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**Original Research Article**

# Study of the effectiveness and accuracy of transcutaneous bilirubinometer in early diagnosis of neonatal hyperbilirubinemia in North India

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## ABSTRACT

**Background:** Neonatal hyperbilirubinemia affects 60% of full-term and 80% of premature infants leading to jaundice when serum bilirubin levels reach 5 mg/dl. As the red blood cells undergo the process of lysis, it increases the levels of serum bilirubin. The standard criteria to measure the levels of total serum bilirubin is via taking a blood sample but in contrast to it transcutaneous bilirubin measurement offers non-invasive, rapid results, typically within a minute, for assessing bilirubin levels. To determine the accuracy and reliability of transcutaneous bilirubinometer. Additionally, to investigate the capability of transcutaneous bilirubinometers in facilitating the early diagnosis of hyperbilirubinemia in preterm babies.

**Methods:** For this study newly, registered neonates were assessed for hyperbilirubinemia, with MBJ20 bilirubinometer on the forehead within 24 hours of life and following up the patients for serum bilirubin levels. We took 400 neonates late preterm and term. The babies who had readings of 6 or more than 6 mg/dl, were further evaluated by total serum bilirubin levels.

**Results:** In our study using the MBJ-20 transcutaneous bilirubinometer, the mean bilirubin concentration measured via TCB at the forehead was 8.75±2.27 mg/dl, compared to a mean TSB value of 12.28±2.33 mg/dl. A strong positive correlation was observed between TCB and TSB levels (r=0.86). Furthermore, the diagnostic performance of TCB was high, with an area under the ROC curve (AUC) of 89.9%. The sensitivity of TCB forehead ranges between 80.0%–93.5% and the specificity is between 63.5%–79.4%.

**Conclusions:** The data of our study arrived at a conclusion that the use of TCB is potentially safe and effective. Its measurements are reliable and accurate.

**Keywords:** Hyperbilirubinemia, Non-invasive, Neonates, Neonatal jaundice, Transcutaneous bilirubinometer

## INTRODUCTION

Neonatal hyperbilirubinemia affects 60% of full-term and 80% of premature infants, causing jaundice when bilirubin levels reach 5 mg/dl.[1,2] Risk factors include low gestational age, hemolysis and exclusive breastfeeding.[3] Bilirubin-induced encephalopathy (BIE) can occur, leading to symptoms like lethargy and poor feeding, with potential long-term effects such as visual and auditory impairments and cerebral palsy.[4,5] The primary management goals are early identification of pathological causes of hyperbilirubinemia and to initiate treatment aimed at preventing bilirubin neurotoxicity and thereby, preventing long term complications and decreasing mortality of premature newborns. Measuring serum bilirubin levels is a common laboratory test conducted on

neonates. Serial measurements are essential for evaluating both the bilirubin concentration and its rate of change, which requires taking multiple blood samples. This can increase the risk of complications such as sepsis, hematoma formation and thrombophlebitis. Consequently, there is a growing need for a non-invasive, painless and reliable method to assess bilirubin levels and their changes within the first 36 to 72 hours after birth.[6] Transcutaneous bilirubin (TCB) measurement is a non-invasive technique used to assess serum bilirubin levels. It functions by directing light into the skin and measuring the intensity of the reflected light wavelengths.[7]

Transcutaneous bilirubin measurement offers rapid results, typically within a minute, for assessing bilirubin levels. While studies have explored the use of transcutaneous bilirubinometers, a literature review reveals a lack of research specifically examining their effectiveness in the early detection and prognosis enhancement for neonates at risk for hyperbilirubinemia. This study aims to develop a reliable predictive model to assist clinicians in identifying at-risk infants and customizing interventions accordingly.

## METHODS

The study was approved by the Ethics Committee of my Institution after its protocol was submitted and thoroughly reviewed by them. This is a prospective cross-sectional observational study conducted in the NICU of the Pediatric Department at the Punjab Institute of Medical Sciences in Jalandhar, Punjab, India over a duration of one year.

### *Inclusion criteria*

The study included both term and late preterm inborn babies POG 35 weeks to 36 weeks+6 days, parents who give consent.

