

Accuracy of non-invasive smartphone bilirubin measurements on neonates before and during phototherapy

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Abstract

Purpose

Previous publications have reported the accuracy of the Picterus Jaundice Pro (Picterus JP), a smartphone-based medical device app for screening neonatal jaundice prior to phototherapy. The purpose of this study was to evaluate the accuracy of the Picterus JP app before and during phototherapy.

Methods

Between April 2025 and April 2026, newborns whose total serum bilirubin concentration (TSB) reached or exceeded the American Academy of Pediatrics phototherapy thresholds were enrolled in the study after written informed consent was obtained from their parent or legal guardian. A Picterus JP scan was obtained from the chest of the newborn (within 60 minutes of the TSB blood sample collection), a light-occlusive patch was placed on the newborn's chest, and phototherapy was initiated. Then, up to five Picterus JP scans per newborn were obtained from the newborn's chest, from the region covered by the phototherapy patch, within one hour of the blood collection for subsequent TSBs. We calculated diagnostic accuracy statistics to summarize the accuracy of Picterus JP.

Results

A total of 137 paired Picterus JP–TSB measurements were analyzed. Overall, Picterus JP correlated well with TSB ($r = 0.720$; bias $-38.5 \mu\text{mol/L}$; RMSE $73.7 \mu\text{mol/L}$). Restricted to a phototherapy course of ≤ 3 days, correlation was strong before phototherapy ($n = 45$ measurements; $r = 0.849$; bias $-46.5 \mu\text{mol/L}$; RMSE $65.3 \mu\text{mol/L}$) and weaker during phototherapy ($n = 83$ measurements; $r = 0.520$; bias $-40.7 \mu\text{mol/L}$; RMSE $79.6 \mu\text{mol/L}$), although the magnitude of bias and RMSE was similar in both periods. The relative (fractional) decline in Picterus JP during phototherapy correlated well with the relative decline in TSB ($n = 97$ paired change measurements; $r = 0.752$), and the direction of the bilirubin trend agreed between methods in 83% of assessed trajectories. A fixed offset correction reduced the bias during phototherapy from -40.7 to $+5.8 \mu\text{mol/L}$.

Conclusion

Although the correlation between Picterus JP results and TSB measurements decreased during phototherapy, the direction of change in Picterus JP results almost always agreed with the direction of change in associated TSB measurements. This suggests that Picterus JP may be useful for monitoring bilirubin trends and treatment response during phototherapy, while also providing non-invasive bilirubin assessment before treatment initiation.

What is Known

- Total serum bilirubin (TSB) is the reference standard for guiding phototherapy but requires invasive blood draws; smartphone-based tools are validated mainly before phototherapy.

What is New:

- Picterus JP tracked bilirubin trends during phototherapy despite reduced correlation; an offset correction reduced bias, extending validation to severe hyperbilirubinemia.

INTRODUCTION

The goal of a neonatal hyperbilirubinemia screening and management program is to prevent hazardous hyperbilirubinemia and thereby prevent kernicterus spectrum disorder [1]. Total serum bilirubin (TSB) remains the reference standard for diagnosis and for guiding phototherapy, but obtaining TSB requires invasive blood sampling and laboratory access. Repeated TSB measurements to guide phototherapy contribute to pain, blood loss, parental stress, and resource use, and frequent laboratory testing may not always be feasible, particularly in outpatient or resource-limited settings. Transcutaneous bilirubinometers (TcB) have reduced the need for blood draws, but device cost and variable performance across different skin tones and during phototherapy limit their universal uptake [2–4].

In recent years, smartphone-based bilirubin estimation technologies have emerged as promising, low-cost alternatives for neonatal jaundice screening. These technologies use smartphone cameras and image-processing algorithms to estimate bilirubin concentration from skin color characteristics [5–8]. More recently, machine-learning-enhanced smartphone applications have been validated in large, multi-ethnic cohorts and in resource-limited settings, reporting correlation coefficients of approximately 0.7–0.85 with TSB and sensitivities exceeding 90% for detecting clinically significant hyperbilirubinemia, further supporting the feasibility of this approach across diverse healthcare contexts [8–10]. Picterus Jaundice Pro (Picterus JP) is a smartphone application designed to estimate the neonatal total serum bilirubin (TSB) level non-invasively. The concept originated in 2012 in an effort to provide a portable, affordable, and user-friendly tool to support bilirubin screening in settings with limited laboratory access.

