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**ORIGINAL RESEARCH ARTICLE:**

# Role of Transcutaneous Bilirubinometer in the assessment of Neonatal Jaundice – A Cohort Study

**Dr. Logeshwaran. K[1], Dr R.K. Viswanathan[2], Dr. Divya Masilamani[3], Dr. Saranya Balasubramaniam[4], Dr. Deepha.S[5], Dr Arbind Kumar C[6].**

1. Dr. Logeshwaran. K, Assistant Professor, Department of Pediatrics, Government Erode Medical College Hospital, Perundurai. Mobile: 9894105085, Email: logeemavericks@gmail.com
2. Dr. R.K. Viswanathan, Assistant Professor, Department of Pediatrics, Government Erode Medical College Hospital, Perundurai.Mobile: 9486555348 Email: viswa3009@gmail.com
3. Dr. Divya Masilamani, Assistant Professor, Department of Pediatrics, Government Erode Medical College Hospital, Perundurai. Mobile: 9445762736 Email: divmmn@yahoo.com
4. Dr. Saranya Balasubramaniam, Assistant Professor, Government Erode Medical College & Hospital, Perundurai.Mobile: 9994777404, Email: sibisaran29tup@gmail.com
5. Dr. Deepha.S, Junior Resident, Department of Pediatrics, Coimbatore Government Medical College Hospital, Coimbatore. Email: deephasithambaram@gmail.com Phone: 8675721901
6. Dr. Arbind Kumar C, Department of Pharmacology, Government Erode Medical College Hospital, Perundurai. Phone: 7871797278, Email: drakc.r@hotmail.com

Corresponding Author:

Dr. Saranya Balasubramaniam, Department of Pediatrics, Assistant Professor, Government Erode Medical College & Hospital, Perundurai. Phone: 9994777404 Email: sibisaran29tup@gmail.com

Abstract:

**Background:** The cost of transcutaneous bilirubin (TcB) assessments in neonates restricts its availability outside of high-resource environments. There are typically only a few instruments, even in hospitals. Accurate bilirubinometers are becoming increasingly important for outpatient care and home monitoring, since many families these days are sent home before the period that neonatal hyperbilirubinemia peaks. We designed a novel, straightforward Tc bilirubinometer specifically for this purpose, and in this work, we assess the degree of agreement between TcB and TsB before, during, and after phototherapy treatment. **Methods:** In the newborn unit of the paediatric department at MGMGH and KAPV GMC in Trichy, a prospective cohort research was conducted. Included were newborns with ABO and Rh incompatibility who needed phototherapy after developing clinical jaundice within 10 days of birth. However, those who required an exchange transfusion or post-exchange, had bruises, birth marks, subcutaneous hematomas, or were suffering from conjugated hyperbilirubinemia were prohibited from taking part in the trial. This study involved

400 newborns in all. **Results:** The majority of newborns had gestational ages more than 35 weeks. For all gestational ages of newborns, there is a strong correlation between baseline transcutaneous bilirubinometer values and total serum bilirubin. Good agreement was found in the agreement study between TcB and TSB, with limits of agreement ranging from 0.6 to 4.1. Compared to the unpatched area, there was good agreement between the patched area TcB and TSB during the whole-time interval following the start of phototherapy. The results of the analysis of Rebound TcB and TSB were also same. **Conclusion:** A secure instrument for determining bilirubin levels in neonates—term and preterm—is the MBJ-20 Tc bilirubinometer. Since there is minimal possibility of overestimation when utilising TcB from a covered forehead before to, during, and following phototherapy, TcB can be used to monitor neonatal jaundice. Validating TcB's high value or bilirubin in exchange level with serum bilirubin is essential.

**Key words:** Transcutaneous bilirubin, Total serum bilirubin, neonatal jaundice.

## Introduction

One of the most frequent reasons for hospital stay in the first week following delivery is neonatal jaundice. Hyperbilirubinemia is the cause of it[1,2]. Although bilirubin encephalopathy (kernicterus) can result from severe newborn hyperbilirubinemia, the majority of cases are benign. Kernicterus is linked to a significant death rate, and those who survive typically experience sequelae such intellectual impairment, high-frequency hearing loss, and athetoid cerebral palsy[3]. Early treatment with phototherapy or exchange blood transfusion, along with adequate serum bilirubin monitoring, can prevent severe neonatal hyperbilirubinemia and its consequences.

