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Sinem Gülcan Kersin, İrem Ünal, Sinem Toprak Sevinç, Hülya Ozdemir, Aslı Memişoğlu & Hülya Selva Bilgen

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Diagnostic Accuracy of the Picterus Jaundice Pro App for Neonatal Jaundice: A Single-Center Study from Turkiye

Sinem Gülcan Kersin*
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
sinemgulcan@hotmail.com

İrem Ünal
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
driremunal37@gmail.com

Sinem Toprak Sevinç
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
stoprakk@hotmail.com

Hülya Ozdemir
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
hulyaakdenizozdemir@gmail.com

Aslı Memişoğlu
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
acinarmemisoglu@gmail.com

Hülya Selva Bilgen
Department of Pediatrics, Division of Neonatology, Marmara University Pendik Training and Research Hospital, Istanbul 34899, Türkiye
hulya.bilgen@gmail.com

*****Corresponding author

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Abstract

Background/Objectives: Neonatal jaundice is common and may lead to severe complications if not identified early. Although transcutaneous bilirubinometry (TcB) is widely used for noninvasive screening, its cost limits accessibility. Smartphone-based applications such as Picterus® Jaundice Pro (Picterus JP) may provide a low-cost alternative. We aimed to evaluate the correlation and agreement between Picterus JP and standard TcB measurements in newborns in Turkiye.

Materials and methods: This prospective observational study was conducted at a single tertiary center between December 2025 and January 2026. Newborns aged <7 days with gestational age ≥35 weeks were included. Paired TcB (Dräger JM-105) and Picterus JP measurements were obtained from the sternal area under standardized conditions. Correlation was assessed using Spearman's rank correlation. The agreement was evaluated using the Bland–Altman analysis and the concordance correlation coefficient (CCC). Clinically relevant disagreement was defined as an absolute difference ≥2 mg/dL.

Results: A total of 215 measurements from 165 newborns were analyzed. Median TcB and Picterus JP values were 6.7 mg/dL (IQR 4.85–8.9) and 7.0 mg/dL (IQR 5.3–9.9), respectively. Picterus JP showed a strong correlation with TcB (ρ=0.78, $p<0.001$). The mean bias (TcB–Picterus) was −0.94 mg/dL, with 95% limits of agreement from −5.35 to 3.47 mg/dL. The CCC was 0.73. Clinically acceptable agreement was highest at lower TcB levels and declined significantly at TcB ≥11 mg/dL.

Conclusion: Picterus JP demonstrates good performance as a screening tool at low-to-moderate bilirubin levels but should not replace serum bilirubin measurement near treatment thresholds.

Keywords: newborn; jaundice; transcutaneous bilirubin; smartphone

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Introduction

Neonatal jaundice is a common clinical condition characterized by yellow discoloration of the skin and sclera resulting from elevated bilirubin levels in the newborn's bloodstream [1]. It affects approximately 60% of term infants and up to 80% of preterm infants during the first 48–72 hours of life [2]. Although neonatal jaundice is generally a benign and self-limiting condition, nearly one million newborns worldwide develop severe hyperbilirubinemia each year, which may lead to serious complications if not recognized and managed promptly [3]. Consequently, timely identification, close monitoring, and appropriate treatment of neonatal jaundice are of critical importance.

The gold standard for diagnosing neonatal jaundice is the measurement of total serum bilirubin (TSB), which requires blood sampling and access to a laboratory. Approximately 40 years ago, transcutaneous bilirubinometer devices, a non-invasive technique alternative to TSB, were developed to facilitate the monitoring of jaundice in newborns [4]. Whereas first-generation devices introduced in the early 1980s were substantially affected by skin pigmentation, skin thickness, gestational age, and ambient light conditions, fourth-generation devices currently used in clinical practice demonstrate a significantly stronger correlation with serum bilirubin levels in term and late preterm neonates [5]. Over the past two decades, transcutaneous bilirubin (TcB) measurement has become a key component of neonatal screening strategies for the risk of extreme hyperbilirubinemia, particularly in high-income countries; however, the high cost of these devices limits their accessibility not only in high-income countries but worldwide [6].

