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Correlation of transcutaneous bilirubin and serum bilirubin concentration in term and late preterm newborns

Sushil Gunaseelan, Sahana Devadas, Nandita Pai
Department of Pediatrics, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

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Correspondence Address:
Sushil Gunaseelan
#45, Heerachand Layout, Cox Town, Bengaluru - 560 005, Karnataka
India
Login to access the email ID

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Abstract

Objective: Neonatal jaundice is a common condition requiring evaluation and treatment for most newborns. However, kernicterus is just a "tip of the iceberg" of bilirubin-induced neurologic dysfunction. The objective of this study is to evaluate the use of a transcutaneous bilirubinometer for the detection of hyperbilirubinemia in newborns. **Design and Setting:** In this prospective study, we measured Transcutaneous bilirubin (TcB) concentration in clinically icteric term and late preterm babies. Total serum bilirubin (TSB) was measured if the initial TcB level was higher than the 50th centile in Bhutani's nomogram. Paired TcB and TSB results were correlated, and the mean difference was calculated. **Patients:** Neonates of gestational age more than 35 weeks and weighing more than 2 kg were included in this study. TcB recordings were taken in neonates who appeared clinically icteric. **Results:** Four hundred paired TcB and TSB measurements were taken. TcB was significantly correlating with TSB ($P < 0.001$) in both low-risk and medium-risk thresholds for phototherapy. TcB had a sensitivity and negative predictive value of 100% each, a specificity of 56%, and a positive predictive value of 23%. For high-risk cases, using the 75th centile as cutoff, the sensitivity and negative predictive value were reduced to 88% and 97.0%, respectively. **Conclusion:** TcB correlates closely with TSB concentration in neonates born after 35 weeks gestation. The rate of rise in TcB may help in identification of neonates at risk and minimizing invasive blood investigations.

Keywords: *Hyperbilirubinemia, jaundice, newborn, transcutaneous bilirubin*

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Introduction

Newborn jaundice due to severe hyperbilirubinemia, with its potential for producing brain damage, remains a continuing problem for pediatricians. Recent reports and evaluation of safety data have demonstrated visual assessment of jaundice as an unreliable and unsafe indicator. Hence, knowledge of the infant at risk of developing hyperbilirubinemia allows early intervention before critical concentration is reached.[1] In recent years, however, new methods have been developed to evaluate the severity of neonatal jaundice, involving transcutaneous bilirubinometry (TcB), which is an easy and noninvasive method.[2]

In 2004, the American Academy of Pediatrics recommended predischarge measurement of the bilirubin level using total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) or assessment of clinical risk factors. The best-documented method for assessing the risk of developing subsequent hyperbilirubinemia was to measure the TSB or TcB concentration and plot the results on a nomogram.[3],[7],[8] The American Academy of Pediatrics recommends that newborns discharged within 48 h should have a follow-up visit after 2–3 days for any significant jaundice and other problems. This recommendation is not appropriate for our country due to limited follow-up facilities in the community. Therefore, it is difficult to predict which infants are at increased risk for significant and relatively late hyperbilirubinemia.[4],[5],[6]

Hence, at the time of discharge, there is a need to adopt a method to predict the likely development of hyperbilirubinemia. Early prediction facilitates the use of effective preventive measures and early treatment, thereby reducing mortality and morbidity. And as such, from the obvious need to design and implement a follow-up program, the present study was conducted to measure bilirubin concentration using a transcutaneous bilirubinometer, which could help diagnose neonatal hyperbilirubinemia in the early stages, thus enabling timely intervention and better outcome in newborns with hyperbilirubinemia.

Study design and methods

The study participants included 400 babies which included both full-term and late preterm newborns born at a tertiary

government hospital during the study period from November 2012 to October 2014. Informed consent was obtained from all the parents of the newborns to be enrolled for the study. All relevant information was collected in a predesigned pro forma which included details of the mother and baby.

Clinically, icteric newborns which fulfilled the inclusion criteria (gestational age >35 weeks and birth weight >2 kg) were included in the study; the level of jaundice based on Kramer's rule was assessed.[9] Bilirubin-induced neurological dysfunction (BIND) was assessed by the muscle tone, mental status, and the cry pattern of the baby. A BIND score of above 3 was significant and more suggestive of acute bilirubin encephalopathy.[10] Transcutaneous bilirubin (TcB) measurements were taken using a Draeger JM 103 transcutaneous bilirubinometer over the mid-sternum area and the mean of three values was considered as the final value. The recorded value was compared with standard TcB nomogram. TSB concentration was measured using the modified Jendrassik-Grof photometric method if TcB concentration was above the 50th centile level on the nomogram. TSB was measured within 30 min of checking TcB concentration. The babies were monitored for any secondary complications related to hyperbilirubinemia.