### *Exclusion criteria*

The study excludes outborn babies, babies whose blood samples have already been sent before assessment with trans bilirubinometer, babies who have already received prophylactic phototherapy, babies with family history of hemolytic disease, parents who refused to give consent.

After applying an appropriate criterion, a sample size of 400 newborns was computed and they were assessed for hyperbilirubinemia, with MBJ20. Transcutaneous bilirubinometer on the forehead within 24 hours of life prior to blood testing and also following up the patients for serum bilirubin levels. Characteristics of mother, pregnancy and newborns were gathered. These included the period of gestation, mother's blood group, baby's blood group, weight of the baby at birth, any history of jaundice in mother or previous sibling, any antenatal infection or metabolic disease like diabetes, hypo or hyperthyroidism history in the mother, mode of delivery, use of oxytocin, history of cephalohematoma at birth of the baby, type of feed, feeding adequacy and use of phototherapy.

### *Transcutaneous bilirubin measurement method*

The inborn babies were assessed within day one of life via MBJ20 Transcutaneous bilirubinometer. The use bilirubinometer to record the readings was done by the Pediatrician. The forehead was taken as the site of assessment. After switching on the device, it was positioned in contact with the skin of the newborn's forehead kept in supine pose. Gentle pressure was applied for one to three seconds, likewise three readings were taken which gave a single average reading of TCB in mg/dl. Those who had readings of 6.0 mg/dl or more, were further evaluated by sending blood samples for serum total serum bilirubin levels.

### *TSB measurement*

The venous blood sample was obtained under aseptic conditions by a trained nurse practitioner. The blood samples were sent to the laboratory for the results calculated by the diazo method. After the confirmation of total serum bilirubin levels those with levels greater or equal to 10.2 mg/dl were advised phototherapy.

### *Statistical methods*

Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). For each assessment point, data were statistically analyzed using t test and chi square test. The level of significance was set at $p<0.05$.

## RESULTS

Out of 400 subjects, male and female babies' population comprised 48.8% and 51.2% respectively, hence there was nearly equal distribution of male and female. All the babies were born in Punjab.

In this study 56.25% of babies had a birth weight more than 2.5 kg whereas 43.75% babies had birth weight less than and equal to 2.5 kg. As per the mode of delivery, LSCS was done in 46.4% of pregnant women and normal vaginal delivery was conducted in 53.6% pregnant women. The use of oxytocin was present in 53.5% of deliveries (inclusive of both LSCS and NVD). The percentage of babies born late preterm were 29.5% and those born at term were 70.5%. The percentage of mothers who had a history of jaundice during pregnancy was 4.8%. The Rh ABO incompatibility was present in 2.8% of mothers. The most common comorbidities among all other antenatal conditions were diabetes in 19 pregnancies (4.75%). The second common was hypothyroidism (2.25%). Other comorbidities like

infection, anemia, chickenpox, hepatitis B, oligohydraminos and history of amniocentesis were observed in 0.25% of pregnant women each. A single pregnant woman had presented with a combination of hypothyroidism, diabetes and anemia (0.25%). Cephalohematoma was the most common birth condition observed in babies (6%). The second most common being respiratory distress syndrome (1%). Other conditions such as amniocentesis, bruising, delay cry after birth resuscitation, fetal distress, hemolysis and meconium staining were seen in 0.25% of babies each. Mean±SD of serum bilirubin according to TSB and TCB forehead was 12.283±2.33 and 8.752±2.2702 respectively.

### *Pearson correlation (r) analysis*

According to Pearson correlation (r) analysis, the significant positive correlation found between TCB sternum and TSB, r equal to 0.86 ($p<0.01$) with respect to serum bilirubin as shown in Figure 1.