Turkiye spans a geographical area of approximately 800,000 km² and has a well-established healthcare system comprising more than 1,500 hospitals and over 8,000 family health centers [7]. The country records over one million live births annually and has a demographically diverse population, comprising multiple ethnic groups that coexist. However, TcB devices are costly and not available in all hospitals, which limits their widespread use for universal neonatal screening. In this context, digital health–based approaches, such as mobile application–supported bilirubin assessment, have emerged as potential screening solutions due to their cost-effectiveness and accessibility.

Picterus® Jaundice Pro (Picterus JP) is a device designed to screen for neonatal jaundice using the Picterus® Calibration Card and a smartphone app, and is approved as a medical

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device for assessing neonatal jaundice in Europe [8]. This user-friendly device can be used by healthcare professionals and parents. Our hospital serves a population that is predominantly Turkish, with a smaller number of Syrians and other immigrants. This study aims to evaluate the correlation between TcB and Picterus JP, and to assess its clinical validity in Turkiye.

Materials and Methods

Subjects

This prospective observational study was conducted at a training and research hospital between December 2025 and January 2026, in accordance with the Declaration of Helsinki. Ethical approval was obtained from the Marmara University Ethics Committee (Protocol Number: 09.2025.25-0919) for studies involving human participants. Written informed consent forms have been obtained from the parents of all participants. This study included newborns younger than 7 days old who were followed up in the neonatal intensive care unit or the postpartum obstetrics ward, or who attended routine outpatient follow-up visits. Infants with a gestational age less than 35 weeks, newborns older than eight days, those with major congenital anomalies, those who had previously received phototherapy, or those whose parents had not provided informed consent were excluded from the study.

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Interventions

At our clinic, neonatal jaundice screening is routinely performed twice daily in all newborns using a transcutaneous bilirubinometer (Dräger Jaundice Meter JM-105, Lübeck, Germany). Decisions regarding the start of treatment for hyperbilirubinemia or post-discharge management follow the Turkish Neonatal Society jaundice guideline and the Clinical Practice Guideline of the American Academy of Pediatrics (AAP) [9,10]. The transcutaneous bilirubinometer device is calibrated regularly according to the manufacturer's instructions. During the study period, measurements were taken on working days between 8:00 a.m. and 3:00 p.m. TcB was obtained first, then measurements with the Picterus JP, with minimal time between them to minimize effects of bilirubin fluctuation. All readings were taken from the sternal area under standardized ambient lighting. Simultaneously, as shown in Figure 1, a color calibration card was placed on the sternum, and six images were captured at 30 cm using the Picterus® Jaundice Pro mobile app on a smartphone. If a venous blood sample was collected for clinical reasons, the corresponding TSB level was also recorded. Data such as

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gestational age, birth weight, postnatal age at hyperbilirubinemia screening, TcB measurement, bilirubin value from the mobile app, and the presence of ABO/Rhesus hemolytic disease or hospitalization for phototherapy were documented.

Statistical analysis

In this study, the primary analysis evaluated the correlation between the TcB and Picterus JP measurements. The required sample size for the correlation analysis was calculated using G*Power 3.1 (Heinrich Heine Universität Düsseldorf, Düsseldorf, Germany). Assuming an expected correlation coefficient of $\rho=0.40$ between the Picterus JP and TcB, a two-sided type I error rate of $\alpha=0.01$, and a power $(1-\beta)$ of 0.99, the minimum required sample size was estimated to be 137 measurements. To allow for potential missing or unusable data, we planned to enroll approximately 150 newborns in total.

All statistical analyses were performed using the Jamovi statistical software (The Jamovi Project, version 2.6.45.0, Sydney, Australia). The distribution of the variables was evaluated using visual methods (histograms and Q–Q plots) and the Shapiro–Wilk test. Since normality was violated, Spearman's rank correlation coefficient (ρ) was used. Correlation coefficients were reported along with their 95% confidence intervals. Non-normally distributed variables were summarized as median (interquartile range), whereas categorical variables were presented as counts and percentages.

