



Q/ How accurate is transcutaneous bilirubin testing in newborns with darker skin tones?

EVIDENCE-BASED ANSWER

A / **FAIRLY ACCURATE.** Photometric transcutaneous bilirubin (TcB) testing may overestimate total serum bilirubin (TSB) in neonates with darker skin tones by a mean of 0.68 to > 2 mg/dL (strength of recommendation [SOR]: C, diagnostic cohort studies with differing reference standards). Overall, TcB meters retain accept-

able accuracy in infants of all skin tones across a range of bilirubin levels, despite being more likely to underestimate lighter skin tones and overestimate darker ones (SOR: C, diagnostic cohort studies with differing reference standards). It is unclear if the higher readings prompt an increase in blood draws or otherwise alter care.

Evidence summary

Some evidence suggests overestimation in all skin tones

In a prospective diagnostic cohort study of 1553 infants in Nigeria, the accuracy of TcB measurement with 2 transcutaneous bilirubinometers (Konica Minolta/Air Shields JM-103 and Respironics BiliChek) was analyzed.¹ The study population was derived from neonates delivered in a single maternity hospital in Lagos who were ≥ 35 weeks gestational age or ≥ 2.2 kg.

Using a color scale generated for this population, researchers stratified neonates into 1 of 3 skin tone groups: light brown, medium brown, or dark brown. TcB and TSB paired samples were collected in the first 120 hours of life in all patients. JM-103 recordings comprised 71.9% of TcB readings.

Overall, TcB testing overestimated the TSB by ≥ 2 mg/dL in 64.5% of infants, ≥ 3 mg/dL in 42.7%, and > 4 mg/dL in 25.7%. TcB testing underestimated the TSB by ≥ 2 mg/dL in 1.1% of infants, ≥ 3 mg/dL in 0.5%, and > 4 mg/dL in 0.3%.¹

Local variation in skin tone was not associated with changes in overestimation, although the researchers noted that a key

limitation of the study was a lack of light-toned infants for comparison.¹

A prospective diagnostic cohort study of 1359 infants in Spain compared TcB measurements to TSB levels using the Dräger Jaundice Meter JM-105.² Patients included all neonates (gestational age, 36.6 to 41.1 weeks) born at a single hospital in Barcelona.

Using a validated skin tone scale, researchers stratified neonates at 24 hours of life to 1 of 4 skin tones: light ($n = 337$), medium light ($n = 750$), medium dark ($n = 249$), and dark ($n = 23$). They then obtained TSB samples at 48 to 72 hours of life, along with other routine screening labs and midsternal TcB measurements.

TcB testing tended to overestimate TSB (when < 15 mg/dL) for all skin tones, although to a larger degree for neonates with dark skin tones (mean overestimation, 0.7 mg/dL for light; 1.08 mg/dL for medium light; 1.89 mg/dL for medium dark; and 1.86 mg/dL for dark; $P < .001$ for light vs medium dark or dark).²

Stated limitations of the study included relatively low numbers of neonates with dark skin tone, no test of interobserver reliability

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The research reinforces the need for review and adjustment of transcutaneous bilirubin cut-off levels based on the local population.

in skin tone assignment, and enrollment of exclusively healthy neonates with low bilirubin levels.²

Other studies report overestimation in infants with darker skin tone

Two Canadian diagnostic cohort studies also found evidence that TcB testing overestimated TSB in infants with darker skin tones, although TcB test characteristics proved stable over a wide range of bilirubin levels.

The first study enrolled 451 neonates \geq 35 weeks gestational age at a hospital in Ottawa and assessed TcB using the JM-103 meter.³ The neonates were stratified into light ($n = 51$), medium ($n = 326$), and dark ($n = 74$) skin tones using cosmetic reference color swatches. All had a TcB and TSB obtained within 30 minutes of each other.

TcB testing underestimated TSB in infants with light and medium skin tones and overestimated TSB in infants with darker skin tone (mean difference, -0.88 mg/dL for light; -1.1 mg/dL for medium; and 0.68 mg/dL for dark; P not given). The mean area under the curve (AUC) was ≥ 0.94 for all receiver-operator characteristic (ROC) curves across all skin tones and bilirubin thresholds (AUC range, 0-1, with > 0.8 indicating strong modeling).³

Limitations of the study included failure to check interrater reliability for skin tone assessment, low numbers of infants with elevated bilirubin (≥ 13.5 mg/dL), and very few infants in either the dark or light skin tone groups.³

The second Canadian study enrolled 774 infants born at ≥ 37 weeks gestational age in Calgary and assessed TcB with the JM-103.⁴ Infants were categorized as having light ($n = 347$), medium ($n = 412$), and dark ($n = 15$) skin tones by study nurses, based on reference cosmetic colors. All infants had paired TcB and TSB measurements within 60 minutes of each other and before 120 hours of life.

Multivariate linear regression analysis using medium skin tone as the reference group found a tendency toward low TcB levels in infants with light skin tone and a tendency toward high TcB levels in infants with dark skin tone (adjusted $R^2 = 0.86$). The

AUC was ≥ 0.95 for all ROC curves for light- and medium-toned infants at key TSB cutoff points; the study included too few infants with dark skin tone to generate ROC curves for that group.⁴

Recommendations from others

In 2009, the American Academy of Pediatrics (AAP) recommended universal predischarge screening for hyperbilirubinemia in newborns using either TcB testing or TSB. The AAP statement did not address the effect of skin tone on TcB levels, but did advise regular calibration of TcB and TSB results at the hospital level.⁵

In 2016, the National Institute for Health and Care Excellence (NICE) updated their guideline on jaundice in newborns younger than 28 days old. NICE recommended visual inspection of all babies for jaundice by examining them in bright natural light and looking for jaundice on blanched skin; it specifically advised checking sclera and gums in infants with darker skin tones.⁶

The Nigerian researchers noted earlier have published an updated TcB nomogram for their patient population.⁷

Editor's takeaway

Even with the small variation of 2 mg/dL or less between transcutaneous and serum bilirubin, and the SOR of C due to lab values being labeled disease-oriented evidence, TcB proves to be useful. In practice, concerning TcB values should lead to serum bilirubin confirmation. This evidence indicates we might be ordering TSB measurements more or less often depending on skin tone, reinforcing the need for review and adjustment of TcB cut-off levels based on the local population.

JFP

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