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Research Article

A Study Comparing the Transcutaneous and Serum Bilirubin Values In Term and Preterm Babies at a Tertiary Care Hospital

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ABSTRACT

Introduction: The estimation of transcutaneous bilirubin is a newer, less invasive approach used to determine the pathway for effective monitoring and management of neonatal jaundice. However, its reliability in comparison with total serum bilirubin is yet to be fully established especially in preterm infants and those who undergo phototherapy. This study aims at finding the correlation between Total Serum Bilirubin (TSB) and Transcutaneous Bilirubin (TcB) in term and preterm babies, both before and during phototherapy.

Methods: This study was a prospective observational study conducted in the NICU, postnatal ward and the outpatient department of a tertiary health care center in Bahrain. A total of 210 infants were included in the study and were categorized into term infants and preterm who were further subdivided into two groups (between 30 weeks to 39 weeks and 34 weeks to 40 weeks) according to their gestational age. Transcutaneous bilirubin was estimated by Drager JM-105 bilirubinometer from the forehead of the babies and were compared with total serum bilirubin collected simultaneously. The measurements were taken before and during phototherapy. The statistical correlation of transcutaneous bilirubin and total serum bilirubin was shown using Bland Altman analysis and scatter plot.

Result: In term infants, the mean difference between the TSB and Tcb estimation before phototherapy was approximately 21.6 μmol/L and during phototherapy was about 17.7 μmol/L. Most of the data points fall within the 95% limits of agreement, which range from about 49.5 to 92.7 μmol/L before phototherapy and approximately 36.2 to 71.6 μmol/L while under phototherapy. According to Pearson correlation test, the magnitude of correlation was significant with r=+0.840, p<0.001, in those babies who were of term gestation whose TSB and TCB were compared before phototherapy while it was r=+0.869, p<0.001 during phototherapy. In preterm babies between 30 weeks to 39 weeks of gestation, the mean TcB-TSB difference before phototherapy was17.7 μmol/L (95% LOA-14.7 to 50.2) and during phototherapy was 21.4 μmol/L (95% LOA-19.0 to 61.9) while those between 34 weeks to 40 weeks of gestation showed a difference between TcB and TSB of 22.2 μmol/L (95% LOA-39.9 to 84.2) and 25.2 μmol/L (95% LOA-37.7 to 88.1) before and during phototherapy respectively.

Conclusion: Our study shows a strong positive correlation between TcB and TSB in term and preterm babies before and during phototherapy. The results need to be interpreted with caution in preterm babies less than 34 weeks of gestation especially during phototherapy owing to the possibility of wider variations. Although Tcb is very helpful as a screening tool, the decision regarding the initiation of phototherapy and management of neonatal jaundice especially in preterm babies of lower gestational age should be based on TSB values. Further studies especially in preterm babies and during phototherapy may aid in providing further clarity in the role of transcutaneous bilirubin measurement in the management of neonatal hyperbilirubinemia.

Keywords: Neonatal jaundice; Total serum bilirubin; Transcutaneous bilirubin; Phototherapy; Preterm

INTRODUCTION

Neonatal jaundice is a common problem encountered in the first few days of life especially in a setting of ABO, Rh incompatibility, prematurity and any sick baby. Majority are physiological jaundice which runs its normal course without requiring any phototherapy or other intervention. But in some cases, especially with associated risk factors, the jaundice can rapidly rise. It is essential to detect these cases at early stages, plot on the appropriate standardized bilirubin charts and start phototherapy in order to avoid jaundice worsening and eventually leading to kernicterus. Clinical evaluation of jaundice by visual estimation is often subjective and inaccurate. It can be affected by variety of factors like skin colour and hemoglobin. Total Serum Bilirubin (TSB) estimation is used as a gold standard in the decision making, monitoring and management of neonatal jaundice [1]. An alternative non-

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invasive, cost effective, easy to use method like transcutaneous bilirubin estimation by modern bilirubinometer, can significantly improve the quality of care. At the same time relying too much on a new method with insufficient scientific data to back it up can result in underestimating the risks involved and lead to adverse consequences. Transcutaneous Bilirubin (Tcb) estimation is a non-invasive, less painful, easy to use technique which yields immediate result and can be performed efficiently by less skilled staff with proper training [2]. Many studies show no significant differences between transcutaneous bilirubin and serum bilirubin obtained simultaneously [3-5]. Transcutaneous bilirubin is increasingly being used in several centers to make decisions on initiating phototherapy or use as a screening tool to pick at risk babies in whom serum bilirubin is done for confirmation and further management. Frequent blood collection for Total Serum Bilirubin (TSB) is a drain on hospital manpower and resources. It adds to the financial burden and stress that the patient's family has to undergo. Moreover, it is painful to the babies and a risk for sepsis and anemia. Hence, a study comparing serum bilirubin and transcutaneous bilirubin is important to address a common problem of neonatal jaundice in babies admitted to the NICU and newborn nursery and will positively contribute to the quality of care. It will also help in the judicious use of hospital resources, manpower and reduce the health care expenses.

