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Accuracy of enhanced transcutaneous bilirubinometry according to various measurement sites

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What is already known on this topic?

Universal predischarge laboratory or transcutaneous measurement of bilirubin level is recommended to prevent serious hyperbilirubinemia. Transcutaneous bilirubinometry is a noninvasive, rapid, and convenient screening method. The older bilirubinometers were found to be reliable screening tools in term and preterm infants without phototherapy. It is important to test the accuracy of the newest and most widespread bilirubinometers and to define the most reliable measurement body sites.

What this study adds on this topic?

Transcutaneous bilirubin (TcB) measurements using the JM-105 device on the forehead, sternum and abdomen in term Caucasian neonates are reliable and sensitive; the forehead is the most accurate and convenient measurement site. The candidate TcB cut-off value has been defined as 8 mg/dL for detecting total serum bilirubin (TSB) levels >10 mg/dL, 10 mg/dL for TSB >13 mg/dl, and 11.5 mg/dL for TSB >15 mg/dL. Because transcutaneous measurements underestimate serum bilirubin levels significantly when TSB values are higher than 15 mg/dL, it is necessary to confirm higher transcutaneous values with a TSB measurement.

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ABSTRACT

Objective: The goal of the study was to provide missing data on the accuracy of enhanced transcutaneous bilirubinometry in a monoracial population of term neonates, considering three different measurement sites.

Material and Methods: Transcutaneous bilirubin was measured using the JM-105 device on the forehead, chest, and abdomen. Blood sampling for total serum bilirubin concentration has been performed within 10 minutes of transcutaneous measurements. Paired transcutaneous bilirubin and total serum bilirubin measurements were statistically analyzed.

Results: The study group consisted of 102 healthy term Slovak infants. The correlation between total serum bilirubin and transcutaneous bilirubin was significant (coefficient of determination R2: 0.9045 forehead, 0.8808 sternum, 0.8467 abdomen). Transcutaneous measurements underestimated serum bilirubin levels significantly when total serum bilirubin values were higher than 15 mg/dL, irrespective of the site of transcutaneous measurements. The lowest mean difference between total serum bilirubin and transcutaneous bilirubin was identified on the sternum (median: –1.1 mg/dL). The area under the curve was >0.97 and >0.93 for detecting total serum bilirubin levels >10 mg/dL and >13 mg/dL, respectively, for all measurement sites. Transcutaneous measurements on the forehead and sternum provided very high sensitivity, with the best performance at the forehead.

Conclusion: Transcutaneous bilirubinometry using an enhanced device is an accurate, sensitive, and convenient screening method in term Caucasian neonates. Transcutaneous bilirubin measurements on the forehead, sternum, and abdomen are reliable, with the best performance on the forehead. It is necessary to confirm higher transcutaneous bilirubin values with a total serum bilirubin measurement.

Keywords: Bilirubin, hyperbilirubinemia, jaundice, neonates, transcutaneous bilirubinometry

Introduction

Visible jaundice is present in most term and near-term newborns during the first week of life. Although it is mostly a benign condition, healthcare professionals should keep in mind rare but severe adverse outcomes of serious hyperbilirubinemia (1). Universal early follow-up of hyperbilirubinemia is necessary, and the American Academy of Pediatrics recommends predischarge measurement of the bilirubin level using transcutaneous bilirubin (TcB) or total serum bilirubin (TSB) (2).

Transcutaneous bilirubin measurement is noninvasive, rapid, and convenient. The most widespread TcB devices are BiliChek and Draeger JM-103 (Draegerwerk AG and Co., Luebeck, Germany). The newest rendition of the Draeger JM line is the JM-105 bilirubinometer. The use of this device has not been evaluated in European term neonates without phototherapy (3). The goal of this study was to provide missing data on the reliability of enhanced

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transcutaneous measurement of bilirubin concentration in term European infants, considering three measurement sites.

Material and Methods

The cross-sectional noninterventional clinical study was performed at the Department of Neonatology in University Hospital Martin, Slovakia. The study was approved by the institutional Ethical Committee of Jessenius Faculty of Medicine in Martin, Comenius University Bratislava (EK 1817/2016), which is registered by the Office for Human Research Protections (IRB00005636). Parental informed consent was obtained from all subjects.

