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Evaluation of a New Transcutaneous Bilirubinometer

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ABSTRACT. *Objective.* **The objective of this study was to evaluate the Minolta/Hill-Rom Air-Shields Transcutaneous Jaundice Meter model JM-103.**

Methods. **We studied a convenience sample of 849 newborns ≥35 weeks of gestation in 3 hospitals. These infants had total serum bilirubin (TSB) levels measured on clinical indication, and transcutaneous bilirubin (TcB) levels were obtained within 1 hour of the TSB levels. The population was 59.2% white, 29.8% black, 4.5% East Asian, 3.8% Middle Eastern, 1.6% Indian/Pakistani, and 1.1% Hispanic.**

Results. **There was a close correlation between TSB and TcB values in all of the population groups: white (n = 503, r = .949); black (n = 253, r = .822); and East Asian, Indian/Pakistani, and Hispanic (n = 93, r = .926). In the black population, the correlation was less close than in the other groups, and differences between the TcB and TSB measurements tended to increase with rising TSB values. JM-103 values differed from TSB values by 3 mg/dL or more in 2% of white, 3.2% of other, and 17.4% of black infants. In these black infants, the JM-103 value was always greater than the TSB value.**

Conclusions. **We conclude that TcB measurements using the JM-103 jaundice meter correlate very closely with TSB levels over the range of TSB encountered in this study. Because only 3.3% of our infants had TSB values >15 mg/dL (257 μmol/L), more data are needed in this range of TSB concentration. The correlation in black infants is not as close as in other groups, but because the tendency in blacks is for the JM-103 to overestimate serum bilirubin levels, dangerous clinical errors are unlikely to occur. The measurement technique is rapid and simple, and it is easy to perform repeated measurements over time, thus reducing the likelihood of error. TcB measurements with the JM-103 jaundice meter should obviate the need for most serum bilirubin levels in newborn infants ≥35 weeks of gestation, although serum bilirubin measurements are still required when treatment with phototherapy or exchange transfusion is being considered. *Pediatrics* 2004;113:1628–1635; *newborn jaundice, transcutaneous bilirubin measurement, JM-103 jaundice meter.***

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ABBREVIATIONS. TSB, total serum bilirubin level; TcB, transcutaneous bilirubin level; CI, confidence interval; CV, coefficient of variation; HPLC, high-pressure liquid chromatography.

Other than the routine screen for inborn errors of metabolism, the most frequent laboratory test performed in the normal newborn nursery is a total serum bilirubin (TSB) measurement. The Minolta/Hill-Rom Air-Shields Transcutaneous Jaundice Meter JM-102 (predecessor to the JM-103), provides an objective measurement of the degree of newborn jaundice and, when used as a screening tool, identified infants who required a TSB measurement.[1,2] Routine use of this jaundice meter in the newborn nursery reduced cost and the need for TSB measurements,[3,4] but the JM-102 has some disadvantages: 1) it does not provide a readout of the serum bilirubin level—a transcutaneous bilirubin level (TcB) index is displayed and TSB levels are derived from the TcB index on the basis of data obtained in individual hospital laboratories—and 2) readings with the JM-102 are significantly affected by skin pigmentation.[5] Thus, this instrument has achieved limited acceptance in hospitals in the United States.

The new JM-103 Jaundice Meter uses 2 wavelengths and a dual optical path system. The principle of operation has been described in detail by Yasuda et al.[6] This includes the formation of 2 beams, 1 of which reaches only the shallow areas of the subcutaneous tissue while the other penetrates the deeper layers. The differences between the optical densities are detected by blue and green photocells. The measurement of bilirubin accumulated primarily in the deeper subcutaneous tissue should decrease the influence of other pigments in the skin such as melanin and hemoglobin. In a study of 77 Japanese infants, measurements of TcB with the JM-103 correlated well with TSB measurements and better than the JM-102.[6]

Another transcutaneous device, the BiliChek (Respironics, Marietta, GA), uses multiple wavelengths, and a close correlation was found between TcB and TSB measurements in mixed racial populations.[7–9] In a study of Hispanic newborns, however, there was a tendency for the BiliChek to underestimate the TSB, particularly at higher bilirubin levels.[10]

METHODS

We studied a convenience sample of 849 newborns who were ≥35 weeks of gestation and had TSB levels measured on clinical indication between February 1, 2001, and December 31, 2002. The