MATERIALS AND METHODS

This was a prospective observational study conducted in the Neonatal intensive care unit and Newborn nursery of a tertiary care hospital in Bahrain over a period of 2 years. Late preterm babies more than 35 weeks of gestation and term babies aged upto 10 days, who required serum bilirubin estimation, were included in this study. Exclusion criteria were those babies with conjugated hyperbilirubinemia, liver disorder, skin disease, sepsis, perinatal asphyxia, major congenital malformation and previous history of exchange transfusion. A written informed consent was obtained from parents or legal guardians of the neonates, involved in the study. After obtaining the parent's consent, data showing the baby's demographic details, gestational age, birth weight, mother's and baby's blood group, antenatal history and other relevant details was recorded using a questionnaire/proforma. Total serum bilirubin samples were collected as per the requirement and sent to the laboratory within 1 h of blood collection. Measurement was done using the modified diazo method in the laboratory. Tcb measurement was done using the instrument Drager JM 105 bilirubinometer. The measurements are performed over the skin of the forehead by a trained nurse or resident physician and were taken simultaneously within 1 hour of sample collection for serum bilirubin. The mean of 3 values was considered as the final value and documented.

RESULTS

The correlation of transcutaneous bilirubin and total serum bilirubin is shown using Bland Altman analysis and scatter plot. The sample contained 210 infants with jaundice out of which, 51.9% were male and 48.1% were female (Figure 1). Among the babies involved in our study, 32.4% were preterm and 67.6% were term. When they were classified according to gestational age, 4.8% were between 33 weeks-39 weeks, 27.6% between 34 weeks-39 weeks, and 67.6% were over 37 weeks. The weight distribution showed that 11.9% of infants weighed between 1-2 kg, 86.7% weighed between 2.1-4 kg, and 1.4% weighed more than 4 kg (Figure 1). Regarding the mode of delivery, 57.1% were born *via* Spontaneous Vaginal Delivery (SVD), while 42.9% were delivered by Cesarean Section (CS). Apgar scores at 1 min and 5 min indicated that majority had a normal score with 1-minute score 8 or more in 88.6% of the cases, while at 5 min almost all had normal score. Blood group distribution showed that 29.5% of infants had blood group A, 1.9% had AB, 35.7% had B, and 32.9% had O. Finally, the Rh group distribution indicated that 6.2% of infants were Rh-negative, while 93.8% were Rh-positive (Table 1). The correlation between TSB and TcB among term neonates before and during phototherapy were illustrated by Figure 2, respectively According to Pearson correlation test, the magnitude of correlation was significant with $r=+0.840$, $p<0.001$, in those babies who were of term gestation whose TSB and TCB were compared before phototherapy while it was $r=+0.869$, $p<0.001$ during phototherapy. These finding indicates that there is a strong positive statistically significant correlation between the TSB and TcB before and during phototherapy among term neonates. The Bland-Altman plot illustrates the agreement between two measurement methods, TSB (Total Serum Bilirubin) and TcB (Transcutaneous Bilirubin) before and during phototherapy. The mean difference between the two methods before phototherapy is approximately 21.6 µmol/L, indicating that, on average, TSB measurements are slightly higher than TcB measurements. Most data points fall within the 95% limits of agreement, which range from about -49.5 to 92.7 µmol/L, though there are a few outliers beyond these limits. The plot suggests that while the two methods generally agree, there is some variability, as indicated by the spread of differences. The presence of outliers and the width of the limits of agreement may imply that in certain cases, the methods do not align closely. Overall, while the mean difference is relatively small, the variability and occasional outliers suggest that the methods may not always be interchangeable. During phototherapy, the mean difference between the two methods is about 17.7 µmol/L, suggesting that TSB measurements tend to be slightly higher than TcB measurements during phototherapy. The 95% limits of agreement range from approximately-6.2 to 71.6 µmol/L, indicating the range within which most differences between the two methods lie. The scatter of points around the mean difference suggests some variability between the methods, although most points fall within the 95% limits of agreement. There are a few outliers beyond these limits, which could indicate instances where the two methods differ significantly. Overall, the plot suggests that while the methods generally agree, there is some variation, and in some cases, the two measurements may not be interchangeable (Figure 3). In preterm babies between 34 weeks-42 weeks of gestation, as per the Pearson correlation test, the magnitude of correlation was ($r=+0.811$, $p<0.001$) before phototherapy and ($r=+0.693$, $p<0.001$) during phototherapy respectively. These finding indicates that there is a strong positive statistically significant correlation between the TSB and TcB before as well as during phototherapy among preterm neonates in this category (Figure 4). The Bland-Altman plot compares TSB (Total Serum Bilirubin) and TcB (Transcutaneous Bilirubin) measurements in preterm infants (34 weeks-36 weeks) before phototherapy show a mean difference between the two methods is 22.2 µmol/L, indicating that TSB measurements are generally higher than TcB measurements. The 95% limits of agreement range from approximately -39.9 to 84.2 µmol/L, capturing the spread of differences between the two methods. The distribution of points shows a consistent spread around the mean difference,

