

Original Research Article

Clinical utility of hand held, non invasive transcutaneous bilirubinometer in neonatal jaundice: a prospective observational study

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ABSTRACT

Background: Neonatal Jaundice is the most common morbidity in the first week of life, occurring in 60% of term and 80% of preterm newborn. However, visual inspection, being subjective, usually inaccurate and unreliable and will result in a number of unnecessary blood sampling. Taking all these in to considerations, transcutaneous bilirubinometer (TCB) may provide a solution which is an objective, noninvasive, fast and painless method of bilirubin estimation.

Methods: Transcutaneous bilirubinometer levels were measured at forehead and sternum and blood samples for TSB were collected by venepuncture within 30 minutes and sent to biochemistry lab. After getting serum bilirubin reports, TCB and TSB values were compared by using Bhutani's hour specific nomogram.

Results: The correlation between serum bilirubin and transcutaneous bilirubin measured at forehead and sternum is very good at serum bilirubin <15 mg/dl, r value (Karl Pearson's Correlation co-efficient) is 0.93 and 0.94 respectively.

Conclusions: The findings of the present study indicate that the TCB is a reliable screening tool for hyperbilirubinemia in newborns ≥ 35 weeks of gestation, especially with bilirubin levels ≤ 15 mg/dl in 2-7 days of life. TCB can be a viable option for universal screening. Incorporating the use of TCB devices in clinical practice, can reduce the need for blood sampling for the management of neonatal jaundice.

Keywords: Neonatal jaundice, Transcutaneous bilirubinometer, Serum bilirubin, Kernicterus

INTRODUCTION

The incidence of neonatal hyperbilirubinemia has been reported to be between 30-60% in full-term newborns and nearly 100% in premature infants.¹ Though jaundice is not harmful for most term infants but high levels of unconjugated bilirubin may cause brain damage in susceptible neonates. Preventive, screening and management strategies therefore remain a significant practice issue during the early postnatal period. Although intensity and localization of jaundice is commonly used

as an indicator of bilirubin blood concentration, the correlation between visual estimation and actual bilirubin concentration is poor.^{2,3} The gold standard remains the measurement of serum bilirubin concentration. This method however is invasive, painful and costly in terms of workload, time and money. Repeated blood sampling may lead to anaemia which may be a concern in low birth weight neonates. Trying to overcome these drawbacks, non-invasive methods of bilirubin measurements have been proposed. Transcutaneous bilirubinometer (TCB) has been shown to correlate with serum bilirubin

concentration in term infants.⁴⁻⁷ It is reported that TCB reduced the need for blood sampling in neonates with visible jaundice.⁸ TCB could also decrease the readmission rate for hyperbilirubinemia.^{9,10} In previous studies, TCB has been shown a good relationship with serum bilirubin level in various ethnic neonates.¹¹⁻¹³ However, race, gestational age (GA), and body weight may affect the accuracy of the TCB measurements.

Most importantly, the transcutaneous bilirubinometer devices tend to underestimate bilirubin values, particularly at higher concentrations.¹⁴ Visual inspection, being subjective, usually inaccurate and unreliable and will result in a number of unnecessary blood sampling. Taking all these in to considerations, TCB may provide a solution which is an objective, noninvasive, fast and painless method of bilirubin estimation. The purpose of our study is to assess the diagnostic accuracy of TCB compared with the total serum bilirubin (TSB) measurement in infants more than and equal to 35 weeks at different sites during the neonatal period and implementation of the results for better management of jaundiced neonates.

METHODS

This is a prospective, observational, cross sectional, hospital based study done on newborn babies between 35^{0/7} weeks to 41^{6/7} weeks of gestation from January 2015 to December 2016 at neonatal unit of Jawaharlal Nehru Hospital and Research Centre, Bhilai, India.

Inclusion criteria

Age of 2 to 7 days of life, born after ≥ 35 weeks gestational age, visible jaundiced neonates born with birth weight ≥ 2500 gm were included in the study.