Term neonates were enrolled in the study if they required venous blood sampling for TSB assessment during the first five days of their lives. The study group consisted of 102 mature infants with nonhemolytic jaundice. The study group was racially and ethnically homogenous, as all neonates were Slovak of Caucasian race. The exclusion criteria were phototherapy, exchange transfusion, conjugated hyperbilirubinemia, poor peripheral circulation, edema, perinatal infection, and major congenital malformations. The vitamin K administered intramuscularly immediately after birth was the only drug given to the enrolled infants. Birthmarks or nevi, hairy areas, bruises, and any anomalous parts of the skin were avoided during TcB measurements.

TcB value was determined as a computerized mean value of three consecutive readings on each measurement site: forehead (just above the glabella), chest (mid-sternum), and abdomen. A single JM-105 instrument was used, and a single person carried out all TcB measurements. The bilirubinometer was calibrated regularly. Blood sampling was performed within 10 minutes of TcB assessment. TSB concentrations were measured using the photometric method in the clinical biochemical laboratory at University Hospital Martin. The photometric method was used as a reference because this technique is used in daily routine and is reported to have a better agreement with high pressure liquid chromatography than any other technique (4). Paired TcB and TSB measurements were statistically analyzed.

Statistical analysis

Linear regression analysis was used to assess the correlation between TcB at three body sites and TSB levels. The coefficients of determination (R^2) and Pearson correlation coefficients (r) were determined to quantify the strength of the relationship between TcB and TSB values. Bland-Altman plots (mean ± [1.96 × standard deviation (SD)]) were used to visualize the difference between TcB at each body site and TSB levels. TcB cut-off values for detecting TSB levels >10, >13, and >15 mg/dL for each body site were analyzed by receiver operating characteristics (ROC) curve analyses. The sensitivity, specificity and positive and negative predictive values (NPV) were calculated and determined for the TcB cut-off value and the best measurement site. A $p<0.05$ was considered to be statistically significant. All data were analyzed using R3.1.1 and ROC curve analyses using ROCR package (5, 6).

Results

The study group consisted of 102 jaundiced term Caucasian neonates (48 males, 54 females). Median birthweight was 3,430 g (range: 2,510–4,880 g; mean [SD]: 3,410 [446] g), and median postnatal age was 59 hours (range: 9–111 hours; mean [SD]:

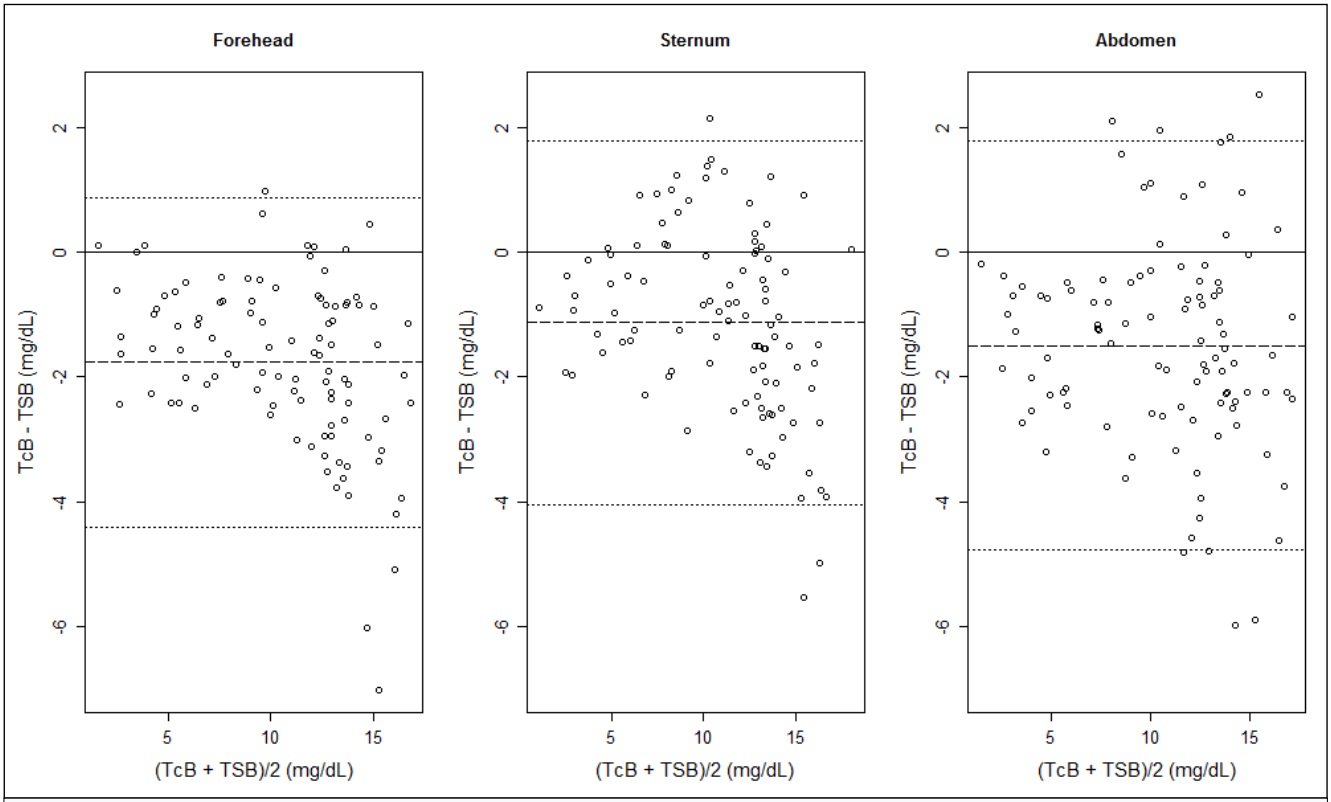

Figure 1. The Bland-Altman plots for the study group (n=102) at the three measurement sites (forehead, sternum, abdomen). The lines represent mean differences between TSB and TcB for each site and ±1.96 × SD of the difference
SD, standard deviation; TcB, transcutaneous bilirubin; TSB, total serum bilirubin

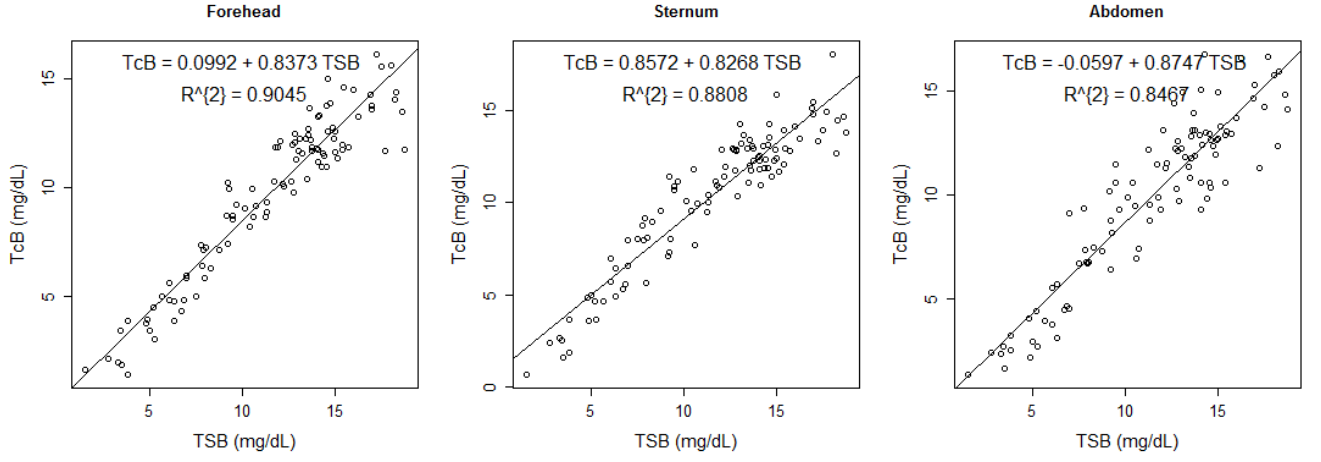

Figure 2. Linear regression plots of TSB versus JM-105 TcB measurements obtained from different body sites (forehead, sternum, abdomen) of the study group (n=102). p<0.0001 for each measurement site
TcB, transcutaneous bilirubin; TSB, total serum bilirubin

Table 1. Test performance characteristics for TcB cut-off values for detecting TSB levels of >10 mg/dL