Several validation studies have demonstrated a strong correlation between Picterus JP estimates and laboratory-measured TSB concentrations across diverse neonatal populations [5, 7, 11–13]. Furthermore, implementation studies in resource-limited settings have demonstrated feasibility and improved screening when Picterus JP was integrated with clinical workflows [12]. A subsequent cross-sectional validation in a resource-limited Mexican hospital similarly reported good correlation between Picterus JP and TSB, as well as good sensitivity for identifying bilirubin levels above the phototherapy threshold, reinforcing the tool's potential utility across varied low-resource clinical settings [9]. However, an important unresolved issue is the performance of smartphone-based bilirubin estimation during or after phototherapy treatment. Changes in skin bilirubin and reflectance properties after phototherapy may reduce the accuracy of optical bilirubin measurement techniques [14, 15]. Previous studies evaluating

TcB devices during phototherapy demonstrated improved agreement with TSB when measurements were performed on covered skin areas protected from phototherapy exposure by opaque patches [16–19]. Nevertheless, most smartphone-based bilirubin estimation systems have so far only been evaluated prior to phototherapy initiation, and evidence regarding their performance during active phototherapy treatment remains limited [8, 10].

This study was conducted in North Macedonia, where jaundice continues to be a prevalent cause of neonatal readmissions to hospitals following discharge from maternity care. While national standards for neonatal care have significantly improved in recent years, early detection and ongoing monitoring of hyperbilirubinemia still pose challenges, particularly after early postnatal discharge, in a setting where frequent laboratory testing is not always feasible.

The present study aimed to evaluate the accuracy of the Picterus Jaundice Pro application before and during phototherapy in neonates admitted for treatment of hyperbilirubinemia.

METHODS

Study Design and Settings

This prospective observational diagnostic accuracy study was conducted at the Department of Neonatology, University Children's Hospital, Skopje, North Macedonia, between April 2025 and April 2026.

Smartphone-based medical device, Picterus Jaundice Pro (JP), and Total Serum Bilirubin (TSB) Measurements

The smartphone based medical device Picterus JP we used was developed by Picterus AS (Trondheim, Norway) in collaboration with the Norwegian University of Science and Technology. The system consists of a smartphone application and a color calibration card designed to standardize image acquisition and compensate for variations in lighting conditions and smartphone camera characteristics. A Picterus Jaundice Pro clinical trial application for Android and iOS, together with calibration cards, was provided by the manufacturer for research use only. The principal investigator received training from the manufacturer and subsequently trained the neonatal nursing staff using a standardized protocol covering image acquisition, light control, camera positioning, patch application, and documentation.

TSB measurements were performed by the hospital clinical laboratory using the ARCHITECT c4000 analyzer (Abbott Laboratories, Abbott Park, U.S.A.) according to the manufacturer's specifications. The analyzer was calibrated twice weekly as part of the laboratory quality assurance procedures. TSB values were recorded in $\mu\text{mol/L}$ with time of blood draw.

Study Population

Eligible participants included term neonates ($\geq 37 + 0$ weeks' gestation) and late preterm neonates ($34 + 0$ to $36 + 6$ weeks' gestation) up to 14 postnatal days of age who were admitted for neonatal jaundice and had a TSB measurement that met or exceeded the American Academy of Pediatrics phototherapy thresholds according to postnatal age and risk category. Exclusion criteria included skin abnormalities at the measurement site (rash, bruising, congenital lesions, or significant skin discoloration), hemodynamic instability that prevented safe patch placement, or any condition judged by the investigators to compromise measurement reliability.

Demographic and clinical variables collected included gestational age, birth weight, sex, ethnicity, postnatal age at enrollment, feeding method, known hyperbilirubinemia risk factors, and details regarding phototherapy treatment.