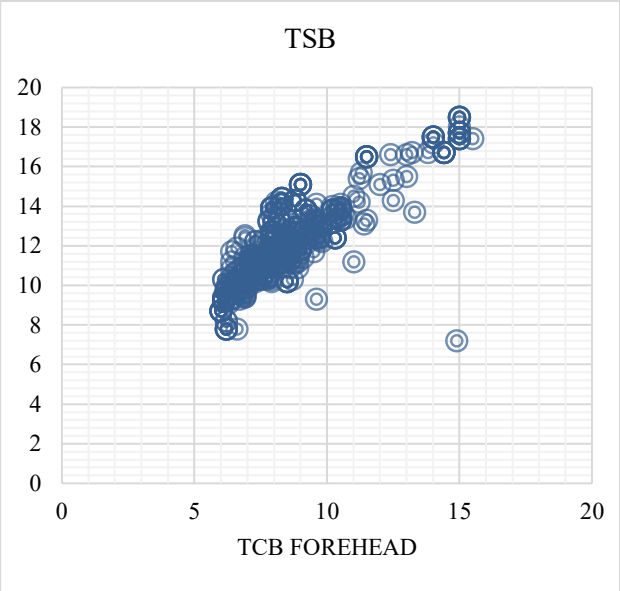


**Figure 1: Pearson correlation.**

A total of 229 babies underwent phototherapy, comprising 115 males and 114 females. The mean TCB value at the forehead at which phototherapy was initiated was 9.83 mg/dl, ranging from 6.1 mg/dl to 15.5 mg/dl. The corresponding mean total serum bilirubin (TSB) level at the start of phototherapy was 13.68 mg/dl, with a range of 10.2 mg/dl to 18.5 mg/dl. They under conventional phototherapy, emitting blue, fluorescent light with a wavelength range of 420–470 nm, phototherapy was administered from approximately 30–45 cm from the infant. The eyes and genitals of the babies were covered to protect from unwanted side effects of phototherapy including retinal damage and skin irritation.

### *Area under the curve*

Receiver operating characteristic (ROC) analysis for transcutaneous bilirubin measured at the forehead demonstrated excellent diagnostic performance. The area under the ROC curve as in Figure 2 (AUC) was 0.899, indicating high accuracy of the test in discriminating between neonates with and without significant hyperbilirubinemia. The standard error of the AUC was 0.015 and the result was statistically significant ($p<0.001$) when tested against the null hypothesis of an AUC of 0.5. The 95% confidence interval ranged from 0.869 to 0.929, reflecting good precision and reliability of the estimate. Although at least one tied value was noted between the positive and negative outcome groups which may introduce minimal bias the overall findings support the strong diagnostic utility of forehead TCB measurements.

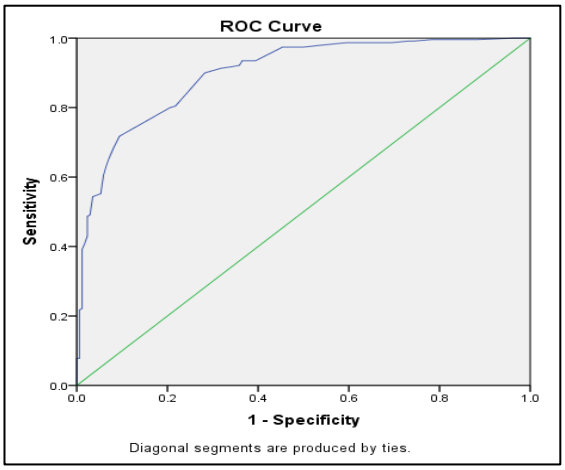


**Figure 2: ROC curve.**

The ROC curve analysis for TCB (forehead) showed varying sensitivity and specificity across different bilirubin cutoff values. Each point on the curve represents a TCB threshold with corresponding sensitivity and false positive rate. The table shows selected cutoff values of TCB (mg/dl) with corresponding sensitivity and false positive rate (1-specificity). For example, a TCB cutoff of 7.45 mg/dl yielded a sensitivity of 93.5% with a false positive rate of 36.5%, while a cutoff of 8.15 mg/dl showed a sensitivity of 80.0% and a lower false positive rate of 20.6%. These coordinates were used to plot the ROC curve and assess the diagnostic performance of TCB in predicting significant hyperbilirubinemia.