TSB >10 mg/dL	Forehead	Sternum	Abdomen
TcB cut-off value (mg/dL)	8	8	8
Sensitivity (%)	**100.0**	98.5	97.0
Specificity (%)	**83.3**	69.4	77.8
PPV (%)	**91.7**	85.5	88.9
NPV (%)	**100.0**	96.2	93.3
TcB cut-off value (mg/dL)	7	7	7
Sensitivity (%)	100.0	**100.0**	98.5
Specificity (%)	69.4	**58.3**	69.4
PPV (%)	85.7	**81.5**	85.5
NPV (%)	100.0	**100.0**	96.2
TcB cut-off value (mg/dL)	6	6	6
Sensitivity (%)	100.0	100.0	**100.0**
Specificity (%)	63.9	50.0	**55.6**
PPV (%)	83.5	78.6	**80.5**
NPV (%)	100.0	100.0	**100.0**

Bold type indicates the best test performance at each body site.
NPV, negative predictive value; PPV, positive predictive value; TcB, transcutaneous bilirubin; TSB, total serum bilirubin

Table 2. Test performance characteristics for TcB cut-off values for detecting TSB levels of >13 mg/dL

TSB >13 mg/dL	Forehead	Sternum	Abdomen
TcB cut-off value (mg/dL)	10	10	10
Sensitivity (%)	**100.0**	**100.0**	95.7
Specificity (%)	**78.6**	**66.1**	75.0
PPV (%)	**79.3**	**70.8**	75.9
NPV (%)	**100.0**	**100.0**	95.5
TcB cut-off value (mg/dL)	9	9	9
Sensitivity (%)	100.0	100.0	**100.0**
Specificity (%)	66.1	55.4	**58.9**
PPV (%)	70.8	64.8	**66.7**
NPV (%)	100.0	100.0	**100.0**

Bold type indicates the best test performance at each body site.
NPV, negative predictive value; PPV, positive predictive value; TcB, transcutaneous bilirubin; TSB, total serum bilirubin

Table 3. Test performance characteristics for a TcB cut-off value for detecting TSB levels of >15 mg/dL

TSB >15 mg/dL	Forehead	Sternum	Abdomen
TcB cut-off value (mg/dL)	11.5	11.5	11.5
Sensitivity (%)	94.4	100.0	88.9
Specificity (%)	65.5	60.7	66.7
PPV (%)	37.0	35.3	36.4
NPV (%)	98.2	100.0	96.6

NPV, negative predictive value; PPV, positive predictive value; TcB, transcutaneous bilirubin; TSB, total serum bilirubin

58.3 [31.0] hours). All included infants were mature with median gestational age at birth of 39 weeks (range: 37–41 weeks; mean [SD], 39.3 [1.3] weeks). We carried out 102 laboratory assessments of TSB and 102 simultaneous transcutaneous measurements of TcB on each of three different body sites.

Values of TSB ranged from 1.5 to 18.8 mg/dL (mean [SD]: 11.5 [4.3] mg/dL; median: 12.7 mg/dL). The highest mean difference between TSB and TcB was identified on the forehead (mean [SD]: –1.8 [1.4] mg/dL; median: –1.6 mg/dL), and the lowest mean difference was found on the sternum (mean [SD]: –1.1 [1.5] mg/dL; median: –1.1 mg/dL). The median difference between TSB and TcB on the abdomen was –1.5 mg/dL (mean [SD]: –1.5 [1.7] mg/dL). Bland-Altman differential graphs describe the similarity of laboratory and transcutaneous measurement results (Figure 1). Transcutaneous measurements underestimated serum bilirubin levels irrespective of the site of measurements. This phenomenon of transcutaneous underestimation was significant, especially when TSB values were >15 mg/dL.

The correlation between TSB and TcB was found to be close and significant (p<0.0001) irrespective of the site of transcutaneous measurements. Coefficient of determination (R^2) was the highest for the forehead (R^2: 0.9045; r: 0.9511) and the lowest for the abdomen (R^2: 0.8467; r: 0.9201). R^2 for the sternum was 0.8808, and r was 0.9385 (Figure 2).

ROC curve analyses were performed at each of three body sites for detecting TSB levels: >10, >13, and >15 mg/dL by TcB (Figure 3).