Baseline procedure and phototherapy treatment

An initial baseline Picterus JP scan was obtained from the sternum, from approximately 20–30 cm distance, within 60 minutes of the TSB measurement that triggered phototherapy initiation, using the same standardized imaging protocol for all measurements. Immediately afterward, a light-occlusive patch (shown to block 93.5% of phototherapy light in vitro) was placed over the sternum and remained in place throughout treatment, being briefly removed and replaced in the same position for each subsequent scan. Phototherapy was delivered using standard equipment (Draeger Babytherm 8000/8010, supplemented as needed with Bistos BT-400, Natus/BiliBed, or Neoblu LED units), with initiation and discontinuation following institutional practice aligned with 2022 AAP guidelines. TSB monitoring frequency was individualized by the clinical team; all clinically ordered TSB draws were eligible for pairing with a Picterus JP scan, up to five paired measurements per neonate. The time of each Picterus JP measurement and TSB blood draw was documented, and paired measurements were considered valid when obtained within 60 minutes of each other, with a target interval of less than 30 minutes. Ambient lighting and measurement technique were standardized throughout the study. Picterus JP results were blinded to clinicians throughout, and all treatment decisions were guided exclusively by laboratory TSB and standard guidelines.

Ethics

The study protocol was approved by the institutional ethics committee, and the study was conducted in accordance with the Declaration of Helsinki. Parents/legal guardians provided written informed consent before enrollment.

Statistical Analysis

Picterus AS had input during study design but no role in data collection or analysis, which were performed solely by the investigators. Diagnostic accuracy of Picterus JP against TSB was assessed

overall and for measurements obtained before versus during phototherapy using Pearson correlation coefficient (r), mean bias (Picterus JP minus TSB), root mean square error (RMSE), and Bland–Altman limits of agreement. To account for the narrower range of bilirubin values later in treatment, we also calculated each neonate's relative (fractional) change in bilirubin at each measurement relative to their own pre-phototherapy baseline, and assessed agreement between the relative change in Picterus JP and in TSB using the same metrics. For neonates with at least three paired measurements spanning treatment, we compared the sign of the linear-regression slope of TSB over time with that of Picterus JP to assess concordance in the direction of the bilirubin trend. As an exploratory, post-hoc analysis, we tested whether adding a constant equal to the pre-phototherapy bias to Picterus JP measurements obtained during phototherapy could reduce the mean measurement difference between the methods; this correction was derived and evaluated within the same dataset and is hypothesis-generating. Continuous variables are presented as mean $\pm$ SD or median (IQR), categorical variables as n (%); with significance defined as $p < 0.05$. Enrollment targets were instead based on feasibility over the planned 12-month study period.

RESULTS

Study population and participant flow

Of 46 neonates initially screened during the study period, 40 were included in the final analysis, contributing 137 paired Picterus JP–TSB measurements (mean 3.4 pairs per neonate). Paired measurements or neonates were excluded because of missing Picterus JP or TSB values (11 measurements), an interval between paired Picterus JP and TSB measurements exceeding 60 minutes (4 measurements), exchange transfusion therapy (1 neonate), a displaced occlusive patch during phototherapy (3 neonates), and low birth weight requiring repeat analysis (1 neonate). Seven neonates (17.5%) were late preterm ($34 + 0$ – $36 + 6$ weeks' gestation), while the remaining were term ($\geq 37 + 0$ weeks' gestation). 30 neonates (75%) had a complete set of paired measurements obtained both before and during phototherapy. Gestational age ranged from 35 to 41 weeks', birth weight ranged from approximately 2000 to 4300 g, and postnatal age at the time of scanning ranged from 2 to 14 days, with most measurements obtained within the first postnatal week.

Overall diagnostic accuracy

Across all 137 paired measurements, obtained before and during phototherapy, Picterus JP estimates correlated well with TSB (Pearson $r = 0.720$). Picterus JP systematically underestimated TSB, with a mean bias of -38.5 $\mu\text{mol/L}$ (Picterus JP minus TSB), a root mean square error (RMSE) of 73.7 $\mu\text{mol/L}$, and a standard deviation of the differences of 63.0 $\mu\text{mol/L}$ (Table 1).