with the majority of points falling within the limits of agreement. The curved nature of the limits suggests variability in agreement across the range of bilirubin levels, with some data points deviating more significantly from the mean difference. The overall spread of points indicates a varied degree of agreement between the TSB and TcB methods in this preterm population. During phototherapy, the mean difference between the two methods among these preterm babies are 25.2 µmol/L, with TSB measurements generally being higher than TcB measurements. The 95% limits of agreement range from approximately -37.7 to 88.1 µmol/L. The data points exhibit a noticeable spread around the mean difference, with some points deviating more significantly from the mean, particularly as the mean of the measurements increases. The curved nature of the limits of agreement suggests variability in the agreement between the methods across different bilirubin levels. The overall pattern indicates some variability in the agreement between TSB and TcB measurements during this period in this preterm population (Figure 5). Statistical analysis comparing the differences between transcutaneous and serum bilirubin were also made in preterm babies between 30 weeks to 39 weeks of gestation. Owing to small number of babies (n=9) in this category, although a significant correlation was found between the 2 methods before and during phototherapy, a study with more sample size is required for a more accurate interpretation of the results.

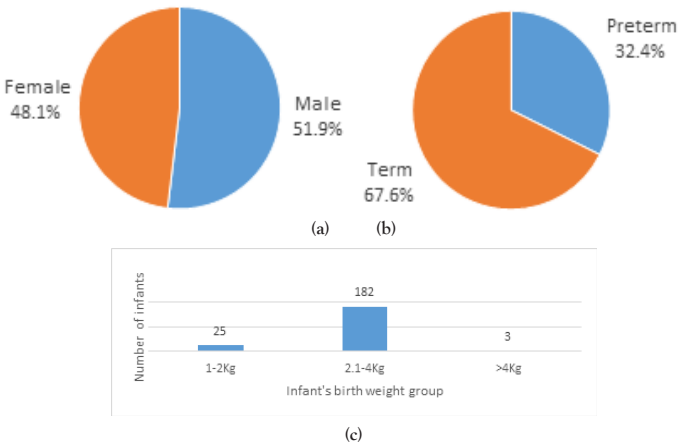


Figure 1: (a) Gender distribution in the sample; (b) Term and preterm babies among the study group; (c) Number of infants per birth weight category.

Table 1: Subject's characteristics.

Characteristics		Count	Percentage%
Location	In-patient	101	48.1%
	Out-patient	109	51.9%
Gender	Male	109	51.9%
	Female	101	48.1%
GA	33-36+6 weeks	10	4.8%
	34 to 36+6 weeks	58	27.6%
	>37 weeks	142	67.6%
Term	Preterm	68	32.4%
	Term	142	67.6%
Baby weight	1-2 Kg	25	11.9%
	2.1-4 Kg	182	86.7%
	>4 Kg	03	1.4%
Mode of delivery	SVD	120	57.1%
	CS	90	42.9%
Apgar 1min	5	01	0.5%
	6	01	0.5%
	7	22	10.5%
	8	55	26.2%
	9	131	62.4%
Apgar 5 min	8	10	4.8%
	9	70	33.3%
	10	130	61.9%
Baby blood group	A	62	29.5%
	AB	04	1.9%
	B	75	35.7%
	O	69	32.9%
Baby Rh group	Negative	13	6.2%
	Positive	197	93.8%

