Original Research Article

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Comparison of transcutaneous bilirubin with serum bilirubin measurements in neonates at tertiary care center in western part of India

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ABSTRACT

Background: Noninvasive transcutaneous bilirubin measurement is an attractive option for jaundice evaluation in newborns. But variable accuracy had been reported in different studies. The aim of the study was to find out the correlation and agreement between TcB and TSB measurements in neonates.

Methods: Prospective analytic study carried out in neonatal unit of tertiary care center. Newborns up to 10th postnatal DOL with visually found jaundice were enrolled in study. TcB was measured over forehead with Dragor JM 103 device. Simultaneous TSB measurements were done for all readings. Pearson's correlation coefficient calculation and Bland Altaman analysis were done. ROC curve of mean TcB at different TSB level were constructed.

Results: Total 160 newborns with male: Female ratios of 1.3:1 were enrolled. Mean values: gestational age 38.23 ± 2.01 ; birth weight 2.403 ± 0.61 ; age in hour at first reading 83.76 ± 26.62 ; TSB11.65 ±4.58 mg/dl and TcB 11.73 ± 3.53 mg/dl. A strong, positive and significant correlation was found between TcB and TSB measurements (r=0.836, r²=0.69, p <0.001). The average error in evaluating hyperbilirubinemia with TcB as compared to TSB was 0.856 with limits of agreement between -3.41 to +5.48. The AUOC at three TSB levels (>10mg/dl, >12 mg/dl, >15 mg/dl) of TcB were 0.899, 0.937 and 0.963 respectively. ROC analysis showed good sensitivity for all. Specificity was found to fall with increasing TSB concentration.

Conclusions: In our study TcB correlated well with TSB measurements and showed good sensitivity and satisfactory specificity, thus validating its use as a screening tool for evaluation of jaundice in newborns.

Keywords: Comparison, Hyperbilirubinemia, Newborn, Transcutaneous bilirubinometry, Total serum bilirubin

INTRODUCTION

Neonatal hyperbilirubinemia is a common problem with incidence of around 60% in term babies and nearly 80-100% in preterm babies. The bilirubin level above 95th percentile may lead to acute bilirubin encephalopathy and or kernicterus which also has long term morbidity in form of cerebral palsy.^{1,2} This complication is preventable

through early recognition, appropriate follow up and treatment such as phototherapy and exchange transfusion.²⁻⁶ The AAP guideline recommends assessment of jaundice in all newborns before hospital discharge. However, the method by which jaundice must be assessed is not specified. Both transcutaneous bilirubin (TcB) and total serum bilirubin (TSB) measurements are cited as acceptable method.⁵

TSB measurement is still considered the gold standard. But it is invasive, painful and costly in terms of workload, time and money. Moreover, there is a concern of significant blood loss due to repeated sampling especially in preterms. TcB being a noninvasive method can overcome these problems.^{7,8}

Studies have shown good correlation between TSB and TcB in various ethnic groups by various authors. However, correlation was affected by various factors like race, gestational age, birth weight, skin color, type of TcB instrument.⁹⁻¹³

There is also variable level of agreement has been reported by different authors. ¹⁴ As there is a variation in reported correlation and agreement in different studies, it is worthwhile to test whether the basic assumption of accuracy of TcB is true for different regions.

This study was done to investigate the accuracy of TcB in evaluation of jaundice in newborn by comparing it with TSB values.

METHODS

A prospective study was performed at neonatal intensive care unit of SMIMER hospital, Surat, located in western part of India. An informed consent was taken from parents of the participants. Both term and preterm babies upto 10 days of life, who were found to be jaundiced visually, were included in the study.

TcB measurement was done by Dragor JM 103 transcutaneous bilirubinometer. The bilirubin concentration was displayed in mg/dl. TcB was measured over forehead of the babies by the same person. TSB measurement was done within half hour of taking TcB

for all readings. TSB estimation was done in venous blood by Diazo method.

