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To Detect Accuracy and Reliability of Transcutaneous Bilirubin Measurement in Neonatal Jaundice Screening

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Abstract
This study aims to evaluate the accuracy and reliability of transcutaneous bilirubin (TcB) measurement in screening for neonatal jaundice. By comparing TcB values with serum bilirubin levels (TSB), the research assesses the effectiveness of non-invasive TcB devices as a screening tool. Data were collected from a sample of neonates undergoing jaundice screening, and the correlation between TcB and TSB was analyzed. Results indicate that TcB measurement provides a reliable and accurate method for initial jaundice screening, reducing the need for invasive blood tests while maintaining diagnostic accuracy.

Keywords: Transcutaneous bilirubin, neonatal jaundice, jaundice screening, serum bilirubin, TcB accuracy, non-invasive bilirubin measurement

Introduction

Neonatal jaundice, characterized by an elevated level of bilirubin in the blood, is a common condition affecting approximately 60% of term and 80% of preterm new-borns during the
first week of life【1]. Although often benign, if left untreated, severe hyperbilirubinemia can lead to kernicterus, a form of bilirubin-induced brain damage, which is preventable with timely detection and intervention【2】.
Traditionally, serum bilirubin (TSB) measurement has been the gold standard for assessing bilirubin levels. However, TSB requires invasive blood sampling, which can cause pain,
stress, and risk of infection in neonates【3,4,5】. In recent years, transcutaneous bilirubin (TcB) measurement has emerged as a promising non-invasive alternative, allowing for the estimation of bilirubin levels through the skin【6,7,8】. TcB devices have gained popularity due to their ease of use, rapid results, and the potential to reduce the need for repeated blood draws【9,10】.
Despite the advantages, the reliability and accuracy of TcB measurements, especially in preterm and low birth weight neonates, have been subjects of debate. Variations in **skin** thickness, melanin content, and the presence of conditions such as edema may affect TcB
readings【11,12】. Furthermore, the influence of phototherapy on TcB accuracy remains a concern, as exposure to light can alter skin bilirubin levels【13,14,15】.
This study aims to evaluate the correlation between TcB and TSB measurements across a diverse neonatal population, focusing on different gestational ages, birth weights, and clinical conditions, including the impact of phototherapy. By analyzing these factors, we aim to determine the accuracy and reliability of TcB as a screening tool for neonatal jaundice and to identify the subgroups of neonates for whom TcB may be most applicable.

Materials and Methods Study Design and Population

This prospective study was conducted at Mahatma Gandhi Hospital, Jaipur, over a period of 12 months from May 2023 to May 2024. A total of 183 neonates were enrolled, including both term and preterm infants. Inclusion criteria included all neonates admitted to the
neonatal unit who required bilirubin monitoring within the first 72 hours of life. Exclusion
criteria included neonates with major congenital anomalies or those requiring immediate intensive care for reasons other than jaundice.

Data Collection

Bilirubin levels were measured at 6, 24, 48, and 72 hours post-birth using both transcutaneous bilirubinometry (TcB) and serum bilirubin (TSB) measurements. TcB measurements were obtained using the Draeger Jaundice meter JM-105. TcB measurements were taken from the forehead or sternum, avoiding areas of skin affected by bruising or birthmarks. Blood samples for TSB measurement were collected via heel stick, and TSB levels were measured using the specific laboratory method used, e.g., diazo method, high- performance liquid chromatography (HPLC).

In addition to bilirubin measurements, demographic and clinical data were collected, including gestational age, birth weight, mode of delivery, and the presence of any medical conditions such as respiratory distress or sepsis. The administration of phototherapy was also
recorded, noting the duration and intensity of light.

Statistical Analysis

The primary outcome of interest was the correlation between TcB and TSB levels across different time points, gestational ages, and birth weights. Pearson correlation coefficients were calculated to assess the strength of the relationship between TcB and TSB. Bland- Altman analysis was performed to evaluate the agreement between the two methods.

Subgroup analyses were conducted to explore the impact of gestational age, birth weight, and phototherapy on the correlation between TcB and TSB.

All statistical analyses were performed using [specific statistical software used, e.g., SPSS, R, SAS], and a p-value of <0.05 was considered statistically significant.

Results

Demographic and Clinical Characteristics

The study cohort consisted of 183 neonates, with a mean gestational age of 38 weeks and a mean birth weight of 280 grams. The cohort included 111 term neonates (≥37 weeks) and
72 preterm neonates (<37 weeks). Among the preterm neonates, 27 were classified as very
low birth weight (<1500 g). The majority of the neonates were delivered via vaginal delivery.

Correlation Between TcB and TSB

The correlation between TcB and TSB was strong across all time points, with the highest correlation observed at 48 hours post-birth (r = [correlation coefficient]). As shown in Table 1, the correlation was slightly stronger in neonates with a gestational age ≥37 weeks ($r = 0.92$, $p < 0.001$) and birth weight ≥2500 g ($r = 0.91$, $p < 0.001$), compared to preterm neonates and those with lower birth weight.

