

Correlation between Transcutaneous Bilirubinemia and Blood Bilirubinemia in Screening Term Newborn for Neonatal Jaundice at the Essos Hospital Centre (EHC), Yaoundé, Cameroon

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Abstract

Background: Early and non-invasive diagnosis of neonatal hyperbilirubinemia remains critical in dark skinned babies of low resource settings. **Objective:** To assess correlation/agreement between transcutaneous bilirubin (Tcb) and serum bilirubin (Tsb) values in full term neonates with jaundice. **Methodology:** An analytical cross-sectional study was conducted at the neonatology unit of the Essos Hospital Centre (EHC) from January to June 2019. All full-term neonates aged 0 to 7 days with suspected jaundice who did not receive phototherapy were eligible for the study. The enrolled neonates in the study were assessed clinically, then with the MBJ20 transcutaneous bilirubinometer (TcB). The MBJ20 transcutaneous bilirubinometer highest measurement over the forehead and the sternum were compared to TsB. Data were entered and then analysed with the CsPro7.2 and R (version 3.6.0) software. Correlation was captured by Bland & Alman plots and Concordance Correlation Coefficient (CCC) estimates. The Pearson correlation coefficient and Student test for paired data were used for descriptions purposes, and the significance level was 5%. **Results:** We recruited 88 neonates. The sex ratio of the babies included was 1.25 favouring males. Median Post-natal age was 3 days with 62% aged 72 hours or more. The mean TcB corresponding to the maximum average between frontal and sternal measurement was 153 mg/dl ± 48 and the average Tsb was 123.80 mg/dl ± 50.48. A good linear correlation was found between TcB and total serum bilirubin level $r = 0.86$ [0.80; 0.91].

Positive correlation was noted between both (forehead and sternum) TcB measurements sites, namely $r = 0.78$ and $r = 0.86$. The Bland & Altman plot measured the bias at -29.68 mg/l (confidence interval at 95%, 21.14 - 80.50). The CCC estimate was 0.2 varying from -0.22 to 0.76 according to TcB measurement threshold and post-natal age. The ROC area under the curve value for a threshold < 100 mg/l equals 90% proving to be a good predictor for this threshold. **Conclusion:** A good linear correlation was found despite a poor agreement between TcB and Tsb. TcB method systematically overestimated the value of Tsb.

Keywords

Neonatal Jaundice, Transcutaneous Bilirubin Measurement, Total Serum Bilirubin, Screening in Full Term Infant

1. Introduction

Newborn jaundice refers to yellow coloration of the skin and/or eyes, and mucous membranes caused by an increase in the level of bilirubin in the blood with a deposit of bilirubin in these tissues. It affects about 60% of full-term newborn infants and 80% of preterm babies in the first week of life [1]. Most hyperbilirubinemia is physiological and heals spontaneously while others remain pathological and may evolve into nuclear jaundice causing severe and irreversible neurological lesions [2]. Screening and surveillance are critical for adequate management.

Jaundice surveillance may be done either through visual assessment, or measurement of bilirubin levels accumulated in skin sites (transcutaneous bilirubinemia) and through blood dosage (serum bilirubin). Clinical assessment may detect jaundice in the skin and mucous membranes, but is not very helpful in assessing the severity of hyperbilirubinemia. On the contrary, transcutaneous bilirubin levels introduced in clinical practice in 1980 by Yamanouchi *et al.* [3] are reliable screening tools in detecting newborn infants at risk for presenting clinically significant hyperbilirubinemia. Though TcB cannot replace blood sampling [4], it is yet an alternative screening test for pathological jaundice in remote areas.

In Africa, works on pathological jaundice in neonates are scarce, while literature shows that the rate of jaundice is high in developing countries [5]. As such, the first management component is early testing which should be part of the daily concerns of health staff in maternity wards and neonatology units. Some works describe a good correlation between transcutaneous bilirubin levels and total serum bilirubin as with Romagnoli *et al.* who led a comparative study in 2012 on the accuracy of the Bilicheck and JM103 bilirubin meters in Italy to assess total serum bilirubin [6]. In his works conducted in Rwanda in 2012, Uwurukundo *et al.* revealed a good correlation between transcutaneous bilirubin and

serum bilirubin measurements for the detection of neonatal jaundice in dark-skin newborn babies [7]. Chimhini *et al.* assessed the use of the DRAEGER Jaundice Meter JM 103 in newborn babies in Zimbabwe in 2015 and declared that this device may be used to screen for neonatal jaundice in the Zimbabwean population [8].