TABLE 1. Number (%) of Infants in Each Racial Group at Each Hospital

	White Infants	Black Infants	All Other Infants
n	503	253	93
Beaumont (n = 670)	459 (91.2)	132 (52.2)	79 (84.9)
Hutzel (n = 86)	7 (1.4)	78 (30.8)	1 (1.1)
Jefferson (n = 93)	37 (7.4)	43 (17.0)	13 (14.0)

infants were part of the normal newborn nursery population of William Beaumont Hospital (Royal Oak, MI; n = 670), Hutzel Hospital (Detroit, MI; n = 86), and Thomas Jefferson University Hospital (Philadelphia, PA; n = 93). Included in the Beaumont infants are 40 infants who were born at Beaumont and had TSB and TcB levels measured during outpatient follow-up visits to a single private practice group. Any infant in the well-infant nursery who was ≥35 weeks of gestation and had not received phototherapy could be included as a subject.

All TSB levels were obtained on clinical indication. The total population consisted of 503 (59.2%) white, 253 (29.8%) black, 38 (4.5%) Asian-American (East Asian heritage), 32 (3.8%) Middle Eastern, 14 (1.6%) Indian/Pakistani, and 9 (1.1%) Hispanic infants. The racial distribution of the population of each hospital is shown in Table 1. At Beaumont and Hutzel, triplicate TcB measurements over the midsternum were obtained on each infant and averaged, but at Jefferson, only a single measurement was obtained. The mean of 3 TcB measurements provided the highest degree of correlation (the relationship between measurements, r = .965) and agreement (the similarity between measurements, r = .965) but differed minimally from the data provided when only the first of 3 measurements was used (correlation r = .963, agreement r = .962). Only 1 TcB measurement from each infant was entered into the study database, providing 849 independent measurements.

In a subset of 146 infants at Beaumont, we performed simultaneous TcB measurements with the BiliChek and the JM-103. This population consisted of 125 (86%) white, 4 (3%) black, 14 (10%) Middle Eastern, 2 East Asian infants, and 1 Indian/Pakistani infant. We also compared the time needed to obtain TcB measurements with the JM-103 and the BiliChek.

TcB levels were obtained within 1 hour of TSB levels. Blood was drawn by heel puncture, and TSB levels were measured in the hospital clinical chemistry laboratories. (Beaumont, Advanced Instruments Bilirubinometer; Hutzel, Dupont Dimension XL; Jefferson, Beckman LX20). This study was approved by the institutional review boards of each hospital.

We assessed interinstrument variability by comparing measurements from 6 instruments in 30 infants, and we assessed precision by performing 10 repeat measurements in 9 infants. For the site of sampling, we compared JM-103 measurements obtained from the forehead and the midsternum in 475 infants.

RESULTS

The distribution of the TSB measurements for the total study population is shown in Fig 1. TSB levels ranged from 1.1 to 20.8 mg/dL (18.8-356 μmol/L); 28 (3.3%) were >15 mg/dL (257 μmol/L), and 178 (21%) were >10 mg/dL (171 μmol/L). Linear regression analysis and Bland-Altman plots (mean and 95% confidence interval [CI])[11] are shown in Figs 2 and 3. The Pearson correlation coefficients (r) were as follows: total population, 0.915; white, 0.949; black, 0.822; Asian-American, 0.941; and Middle Eastern, 0.866. Assessment of equality of means and variances by the Bradley-Blackwood test[12] was calculated for different populations and is shown in Fig 3.

The number of infants whose JM-103 levels differed from the TSB level is shown in Table 2. JM-103 values differed from TSB values by 3 mg/dL (51.3 μmol/L) or more in 2% of white, 17.4% of black, and 3.2% of other infants. In all of these black infants, the JM-103 value was higher than the TSB value. Receiver operating characteristics curves are shown in Fig 4.

Interinstrument Variability

Using analysis of variance of repeated measures, the mean variability between instruments was 0.02 (P = .796) and the index of consistency as measured