All data were analysed with SPSS 11 software. Mean of the three TcB readings was taken and then compared with TSB. Pearson's correlation coefficient (r) was used to assess the strength of relationship between the two measurement methods.

The agreement between two methods was assessed by Bland-Altman analysis. Statistical significance was defined for p<0.05. The Receiver operating characteristic (ROC) curve of mean TcB at TSB >10mg/dl, >12mg/dl and >15mg/dl were constructed to predict the sensitivity and specificity of TcB for different cutoffs.

RESULTS

A total of 160 neonates were included in the study, of which 31 were preterm and 129 were full term. Male:female ratio was 1.3:1. The gestational age ranged from 30 to 42 weeks with mean of 38.23±2.01 weeks. Mean birth weight was 2.403±0.61 kg; range (1-4 kg). Mean age at time of data collection in hours was 83.76±26.62; range (24 -144 hours). The TSB levels ranged from 4.9-21 mg/dl with mean of 11.65±4.58mg/dl. The TcB levels ranged from 3.9-19.5 mg/dl with mean of 11.73±3.53.

In Figure 1, there was positive and significant correlation found between TcB and TSB measured values. The Pearson's correlation coefficient (r) was 0.836, (p<0.001) and the linear regression equation was y=0.827x+1.032. The coefficient of determination (r²) was 0.6993. Thus 69% of variance for serum bilirubin concentration could be anticipated by TcB values. A Bland Altman plot for all comparison is shown in Figure 2.

Study TSB > 10 mg/dlTSB > 12 mg/dlTSB > 15 mg/dl**AUOC AUOC** Sensitivity **Specificity** AUOC Sensitivity **Specificity Sensitivity Specificity** (%) (%) (%)(%) (%)(%) MMJ et 0.962 NA NA 0.963 NA 0.975 NA NA al^{21} BYA et 0.958 89.4 100 0.971 93.6 90.5 0.976 100 100 al^{25} PJ et 0.851 89.4 37 0.830 93.6 65.7 0.958 100 85.4 al^{26} 100 0.907 100 AM et 0.961 82 0.945 96 85 66 al^{24} SS et 91** 98.4* 91.6* 0.93 72.4 95.7 0.97 66** al^{27} 79 0.937 100 59 0.963 92 Present 0.899 100 23 study

Table 1: Comparison ROC analysis with different studies.

^{*}TSB > 7mg/dl; ** TSB >25 mg/dl

There were very few data points fell outside the 2 S.D of difference which suggests normal distribution of data. The average error in evaluating hyperbilirubinemia with TcB as compared to TSB was 0.856 with limits of agreement between (-3.41) to (+5.48).

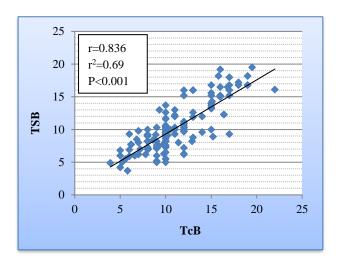
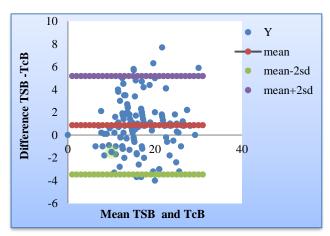


Figure 1: Correlation between TcB and TSB (mg/dl) (n=160).



The lines represent mean difference (+0.856) and ± 2 SD of the difference (-3.41 to +5.48).

Figure 2: Bland Altman plot of TcB Vs TSB.

In Figure 3, 4 and 5, the area under operator characteristic curve (AUOC) was 0.899 (95% CI= 0.851-0.947), 0.937(95% CI=0.896-0.979) and 0.963 (95% CI= 0.936-0.990) at TSB predictive values of >10, >12 and >15 mg/dl respectively. Thus, TcB could be considered good at separating sample values for different predictive values of TSB. The analysis of ROC curved showed 100% sensitivity and 79% specificity for cut-off point of >10 mg/dl. For cut off value of >12 mg/dl produced sensitivity of 100% and specificity of 59% while for cut off value >15 mg/dl showed sensitivity of 92% and specificity of 23%. There is a tendency of increase in false negative rate with an increasing TSB concentration.