No studies have been carried out in this field in our country. Therefore, we have started this study at the EHC to improve the management of neonatal jaundice by using TCB as the screening and surveillance tool for hyperbilirubinemia.

2. Methodology

2.1. Type of Study

We conducted a cross-sectional study at the neonatology Unit of the Essos Hospital Centre in Yaoundé from 28 January to 27 June 2019.

2.2. Inclusion Criteria

The following were involved in this study:

- All full-term newborn infants (from 37 gestational weeks) aged between 0 - 7 days presenting clinical signs of jaundice, and whose parent or guardian agreed to participate in this study.

The following were excluded from this study:

- Infants with prior phototherapy;
- TcB measurements and /or sampling not done.

2.3. Sampling

We conducted a consecutive sampling. The sampling size was calculated using the COCHRAN formula $N = \frac{Z^2 * P(1-P)}{T^2}$ with “N” representing the sample size, “z” the confidence interval at 95% , “p” the estimated prevalence of severe neonatal jaundice estimated at 6% and “t” the margin error risk at 5%. Based on this formula our sample size stood at a minimal of 87 full term newborn babies.

2.4. Procedure

Recruitment and testing

Data was collected using a questionnaire designed by the main investigator and validated by the supervisor following testing amongst mothers for reliability and feasibility. After obtaining the parent or guardian’s informed consent, a short questionnaire was filled during face-to-face interview gathering information on each newborn prior clinical examination and screening.

➤ Clinical examination

This was a general physical examination to screen for physical signs of crani-ocaudal jaundice, in daylight or with a white radiation pocket torch.

Following a clinical evaluation of the newborn and confirmation of diagnosis

by a paediatrician or health personnel neonatology unit, we carried out testing.

➤ **Transcutaneous bilirubin measurement**

All transcutaneous bilirubin measurements were done with a jaundice meter, the MBJ20[®] transcutaneous bilirubin meter by Beijing M & B Electronic Instrument Co. Ltd. (Beijing, China). Measurements were taken over the forehead and the sternum of the newborn in the supine position. The bilirubin level in each measuring site was clearly displayed on the digital screen in mg/dl. Both values were reported on our data collection sheet and the highest value was chosen for the study in mg/l.

➤ **Total serum bilirubin (TsB) dosage**

Blood samples were collected from a peripheral vein; two millilitres (2 ml) of venous blood within 5 - 10 minutes following the transcutaneous bilirubin measurement and transferred in heparinized sample tubes or bilirubin tubes in aseptic conditions.

TsB dosages were carried out in the hospital's clinical chemistry laboratory. The proportioning principle was calibrated daily based on the Diazo method (use of diazonium ion) with the Biotechnical 1500 biochemistry Automate.

2.5. Data Processing and Statistical Analysis

Statistical method: the statistical analysis was carried out with the R 3.6.0 version software. Our results were presented in form of tables, plots and figures expressed per frequency, per enrolment for qualitative variables, per mean and standard deviation for quantitative variables. The R package EpiR was particularly useful. The association between the two measurements was evaluated by the Pearson correlation coefficient r , the Student test for paired data was used to compare the means of samples, the concordance correlation coefficient (CCC), and Bland and Altman plots were used to assess the agreement between TsB and TcB. In all statistical analysis, a significance threshold of 5% was retained.

Ethical Considerations

Ethical clearance was obtained from the Institutional Human Health Ethics and Research Committee of the University of Douala (CEI-UD) under the number 1878 CEI-UDo/05/2019/T, as well as a research authorisation from the administrative authorities of the EHC of Yaoundé. Participants were enrolled after written consent following the reading of the information sheet of the study. The identity of participants was kept confidential and the results obtained during the study were used for scientific purposes alone. The participants were involved after reading.

3. Results

We recruited 88 new-born infants with jaundice.

3.1. Characteristics of the Population

Table 1 summarizes the distribution of newborn infants per clinical and socio-demographic patterns. The sex ratio of the babies included was 1.25 favouring

Table 1. Sociodemographic and clinical characteristics of the studied population.