Agreement between Picterus JP and both comparator methods, TcB and TSB, was assessed using Bland-Altman analysis in infants with available paired measurements. For each paired measurement, the difference between methods and the mean of the two methods was calculated. For the Picterus JP and TcB comparison, the difference was defined as |TcB-Picterus|; for the Picterus JP and TSB comparison, the difference was defined as |TSB-Picterus|. Mean bias with its 95% confidence interval (CI) and the 95% limits of agreement (LoA; mean bias ± 1.96 × SD of the differences) were estimated and presented in Bland-Altman plots. In addition, Lin's concordance correlation coefficient (CCC) with 95% CIs was calculated to quantify overall agreement. For the supplementary paired-sample Picterus JP and TSB analysis, Pearson's correlation coefficient was also used to assess linear association.

To explore whether the magnitude of disagreement between TcB and Picterus JP varied across bilirubin levels, TcB values were categorized into 2 mg/dL intervals (<5 mg/dL, 5-6.99 mg/dL, 7-8.99 mg/dL, 9-10.99 mg/dL, 11-12.99 mg/dL, ≥13 mg/dL). Within each TcB category, the distribution of the difference |TcB-Picterus| was summarized as median (IQR).

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Differences across TcB categories were compared using the Kruskal-Wallis test, followed by Dwass-Steel-Critchlow-Fligner pairwise comparisons when appropriate.

Finally, we examined how often TcB and Picterus JP differed by a clinically relevant amount at different TcB levels. The absolute difference between the methods was calculated; a difference of ≥2 mg/dL was defined as an inaccurate measurement, and a difference of <2 mg/dL was defined as an accurate measurement. The ratio of these two groups was compared between TcB categories using the chi-square test. Effect size was quantified using Cramer's V. Standardized residuals were inspected to identify TcB categories that contributed most to the overall association. All statistical tests were two-sided, and p-values <0.05 were considered statistically significant.

Results

A total of 215 measurements from 165 newborns were analyzed. As shown in Table 1, the median TcB level was 6.9 mg/dL (IQR: 4.95–9.1), while the median Picterus JP was 7.3 mg/dL (IQR: 5.45–10.7).

There was a strong positive correlation between TcB and Picterus JP measurements (Spearman's ρ=0.780, p<0.001; n=215) (Figure 2). This finding indicates a strong monotonic association between standard TcB assessment and smartphone-based Picterus method across the measured bilirubin range and time interval (first seven days); agreement was evaluated separately using Bland-Altman analysis and CCC (Figure 3).

The median |TcB-Picterus| was 1.0 mg/dL [0.3 to 2.2] for TcB <5 mg/dL, -0.2 mg/dL [-0.93 to 0.93] for 5-6.99 mg/dL, 0.2 mg/dL [-0.6 to 2.6] for 7-8.99 mg/dL, 1.3 mg/dL [-0.75 to 3.0] for 9-10.99 mg/dL, -0.1 mg/dL [-1.1 to 4.0] for 11-12.99 mg/dL, and 3.45 mg/dL [0.9 to 4.2] for TcB ≥13 mg/dL. The Kruskal-Wallis test indicated a significant overall difference in the distribution of |TcB-Picterus| across TcB categories (χ^2=16.5, p=0.006, ε^2=0.08). Pairwise comparisons showed that the lowest TcB category (<5 mg/dL) had significantly larger positive differences than the 5-6.99 mg/dL category (p<0.001), whereas no other pairwise contrasts reached statistical significance. Overall, differences in TcB-Picterus varied across TcB strata (Kruskal-Wallis p=0.006), but after multiplicity-adjusted pairwise testing, only the <5 mg/dL stratum differed significantly from 5-6.99 mg/dL; estimates in the highest TcB stratum were imprecise due to small numbers.