Table 1
Diagnostic accuracy of Picterus JP compared with TSB, overall and by phototherapy period.

Comparison	N	Pearson r	Bias (μmol/L)	RMSE (μmol/L)	SD of differences (μmol/L)
Overall (all measurements)	137	0.720	−38.5	73.7	63.0
Before phototherapy (course ≤3d)	45	0.849	−46.5	65.3	46.3
During phototherapy (course ≤3d)	83	0.520	−40.7	79.6	68.8
During phototherapy, offset-corrected*	83	0.520	+ 5.8	68.6	68.8
Relative (fractional) change during phototherapy†	97	0.752	−0.017	0.173	0.173

*Fixed offset of + 46.5 μmol/L (the magnitude of the bias observed before phototherapy) added to individual Picterus JP measurements obtained during phototherapy (see Statistical Analysis). †Relative change expressed as measured value ÷ each neonate's own pre-phototherapy baseline value; bias and RMSE for this row are on a dimensionless (fractional) scale, not μmol/L.

Temporal trends during phototherapy

Mean TSB and mean Picterus JP concentrations declined in parallel over the course of phototherapy, from approximately 310 and 260 μmol/L at treatment initiation to approximately 160–165 μmol/L by day 3 of treatment (Fig. 1, left). The bias between Picterus JP and TSB was most negative (approximately −50 to −70 μmol/L) during the first 24 hours of phototherapy and narrowed toward zero by days 2–3 (Fig. 1, right); the apparent divergence beyond day 4 was based on very few paired measurements and should be interpreted cautiously.

Accuracy before and during phototherapy

When the analysis was restricted to neonates with a phototherapy course of three days or less (128 measurements: 45 before and 83 during phototherapy), accuracy differed markedly between the two periods (Fig. 2; Table 1). Before phototherapy, Picterus JP showed strong agreement with TSB ($r = 0.849$; RMSE 65.3 μmol/L; bias −46.5 μmol/L; SD 46.3 μmol/L). During phototherapy, correlation weakened considerably ($r = 0.520$), while RMSE (79.6 μmol/L) and bias (−40.7 μmol/L) remained similar in magnitude to the pre-phototherapy period; the increase in RMSE was driven mainly by a wider spread of individual differences (SD 68.8 μmol/L) rather than by a change in systematic bias.

Relative change and directional concordance

Because absolute bilirubin values changed substantially during phototherapy, we also examined the relative (fractional) change in Picterus JP and TSB from the pre-phototherapy baseline. Both values

declined similarly over time, and the relative change in Picterus JP correlated well with the relative change in TSB ($n = 97$ paired change measurements; $r = 0.752$; RMSE 0.173; bias -0.017) (Fig. 3, Panels A–B).

At the individual patient level, the direction of the bilirubin trend (declining vs. increasing) agreed between Picterus JP and TSB in 20 of 24 neonates with sufficient repeated measurements (≥ 3 paired measurements spanning the treatment period, as defined in Statistical Analysis) (83.3% concordance); disagreement occurred in 4 neonates (16.7%). In each of the four discordant cases, TSB declined steadily and monotonically over the treatment course, whereas the corresponding Picterus JP trajectory fluctuated non-monotonically, including transient increases.

Effect of a fixed bias correction

Because the bias was consistent in magnitude before and during phototherapy, we explored whether a simple additive offset could reduce the mean measurement difference between the methods. Adding a fixed offset of 46.5 $\mu\text{mol/L}$ (the pre-phototherapy bias magnitude) to the during-phototherapy Picterus JP values reduced the bias from -40.7 to $+5.8$ $\mu\text{mol/L}$ and RMSE from 79.6 to 68.6 $\mu\text{mol/L}$; the correlation coefficient ($r = 0.520$) and SD of differences (68.8 $\mu\text{mol/L}$) were, as expected, unchanged by this constant shift (Table 1).