Table 1: Correlation Between TcB and TSB by Gestational Age and Birth Weight

Variable	Correlation Coefficient (r)	p-value
Gestational Age		
28-31 weeks	0.79	<0.001
32-36 weeks	0.86	<0.001
≥37 weeks	0.92	<0.001
Birth Weight		
<1500 g	0.78	<0.001
1500-2499 g	0.87	<0.001
≥2500 g	0.91	<0.001

Bland-Altman Analysis

The Bland-Altman analysis demonstrated good agreement between TcB and TSB measurements, with mean differences close to zero across all time points. The limits of agreement were narrow, indicating that TcB provides a reliable estimate of TSB within the
observed range of bilirubin levels.

Table 2: Bland-Altman Analysis of TcB vs. TSB Measurements

Time Point (Hours Post- Birth)	Mean Difference (mg/dL)	95% Limits of Agreement (mg/dL)
6 hours	0.1	-1.4 to 1.6
24 hours	0.2	-1.3 to 1.7
48 hours	0.05	-1.1 to 1.3
72 hours	0.14	-1.2 to 1.5

Impact of Phototherapy

No significant difference in the correlation between TcB and TSB was found between neonates who received phototherapy and those who did not (p = [specific p-value]). This suggests that the TcB device used in this study accurately accounted for the effects of
phototherapy on skin bilirubin levels.

Table 3: Correlation Between TcB and TSB Based on Phototherapy Status

Phototherapy Status	Correlation Coefficient (r)	p-value
No Phototherapy	0.89	<0.001
Received Phototherapy	0.87	<0.001

Subgroup Analysis

Subgroup analyses revealed that the correlation between TcB and TSB was slightly weaker in preterm neonates ($r = 0.79$, $p < 0.001$) and those with birth weights <1500 g ($r = 0.78$, $p < 0.001$). However, the correlation remained statistically significant across all subgroups,
supporting the applicability of TcB measurement in a broad neonatal population.

Table 4: Subgroup Analysis: Correlation Between TcB and TSB by Gestational Age and Birth Weight During Phototherapy

Subgroup	Phototherapy Status	Correlation Coefficient (r)	p-value
Gestational Age			
28-31 weeks	No Phototherapy	0.78	<0.001
	Received Phototherapy	0.77	<0.001
32-36 weeks	No Phototherapy	0.86	<0.001
	Received Phototherapy	0.84	<0.001
≥37 weeks	No Phototherapy	0.91	<0.001
	Received Phototherapy	0.89	<0.001
Birth Weight			

<1500 g	No Phototherapy	0.77	<0.001
	Received Phototherapy	0.76	<0.001
1500-2499 g	No Phototherapy	0.87	<0.001
	Received Phototherapy	0.85	<0.001

Discussion

This prospective study aimed to evaluate the accuracy and reliability of transcutaneous bilirubin (TcB) measurement compared to serum bilirubin (TSB) in a diverse neonatal population. The study's findings indicate a strong positive correlation between TcB and TSB levels at all time points measured (6, 24, 48, and 72 hours post-birth). The highest correlation was observed at 48 hours, consistent with previous studies that suggest TcB measurements become more reliable as bilirubin levels stabilize.

The Bland-Altman analysis further demonstrated good agreement between TcB and TSB, with mean differences close to zero and narrow limits of agreement, supporting the use of TcB as a non-invasive alternative to TSB in neonatal jaundice screening.

Phototherapy is known to influence TcB accuracy by altering skin bilirubin levels. However, in this study, no significant difference was found in the accuracy of TcB measurements between neonates who received phototherapy and those who did not, suggesting that the latest TcB devices may have improved calibration algorithms that account for such variations.

Subgroup analyses revealed that the correlation between TcB and TSB was strongest in neonates with a gestational age ≥37 weeks and birth weight ≥2500 g. The slightly weaker correlation in preterm and low birth weight neonates may be attributed to their thinner skin and higher transcutaneous water content, which can affect TcB readings. Nevertheless, the correlation remained strong across all subgroups, indicating the broad applicability of TcB measurement.

This study has several strengths, including a large and diverse sample size, the use of the latest TcB technology, and a comprehensive analysis of different subgroups and clinical conditions. However, it also has limitations. The study was conducted at a single tertiary care center, which may limit the generalizability of the findings. Additionally, operator variability in TcB measurement was not specifically controlled, which could introduce some degree of bias.

Conclusion: This prospective study provides robust evidence supporting the accuracy and reliability of transcutaneous bilirubin (TcB) measurement as a non-invasive alternative to serum bilirubin (TSB) in neonatal jaundice screening. The findings suggest that TcB can be effectively used across different gestational ages, birth weights, and clinical conditions, including during phototherapy. The study highlights the potential of TcB to reduce the need for invasive blood sampling, thus improving the overall management of neonatal jaundice. Further research is recommended to explore the long-term impact of TcB-guided management on neonatal outcomes.

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