The frequency of clinically acceptable agreement between TcB and Picterus JP (defined as |TcB–Picterus| <2 mg/dL) differed significantly across TcB categories (χ^2=21.20, p=0.002;

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Cramer's V=0.266). As shown in Table 2, acceptable agreement was highest in the lower TcB ranges (<5 mg/dL: 70.2%; 5–6.99 mg/dL: 75.0%) and declined with increasing TcB, reaching 40.0% at 11–12.99 mg/dL and 16.7% at ≥13 mg/dL. Standardized residuals indicated that the 11–12.99 mg/dL and ≥13 mg/dL strata contributed disproportionately to the overall association due to higher-than-expected rates of inaccurate measurements (residuals 2.03 and 2.46, respectively).

As a supplementary analysis, we directly compared Picterus JP measurements with available paired venous samples (n=24). Picterus JP showed a strong positive correlation with TSB (Spearman's r=0.716, p<0.001) (Figure 4). In the Bland-Altman analysis, the difference was defined as |TSB-Picterus|. The mean bias was 1.27 mg/dL (95% CI, -2.435 to -0.099), and the 95% limits of agreement ranged from -6.69 to 4.15 mg/dL (Figure 5). The concordance correlation coefficient was 0.750 (95% CI, 0.517 to 0.879), indicating moderate-to-good concordance but substantial variability at the individual measurement level.

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Discussion

TcB is a practical and non-invasive method for screening and is increasingly included in routine newborn care. AAP and National Institute for Health and Care Excellence guidelines recommend using TcB as an alternative to TSB measurement when assessing newborns [10, 11]. TcB has been adopted worldwide because it can reduce the need for invasive blood sampling. Despite its clinical benefits, transcutaneous bilirubin devices are not widely used. The high cost of traditional devices and limited access in some settings have driven growing interest in experimental research and emerging trends in noninvasive bilirubin assessment, such as optical imaging of the conjunctiva and sclera, smartphone-based imaging techniques incorporating machine-learning algorithms [12-15].

In this study, we evaluated the performance of a smartphone-based bilirubin assessment Picterus JP in comparison with TcB measurement in newborns. Our findings indicate that Picterus JP showed a strong positive correlation with TcB and, similar to the validation study using this application, generally demonstrated good validity accuracy [8].

In our study, we found that the discrepancy between |TcB-Picterus| varied significantly across TcB categories. Stratified analysis showed that agreement between the two methods was not constant across bilirubin ranges. The proportion of clinically acceptable concordance differed significantly by TcB category, with a small-to-moderate association (Cramer's V=0.266). Agreement was relatively high at lower TcB levels, but progressively decreased as

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TcB increased. Starting at TcB ≥11 mg/dL, this difference tended to be greater, particularly at TcB ≥13 mg/dL, which may be clinically relevant when bilirubin levels are close to treatment thresholds.

Consistent with our findings, the Picterus JP validation study reported a similar cutoff value of 12.5 mg/dL [8]. Moreover, a study evaluating the latest version of the JM-105 transcutaneous bilirubinometer showed that when TcB values exceeded approximately 11 mg/dL, both overestimation and underestimation became more frequent [16]. Similarly, it has been reported that TcB measurements obtained using BiliChek provided comparable information to capillary plasma bilirubin concentrations when bilirubin levels were <14 mg/dL [17]. In addition, an Android-based smartphone application using a color calibration card and microscope clip to capture forehead skin images for jaundice screening demonstrated excellent specificity (100%) for identifying infants with bilirubin levels below 15 mg/dL [18]. A recent systematic review and meta-analysis suggested that, although these applications show promising accuracy, further validation is needed before they can be recommended as a reliable alternative to standard TcB devices in routine clinical practice [19].

This study has several limitations. First, it was conducted in a single center, which may limit the generalizability of our findings to other clinical settings and populations. Second, during the study period, the number of births among refugee families was lower than expected, which may have reduced the sample's representativeness in terms of ethnic and skin-tone diversity and potentially limited the evaluation of device performance across different subpopulations. Thirdly, those with hemolytic disease constituted one-fifth of the participants, which may have influenced bilirubin dynamics and device performance. Additionally, the number of participants requiring phototherapy during the study period was low.