DISCUSSION

In this prospective study, Picterus JP, a smartphone-based non-invasive bilirubin screening tool, correlated well with TSB overall, but its performance changed once phototherapy was initiated. Before phototherapy, Picterus JP tracked TSB closely ($r = 0.849$), whereas during phototherapy the correlation with TSB was weaker ($r = 0.520$), a difference explored further below. Despite the reduced correlation, Picterus JP correctly identified bilirubin trends in most neonates (83%) and tracked the magnitude of change reasonably well ($r = 0.752$). A simple offset correction largely eliminated the systematic bias observed during phototherapy.

The reduction in the correlation coefficient during phototherapy is, in part, a predictable statistical phenomenon rather than solely a reflection of worsening measurement precision. As phototherapy lowers TSB toward the discontinuation threshold, the range of bilirubin values narrows considerably compared with the wider range present at treatment initiation; because the Pearson correlation coefficient is sensitive to the range of the underlying variable, restriction of range alone can markedly reduce r even when the absolute measurement error is unchanged. This interpretation is consistent with our finding that RMSE and bias during phototherapy were similar in magnitude to the pre-phototherapy period, even though the correlation coefficient fell.

Nonetheless, true measurement challenges specific to phototherapy are likely to have contributed. Continuous blue-light exposure alters skin bilirubin photoisomer content and reflectance, which may affect optical techniques calibrated using non-phototherapy skin [14, 15]. There may also be a lag

between skin and serum bilirubin changes: photodegradation acts directly within the skin, so exposed skin can show an apparent decline that outpaces the true fall in TSB, whereas covered skin should track serum levels more closely but may still lag behind acute changes [17, 18, 20]. Although we used a light-occlusive patch to protect a defined skin area from direct phototherapy exposure, as has been described for transcutaneous bilirubinometry [16–18], intermittent illumination of adjacent skin, incomplete occlusion, or brief patch displacement may still have introduced variability at the shielded measurement site. This is in line with the transcutaneous bilirubinometry literature, in which agreement with TSB during phototherapy improves substantially when covered-skin protocols are used, but does not fully return to pre-phototherapy levels [16–18].

The preserved directional concordance and reasonable tracking of relative bilirubin change (Fig. 3) may be of greater practical relevance than absolute agreement for many bedside decisions during phototherapy, such as judging whether bilirubin is trending down as expected or whether a confirmatory TSB should be obtained sooner than scheduled.

The observation that a single fixed offset reduced bias during phototherapy to near zero, without requiring knowledge of the underlying TSB, is potentially useful from an implementation perspective: it suggests that a phototherapy-specific correction factor, rather than a wholesale redesign of the underlying algorithm, may be sufficient to improve the accuracy of Picterus JP once treatment begins. This correction was derived and applied within the same dataset, however, and requires prospective validation in an independent cohort before clinical adoption.

Our study has several limitations. The modest sample size, particularly for the offset correction and trend concordance analyses, means these exploratory findings should be regarded as hypothesis-generating rather than confirmatory. Although the population included term and late preterm neonates, the study was not designed to evaluate performance across a broad range of skin pigmentation, which is a recognized limitation of optical bilirubin-estimation devices [15]. Phototherapy was delivered using several different device types, which may have introduced some heterogeneity in light exposure and, in turn, in the reliability of the occlusive patch. Following neonates after phototherapy discontinuation to determine when accuracy returns to baseline would also have been valuable, but was not pursued given the additional blood draws this would require.

Strengths of this study include its prospective design, standardized and blinded measurement protocol, use of a validated occlusive-patch technique, and inclusion of up to five repeated paired measurements per neonate, which allowed within-patient analysis of bilirubin trends in addition to cross-sectional accuracy. Notably, our cohort included neonates with severe hyperbilirubinemia, with TSB values exceeding 450 $\mu\text{mol/L}$, a range that, to our knowledge, has not previously been evaluated with a smartphone-based bilirubin estimation tool; this extends the evidence base for Picterus JP to the more clinically urgent end of the bilirubin spectrum, where accurate monitoring matters most.