Statistical analysis

Data analysis was performed using Epidemiological Information Package (EPI 2012) version 7.1.1.0 developed by Centers for Disease Control, Atlanta, USA. Using this software, range, frequencies, percentages, means, standard deviations, Chi-square, and "*P*" values were calculated. A *t*-test was used to test the significance of difference between quantitative variables and Chi-square tests for qualitative variables. A $P < 0.05$ was taken to denote significant relationship. Correlation coefficient and percentiles were calculated using the Excel Software. If the value of "*r*" between two variables was more than + 0.5, then those two variables were taken to be correlated.

Results

In the present study, 400 babies included were from day 1 to day 6 of life; majority (50.5%) of the babies were included on day 3 of life and the male:female ratio was 1.2:1. The gestation weeks of babies enrolled ranged from 36 to 40 weeks gestation, and maximum were of 38 weeks gestation (44%). There was no significant correlation between gestational age and TcB ($P = 0.068$). Antenatal complications were present in 47% of the mothers participating in this study, out of whom 16% had anemia and 14.5% had pregnancy-induced hypertension. Majority of the babies had normal vaginal delivery, and only 22% were delivered by cesarean section. The mean TcB (14.8) was higher in babies delivered by cesarean [Table 1].

	Present study (*n*=400)	Keren *et al.*[8] (*n*=812)	Varvarigou *et al.*[15] (*n*=2039)	Chawla *et al.*[18] (*n*=392)
Male	221	401	999	201
Female	179	411	1040	191
P	0.1947		0.61	0.13
Gestational age (weeks)				
36-37	64	109	437	-
38-39	243	403	1161	-
>40	93	300	441	-
Mean	38.4			38
P	0.0689		0.07	
Mode of delivery				
Normal	312	621	1265	230
LSCS	88	191	774	146
P	0.3482		0.23	0.17
Oxytocin during delivery	30	418	-	134
P	0.1453			
Mean birth weight (kg)±SD	2.61±0.33	3.3±0.5	-	2.6±0.4
P	<0.0001**			0.06
Feeding				
Breastfeeds	256	360	872	-
Bottle	50	342	921	-
Mixed	94	108	246	-
P	0.0768		0.73	
Baby blood group				
A	118	268	-	-
B	98	149	-	-
AB	23	35	-	-
O	161	360	-	-
Incompatibility	88	-		106
P	0.1268			0.13

SD – Standard deviation; LSCS – Lower segment Cesarean section; *(P <0.01)

Table 1: Comparison of variables associated with hyperbilirubinemia in our study and previous studies

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Out of 400 babies, 64% were exclusively breastfed and had a mean TcB of 14.4 mg/dl as compared to 24% of babies who received mixed feeds and had a higher mean TcB of 15.06 mg/dl. Visual assessment of jaundice was performed using Kramer's rule, and the level of jaundice was correlated with the BIND score. Around 34% of the babies were in zone 3 (involving lower limbs and thighs) when visually assessed. There was a significant correlation between TcB and visual assessment ($P < 0.001$). Moreover, 88% of the babies had a BIND score of 0 and 0.2% of the cases had a BIND score of 3. There was a strong correlation between TcB and BIND score ($P < 0.0001$). The range of TcB recorded in 400 babies was 8.8–19.2 mg/dl and TSB was 7.4–22 mg/dl. The mean TcB and TSB were both 14.6 mg/dl. There was a significant correlation between TcB and TSB with a correlation coefficient of 0.9427 [Figure 1]. When the TcB cutoff value was taken at 13 mg/dl and the corresponding TSB values were measured, 290 out of 400 cases were positive and sensitivity was found to be 73%. Similarly, cutoff values were taken at 15 md/dl and 17 mg/dl and the sensitivities were found to be 45% and 18%, respectively.