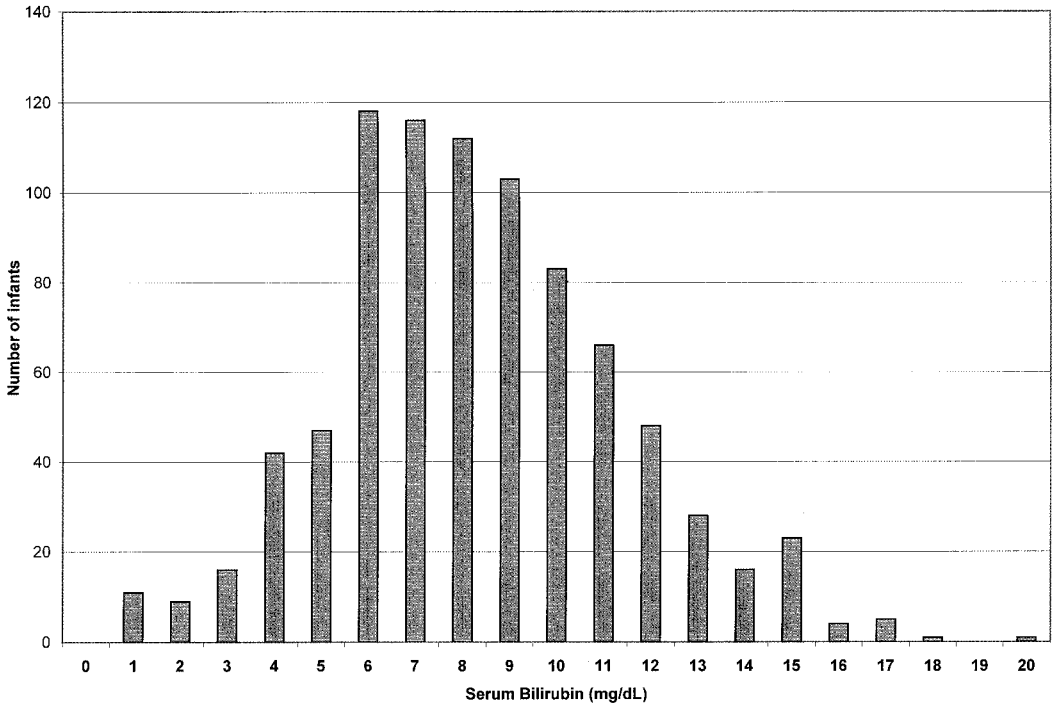

Fig 1. Distribution of TSB levels for the total study population (n = 849; mean: 8.68 ± 3.06 [standard deviation] mg/dL). Each bar represents the number of infants with TSB levels 1 to 1.9 mg/dL, 2 to 2.9 mg/dL, 3 to 3.9 mg/dL, etc.