The biochemical laboratory's total serum bilirubin (TsB) measurement is still the gold standard for determining bilirubin levels, but it is intrusive, requiring needle pricks that put the neonates at risk for infection and causing discomfort and stress[4]. The start of therapy for newborn hyperbilirubinemia may be delayed due to the turnaround time for bilirubin test results. An alternate method for estimating bilirubin levels has been the Tc bilirubinometer, which measures bilirubin levels via photometry. A Tc bilirubinometer is a non-invasive, painless, and portable tool. By applying pressure with a probe to the newborn's forehead or sternum, bilirubin can be determined. It produces an instantaneous outcome, enabling the start of therapy right away and lessening the load on medical professionals[5,6].

The 1980s saw the introduction of the first Tc bilirubinometer, and in the intervening years, the devices' corresponding technologies have advanced significantly. Since then, a great deal of research has been done to demonstrate the accuracy and sensitivity of Tc bilirubinometers utilising a variety of equipment. The Tc bilirubinometer is a useful screening tool for TSB in the management of hyperbilirubinemia globally because to the strong association seen between TSB and TcB levels[7,8]. In fact, the American Academy of Paediatrics advises evaluating TSB or TcB in all newborns as part of a pre-discharge assessment of bilirubin levels[8]. In

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fact, some nations, like Mongolia and India, have carried out research to use the Tc bilirubinometer as a screening tool for infant jaundice in their underdeveloped and rural populations[9,10]. The study's goal was to evaluate the level of agreement between TcB and TsB prior to, during, and following phototherapy treatment (post phototherapy at 24 hours after treatment).

**Methods**

In the years 2019–2021, a prospective cohort study was carried out in the newborn unit at the paediatric department of MGMGH and KAPV GMC in Trichy. newborns admitted to the neonatal intensive care unit due to acute jaundice, then those who need phototherapy in accordance with the Maisels table and AAP nomogram[11]. Newborns with ABO and Rh incompatibilities, who developed clinical jaundice within 10 days of birth and required phototherapy, were included. But individuals with conjugated hyperbilirubinemia, bruises, birthmarks, subcutaneous hematomas, and those in need of exchange transfusion and post-exchange were not allowed to participate in the study.

Four hundred samples in total are needed to obtain an agreement of 0.8 with a 5% sample error. Babies who had already been admitted and developed clinical jaundice were included in the trial. Newborns who showed signs of jaundice were admitted to the newborn unit.

Parents' informed consent will be sought before blood samples are taken from a peripheral vein. Within thirty minutes after ingesting TcB, blood samples were obtained.The Diazo technique was used to assess the TSB. A thorough history and clinical assessment were conducted. Three forehead readings with the MBJ-20 will be obtained, and the average of the three recorded values is used to determine the TcB. Following blood and TcB administration, the infant underwent phototherapy. Babies' foreheads, where TcB is measured, are covered with a protective patch called BilEclipse phototherapy prior to phototherapy exposure.

The eyes and genitalia were covered during phototherapy. Every newborn had a clinical evaluation for jaundice at least twice a day in soft natural light. Using irradiants in the blue-green spectrum between 425 and 475 nm, intensive phototherapy will be administered to as much of the infant's surface as feasible. Those who did not meet the exclusion criteria for phototherapy were not allowed to participate in the study. Phototherapy using LEDs or CFLs is employed.

The AAP nomogram was used to classify the risk following phototherapy exposure into three categories: high, medium, and low. Following the conclusion of phototherapy, TSB and TcB were measured concurrently in 8, 12, 24, and 48 hours. TSB and TcB are measured in the patch's covered and uncovered areas. Less than 35 weeks preterm newborns with jaundice should be treated according to Maisels et le[12], which takes into account both sick and healthy babies. SPSS software was used to analyse all of the data using statistical inference. Bland and Altman plots are used to evaluate the agreement between TcB and TSB measurements.

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**Results**

In 358 babies both TSB, TcB were measured simultaneously or within 30 minutes. While on phototherapy, according to the risk category TcB and TSB were taken concurrently. No phototherapy required after 72hrs. TcB values taken in both patched and unpatched area. 24 hrs after stopping phototherapy in TcB (both patched and unpatched area) and TSB were taken. Results were entered and analyzed by the SPSS 21.0 software. The agreement between TcB and TSB is analysed by Bland Altman plots, using MEDCALC software.