**Table 1: Baseline characteristics among the study subjects.**

| Variables | n=400 | % |
|---|---|---|
| **Gender** | | |
| Male | 195 | 48.8 |
| Female | 205 | 51.2 |

Continued.

| Variables | n=400 | % |
|---|---|---|
| **Birth weight (in kg)** | | |
| ≤2.5 | 175 | 43.75 |
| >2.5 | 225 | 56.25 |
| **MOD** | | |
| NVD | 214 | 53.6 |
| LSCS | 186 | 46.4 |
| **Preterm** | | |
| Yes | 118 | 29.5 |
| No | 282 | 70.5 |
| **History of jaundice in mother** | 19 | 4.8 |
| **Oxytocin use** | 214 | 53.5 |
| **RH ABO incompatibility** | 11 | 2.8 |

**Table 2: Antenatal condition among the study subjects.**

| Variables | n=400 | % |
|---|---|---|
| **Amniocentesis** | 1 | 0.25 |
| **Diabetes** | 19 | 4.75 |
| **Hypothyroidism** | 3 | 0.75 |
| **Infection** | 1 | 0.25 |
| **Amniocentesis** | 1 | 0.25 |
| **Anemia** | 1 | 0.25 |
| **Chickenpox** | 1 | 0.25 |
| **Hepatitis B** | 1 | 0.25 |
| **Hypothyroidism** | 6 | 1.5 |
| **Hypothyroidism, Diabetes, Anemia** | 1 | 0.25 |
| **Oligohydramnios** | 1 | 0.25 |

**Table 3: Birth condition among the study subjects.**

| Variables | n=400 | % |
|---|---|---|
| **Amniocentesis** | 1 | 0.25 |
| **Bruising** | 1 | 0.25 |
| **Cephalohematoma** | 24 | 6 |
| **Delay cry after resuscitation** | 1 | 0.25 |
| **Fetal distress** | 1 | 0.25 |
| **Haemolysis** | 1 | 0.25 |
| **RDS** | 4 | 1 |
| **Meconium passed** | 1 | 0.25 |

**Table 4: Descriptive analysis of TCB forehead and TSB.**

| Variables | Minimum | Maximum | Mean | SD |
|---|---|---|---|---|
| **TSB** | 7.2 | 18.5 | 12.283 | 2.3300 |
| **TCB Fforehead** | 6.0 | 15.5 | 8.752 | 2.2702 |

**Table 5: No. of babies undergoing phototherapy.**

| Gender | No. of babies who underwent phototherapy |
|---|---|
| **Male** | 115 |
| **Female** | 114 |
| **Total** | 229 |

**Table 6: TCB forehead value at the start of phototherapy.**

| Parameter | Mean (mg/dl) | Range (mg/dl) |
|---|---|---|
| **TCB forehead (mg/dl)** | 9.83 | 6.0-15.5 |

**Table 7: Corresponding serum bilirubin (TSB) at the start of phototherapy.**

| Parameter | Mean (mg/dl) | Range (mg/dl) |
|---|---|---|
| **TSB (mg/dl)** | 13.68 | 10.2-18.5 |

**Table 8: Coordinates of the ROC curve for transcutaneous bilirubin (TCB) measured at the forehead.**

| Coordinates of the curve | | |
|---|---|---|
| **Test result variable(s): TCB forehead** | | |
| **Positive if greater than or equal to** | **Sensitivity** | **1 - Specificity** |
| **7.450** | 0.935 | 0.365 |
| **7.550** | 0.922 | 0.359 |
| **7.650** | 0.917 | 0.341 |
| **7.750** | 0.913 | 0.318 |
| **7.850** | 0.900 | 0.282 |
| **8.000** | 0.804 | 0.218 |
| **8.150** | 0.800 | 0.206 |

## DISCUSSION

This study is the first one to be done particularly on the babies born in Punjab, North India. A similar study was done in 2020 by Kumar et al on Indian neonates but there is a difference with respect to region of study, the device used for the study and sample size of study population.[8] The study mentioned above was conducted on neonates born in Uttar Pradesh in contrast to our study which is done on neonates born in Punjab. Secondly, the device used by the mentioned study was the Drager JM-105 bilirubinometer whereas we used the MBJ20 Transcutaneous bilirubinometer. Lastly, the study population in their study comprised 276 neonates while our study comprises 400 neonates.

