findings of the current study (r=0.864). Both studies endorse TcB's efficacy, with the prior research achieving 92.5% accuracy in predicting phototherapy necessity, closely aligning with our study's accuracy of 94%. The high sensitivity (78.3% vs. 95.59%) and specificity (94.2% vs. 78.57%) observed in both studies underscore TcB's potential utility in early hyperbilirubinemia

detection.[7] In terms of diagnostic accuracy, the sensitivity and specificity of the TcB in Muzrah et al.'s study ranged from 84.4% to 85.3% and 77.4% to 76.4% respectively, for a TSB threshold of 12 mg/dL. [9] Nagar et al. have shown a comparable correlation between TcB and TSB in newborns less than 32 weeks gestational age as in both the near-term and term populations (r': 0.89, p0,001). [10] Rubio et al. reported a correlation coefficient of 0.81 and suggested it is useful for infants. [11]

According to the American Academy of Pediatrics' published recommendation, newborns with hyperbilirubinemia have a discrepancy of 2 to 3 mg/dL between Transcutaneous Bilirubinometry, and total serum bilirubin readings can be examined using transcutaneous bilirubinometers. [12] In comparison to our study's modest 0.24 mg/dL difference between TcB and TsB, Andrea et al. observed larger variances—1.5 ± 2.1 mg/dL for outpatients and 2.7 ± 1.3 mg/dL for inpatients. While our sensitivity for TcB readings was higher (95.59%), Wickremasinghe et al. reported a specificity of 58%, suggesting TcB's varying reliability across settings.[8] According to Bosschaart et al., correlation coefficients between TcB and TSB were lower in newborns who were seven days old or older and those who were younger. Age-related skin changes, such as thickening, have been suggested as a possible explanation for this discrepancy.[13]

The results of transcutaneous bilirubinometry at different cut-off values of serum bilirubin level were variable. Some transcutaneous bilirubin levels were overestimated, but some readings underestimated 1 to 2 mg/dl regarding TSB. Another research indicated that when total serum bilirubin (TSB) exceeded 15 mg/dl, the corresponding transcutaneous bilirubin (TcB) readings were consistently 1.4 mg/dl beneath the TSB measurements. A notable limitation of TcB screening emerges at elevated TSB concentrations, where its estimations tend to deviate from actual TSB values. Conversely, at reduced TSB levels, TcB assessments tended to exceed the serum measurements. [14]

The Strength of study includes a significant correlation between TcB and serum bilirubin levels, with a modest mean difference of 0.24 mg/dL between TcB and TsB, and a diagnostic accuracy consistent with existing literature. However, limitations such as the small sample size and lack of data on the impact of phototherapy and varying skin tones on TcB readings must be acknowledged. Future research should focus on expanding the sample size, encompassing diverse neonatal demographics, and assessing the accuracy of TcB during phototherapy to solidify its utility across different clinical scenarios and thresholds.

Conclusion

This study confirms that transcutaneous bilirubinometry is an effective tool for serum bilirubin assessments in neonatal jaundice management. Notwithstanding a modest overestimation vis-à-vis serum bilirubin levels, transcutaneous readings exhibited commendable sensitivity and specificity, validating its clinical application in preliminary hyperbilirubinemia screening. The discernible discrepancy between the two methods necessitates cautious clinical interpretation and potential procedural calibration. The diagnostic precision, as reflected by the receiver operating characteristic curve, supports the integration of transcutaneous bilirubinometry into standard care protocols.

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