CONCLUSIONS

Picterus JP correctly identified the direction of bilirubin change during phototherapy in the vast majority of neonates, demonstrating its potential value for monitoring treatment response. Although correlation with laboratory TSB decreased following phototherapy initiation, overall measurement error remained comparable to the pre-phototherapy period. These findings suggest that Picterus JP may serve as a useful non-invasive adjunct for tracking bilirubin trends during phototherapy, particularly where frequent blood sampling is impractical or access to laboratory testing is limited. Further development of a phototherapy-specific calibration and validation in larger independent cohorts are required before Picterus JP can be considered as a substitute for laboratory TSB measurements in clinical decision-making. Future studies could also prospectively evaluate whether incorporating Picterus JP into routine monitoring allows a reduction in the number of blood draws required during phototherapy, without compromising safety.

ABBREVIATIONS

AAP

American Academy of Pediatrics

IQR

interquartile range

JP

Jaundice Pro

RMSE

root mean square error

SD

standard deviation

TcB

transcutaneous bilirubin

TSB

total serum bilirubin.

DECLARATIONS

Competing Interests

TR, DKH and LMG are employees of Picterus AS, the manufacturer of the Picterus JP device evaluated in this study. Picterus AS provided the Picterus JP application and calibration cards for research use and had input during study design, but had no role in data collection, analysis, or manuscript preparation. The remaining authors declare they have no competing interests.

Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Ethics Committee of the University Children's Hospital in Skopje, reference number 03-1671/1, from 26.03.2025.

Consent to Participate

Written informed consent was obtained from the parents or legal guardians of all participants included in the study.

Consent to Publish

Not applicable. This manuscript does not contain any individual person's identifiable data, images, or videos.

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No funding was received for conducting this study.

Author Contribution

All authors contributed to the study conception and design. NZ performed the study, data collection and analysis, and drafted the manuscript. AK contributed to data analysis, methodological guidance, and review. TR prepared the figures for the manuscript. DKH, LMG and TR provided methodological guidance related to the Picterus JP device and reviewed the manuscript for important intellectual content. TMB contributed to data interpretation and critically revised the manuscript. All authors read and approved the final manuscript.

Data Availability

The datasets generated and/or analyzed during the current study are not publicly available due to patient privacy considerations but are available from the corresponding author on reasonable request.