Exclusion criteria

Exclusion criteria for current study were; neonates who were under phototherapy, having exchange transfusion, babies with direct hyperbilirubinemia, babies with sepsis, hemangiomas, ecchymosis on forehead and sternum, Rh and ABO incompatibilities, babies with major congenital anomalies, TCB showing (no numerical value). After obtaining clearance from institutional ethical committee, 370 newborns fulfilling the inclusion/exclusion criteria were taken into the study. Total 3040 live births occurred during study period with 2543 (83.65%) term, 301 (9.90%) late preterms. 600 jaundiced newborns (≥ 35 -42 weeks) were enrolled, out of which 370 were included in study sample and rest were excluded who didn't match the study criteria. They were subdivided into 35-37 weeks, 37-40 weeks and 40-42 weeks groups. Each neonate was checked in broad day light for jaundice. Clinical staging of hyperbilirubinemia as per Kramer's staging were recorded. A detailed clinical assessment of the jaundiced neonates was done thoroughly. TCB determinations were made with the DRAGER JM-103, a

hand-held bilirubinometer. All the measurements were performed with the same device on the forehead and mid sternum by single trained physician. Average of 3 measurements at both sites, reported as a numerical value were taken over a period of less than 60 seconds, simultaneously blood samples for TSB, direct and indirect bilirubin measurements were collected by venepuncture. These procedures were performed within 30 minutes of TCB measurements. TSB measurements were done by the skilled staffs of the bio chemistry laboratory by spectrophotometric method. The recorded values were plotted on Bhutani's nomogram with respect to hours of life. The information collected was tabulated and the data was analyzed using the software SPSS 18 for windows. Percentage, frequency and Chi-square test were used.

RESULTS

Out of 370 neonates 52.7% (n=195) of babies were born by LSCS and 47.3% (n=175) were born by normal vaginal delivery (Table 1). Assisted vaginal deliveries were not considered in study to check the possibilities of cephalohematoma. Among the study population 46.22% (171) neonates were male and 53.78% (199) neonates were female by sex. Female neonates were more in number than male neonates. Among the study population 13.78% (n=51) were between 35 to 36^{6/7} weeks, 66.22% (245) neonates were in 37 to 39^{6/7} weeks and 20% were in 40 -41^{6/7} weeks of gestation. The mean birth weight of the sample is 2946 gm (95% CI-2906.39-2986.01) with a standard deviation of 390.7 gm (Table 1). The neonate with minimum weight in the study population was of 2505 gm and maximum of 4000 gm. Mean transcutaneous bilirubin level measured at forehead is 12.34 mg/dl (95% confidence Interval-12.02-12.66) with a SD of 3.18 mg/dl. Mean transcutaneous bilirubin level measured at sternum is 12.34 mg/dl (95% confidence Interval-11.97-12.71) with a SD of 3.62 mg/dl. Mean serum bilirubin level is 11.96 mg/dl (95% confidence Interval-11.6-12.32) with a SD of 3.55 mg/dl.

Our observation on visual assessment of jaundiced neonates 4.5% fall in Kramer's stage 1, about 13.78% are found in Kramer stage 2, In stage 3 highest percentage 30.81% (n=114) of neonates are falling in, 24.59% (n=91) found in stage 4 and in a stage 5 26.76% (n=99) neonates are seen (Table 3). This observation points towards an easier visual assessment of neonatal jaundice with higher serum bilirubin level. There is a chance of missing jaundiced neonates with lower serum bilirubin level by visual assessment only, which delays the necessary intervention. The correlation between the readings of serum and transcutaneous bilirubinometer ≤ 15 mg/dl is very high at forehead (r=0.94, p=0.001) (Figure 2) and sternum (r=0.92, p=0.001) (Table 2). The correlation between the readings of transcutaneous bilirubinometer and serum bilirubin found not to be very good above 15 mg/dl of transcutaneous bilirubin level (Figure 3). A high positive correlation between the

readings of serum and transcutaneous bilirubinometer exists at forehead ($r=0.954$) and sternum ($r=0.934$) with a significant p value of 0.00001 . The sensitivity of TCB at forehead decreases promptly from 100% at low risk zone to 2.9% at high risk zone, when measured at >120 hrs of life (Table 3). But the sensitivity of TCB at sternum remains 100% at low risk zone as well as at high risk zone, when measured at $\geq 120-168$ hrs of life. The TCB at forehead (taking 75th centile of Bhutani's nomogram as cut off) is 100% sensitive in identifying of neonates having highest risk of developing significant hyperbilirubinemia as per TSB value (i.e. $TSB \geq 95^{\text{th}}$ centile) (Table 4).

Table 1: Sample distribution.