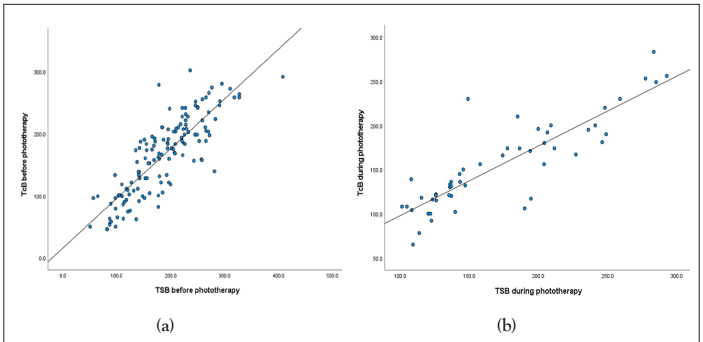
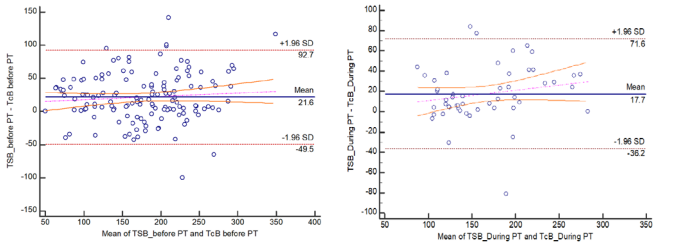
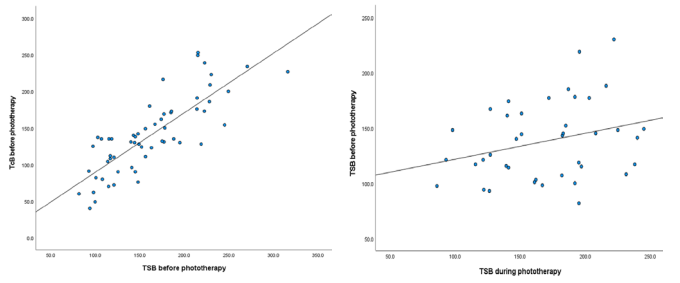


Figure 2: Scatter plot illustrating the correlation between TSB and Tcb among term neonates. **Note:** (a) Before phototherapy; (b) During phototherapy.



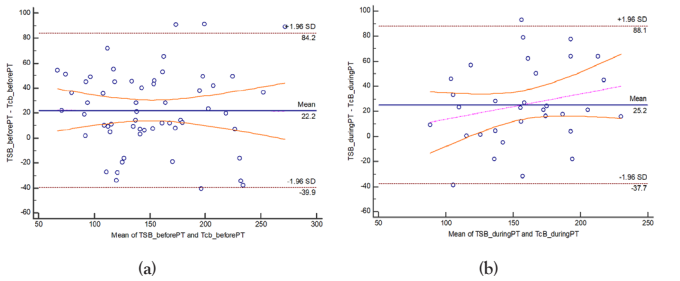
(a) (b)

Figure 3: Bland Altman plot comparing TSB and TcB measurements in term infants. **Note:** (a) Before phototherapy; (b) During in phototherapy.



(a) (b)

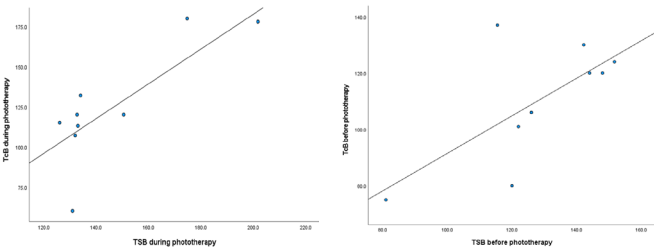
Figure 4: Scatter plot illustrating the correlation between TSB and Tcb among preterm babies between 34 and 36+6 weeks of gestation. **Note:** (a) Before phototherapy; (b) During phototherapy.



(a) (b)

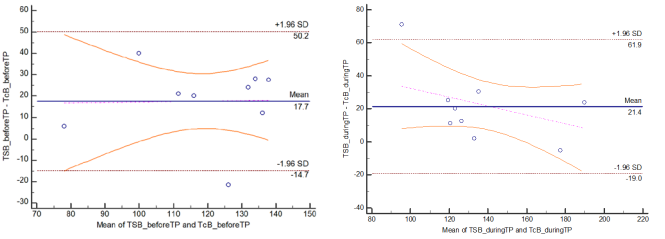
Figure 5: Bland Altman plot comparing TSB and TcB measurements in between 34 and 36+6 weeks of gestation. **Note:** (a) Before phototherapy; (b) During phototherapy.