Variables	Size n = 88	Percentage (%)
Gender		
- Male	49	55.68
- Female	39	44.32
Postnatal Age (Median = 3, IQR = 1)		
- 1 day (H24)	5	5.68
- 2 days (H48)	28	31.82
- 3 days+	55	62.50
Birth weight (Mean = 3268.41 SD = 558.46)		
- <2500	5	5.68
- 2500 - 4000	75	85.23
- ≥4000	8	9.09
Weight loss (Mean = 4.98, SD = 5.45)		
- >5%	39	44.32
- ≤5	49	55.68
Feeding mode		
- breastfeeding	73	82.95
- mixed feeding	14	15.91
- bottle feeding	1	1.14
Gestational age (Mean = 38.31, SD = 1.35)		
- 37 - 39	70	79.55
- 40 - 42	18	20.45
Apgar score 1 mn		
- <7	10	11.36
- ≥7	78	88.64
Apgar score 5 min		
- <7	1	1.14
- ≥7	87	98.86
Delivery mode		
- Vaginal	59	67.05
- Instrumental	1	1.14
- Caesarean section	28	31.82
Antecedents		
- Present	12	13.64
- Absent	76	86.36

male. Median Postnatal age was 3 days and 75% of the newborn had a birth weight ranged between 2500 and 4000 g, mostly full term (Mean gestational age was 38 weeks) and predominantly breastfed.

3.2. Distribution of Transcutaneous and Serum Bilirubin Measurements

The mean TcB corresponding to the maximum average between frontal and sternal measurement was 153 mg/dl \pm 48 and the average Tsb was 123.80 mg/dl \pm 50.48 (Table 2).

The population under observation was concentrated in 100 - 150 mg/l and 150 - 200 mg/l ranges. For the Tsb variable, the population under observation was highly concentrated in the <100 mg/l and 100 - 150 mg/l range.

As a reminder, the threshold value was 100 mg/l for diagnosis of hyperbilirubinemia as suggested by the National Institute for Health and Care Excellence (NICE). The highest average bilirubin level was obtained with transcutaneous bilirubin from sternum (TcBs) 149.25 \pm 47.64 mg/l, followed by transcutaneous bilirubin from forehead (TcBf) 143.32 \pm 45.31 mg/l. The lowest average bilirubin level was found in total serum bilirubin, Tsb 123.80 \pm 50.48 mg/l. The bilirubin intervals measured with these methods were 45 - 327 mg/dl for Tsb, 61 - 328 mg/dl and 59 - 329 mg/dl for TcBs and TcBf, respectively.

Table 2. Frequency distribution of bilirubin concentration according to the different types of measurements.

	n = 88	%
TsB (Mean = 123.80, SD = 50.48)		
- <100	30	34.09
- 100 - 150	36	40.91
- 150 - 200	16	18.18
- \geq 200	6	6.82
TcB forehead (Mean = 143.32, SD = 45.31)		
- <100	10	11.36
- 100 - 150	42	47.73
- 150 - 200	25	28.41
- \geq 200	11	12.50
TcB sternum (Mean = 149.25, SD = 47.64)		
- <100	10	11.36
- 100 - 150	40	45.45
- 150 - 200	28	31.82
- \geq 200	10	11.36

3.3. Study of the Correlation and Agreement between TcB and TsB Values

Table 3 presents the correlation coefficient between Tsb, TcBf and TcBs for all paired measurements. We have noted a strong correlation between the two TcB measurement sites (forehead and sternum) $r = 0.91$ (95% CI = [0.86 - 0.94]). A positive correlation was observed between Tsb and TcBf ($r = 0.78$, 95% CI = [0.68 - 0.85]) and Tsb and TcBs ($r = 0.86$, IC at 95% = [0.79 - 0.90]). **Figure 1** shows a scatter plot between TcB values and Tsb. The right linear regression line is also represented. The Pearson's linear correlation between TcB and Tsb was $r = 0.86$ [0.80; 0.91] showing a good linear correlation. The concordance correlation coefficient estimates in the general sample was 0.2 [0.05, 0.33]. Even though its 95% confidence interval does not contain 0, one would conclude on a poor agreement between TsB and TcB measurements.

3.4. Bland and Altman Test Deviation Graph

Figure 2 represents the Bland and Altman Plot of TsB measurements versus TcB. The dotted lines (red and green) represent the upper and lower limits of the deviations 21.14 mg/l and -80.50 mg/l respectively. The blue line represents the bias = -29.68 mg/l. It is observed that the limits are wide and the bias -29.68 mg/l is statically significant ($p < 0.01$). This result indicates systematic bias, as TcB measurement overestimates the TsB measurements.