In addition to all these limitations, while acknowledging that TcB is not the gold standard, we continued to use non-invasive measurements as part of routine clinical practice to avoid unnecessary invasive blood sampling. However, when TcB values were considered clinically inconsistent or unreliable, TSB levels were obtained for confirmation. Despite the limited number of TSB measurements, the correlation between TSB and Picterus JP was moderate-to-good. Comparing Picterus JP with TcB may introduce a reference standard bias, as method-specific measurement errors inherent to TcB could influence agreement estimates. Therefore, our findings should be interpreted as demonstrating agreement with TcB rather than as definitive validation against TSB concentrations. In particular, further studies including infants born before 35 weeks' gestation are warranted to determine whether the

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Picterus JP application maintains acceptable accuracy and reliability in more premature neonates.

In conclusion, in this single-center study conducted in Turkiye, Picterus JP demonstrated reasonable agreement with TcB and good diagnostic accuracy in the first week of life after day one. Overall, these findings suggest that Picterus JP may perform adequately as a screening tool in the low-to-moderate bilirubin range, whereas measurement discordance becomes more frequent at higher bilirubin values. Clinically, this application may be particularly useful for rapid triage of neonatal hyperbilirubinemia during early postnatal assessments, outpatient follow-up visits, or in settings with limited access to laboratory testing and standard TcB devices. However, although Picterus JP appears promising for screening and monitoring, TSB measurement should remain the reference standard for high bilirubin levels or when a treatment decision needs to be made.

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Informed Consent Statement: Written informed consent was obtained from the parents of all subjects involved in the study.

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest.

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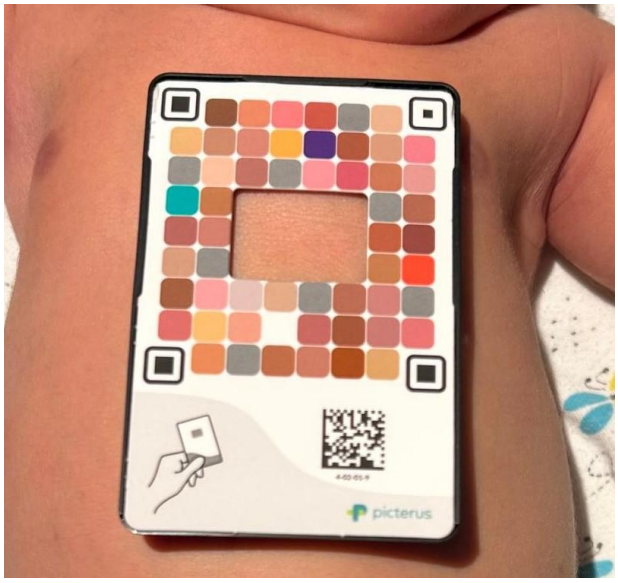

Figure 1. Picterus Jaundice Pro color calibration card

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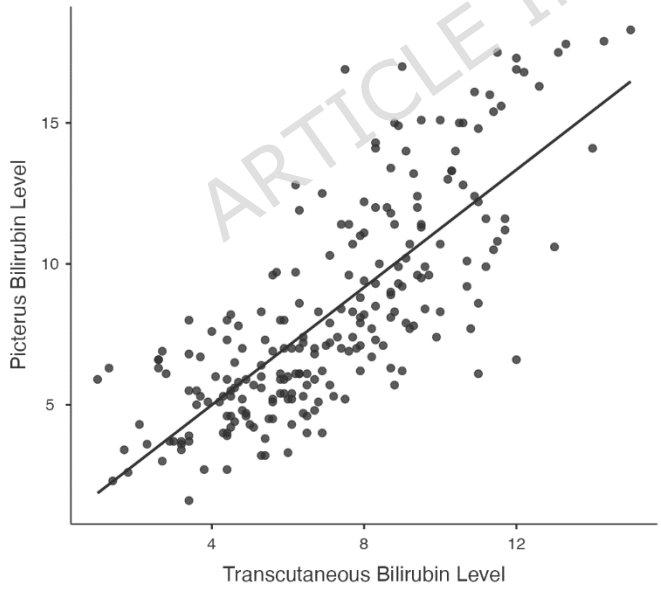

Figure 2. Scatter plot illustrating the relationship between Picterus JP and transcutaneous bilirubin levels.