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Figures

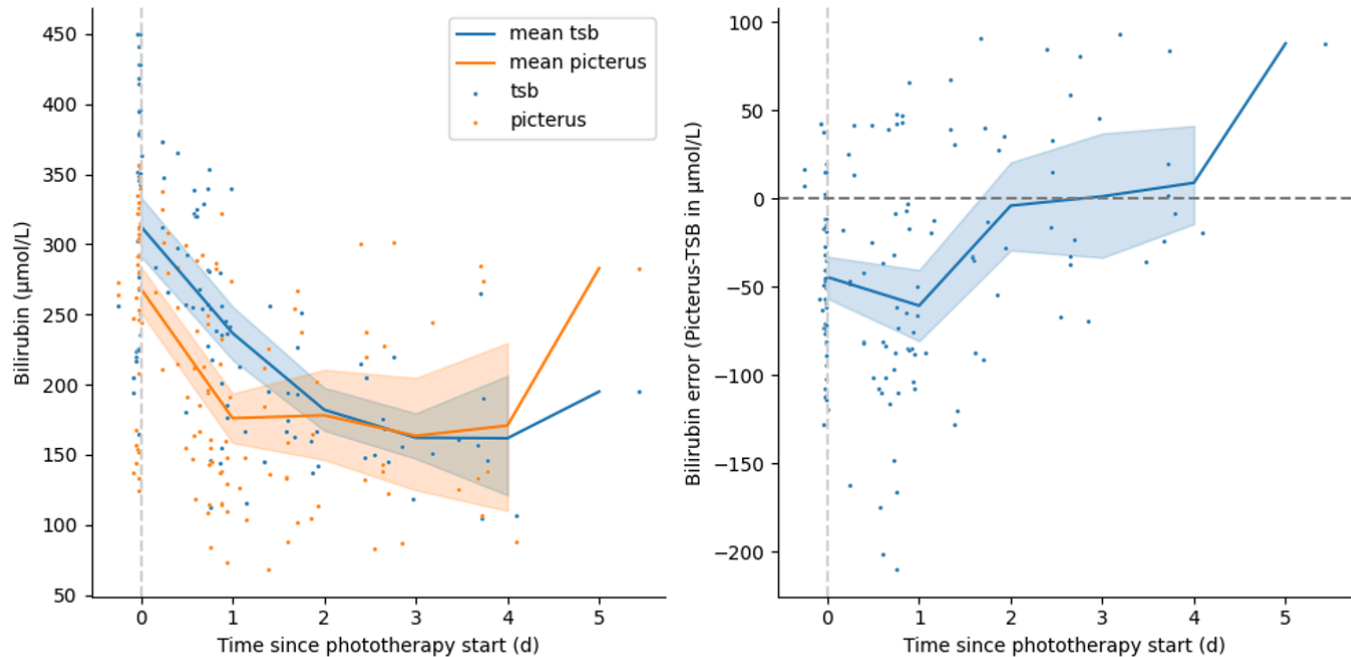


Figure 1

Individual (dots) and mean (lines) values for TSB (blue) and Picterus JP (orange), with shaded areas showing the 95% confidence intervals (left). Individual (dots) and mean (lines) difference between paired

Picterus JP and TSB measurements with shaded 95% confidence interval (right). Data is plotted against time in days (d) since phototherapy initiation.