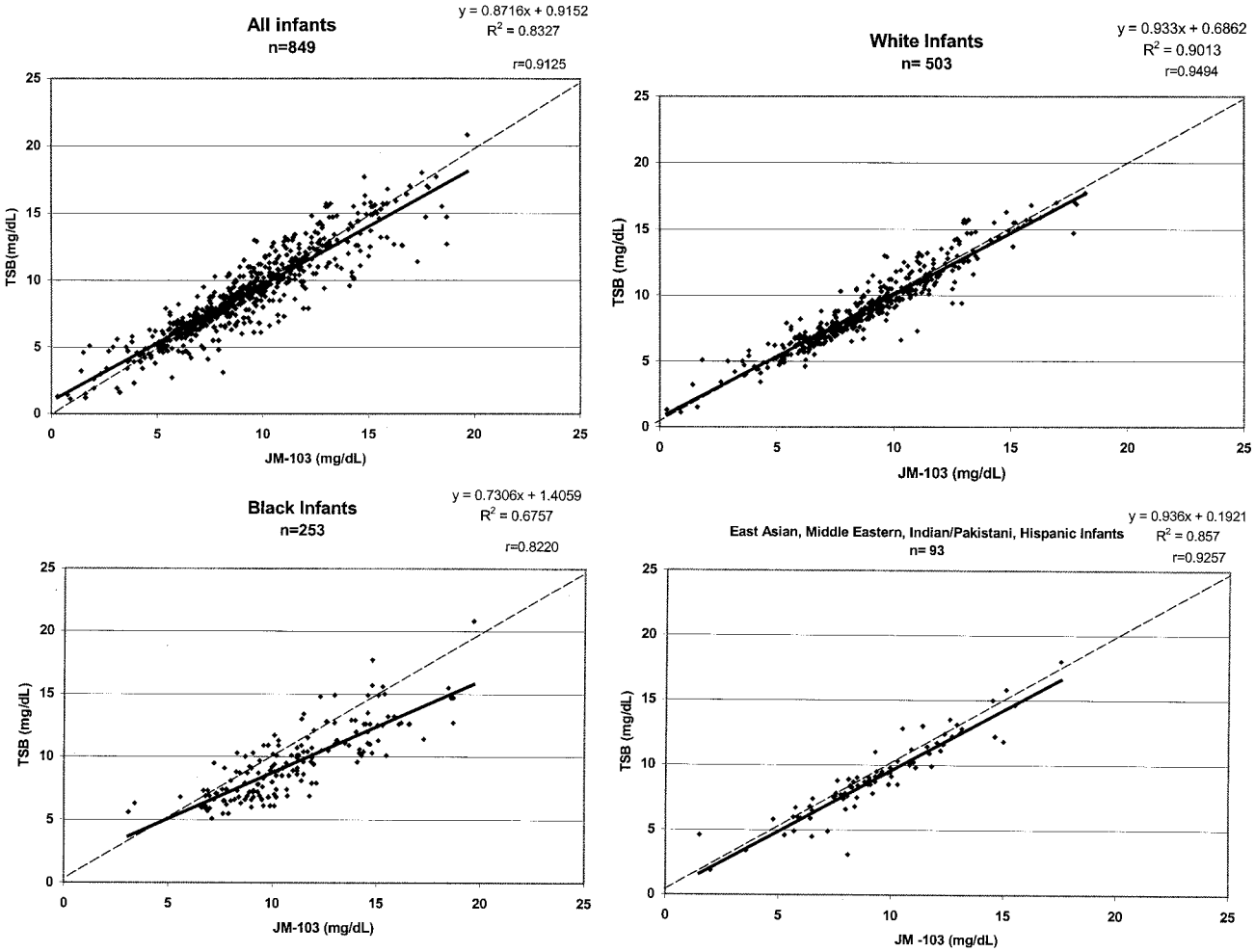

Fig 2. Linear regression plots (solid line) of JM-103 TcB versus TSB measurements in the total population and different racial groups. The dotted line is the line of identity.

by the intraclass correlation was 0.993 (95% CI: 0.989-0.996), indicating no differences between the instruments.

Precision

We performed 10 repeat TcB measurements on 18 infants. In 4 infants with TcB levels of 2.0 to 3.3 mg/dL (34-56 μmol/L), the mean coefficient of variation (CV) was 14.3% (range: 8.5%–19%). In 6 infants with TcB levels of 4.6 to 7.6 mg/dL (79-130 μmol/L), the mean CV was 5.4% (range: 3.0%–8.4%), and in 8 infants with TcB levels of 8.4 to 22.4 mg/dL (144-383 μmol/L), the mean CV was 6.3% (range: 2.7%–8.6%).

Site of Sampling

The Pearson correlation coefficients (r) in 475 infants for forehead and sternum TcB measurements versus TSB were 0.914 and 0.953, respectively. All TcB measurements reported in this study were obtained from the midsternum.

Comparison of BiliChek and JM-103

In 146 infants, the correlation coefficients for TSB versus JM-103 and BiliChek were 0.973 and 0.971, respectively. The mean (±standard deviation) difference between the TSB and JM-103 was 0.26 ± 0.64 mg/dL and between the TSB and BiliChek was 0.13 ± 0.66 mg/dL. The difference between TSB and TcB measurements was <2 mg/dL (34.2 μmol/L) in 98% of measurements with both instruments. The BiliChek requires 5 repeat measurements, and the average time needed to obtain a BiliChek TcB in 10 infants was 55.5 ± 31.5 seconds, compared with 5.7 ± 2.3 seconds and 23.1 ± 6.6 seconds when duplicate and triplicate measurements, respectively, were obtained with the JM-103 ($P < .001$). Because the first of 3 measurements with the JM-103 provided results similar to the average of 3 measurements, 1 reading should suffice, although averaging 2 or 3 measurements in the clinical setting is probably desirable.

DISCUSSION

The shortening of newborn hospital stays after birth and the observation that kernicterus is still occurring[13–15] has drawn attention to the importance of identifying and monitoring the jaundiced newborn infant. Because most infants are now discharged before age 48 hours, peak bilirubin levels will almost always occur after discharge. Thus, additional monitoring and surveillance are essential to ensure that extreme hyperbilirubinemia does not occur.[15–17] Because visual estimates of the degree of