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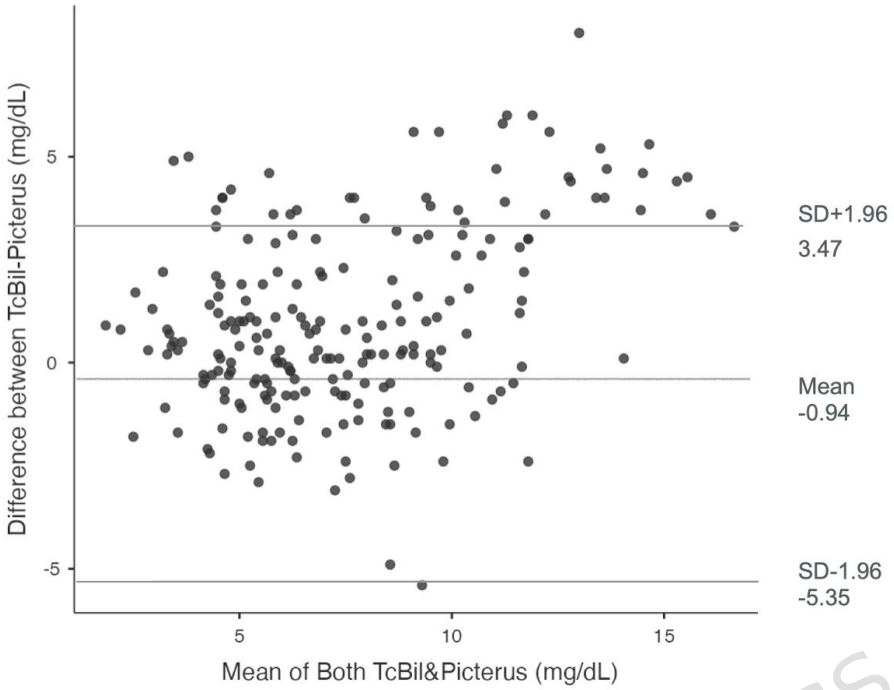

Figure 3. The Bland-Altman plot comparing transcutaneous bilirubin and Picterus JP measurements.

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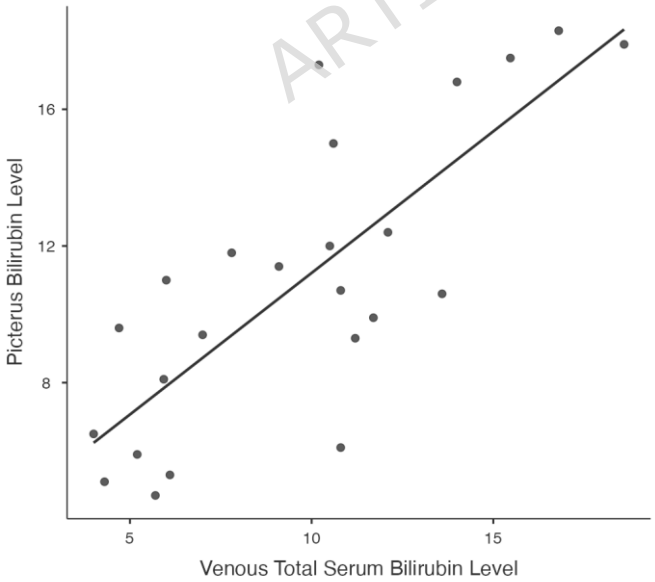

Figure 4. Scatter plot illustrating the relationship between Picterus JP and total serum bilirubin levels.