Parameters	Mean	SD	95% confidence Interval
Birth weight	2946.2	390.68	2906.39-2986.01
Gestational age	38.63	1.54	38.47-38.79
Age (hours)	75.4	34.64	71.87-78.93
TCB (F)	12.34	3.18	12.02-12.66
TCB (ST)	12.34	3.62	11.97-12.71
TSB	11.96	3.55	11.6-12.32

Table 2: Correlation between TCB and TSB at forehead and sternum for whole sample.

Parameters	Karl Pearson's correlation co-efficient (r)	P value
TCB F	0.953	0.0001
TCB ST		
TCB F	0.93	0.0001
TSB		
TCB ST	0.94	0.0001
TSB		

Table 3: Distribution according to Kramer's staging (visual assessment of jaundice).

Kramer ST	N	%
1	15	4.05
2	51	13.78
3	114	30.81
4	91	24.59
5	99	26.76

Table 4: Sensitivity and specificity of TCB in jaundiced neonates in different risk zones aged >120 hours.

Statistics	Value (%)
Sensitivity	100
Specificity	78.96

Sensitivity of TCB at forehead ($>75^{\text{th}}$ centile) in identifying neonates at high risk group ($TSB > 95^{\text{th}}$ percentile).

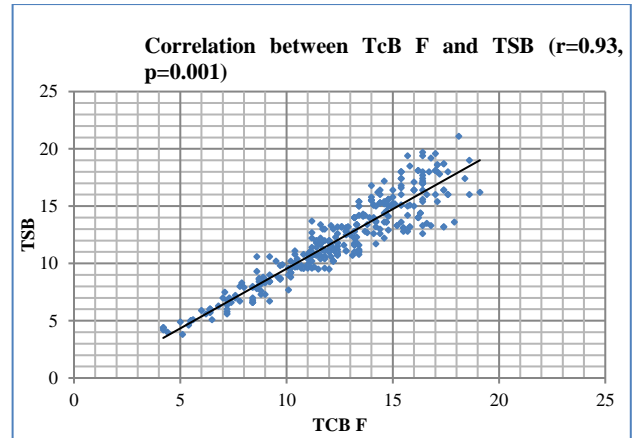


Figure 1: Scatter diagram showing correlation between TCB and TSB at forehead for the total sample.

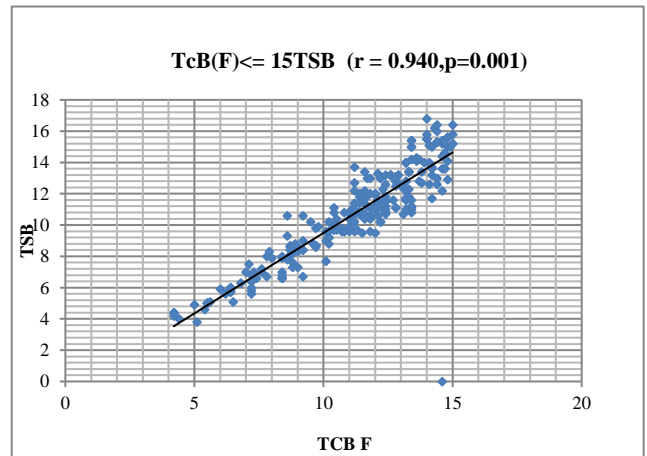


Figure 2: Scatter diagram showing correlation between TCB and TSB at forehead ≤ 15 mg/dl.

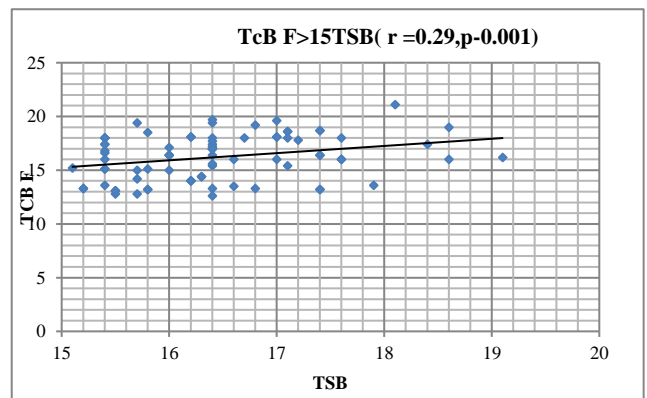


Figure 3: Correlation between TCB and TSB at forehead >15 mg/dl.