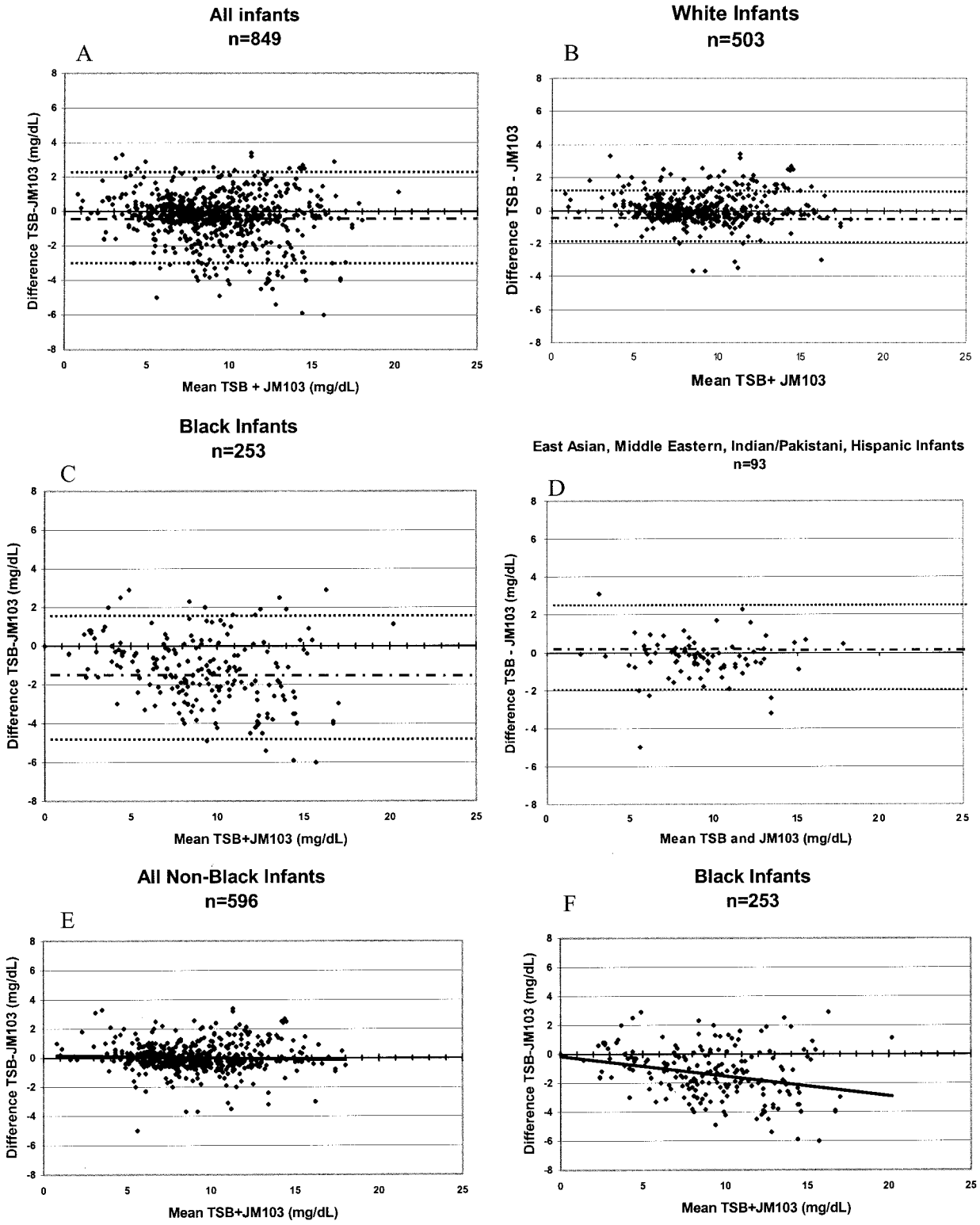

Fig 3. (A– D) Bland-Altman plots (mean and 95% CI) for the total population and different racial groups. (E–F) Assessment of equality of means and variances in all nonblack infants ($n = 596$, slope and y intercept are not different from 0; $P = .600$) and in black infants $n = 253$ (slope and y intercept are different from 0; $P < .001$.)

jaundice and the serum bilirubin level can be misleading,[18–20] it is often necessary to obtain laboratory measurements of the TSB. Currently, this necessitates visits to hospital laboratories, additional blood sampling, and painful heel sticks and creates consternation and inconvenience for families and physicians alike. A convenient, accurate, and noninvasive method for estimating serum bilirubin concentration would be of enormous benefit to physicians, infants, and families.