Out of 358 babies 200 (55.9%) were boys and 158(44.1%) were girls. Mean age at admission was 86.7 hours, Mean gestation was 36.2 weeks. Majority of study population were belongs to above35 weeks of gestational age (63.7%), followed by 29-35wks (35.8%). Around 71.5% (256) babies were delivered by normal delivery, 26.3% by LSCS and 2.2% by assisted vaginal delivery. Mean weight at admission was 2401.13 grams. Out of 358 babies, predominant of babies birth weight were in above 2500 grams (50.6%) followed by 1501-2000 grams (24.6%) then 2001-2500. 1000-1500grams 29(8.1%) and <1000 (1.1%) grams constituted lesser number.

Out of 358 babies, 1.7% had respiratory morbidities like RDS, TTN; 13.1 % had setting of blood group incompatibility, 0.3 % had sepsis, 2.2 % babies had perinatal asphyxia. Out of 388babies, 358 babies were started on phototherapy and 10 babies needed exchange transfusion.

Baseline analysis before Phototherapy includes mean total serum bilirubin (TSB) which was reported as 15.9mg/dl and Mean TcB was 17.71. In this plots Agreement analysis between TcB and TSB showed good agreement with limits of agreement between -0.6 to 4.1.

**Table 1: Comparison between TcB and TSB**

| Time | Mean TSB | Mean TCB (P) | CI | P |
|---|---|---|---|---|
| 8 hrs | 11.37±2.21 | 13.51±2.52 | 0.13 to 4.14 | 0.03 |
| 12 hrs | 12.86±3.14 | 14.68±3.11 | 1.21 to 2.43 | <0.0001 |
| 24 hrs | 13.72±3.57 | 15.34±3.6 | 1.08 to 2.15 | <0.0001 |
| 36 hrs | 10.53±3.31 | 12.15±3.1 | 0.77 to 2.46 | 0.0002 |
| 48 hrs | 14.29±2.8 | 15.72±2.7 | 0.75 to 2.11 | <0.0001 |
| 60 hrs | 10.98±2.55 | 12.74±2.73 | -0.08 to3.60 | 0.06 |
| 72 hrs | 12.25±3.2 | 14.21±3.26 | 0.26to 3.65 | 0.024 |

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**Table 2: Agreement analysis between TcB patched and TSB**

| Time | Mean of differences | Limits of agreement | ICC | CI |
|---|---|---|---|---|
| 8 hrs | 2.12 | 0.8-3.45 | 0.48 | 0.28-0.93 |
| 12 hrs | 1.8 | -0.1-3.8 | 0.88 | 0.84-0.91 |
| 24 hrs | 1.6 | -0.8-4.0 | 0.91 | 0.89-0.93 |
| 36 hrs | 1.7 | -0.4-3.7 | 0.90 | 0.85-0.93 |
| 48 hrs | 1.4 | -0.7-3.6 | 0.89 | 0.84-0.92 |
| 60 hrs | 1.76 | 0.9-2.62 | 0.88 | 0.68-0.95 |
| 72 hrs | 1.89 | 1.03-2.76 | 0.91 | 0.81-0.95 |
| After treatment | 2.3 | 0.8-3.7 | 0.78 | 0.73-0.82 |

**Table 3: Agreement analysis between TcB (Unpatched) and TSB**

| Time | Mean of differences | Limits of agreement | ICC | CI |
|---|---|---|---|---|
| 8 hrs | -3.9 | -9.1-1.2 | -1.76 | -8.1 to-0.19 |
| 12 hrs | -4.1 | -8.8-0.6 | -0.068 | -.040 to-0.18 |
| 24 hrs | -5.5 | -10.8- -0.2 | -0.41 | -0.74to -0.14 |
| 36 hrs | -4.3 | -10.6-1.3 | -0.5 | -1.1 to -0.03 |
| 48 hrs | -7.3 | -12.0- -2.6 | -2.88 | -4.50 to -1.73 |
| 60 hrs | -6.2 | -10.6- -1.8 | -3.09 | -10.9 to -0.49 |
| 72 hrs | -7.2 | -12.3- -2.0 | -0.41 | -0.73 to -0.14 |
| After treatment | -4.4 | -8.2- -0.5 | -0.41 | -0.73 to 0.14 |