DISCUSSION

In the present study, we intended to measure bilirubin levels using a TCB (JM-103) and compared with TSB (gold standard) to find out the accuracy of TCB, which

could help diagnosing neonatal hyperbilirubinemia in the early stages, for timely intervention and better outcome in jaundiced newborns. During the study period, a total of 370 jaundiced neonates aged between $\geq 35^{07}$ weeks to 41^{67} weeks of gestation were studied in the neonatal unit and Postnatal wards. Weerakul et al studied on 195 healthy term neonates of gestational age 37 weeks and birth weight greater than 2,500 grams using JM-103. The mean TCB was 9.5 ± 2.4 mg/dl and the mean serum bilirubin was 10.5 ± 2.5 mg/dl.¹⁵ Gupta et al conducted their study by using JM-103, similar to the transcutaneous bilirubinometer, which we have used in our study.¹⁶ National academy of clinical biochemistry laboratory medicine practice guidelines recommend Bilicheck and JM-103 for use in clinical setting.^{17,18} Reliability and accuracy of transcutaneous bilirubinometers in comparison to serum bilirubin. Noninvasive transcutaneous bilirubin assessment by JM-103 has demonstrated significant correlation when compared to total serum bilirubin measured by laboratory method.

The overall (n=370) correlation of TCB to TSB is very high at both forehead $r=0.93$ (F) and sternum $r=0.94$ (S) which is statistically significant ($p=0.0001$). We compared the TCB readings with TSB readings in different risk groups as per Bhutani's nomogram. The sensitivity of TCB in picking up neonates in the same risk group as by TSB, were assessed. Sensitivity and specificity for transcutaneous bilirubinometer at forehead in low risk zone is very high i.e. 93.33% and 98.21% respectively, the sensitivity and specificity at sternum in same zone is 90% and 98.93% which is equally high. where as in high risk zone, sensitivity and specificity for Transcutaneous bilirubinometer at forehead drops to 67.92% and 93.69% respectively and sensitivity and specificity at sternum is 81.48% and 94.30% respectively. As the serum bilirubin level increases, the sensitivity and specificity seems to decrease. This drop is may be due to the less correlation between TCB and TSB at higher bilirubin levels. Hemmati et al also found a similar correlation between TCB and TSB ($r=0.969$, $r(2)=0.94$) at forehead.¹⁹ Their sensitivity and specificity at the most reliable cut-off value (15 mg/dl) were 96.6% and 99%, respectively. Stillova et al found a close correlation ($r=0.933$) existing between TSB and TCB.²⁰ Janjindamai et al found a correlation coefficient (r)=0.95 in their study which is validates our study.²¹ Kolman et al found that TCB correlates well with TSB in Hispanic neonates ($r=0.87$).²² This disparity is may be due to a different race than our present study population. Also, may be due to the fact that the dermal thickness and pigmentation of Hispanic neonates are different from our study group. Mahajan et al found $r=0.878$ at forehead and $r=0.859$ at sternum which is less than our study.¹³ This difference is may be due to the effect of phototherapy in TCB measurement.

On excluding infants receiving phototherapy, correlation increases ($r=0.90$) at forehead and ($r=0.91$) at sternum

which comes close to our study. Harish et al found the coefficient of correlation ($r=0.71$).²³ The less correlation is may be due to their study population also included preterms, SGA and neonates who had undergone phototherapy. All these parameters are known to decrease the efficacy of TCB. Minor differences between the mentioned studies could be attributed to differences in the type of bilirubinometers, skin color, ethnicity, laboratory methods etc.

Site of measurement for transcutaneous bilirubinometers

The correlation between TCB and TSB is better at sternum ($r=0.94$) than forehead ($r=0.93$), $p=0.0001$. The scatter diagram shows linear association with strong positive correlation between the TCB and TSB at both forehead and sternum. In their study, Maisels et al found a better correlation with TSB when TCB measurements were performed on the sternum ($r=0.953$) compared with the forehead ($r=0.914$).²⁴