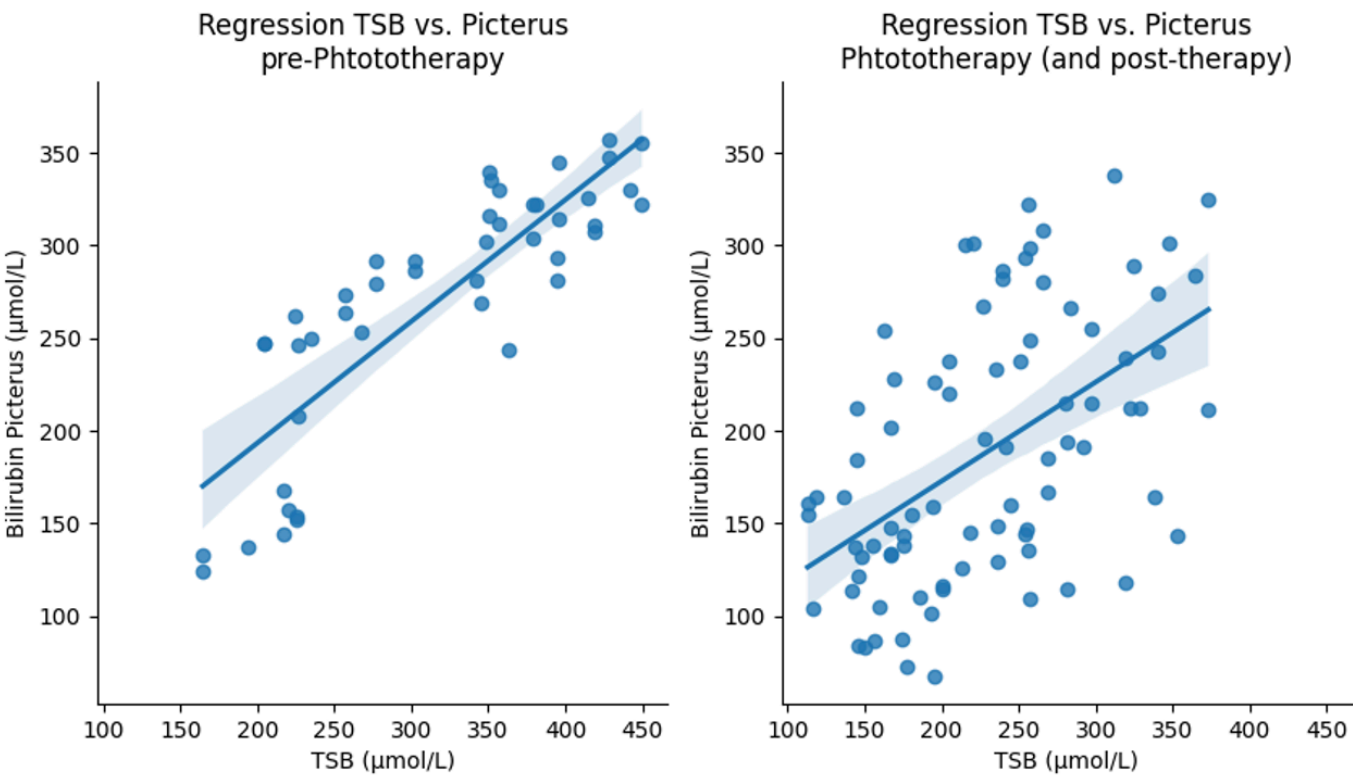


Figure 2

Regression of Picterus JP against paired TSB values, restricted to neonates with a phototherapy course of three days or less, shown before phototherapy (n=45) (left) and during phototherapy, including brief post-therapy measurements (n=83) (right).

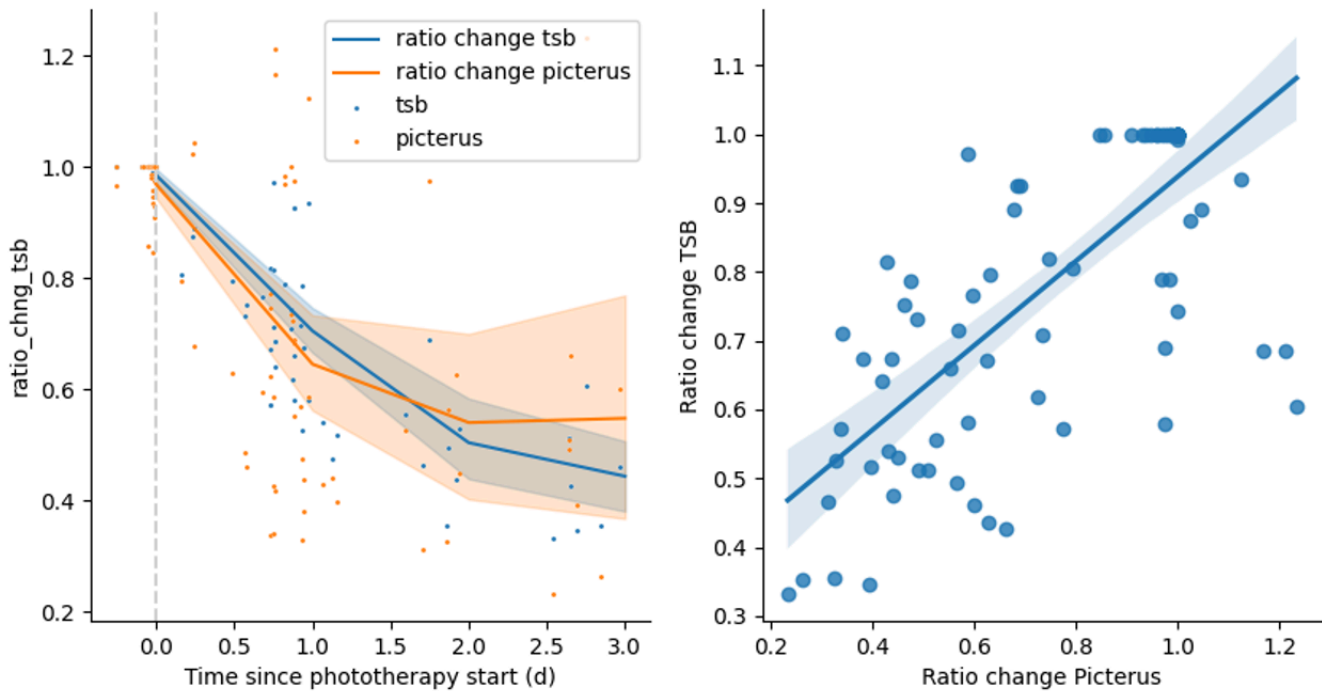


Figure 3

Relative (fractional) change in TSB and Picterus JP during phototherapy. Individual (dots) and mean (line) relative change in TSB and Picterus JP over time in days (d) since phototherapy start, with 95% confidence intervals shown as shaded areas (left). Correlation between the paired relative changes in Picterus JP and TSB, with a simple regression line and 95% confidence interval as shaded area (right).