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**Table 4: Correlation between TSB and TcB -Patched area**

| Time | CC | CI | p value |
|---|---|---|---|
| 8 hrs | 0.96 | 0.82-0.99 | <0.0001 |
| 12 hrs | 0.94 | 0.93-0.96 | <0.0001 |
| 24 hrs | 0.94 | 0.92-0.95 | <0.0001 |
| 36 hrs | 0.92 | 0.92-0.96 | <0.0001 |
| 48 hrs | 0.98 | 0.89-0.94 | <0.0001 |
| 60 hrs | 0.99 | 0.96-0.99 | <0.0001 |
| 72 hrs | 0.95 | 0.98-0.99 | <0.0001 |
| After treatment | 0.95 | 0.95-0.96 | <0.0001 |

**Table 5: Correlation between TSB and TcB - Unpatched area**

| Variable | CC | CI | P value |
|---|---|---|---|
| 8 hrs | 0.51 | -0.52- -0.6 | 0.8163 |
| 12 hrs | 0.64 | 0.55-0.72 | <0.0001 |
| 24 hrs | 0.68 | 0.26-0.62 | <0.0001 |
| 36 hrs | 0.41 | 0.24-0.56 | <0.0001 |
| 48 hrs | 0.50 | 0.36-0.02 | <0.0001 |
| 60 hrs | 0.48 | 0.0002-0.28 | 0.0502 |
| 72 hrs | 0.67 | 0.39-0.83 | 0.0001 |
| After treatment | 0.65 | 0.59-0.71 | <0.0001 |

## Discussion

This study was conducted with the aim of studying agreement between Transcutaneous bilirubin and Total serum bilirubin in neonates with clinical evidence of jaundice by using MBJ-20 TcBr device. In our study majority of babies were >35 weeks of gestational age.

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Baseline transcutaneous bilirubinometer measurements correlate well with Total serum bilirubin in all gestational age babies. Agreement analysis between TcB and TSB showed good agreement with limits of agreement between [0.6-4.1]. After initiation of phototherapy agreement was good between patched area TcB and TSB in all time interval compared to unpatched area. Analysis of Rebound TcB and TSB also gave the same result.

Studies from various countries demonstrated good correlation of TcB with Total Serum Bilirubin in neonates. But only few studies are done in dark skinned people like Indian. Relation to reliability of TcB devices during phototherapy and after phototherapy few studies has been done. Compared with studies like Samiee-Zafarghandy et al[13], Deluca et al[14] had reasonable sample population to do the study. Study population consists of both well baby as well as sick baby. We did the study in < 10 days of age both term and preterm babies who developed clinical evidence of jaundice not studied any apparently normal babies. Our study comprised of predominantly >35weeks like in yaser et al. In their study the mean gestational age and mean birth weight was different from our study.

We did TcB in time period such as before PT, after 8, 12, 24, 36, 48, 60, 72 hours and after 24 hours of stopping PT for rebound compared to R Fonseca et al[15] did TcB before PT and 6, 12, 24 after PT and after 6 hours stopping PT for rebound; Deidre et al[16] did at three interval before during and after PT. We did TcB measurements at forehead before initiation of phototherapy we applied BiliEclipse patch over the forehead as most of the study used the patch over forehead.

**Transcutaneous Bilirubinomter before Phototherapy**

Our study we found forehead correlation coeffcient of 0.93 this was comparable to Ahamed et al[17], Bhutani et al[18], Yasuda et al[19], Blandaltman plot was constructed for TcB at forehead and TSB. At forehead, mean difference was 1.7, with 95% CI of -0.6 to 4.1.

**Transcutaneous Bilirubinometer during and after Phototherapy**

Our study evaluated reliability of TcB devices in monitoring of jaundice after starting phototherapy at the interval of 8, 12, 24, 48, 72, 96 hours over the forehead covered with Bili eclipse photo opaque patch. In most of the babies jaundice were resolved before 96 hours, no babies received phototherapy up to 96 hours and none of the babies in our study population were needed phototherapy beyond 72 hours. During measurement at fixed interval the TcB measurements were slightly in the higher than corresponding TSB.

At 24 hours Mean TcB at patched area is 15.34 and TSB was 13.72 results are slightly differs with the results of R Fonseca et al[15] mean TcB covered 10.7, TSB 11 and De Lucca et al[14]. At 48 hours mean TcB at patched are 15.72 and TSB was 14.29 differs with results of R Fonseca et al[15] (mean TcB 11.1, mean TSB 10.8) and De Lucca et al[14].

Agreement analysis showed good agreement as the duration of phototherapy increases; at 24 hours of phototherapy in patched area mean difference was 1.6 limits of agreement were wide between -0.8 to 4, at 48 hours 1.4 limits between -0.7 to 3.6 and at 72 hours mean 1.89 and limits of agreement 1.3 to 2.76. Compared to Deirdre E et al[16] results differences from our study which had narrow limits of agreement.