The original Minolta Air-Shields Jaundice meter and its successor, the JM-102, have been studied extensively and have been shown to perform well as screening devices.[1,2,4,21,22] Their major disadvantages

TABLE 2. Number (%) of Infants Whose JM-103 Levels Differed From TSB Levels by 2 mg/dL (34.2 μmol/L) or More

Difference TSB - JM-103 (mg/dL)	White Infants (n = 503)			Black Infants (n = 253)			All other infants (n = 93)		
	JM-103 <TSB	JM-103 >TSB	Total (%)	JM-103 <TSB	JM-103 >TSB	Total (%)	JM-103 <TSB	JM-103 >TSB	Total (%)
2–2.9	17 (3.4)	3 (0.6)	20 (4.0)	9 (1.8)	52 (20.6)	61 (24.1)	1 (1.1)	4 (4.3)	5 (5.4)
3–3.9	4 (0.8)	6 (1.2)	10 (2.0)	0	27 (10.7)	27 (10.7)	1 (1.1)	1 (1.1)	2 (2.2)
4–4.9	0	0	0	0	13 (5.1)	13 (5.1)	0	0	
5–5.9	0	0	0	0	4 (1.6)	4 (1.6)	0	1	1 (1.1)

include significant variations in the readings produced by differences in skin pigmentation and that the displayed value is not a serum bilirubin level but is an index that must be converted to a serum bilirubin level in each hospital. In a study of 77 Japanese infants that included 24 preterm infants (at 33.2 ± 3.19 weeks of gestation), Yasuda et al[6] found an excellent correlation (r = .94) between the JM-103 and TSB.

The BiliChek seems to work well in a multiracial population,[5,7,16] and when compared with high-pressure liquid chromatography (HPLC) measurements of TSB, the BiliChek was as good as or better than measurements of TSB in the clinical laboratory.[7] However, its accuracy in a Hispanic population, particularly at higher TSB levels, has been questioned,[10] and when used as a screening tool for hyperbilirubinemia in a (presumably) more homogeneous racial group of Scottish infants, the BiliChek seemed to offer no significant advantage over the JM-102.[21] In a subset of the population in our study, the JM-103 seemed to do as well as the BiliChek, although there were very few black infants in this sample. Preliminary data suggest that the BiliChek might have a better correlation (than the JM-103) with TSB in black infants,[23] but this needs to be confirmed. With the JM-103, we found that the predominant tendency in black infants is for the TcB value to overestimate TSB levels (Table 2), so dangerous errors are unlikely to occur. The main negative effect of this would be to require a potentially unnecessary follow-up visit or more TSB measurements than in the white population. Given that mean TSB levels in black newborns in the United States are significantly lower than those of whites,[24,25] this should not present a major problem.

Measurements with the JM-103 are rapid and convenient. We compared the time necessary to obtain TcB measurements with the JM-103 and the BiliChek. The BiliChek requires 5 repeat measurements, and the total time needed to obtain a BiliChek TcB in 10 infants was 55.5 ± 31.5 seconds/infant. Because the first of 3 measurements with the JM-103 provides results similar to the average of 3 measurements, 1 reading should suffice. Nevertheless, the JM-103 allows the user the choice of obtaining 1 to 5 measurements and automatically provides an average of the readings. Comparison of forehead (r = .914) and sternum (r = .953) JM-103 measurements with TSB suggested a slightly better correlation with sternum measurements. We therefore chose to use TcB measurements from the midsternum. Measurements from the sternum are also less likely to be influenced by the effect of ambient light (particularly sunlight) on the skin. This could be important when outpatient measurements are made.

Our study has several limitations. First, we had few infants with TSB levels >15 mg/dL (257 μmol/L). In the study of Engle et al,[10] 31% of the Hispanic neonates had TSB levels >15 mg/dL (257 μmol/L). Only 3.3% of our infants had TSB levels >15 mg/dL (257 μmol/L), although there were 28 such infants and the data in Figs 2 and 3E and F suggest that with rising TSB levels there was no greater discrepancy between the JM-103 and the laboratory TSB measurements in the nonblack population. In the black population, however, differences in the TcB and TSB measurements show a significant tendency to increase with rising TSB values. Nevertheless, reference to Figs 2 and 3 show that in this population, the predominant tendency is for the JM-103 to overestimate the TSB levels, so dangerous clinical errors are unlikely to occur. In 44 (17.4%) of 253 black infants, the difference between the TcB and TSB measurements was ≥3 mg/dL (51 μmol/L), but in every case, the TcB values were greater than the TSB measurement. Thus, significant underestimation of TSB values in these infants is very unlikely. No black infant with a TcB <11 mg/dL had a TSB >12 mg/dL, and no black infant with a TcB <13 mg/dL had a TSB ≥15 mg/dL. At the very least, the JM-103 can be used as a screening instrument in this population and could also be used to trend bilirubin values once a TSB and TcB have been obtained.