However, because of potential risk of hyperbilirubinemia in newborn babies a lower specificity can be acceptable.

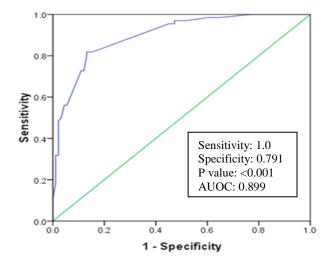


Figure 3: ROC curve for TSB value > 10 mg/dl.

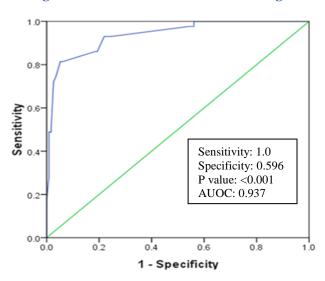


Figure 4: ROC curve for TSB value >12 mg/dl.

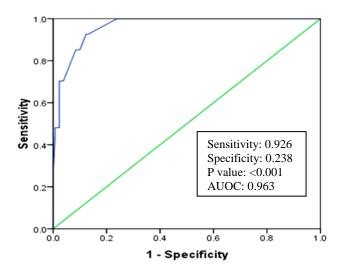


Figure 5: ROC curve for TSB >15 mg/dl.

DISCUSSION

TcB measurement as a screening tool for estimation of neonatal hyperbilirubinemia is based on assumption that serum and tissue bilirubin are in constant equilibrium. TcB works by determining the intensity of specific wave length bands which are reflected from the skin of neonate. 15

Different studies had reported correlation coefficient (r) between TcB and TSB from 0.87 to $0.92.^{16-19}$ We measured TcB over forehead of babies and found high and significant correlation between TcB and TSB (r=0.836, p<0.001). This is in agreement with study, measuring TcB over forehead, done by Andra K et al (r=0.897), Maisel MJ et al and Tommy SK et al (r=0.83), Zohreh et al (r=0.82). $^{16.20-22}$

The coefficient of determination (r²) in present study was 0.69 anticipating 69% of variability of serum bilirubin concentration by TcB measurement. Similar values of 0.67 and 0.64 were reported by Zohreh et al and Luca et al respectively. ^{16,23}

In present study, it was found that AUOC≥0.9 for different predictive values of TSB >10 mg/dl, >12 mg/dl and >15 mg/dl. This is similar to the values reported by Maisel MJ et al, Bental YA et al, Panburana et al and Akharia Moe et al (Table 1). 21,24-26 This suggests that transcutaneous bilirubinometry is good at separating samples with value less than x from samples having values more than x. As seen in table 1, TcB measurement showed sensitivity of 80% to 100% at different cut off TSB values of >10 mg/dl, >12 mg/dl and >15 mg/dl. In current study, it was found to be good sensitivity for three different cut off TSB values. The specificity level is variable in different studies ranging from 35% to 100%. 21,24-26 Samanta et al reported low specificity at higher TSB values.²⁷ Similarly, Holland L et al and EYW Ho et al reported decreased specificity with increasing serum bilirubin concentration. 28,29 The study also showed less specificity with TSB >15 mg/dl but to avoid potential complication of higher bilirubin level in newborns, low specificity can be acceptable. TcB measurement is useful as an alternative, quick and convenient screening tool.

CONCLUSION

TcB measurement using Dragor JM 103 bilirubinometer correlated well with serum bilirubin measurement. Transcutaneous bilirubinometry provided reasonably accurate estimation of TSB values. It is a useful method as a screening tool for evaluation of jaundice in newborns.

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Ethical approval: The study was approved by the Institutional Ethics Committee in neonatal intensive care unit of SMIMER hospital, Surat, Gujarat

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