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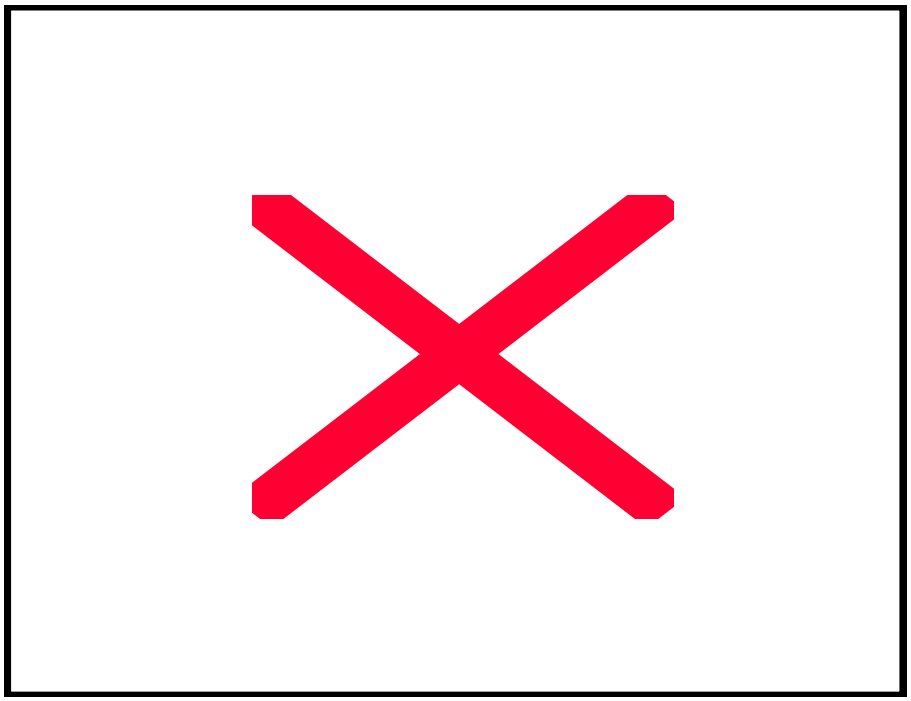

Figure 5. The Bland-Altman plot comparing total serum bilirubin and Picterus JP measurements.

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Table 1. Baseline demographic and clinical characteristics of the study populations

Infant-level baseline data (n=165)	
Variable	**Median [IQR] / n (%)**
Nationality	
Turkish	156 (94.5)
Syrian	7 (4.3)
Azerbaijani	1 (0.1)
Russian	1 (0.1)
Gender	
Male	84 (52.2)
Gestational age (weeks)	38 [37-39]
Birth weight (gram)	3220 [2970-3560]
Hemolytic disease	31 (19.2)
ABO incompatibility	26 (16.1)
Rh incompatibility	5 (3.1)
Both	0 (0)
Measurement-level baseline data (n=215)	
Postnatal age at measurement (hour)	45 [24.5-72]
Transcutaneous bilirubin level (mg/dL)	6.7 [4.85- 8.9]
Picterus JP bilirubin level (mg/dL)	7.0 [5.3-9.9]
Absolute difference |TcB – Picterus| (mg/dL)	1.3 [0.55–2.95]
Venous bilirubin level (mg/dL)	10.35 [5.98-11.8]
Phototherapy threshold (mg/dL)	12.0 [9.2-14.97]
Hospitalization for phototherapy	11 (5.2)

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Table 2. Agreement between TcB and Picterus JP according to TcB categories

TcBil category (mg/dL)	Accurate measurement* n (%)	Std. residual	Inaccurate measurement** n (%)	Std. residual	Total n
Total	138 (64.2)		77 (35.8)		215
<5	40 (70.2)	1.10	17 (29.8)	-1.10	57
5-6.99	42 (75.0)	1.96	14 (25.0)	-1.96	56
7-8.99	32 (65.3)	0.18	17 (34.7)	-0.18	49
9-10.99	17 (53.1)	-1.41	15 (46.9)	1.41	32
11-12.99	6 (40.0)	**-2.02**	9 (60.0)	**2.02**	15
≥13	1 (16.7)	**-2.46**	5 (83.3)	**2.46**	6

*Accurate measurement: |TcB-Picterus| < 2 mg/dL

**Inaccurate measurement: |TcB-Picterus| ≥ 2 mg/dL

Overall chi-square test: $\chi^2 = 21.20$, $p = 0.002$, Cramer's V = 0.266.

Cells with |standardized residual| ≥ 2 were considered to contribute meaningfully to the overall chi-square test

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