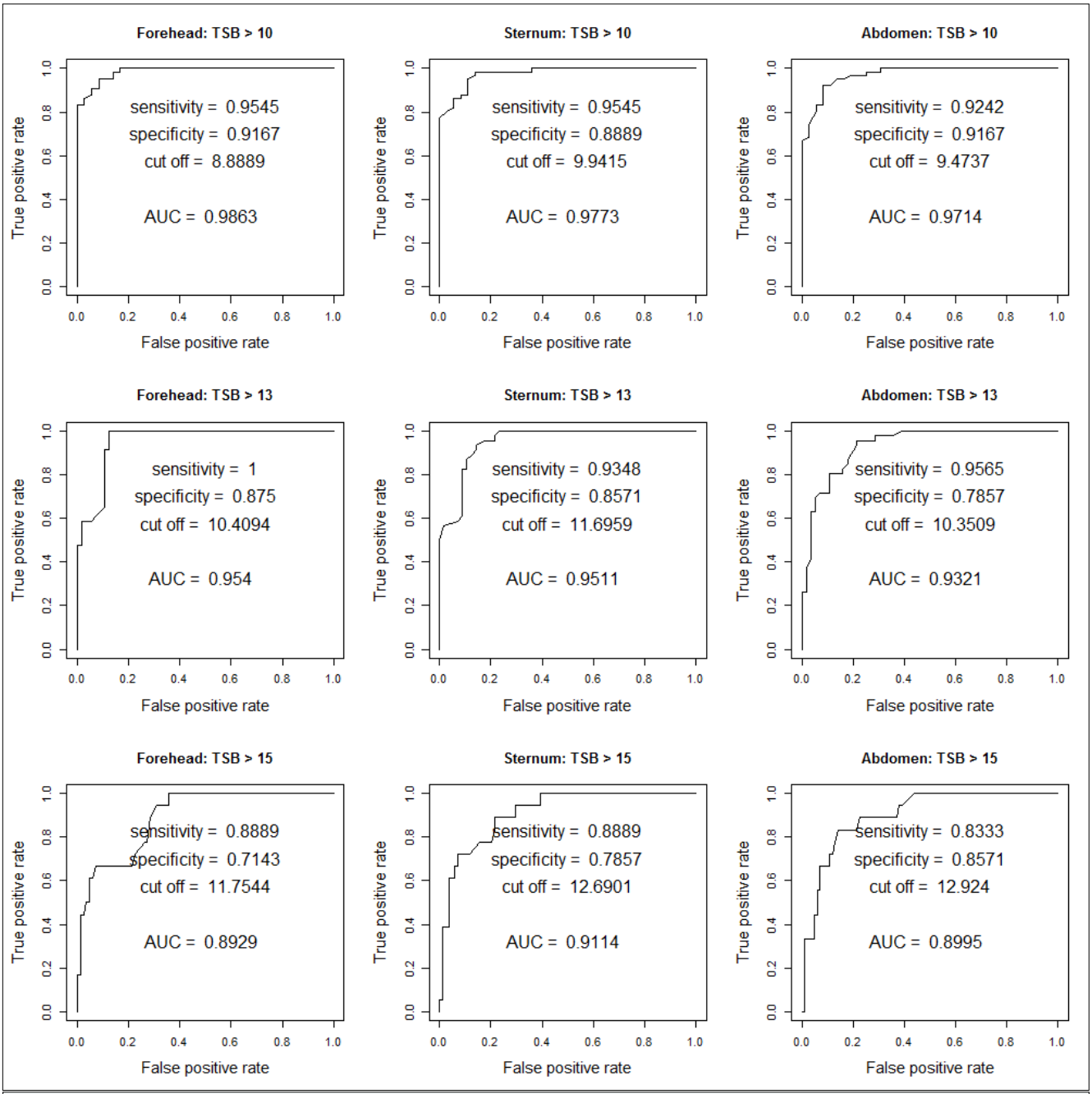

Figure 3. Receiver operating characteristics curve analyses of TcB values for detecting TSB levels of >10 mg/dL, >13 mg/dL, and >15 mg/dL, at the three body sites (forehead, sternum, abdomen)
TcB, transcutaneous bilirubin; TSB, total serum bilirubin