Comparing the correlation coefficient, patched area had good correlation compared with unpatched area after phototherapy. After 24 hours of stopping PT TcB from patched area overestimated whereas unpatched area underestimated TSB comparable with results Nanjundaswamy et al[20] Correlation coefficient was better in patched area compared to unpatched areas results were comparable with results of Tan KL et al[21].

Yadav A et al[22] evaluated the usefulness of Tcbilirubinometry in the treatment of physiological jaundice in infants by assessing the concordance between TcB and TsB. In all, 620 newborns were screened for the study; 498 of those were found to be eligible, and 299 of those babies were ultimately enrolled. Measurements of TcB and TSB showed a substantial correlation with a good strength of linkage with the location of the forehead and sternum. 89.6% at the sternum, 82.25% at the forehead, and 93.67% serum bilirubin made up the ROC curve for the cut-off index used to predict TSB and TcB.

The relationship between TcB and TsB in newborns with jaundice was examined by Juster Reicher A et al[23] both before and after phototherapy, but not during. A total of 673 pairs of measurements were carried out on 371 newborns weighing more than 2000 g at delivery and with gestations longer than 35 weeks. Out of these, 337 sets came from 200 infants who had not received phototherapy treatment (Group 1), and 336 measures came from 171 infants whose photos were collected between one hour and five days later (Group 2). For the entire cohort, the correlation coefficient between TcB and TsB was 0.72. After phototherapy, the correlation was modest for the first eight hours, but it thereafter increased to the 0.65–0.8 range. Additionally, no discernible variation was discovered among the correlation coefficients during the various time intervals, maybe with the exception of a marginally significant difference between 1 and 8 hours and 9 and 16 hours. This study shows that after 8 hours following phototherapy, TcB and TsB have a strong association. This increases the validity of TcB values plotted on TsB nomograms used in community-based screening programmes.

In order to ascertain if TcB can be used safely to guide treatment during phototherapy in the event that TSB is unavailable, Johnson SM et al[24] examined the agreement between TcB and TSB during phototherapy in a group of newborn Haitians. They stated that TSB and TcB have a fair level of agreement. TcB tended to overestimate bilirubin as compared to TSB. But compared to TSB, TcB tended to underestimate bilirubin at greater levels, and the gap grew.

Sarici SU et al[25] examined the progression of early-term newborns' TcB values over the first month of life in comparison to those of term newborns in order to determine whether early-term newborns are more likely to experience severe hyperbilirubinemia that necessitates medical attention. The early-term group's TcB readings were all significantly higher than the term group's. Compared to term neonates, early-term babies had a statistically significant higher chance of developing jaundice that needed medical attention. The TcB levels in each group climbed to and peaked at 96 hours after birth, and then progressively decreased to baseline (first measurement) levels at 30 days following birth, according to the results of the post hoc adjusted multiple comparison analysis and repeated-measures analysis of variance. They argued that because early-term babies have noticeably greater TcB levels than full-term babies, they shouldn't be treated the same way. These babies are more likely to get severe hyperbilirubinemia that will necessitate phototherapy, thus it is important to keep a close eye out for pathologic jaundice.

In newborn infants, Rylance S et al[26] evaluated the relationship between TSB and TcB values and looked into the safety of using TcB to direct phototherapy treatment when TSB findings are not available. The lowest TcB measurement for infants not receiving phototherapy showed the highest connection with TSB (r50.71 for preterm infants and r50.83 for term infants). The highest TcB measurement for infants receiving phototherapy showed the strongest connection with TSB (r50.71 for preterm infants and r50.66 for term infants). The level of jaundice was overstated by TcB readings. The mean bias and imprecision of TcB for newborns not receiving phototherapy was 25 mmol/L for term infants and 37 mmol/L for preterm infants. The mean bias and imprecision for infants receiving phototherapy was 30 mmol/L for term newborns and 44 mmol/L for preterm infants. In a scenario with limited resources, TcB can be utilised to safely guide phototherapy treatment.

## Conclusion

The MBJ-20 Tc bilirubinometer is a safe tool for measuring bilirubin levels in neonates, both term and preterm. TcB can be used to monitor neonatal jaundice because there is little chance of overestimation when using TcB from a covered forehead before, during, and after phototherapy. It is necessary to validate TcB's high value or bilirubin in exchange level with serum bilirubin.

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