Site of measurement based on hours of life

In the subgroup of jaundiced neonates at 24 to 72 hrs of life, the sensitivity and specificity at forehead is 100% and 92.98% which is better than the sensitivity at sternum i.e. 85.71% in high risk zone. In the subgroup of jaundiced neonates at ≥ 120 -168 hrs of life, the sensitivity of TCB at forehead decreases promptly from 100% at low risk zone to 2.9% at high risk zone with a Karl Pearson's correlation coefficient $r=0.87$ ($p=0.0001$). We assume this observation is due to the cephalocaudal progression of jaundice. Similar observation was also seen in the study done by Yamauchi et al which revealed that the most reliable site for TCB was changed from forehead to the sternum with advancing postnatal age (forehead for 0-3 days, chest for 4-5 days, sternum for 6 days and later).²⁵

Comparison of TCB readings at ≤ 15 mg/dl and >15 mg/dl

In the present study, all jaundiced neonates were divided into two groups: total bilirubin level greater than 15 mg/dl and total bilirubin level ≤ 15 mg/dl. The analysis of the association between TCB and TSB at ≤ 15 mg/dl and >15 mg/dl was done to assess the performance of TCB at higher bilirubin levels in neonates at risk of significant hyper bilirubinemia. We found a strong positive correlation between the readings of serum and transcutaneous bilirubinometer ≤ 15 mg/dl at forehead ($r=0.94$, $p=0.001$) and sternum ($r=0.92$, $p=0.001$). Therefore, it can be a reliable screening tool for hyperbilirubinemia with bilirubin levels ≤ 15 mg/dl; this finding is also supported by the study done by Hemmati et al.¹⁹ The correlation between the readings of TCB and TSB found to show poor correlation above 15mg/dl of transcutaneous bilirubin level. The correlation between the two falls as r at forehead is 0.29 ($p=0.008$) and r at

sternum 0.66 ($p=0.001$). Use of transcutaneous bilirubinometer is associated with limitations of decreasing accuracy at higher bilirubin levels. This differences between the TCB and TSB measurements with rising bilirubin values, agrees with the study done by Maisels et al.²⁶ In the present study, evidence is not sufficient to abandon neonatal serum bilirubin testing and replace it with TCB. NICE guidelines recommends that TCB is reliable in neonates whose serum bilirubin level was below $250\mu\text{mol/l}$.²⁷ There is lack of data on the reliability of transcutaneous estimation of bilirubin at levels above $250\mu\text{mol/l}$.

Reliability of TCB as a screening test

The TCB at forehead (taking 75th centile of Bhutani's nomogram as cut off) is 100% sensitive in picking of neonates having highest risk of developing significant hyperbilirubinemia (TSB $\geq 95^{\text{th}}$ centile). None of the jaundiced infants with TCB below the 75th percentile at forehead for age had TSB above the 95th percentile for age as per Bhutani's nomogram. In the study done by Kolman et al found TCB level above the 75th centile could detect all infants with a TSB level above the 95th percentile with a sensitivity 100%, and specificity 66%. Ho HT, Ng TK et al in their study, they found in both low-risk and medium-risk thresholds for phototherapy, using the 75th centile of Bhutani's nomogram as cut off, TCB could identify all cases and had a sensitivity and negative predictive value of 100% each so, the sensitivity of TCB measurements for detecting this level of hyperbilirubinemia was 100%.²² Therefore, we found that TCB can be useful as screening device to detect significant jaundice and decrease a large number of unnecessary skin punctures.

Limitations of the study

Further studies are needed in this field to check the effects of phototherapy, pre-maturity, skin colour, and low birth weight on the accuracy of TCB readings. Our study is limited to healthy jaundiced neonates of ≥ 35 weeks and TCB (JM -103) which has an upper limit of measuring up to 20 mg/dl.

CONCLUSION

The findings of the present study indicate that the TCB is a reliable screening tool for hyperbilirubinemia in newborns ≥ 35 weeks of gestation, especially with bilirubin levels ≤ 15 mg/dl in 2-7 days of life. Although the measurement of TSB remains the gold standard for assessment of neonatal jaundice, TCB can be a viable option for universal screening. Correlation between TCB and TSB is not good above 15 mg/dl. TSB measurement should be performed if TCB is higher than 15 mg/dl. With regards to the site for using TCB, our study showed both forehead and sternum readings correlate well. The use of TCB along with 75th percentile of Bhutani's nomogram as a screening method in neonates would

reduce the use of invasive methods and it will also allow starting treatment more promptly.

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