There is a strong correlation between TCB forehead and TSB found in our study (r=0.86), indicating that the results of TCB measured by MBJ20 Transcutaneous bilirubinometer are reliable. These results are consistent with other researches. In the study by Madubuike et al 2016 a relatively stronger correlation coefficient of 0.904 was calculated using the same device. The study by Kumar et al observed a coefficient correlation of 0.806. Similarly, the study Surana et al showed a positive r value of 0.856.[9] A relatively stronger r value is seen in the study by Andra et al, who used the Drager Jaundice Meter JM-105 device.[10] Similar results were shown in research done by Tommy et al using the JM-103 device (r=0.83) and Bdiee et al on preterm neonates using the BiliCheck device (r=0.75).[11,12] In a study by Khajehei et al the correlation was conducted on the results of two transcutaneous devices compared to TSB.[13] Those two devices were MBJ20 AND JM-105. The results were nearly similar. The coefficient of correlation was 0.777 and 0.751 for JM-105 and MBJ-20 respectively.

Nevertheless, the findings of our study were different from the results measured by Ajay et al who got a weaker correlation coefficient of 0.342.[14] Some studies showed that TCB sternum had stronger correlation than TCB forehead with TSB. These include study by Kosarat et al done on 257 babies and results had better correlation coefficient of >0.8 for TCB sternum.[15] Another study by Chimhini et al also revealed a similar finding.[16] The differences in results might be due to variation in exposure to light on different areas of body, variation in hair growth, collagen and deposition of melanin.[17]

In the study on evaluation of the MBJ-20 device we found out that mean bilirubin concentration via TCB forehead is 8.752±2.2702 mg/dl compared to TSB (12.283±2.33 mg/dl). Similarly, the results obtained from the study by Rodríguez-Capote et al, who used two different bilirubinometers (BiliCheck and JM-103) demonstrated that TCB underestimates TSB values.[15] There is also some similarity in the choice of study population, we selected late preterm (between 34 to 36+6 days) and term neonates and the above-mentioned study also selected neonates of more than 35 weeks of gestation, consisting of both late preterm and term babies.

In contrast, the study by Madubuike et al presented that MBJ20 overestimated the values of serum bilirubin. According to the results of the mentioned study the mean bilirubin concentration measured by transcutaneous method was 14.05±5 mg/dl and via serum bilirubin levels were 12.92±5.11 mg/dl. The study by Mohamed et al 2022 also had different results than our study, this might be due to difference in device used (Drager JM-103), the ethnicity of their neonates was malay and whereas the neonates in our study were Indo-Aryan, less sample size (130) than ours and majority neonates got their transcutaneous bilirubin checked on day 3 of life while in our study the neonates were checked for jaundice on 1st day of life.[16]

The area under receiver operating characteristics (ROC) of TCB forehead showed high diagnostic accuracy (89.9%). The results are similar to the study by Mohamed

et al where the value of area under curve was 89.8%. However, the sensitivity obtained in our study was higher (80.0%–93.5%) than the above-stated study (84.4% to 85.3%). The study by Alanezi et al had sensitivity greater than 94% for TCB forehead like our study.[20] In contrast to our study, Zhang et al in their study described that the sensitivity obtained at sternum via TCB was greater than that on forehead.[21]

In the study those with TCB forehead more than equal to 6.0 mg/dl to 15.5 mg/dl underwent testing of serum TSB levels. Those neonates with 10.2 mg/dl to 18.5 mg/dl range TSB underwent phototherapy treatment. Depending on the levels, the number of days for phototherapy were decided. Thus, this screening protected the neonates from the complication of jaundice like kernicterus, encephalopathy and infections.

Authors conducted the study at one hospital setting, tertiary care centre. Authors didn't involve any other primary or secondary centre. The ethnicity involved in our study is Indo-Aryans. Also, the evaluation of TCB forehead on late preterm and term neonates was done before starting any treatment or phototherapy, on the first day of life. Authors concluded that TCB is a useful non-invasive method for early detection of neonatal jaundice and providing timely intervention.

## CONCLUSION

The data of the study arrived at a conclusion that the use of TCB is potentially safe and effective. Its measurements are reliable and accurate. Thus, it serves as an early screening tool in newborns for neonatal hyperbilirubinemia. Its use will assist clinicians in identifying at-risk infants and customizing interventions accordingly.

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