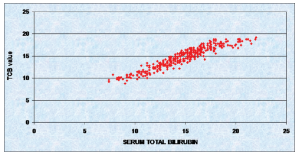

Figure 1: Correlation between transcutaneous bilirubin (TcB) and total serum bilirubin

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Discussion

Sixty to seventy percent of term infants will become clinically jaundiced in the 1st week of life, and approximately 85% of newborn readmissions to the hospital during the 1st week of life are because of hyperbilirubinemia.[11] Early discharge of newborn after delivery is a common practice because of medicosocial reasons and economic constraints. An association between decreased length of stay and the risk of readmission during neonatal period with hyperbilirubinemia has been shown. Early prediction facilitates the use of effective preventive measures and early treatment, thereby reducing mortality and morbidity. A prospective correlation study with 400 newborns was undertaken to examine the correlation of transcutaneous bilirubin and serum bilirubin and its accuracy as a screening tool in detecting hyperbilirubinemia. Transcutaneous bilirubin measurements are made by the absorption of light caused by the presence of bilirubin in the capillary beds and subcutaneous tissue to be isolated by spectral subtraction. This allows an unbiased measurement that is independent of the race, age, and weight of the newborn.[8],[12],[13],[14]

Our study showed a strong association between age of the baby and TcB value ($P < 0.0001$); the mean TcB was least on day 1 (10.4 mg/dl) and highest on day 5 (16.94 mg/dl). Hence, this study infers a strong association between age and TcB. In another similar study conducted by Wainer *et al.* (2012), a large sample of 14,726 was studied and it was found that there was a strong association between age of the baby and TcB value ($P < 0.001$).[13] In another study by Varvarigou *et al*., 2039 babies (gestational age >35 weeks) were studied from birth till 120 h for the development of jaundice. TcB measured was plotted and classified as high-risk, low-risk, and minimal-risk. Results showed a significant

association between age and TcB ($P < 0.01$) with a high likelihood ratio >10 in the high-risk category. Hence, TcB reading varies steadily as the age increases [Table 1].[15] In other similar studies by Ho *et al*.,[3] Bhutani *et al*.,[7] and Kolman *et al*.,[16] results were in accordance with the present study showing a significant correlation between TcB and TSB [Table 2]. In the studies by Maisels *et al*.[17] and Rubaltelli *et al*.,[8] results show decrease in sensitivity and increase in specificity at higher TcB cutoff concentration which is also in accordance with the present study. The study by Maisels *et al.* also found that, as TSB concentration increased, the number of false negative TcB increased. To achieve 100% sensitivity in detecting TSB of >17 md/dl, reported TcB cutoff values varied from >9 mg/dL (with 45% specificity) to >14 mg/dL (with 41% specificity) [Table 3]. The variations in the accuracy that predicts significant hyperbilirubinemia can be explained by the differences in the sample size, method of estimation of bilirubin, and duration between the collection and estimation of bilirubin and by their chosen cutoff values for significant neonatal hyperbilirubinemia.

Table 2: Screening accuracy of TcB in detecting neonatal hyperbilirubinemia

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Table 3: Screening accuracy of TcB at various cutoff concentration

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Conclusion

There was a significant association between visual assessment of jaundice and hyperbilirubinemia. TcB, in adjunct with visual assessment, proves to be an effective screening tool than visual assessment alone. TcB is a rapid, safe, and noninvasive test for predicting neonatal hyperbilirubinemia, which helps in minimizing invasive TSB tests for screening purpose.

Recommendations of this study are that transcutaneous bilirubinometry is a useful noninvasive screening tool in detecting hyperbilirubinemia in newborns and should be used routinely before discharging the baby from the hospital. Visual assessment along with TcB is more effective than visual assessment alone in detecting significant hyperbilirubinemia. Several aspects should be taken into consideration when implementing a universal TcB screening program, including the availability and cost of TcB devices, the need to develop a local TcB nomogram, the selection of appropriate TcB cutoff values, the appropriate quality assurance, training, and education of personnel, and the impact on the demand for community resources.

We acknowledge the weaknesses of this study. Preterms <36 weeks and birth weight <2 kg were not included in the study and the variation of TcB with such babies were not assessed. All babies who were included were clinically icteric and had hyperbilirubinemia. Hence, specificity of the test in ruling out hyperbilirubinemia was not assessed. Serial TcB readings were not taken which could have helped in analyzing the rate of increase in bilirubin concentration.

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Conflicts of interest

There are no conflicts of interest.[18]

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Figures

[Figure 1]

Tables

[Table 1], [Table 2], [Table 3]