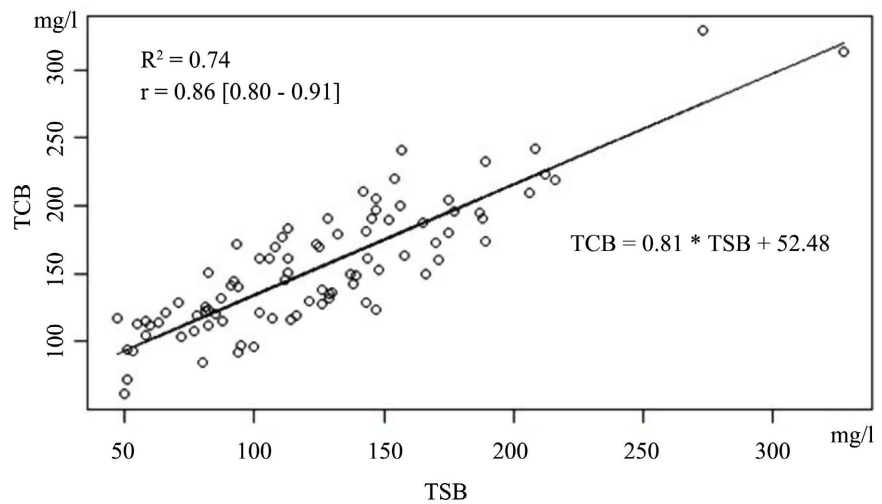


Figure 1. Linear regression scatter plot of TSB versus TCB, and the Pearson correlation coefficient estimate r.

Table 3. Correlation matrix between TcB forehead, TcB sternum and TsB.

	TsB	TcB forehead
TsB		
TcB forehead	0.78 [0.68 - 0.85]	
TcB sternum	0.86 [0.79 - 0.90]	0.91 [0.86 - 0.94]

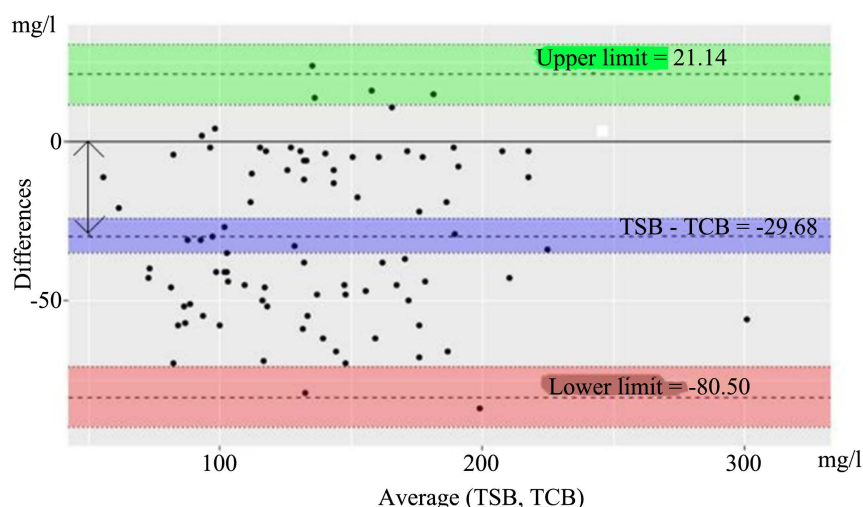


Figure 2. Bland and Altman plot of the difference between measurements of serum bilirubin (TSB) and transcutaneous Bilirubin (TcB) concentration.

3.5. Differential Analysis of the Tsb-TcB and Factors Associated with This Difference

In **Table 4**, it is presented CCC and bias estimates according to the levels of TcB measurements. Basically, for TcB measurements <100 mg/l, there is a fair agreement between TcB and Tsb measurements as the CCC estimate was 0.59 [0.11, 0.85] and the bias (12.33, $p = 0.08$) was not significant. For TcB measurements > 100 mg/l, the bias was significant and a poor agreement was observed. At postnatal age more than 2 days, it is observed a fair agreement between TcB and Tsb as the CCC estimate was 0.61 [0.47, 0.73], although the bias was significant. However, for postnatal age of 1 day and 2 days the CCC confidence interval estimates contains 0, indicating poor agreement for newborns with these postnatal ages. Basically, **Table 4** indicates poor agreement between TcB and Tsb, and that the TcB would overestimate the true Tsb measurements.