The area under the curve, sensitivity, and specificity values for the TSB cut-off values are shown in Figure 3. Because transcutaneous bilirubinometry is a screening test, it should preferably achieve as high sensitivity as possible. The sensitivity and NPV were 100% at the forehead for the candidate cut-off TcB value of 8 mg/dL to detect the TSB levels >10 mg/dL (Table 1). When measured on the forehead and sternum, the candidate cut-off TcB value of 10 mg/dL provided a sensitivity of 100% and NPV of 100% to detect a TSB level of >13 mg/dL, with the best performance at the forehead (Table 2). The candidate cut-off TcB level of 11.5 mg/dL provided a sensitivity of 100% and NPV of 100% to detect a TSB level of >15 mg/dL, when measured on the sternum (Table 3). When the TcB cut-off values decreased, the sensitivity and NPV became 100% at all measurement sites, but the specificity showed lower values (Tables 1-3).

Discussion

Because of the recent recommendation to screen all infants for TSB or TcB before discharge (7), it is important to know whether it is possible to rely on TcB as a screening measurement (8). Our previous studies have demonstrated that transcutaneous bilirubinometry using the widespread JM-103 device is an accurate screening method in term and preterm infants without photo-

therapy (9-11). Data on the use of the newest JM-105 device in term newborns are very limited (12-14). Our results indicate that enhanced transcutaneous bilirubinometry is a reliable screening technique (R^2: 0.8467–0.9045; r: 0.9201–0.9511). However, transcutaneous measurements underestimated TSB levels, especially when TSB values were >15 mg/dL. This is consistent with findings of Taylor et al. (15), who reported that the tendency of TcB to underestimate TSB increased with advancing newborn age. Our data are also consistent with those presented by Simsek et al. (16), who evaluated the older JM-103 device in Turkish term neonates. However, our results are contradictory to those reported by Raimondi et al. (17), who reported that the older JM-103 device had the tendency to overestimate TSB. False negative TcB values can be reduced by setting the TcB cut-off at points below the TSB levels that might warrant investigation or treatment (18). To avoid decreasing prescription of TSB measurements in the most worrisome cases (19), it is necessary to verify all TcB values as ≥12 mg/dL with a TSB measurement, as recommended by Bhutani et al. (1). This is in accordance with Grohmann et al. (20), who compared older TcB devices (BiliChek, JM-102, JM-103) and concluded that a TcB value >15 mg/dL should be confirmed with a standard laboratory method.

We identified that the candidate TcB cut-off value was 8 mg/dL for detecting TSB levels >10 mg/dL, 10 mg/dL for TSB >13 mg/dl, and 11.5 mg/dL for TSB >15 mg/dL. These JM-105 TcB cut-off values are higher than the BiliChek TcB cut-off values reported by Kaynak-Turkmen et al. (21), showing that JM-105 measurements are associated with fewer false-positive results. The threshold bilirubin levels are important when considering treatment of significant hyperbilirubinemia in term infants within the first five days of life (2). Term newborns may be discharged from the nursery within the first days of life, avoiding a blood test if their bilirubin concentration falls into the low-risk zone of the nomogram. Predischarge screening for serious hyperbilirubinemia is helpful in improving outcomes of healthy neonates discharged early (1). Transcutaneous bilirubin measurements provide immediate results and reduce the likelihood of missing a clinically significant TSB concentration (9). The method is also convenient in monitoring discharged infants. Transcutaneous bilirubinometry cannot only reduce the incidence of bilirubin-induced neuronal dysfunction but can lead to a decreased number of newborns readmitted to the hospital for treatment of hyperbilirubinemia (22). However, clinicians should keep in mind that TcB measurements tend to underestimate TSB concentration at higher levels, and therefore the TcB method is less helpful in following newborns with TSB >15 mg/dL. Transcutaneous bilirubinometry is useful in screening the majority of infants with mild jaundice (23).