According to Pearson correlation test, the magnitude of correlation was r=+0.678, p=0.031 before phototherapy and r=+0.842, p=0.002 during phototherapy. These finding indicates that there is a strong positive statistically significant correlation between the TSB and TcB before phototherapy among preterm neonates (30 weeks-33 weeks) (Figure 6). The Bland-Altman plot compares TSB (Total Serum Bilirubin) and TcB (Transcutaneous Bilirubin) measurements in preterm infants (30 weeks-33 weeks) before phototherapy showed a mean difference between the two methods is 17.7 µmol/L, indicating that, on average, TSB readings are higher than TcB readings. The 95% limits of agreement are approximately -14.7 to 50.2 µmol/L, which captures most of the differences between the two methods. The points are mostly concentrated near the mean difference, with a few scattered around the limits of agreement. The curved nature of the limits suggests some non-uniformity in the agreement across the range of measurements. The data points are largely clustered, indicating relatively consistent differences between the two methods within this specific range. During phototherapy, the mean difference between the two methods is 21.4 µmol/L, with TSB readings generally being higher than TcB readings. The 95% limits of agreement range from -19.0 to 61.9 µmol/L. The points are somewhat dispersed with a few outliers, and the curved nature of the limits suggests variability in agreement across different levels of bilirubin. The data points, while generally close to the mean difference, show some degree of spread, indicating varied levels of agreement between the two methods within this population (Figure 7).



(a) (b)

Figure 6: Scatter plot illustrating the correlation between TSB and Tcb among preterm babies between 30 and 33+6 weeks of gestation. **Note:** (a) Before phototherapy; (b) During phototherapy.



(a) (b)

Figure 7: Bland Altman plot comparing TSB and TcB measurements in between 30 and 33+6 weeks of gestation. **Note:** (a) Before phototherapy; (b) During phototherapy.

DISCUSSION

The estimation of transcutaneous bilirubin is increasingly being used in several centers to reduce the burden of serum bilirubin collection in cases of neonatal jaundice. There have been several studies comparing the transcutaneous and serum bilirubin values to determine its effectiveness a screening tool among term and preterm babies. While some of these studies found a significant difference between the bilirubin estimated transcutaneously using bilirubinometer and serum bilirubin, others suggested good correlation between both. The serum bilirubin was over estimated in comparison with transcutaneous bilirubin in some studies; whereas in other studies it was on an average found to be higher than transcutaneous bilirubin [6-11]. Our study showed a strong positive correlation between transcutaneous and serum bilirubin in term and preterm infants before and during phototherapy, with a lower mean TcB level than TSB. There were other studies which indicated a good correlation between TSB and TcB measurements in term and late preterm infants [4,5]. Studies by Afanetti et al., and Olusanya et al., have found higher values in TcB with good overall correlation [12,13]. Similar to our study, Engle et al., found that TSB values were underestimated by TcB in Hispanic infants [14]. In studies by Maisels et al., and Rubaltelli et al., a decrease in sensitivity and increase in specificity at higher TcB cutoff values was noted [15,16]. The study by Maisels et al., also found that, as TSB concentration increased, the number of false negative TcB increased. Van Erk et al., did a study that postulated the variation in TcB measurements as a result of bone depth that can change due

to the pressure exerted through the transcutaneous bilirubinometer and the thickness of the skin [17]. The correlation between TcB and TSB seems to be good often regardless of skin color, but in dark-skinned neonates TcB tends to overestimate serum bilirubin [2,18,19]. Most studies found the better correlation when TcB was measured in covered skin, however most of them were not multiethnic [20-22]. There were wide variations with significant differences between TSB and TcB after initiation of phototherapy and at a greater degree of prematurity. This corroborated with the results seen in previous research that showed good correlation between TcB and TSB prior to starting phototherapy using the JM-103 and JM-105 devices [22-24]. Transcutaneous bilirubin estimation may not be reliable in babies undergoing phototherapy, but some studies have shown favorable results where there is good correlation with total serum bilirubin. [20,24-28] A study by Katayama et al., suggested a significant correlation between TcB and TSB before and during phototherapy [29]. For TSB ≤ 306 µmol/L during phototherapy, a TcB cut-off of 238 µmol/l had a specificity of 100%. Our study used JM-105 bilirubinometer, there were wide variations between TcB and TSB during phototherapy. Another study estimating Tcb using JM-103 bilirubinometer also found that phototherapy reduced the TcB/TSB correlation (JM-103™) [30]. Rylance and Johnson highlighted the reliability of using JM-103™ bilirubinometer to estimate TcB in Black Malawian and Haitian babies requiring phototherapy [31,32].