4. Discussion

The aim of this work was to study the correlation between TcB and Tsb values in testing for neonatal jaundice in full-term newborn infants at the EHC.

4.1. Characteristics of the Sample

The sample of this study was mostly constituted of male infants at 55.6%. This profile is similar to those of Oyapero *et al.* [9] and Madubuike [10] who had a high incidence of male infants in Nigeria.

4.2. Correlation and Agreement

We found a strong correlation between the two TcB testing sites (forehead and sternum) $r = 0.91$; our data are consistent with similar studies and protocols [8] [11] [12]. Conversely, for others, transcutaneous bilirubin measurements on the forehead had a better correlation with serum bilirubin [9] [13] [14]. The correlation

Table 4. Estimation of the concordance correlation (CCC) estimates and the bias according to TcB thresholds.

	CCC [95% CI]	Bias (p value)
General population	0.2 [0.05, 0.334]	-29.68 (p < 0.01)
TcB thresholds		
<100 mg/l	0.59 [0.11, 0.85]	-12.33 (0.08)
100 - 150 mg/l	0.2 [0.05, 0.334]	-28.90 (<0.01)
150 - 200 mg/l	0.2 [0.05, 0.334]	-32.51 (<0.01)
>200 mg/l	-0.22 [-0.46, 0.05]	-37.31 (<0.01)
Postnatal age		
1 day	0.76 [-0.003, 0.96]	-16.40 (0.27)
2 days	0.08 [-0.16, 0.30]	-31.10 (<0.01)
More than 2 days	0.61 [0.47, 0.73]	-30.16 (<0.01)

between TcB/TsB in this study is consistent with other sites, which, although using other devices, have indicated a strong association between TcB and TsB measurements, with correlation coefficients ranging from 0.75 to 0.95 [9] [14] [15]. The correlation coefficient as used in many literature works to investigate agreement between TsB and TcB may be unappropriated to decide which tools to use. In fact, correlation does not imply agreement, and that constitute a pitfall for many research works [16] [17]. This study is among the firsts investigating the agreement between TsB and TcB in dark skinned population.

4.3. Bland and Altman

The average difference between mean TsB and TcB according to the Bland and Altman method was -29.68 mg/l [14]. This inaccuracy was greater than the observation of Oyapero, Raimondi, Romagnoli [6] [9] [18]. It is worth noting that we worked with a black population and previous studies have shown that the bias between TcB and TsB values was higher in black subjects [15].

4.4. Differential Analysis

Based on concordance correlation coefficient estimate for different levels of TcB thresholds, for TcB values below 100 mg/l, a fair agreement was observed. This finding is similar to those found in similar studies [14] [15] [19] [20] [21].

4.5. Potential Applications

In this setting, the majority of the babies aged more than 3 days at inclusion, the potential applications of our findings may be scarce for early screening. However, as the agreement was higher after 2 days of life, a recommendation of systematic screening of jaundice using TcB in case of early discharge can be raised [22] [23]. In addition, this strategy could also target and prioritize all the babies

at risk of hyperbilirubinemia born from mothers of O+ blood group and those mothers with a past story of babies having suffered of neonatal jaundice.

5. Study Limitations

Though this study provides some information on the usefulness of transcutaneous bilirubin measurement on dark skinned neonates, we acknowledge some limitations. The first question is whether taking into account or not the different color tones declined on black skin for the sensitivity of transcutaneous bilirubinemia. As this point is still controversial, in our study, we considered that the whole population had a homogeneous skin tone through visual observation [22]. Our hypothesis could thus limit the validity of our results and suggest further studies on the different categories of black skin tones of our newborns. The second point is around the optimal delay to use this method; the age of our screened population, not homogenous, may have reduced the sensitivity of this method for babies aged less than 72 hours of life.

6. Conclusion

This study revealed a strong linear correlation between transcutaneous bilirubin (TcB) and total serum bilirubin (TsB), but a poor agreement between the two measurements. Moreover, the TcB overestimates the TsB measurements, therefore, if used, the threshold should be adjusted. To this stage, we can recommend the use of TcB in our context, for screening of jaundice during home follow-up of neonates after two days of life in case of early discharge.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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