It was suggested that the accuracy of enhanced TcB measurements varies according to body site (24). Based on our results, we recommend the forehead as the most reliable TcB measurement site (R^2: 0.9045). Although it is suggested to perform TcB measurements either on the forehead or on the chest, we measured also on the abdomen, keeping in mind Bhutani's suggestion that clinicians should seek alternative anatomic sites unexposed to ambient lighting (23). We have found that measurements on the abdomen were reliable (R^2: 0.8467). Our results are different from those reported by Kurokawa et al. (24), who found that measurements on the sternum (R^2: 0.6488) or upper back (R^2: 0.6321) were more reliable than on the forehead or abdomen in Japanese very low birth weight (VLBW) infants. Moreover, we report significantly higher R^2 values than the mentioned authors. We have found the lowest difference between TSB and TcB values on the sternum. Importantly, we have found that TcB measurements on the forehead and sternum provided very high sensitivity, with the best performance on the forehead. Sensitivity achieved 100% when the TcB cut-off value for the forehead was 8 mg/dL and 7 mg/dL for the chest. Therefore, we recommend TcB measurements on the forehead or sternum in term infants as a sensitive screening method.

Comparing the use of two of the most widespread TcB devices in clinical practice, it has been shown that the JM-103 bilirubinometer is superior to the BiliChek. The JM tool provides rapid TcB values, is simple to use, and requires no disposable materials to calibrate (3, 4, 25). Moreover, use of the enhanced JM-105 device has other practical advantages, such as internal data storage or electronic medical record integration using HL7 connectivity.

In our study, we used the calculated mean value of three consecutive scans to reduce measurement error. Because a single person performed all TcB measurements, the interobserver variability was eliminated. Our study group included cases of significant hyperbilirubinemia; as much as 47.1% of the infants had TSB ≥13 mg/dL, and more than 20% of the neonates had TSB ≥15 mg/dL. The study presents a homogenous monoracial cohort, thus eliminating major differences in skin pigmentation. The results are representative of Caucasian race newborns. Van Erk et al. (26) highlighted that skin anatomy in preterm neonates can considerably influence JM-105 reliability. We eliminated gestational age and skin maturity impact on the transcutaneous measurement accuracy, because no preterm or late preterm infants were enrolled. We were also aware that there was a significant time difference between sampling for TSB and TcB measurement in many hospital-based studies (27), and therefore we performed blood sampling within 10 minutes of TcB assessment.

In contrast, the photometric method used for TSB measurement may be considered a limitation of our study. High-performance liquid chromatography is the most accurate method for TSB assessment. However, photometry is the most frequently used reference method owing to the best agreement with high-performance liquid chromatography (28). Another limitation of our study is the relatively small study group size compared to large multiracial population studies describing the use of transcutaneous bilirubinometers used in the past (29-32).

Transcutaneous bilirubinometry is a noninvasive point-of-care screening method, which decreases painful blood draws and unnecessary laboratory measurements, thus reducing iatrogenesis and cost of care. It effectively identifies neonates who require TSB assessments and improves prevention of serious hyperbilirubinemia, bilirubin encephalopathy, and kernicterus. The results of our study reassure clinicians that the new JM-105 TcB test is accurate in term European newborns. Although Japanese authors reported that TcB measurements significantly correlated with TSB in VLBW and term infants (14, 24), and Jones et al. (12) concluded that JM-105 measurements on the

sternum were reliable in United States neonates, further studies should be performed to establish the accuracy of the newest transcutaneous device in neonates of various gestational ages and racial backgrounds. Because it is important to take into account the trend of TcB values (33, 34), future studies to develop JM-105 TcB nomograms are necessary. So far, there have been published several JM-103 TcB nomograms for American (35, 36), Asian (37-43), and Nigerian (44) neonatal populations. Although there have been published an abundance of hour-specific TcB nomograms (45), JM-103 or JM-105 nomograms for European neonates are missing completely.

Our data declare the accuracy of the enhanced JM-105 bilirubinometer in mature Caucasian infants. We conclude that transcutaneous measurements on the forehead, sternum, and abdomen are reliable, and measurements on the forehead and sternum are the most sensitive. We highlight the TcB measurements on the forehead, because they are the most reliable and convenient. TcB measurements underestimate serum bilirubin levels significantly when TSB values are >15 mg/dL. Therefore, it is necessary to confirm higher TcB values with a TSB measurement.

Ethical Committee Approval: Ethics committee approval was received for this study from the ethics committee of Jessenius Faculty of Medicine in Martin, Comenius University Bratislava – Approval EK 1817/2016. The Ethics Committee is registered by the Office for Human Research Protections (IRB00005636).

Informed Consent: Written parental informed consent was obtained from all subjects.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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