The mean difference between TcB and TSB noted globally was -1.02 ± 3.24 mg/dL (95%CI -4.19;2.16) [19].

A study by Castro et al., assessed the correlation of Tcb using JM-103 bilirubinometer and serum bilirubin during phototherapy in a small mostly Caucasian term and moderate-preterm babies and found a strong correlation [24].

Costa-Posada and Pendse used the same device as us (JM-105™) and observed a good correlation between Tcb and TSB during phototherapy in Caucasian preterm and term newborns with biases rarely more than 2 mg/dL [22].

Pendse found a good TcB/SB correlation in preterm Indian neonates, stating that TcB is a good option in low-income countries with high prematurity rates and with SB measurements often unavailable [33].

Many other studies done with Bilicheck drew contradictory conclusions [21,34,35]. The contradictory results could be explained by different study populations, inclusion or not of preterm infants, irradiance of phototherapy etc [35].

Murli et al., found poor agreement between TcB and total serum bilirubin before and during phototherapy in late preterm and term newborns [35]. Different study populations, inclusion of preterm and term newborns in some studies, and different irradiance of phototherapy light can explain these variations in the results of these studies.

The weaker correlation and wider ranges of TSB and TcB biases obtained during phototherapy could be explained by the higher levels of TSB in these patients. In most cases levels of TcB above 15 mg/dL need to be confirmed with a blood sample due to a worsening correlation [2,19,35].

Fonseca et al., and Zecca et al., reported a good agreement between TSB and TcB measured from patched area of the skin, while TcB measurement from unpatched skin underestimates TSB levels [20,26].

Other factors like skin color, gestational age, TcB device, measurement site also influence the effectiveness of transcutaneous bilirubin [18,19,36-38].

Some studies (Olusanya et al., in Africa and Jandial et al., in India) suggested that TcB tends to be overestimated with respect to TSB, due to the darker skin colour in certain races belonging to India and Africa [13,39]. This results in unnecessary treatment of cases of neonatal jaundice with phototherapy.

No significant differences were seen in some studies whether TcB was measured at the forehead or sternum prior to phototherapy; but some studies showed that the forehead may be the more preferred site for TcB measurement after the initiation of phototherapy. This may be due to the reduced exposure to phototherapy at the forehead from the eye mask used during treatment [40-42].

Some data show a poor correlation between TcB and TSB with decreasing gestational age [8,43].

The strength of our study includes a prospective study with a relatively good sample size. We excluded preterm babies less than 30 weeks thereby avoiding greater variation in the gestational age that can influence the comparability of TcB and TSB.

However, there were few limitations in our study. The TcB and TSB values estimated during phototherapy were not uniform as the serum bilirubin sample collection was guided by the clinical situation and there was no fixed time. Therefore, we were unable to determine if the same correlation between TSB and TcB will exist if we measure TcB during different time intervals in babies with ongoing phototherapy. There can be inter person variability in the bilicheck measurements taken by various trained nurses rather than a specific person.

CONCLUSION

Our study concluded that there was a significant correlation between TcB and TSB values with similar variations before and during phototherapy in term and preterm neonates. Therefore, transcutaneous bilirubin may be used as a screening tool to detect babies at risk of developing unconjugated hyperbilirubinemia requiring phototherapy but cannot replace serum bilirubin values which continues to be the gold standard to make decisions on the treatment.

The over reliability on bilicheck values can be detrimental to the babies as the case prone of severe neonatal jaundice can be missed and lack of early initiation of phototherapy can lead to rapid rise in bilirubin values with resultant kernicterus. Research studies to compare transcutaneous and serum bilirubin, especially in preterm infants, should be conducted in the future and their pitfalls evaluated and addressed.

Exploring the changes in bilirubin estimated by both transcutaneous and blood during the various time intervals after starting phototherapy can yield useful information in customizing appropriate management and reducing needless investigations or avoiding inappropriate treatment.

COMPETING INTERESTS

The authors declare that they have no competing interests.

CONFLICT OF INTEREST

No conflict of interest was present.

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