Second, TSB levels were measured in different clinical chemistry laboratories using different methods at the 3 study hospitals. Although all of the laboratories participate in the process of inspection by peer group for quality and standardization of procedures, significant differences in TSB levels measured on the same sample could have occurred. Such interlaboratory differences are well described.[26] We did not perform these comparisons, but we compared the TcB versus TSB measurements in the black infants in the 3 hospitals. (There were insufficient nonblack infants at Hutzel to allow comparison.) In the black infants at Beaumont, 19 (14.3%) of 132 had TSB values that differed by ≥3 mg/dL (51.3 μmol/L) from the JM-103 values, whereas this occurred in 7 (16.3%) of 43 infants at Jefferson and in 17 (21.8%) of 78 at Hutzel. These differences were not statistically significant (χ^2 = 1.923, P = .382), and in all cases, the JM-103 values were lower than the TSB.

If adopted widely in clinical practice, the JM-103 instrument will be used and compared with TSB measurements in different hospital laboratories. Each of these hospitals currently relies on its own laboratory TSB measurements to make clinical decisions in the management of jaundiced newborns. These laboratories do not use HPLC—the putative

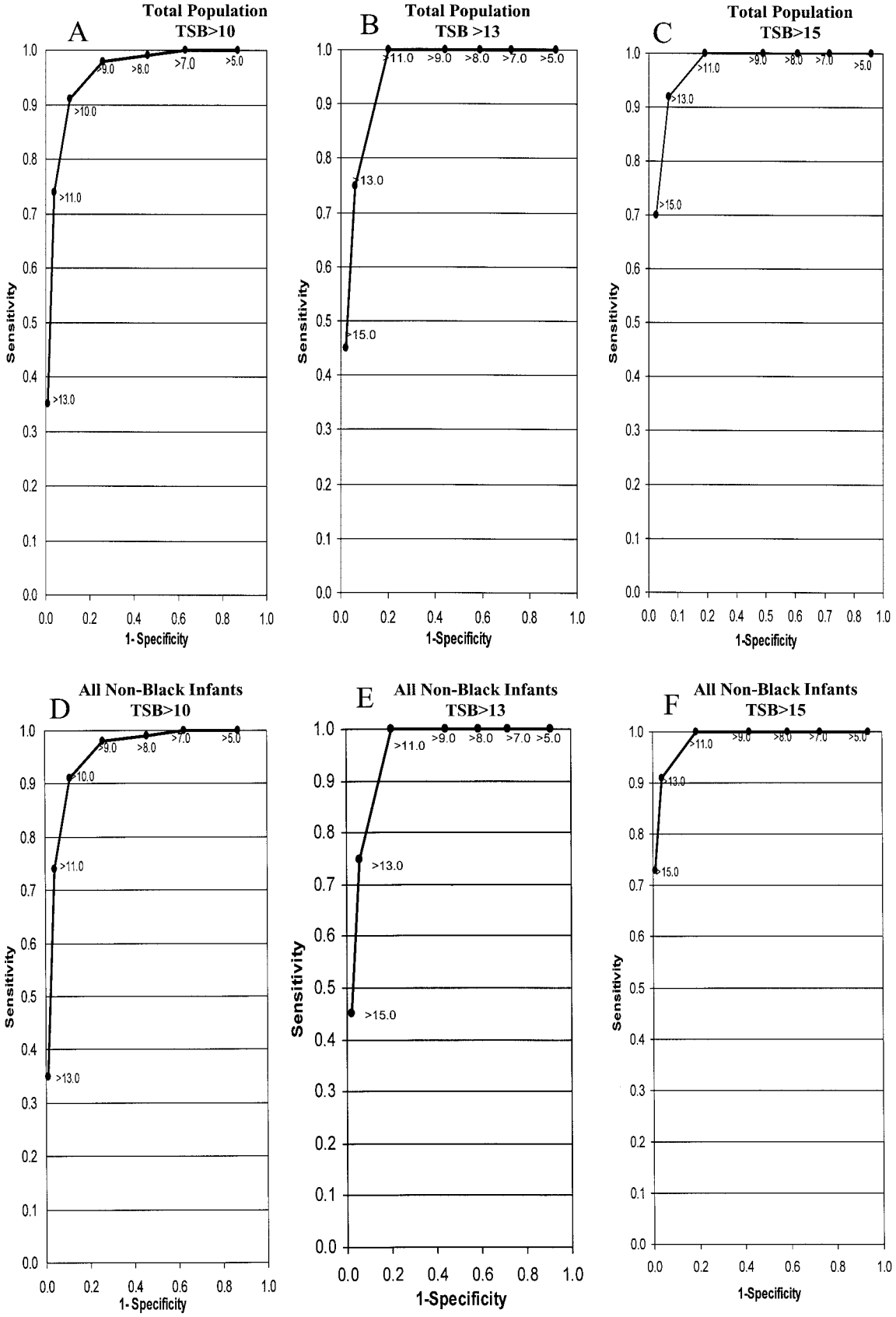

Fig 4. Receiver operating characteristics curves for JM-103 cutoff values (mg/dL) when TSB >10 mg/dL, >13 mg/dL, and >15 mg/dL is the outcome of interest. The areas under the curves are 0.962 (A), 0.963 (B), 0.975(C), 0.972 (D), 0.937 (E), 0.958 (F), 0.972 (G), 0.984 (H), 0.989 (I).

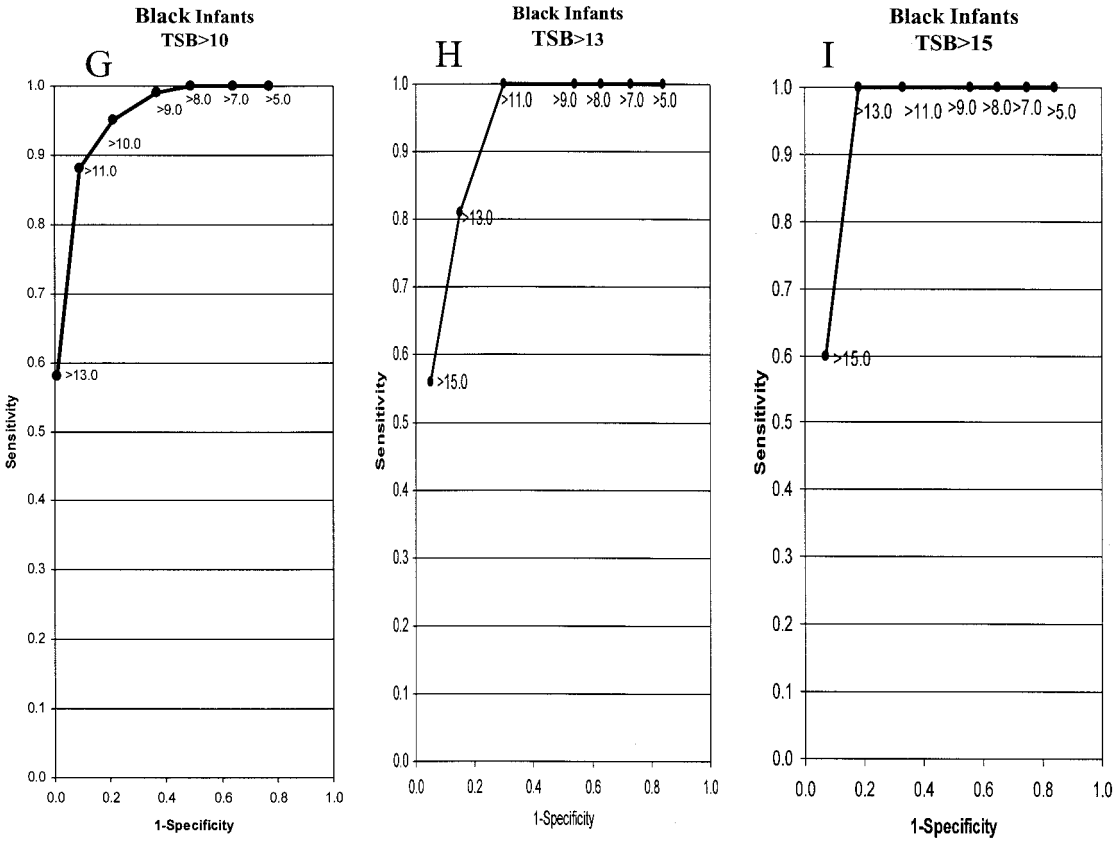

Fig 4. Continued.

"gold standard" for the measurement of TSB.[7] We are not aware of any published data comparing TSB measurements done by HPLC in different hospital laboratories, so there is currently no evidence to show that the CV between laboratories using this technique is any different from standard laboratory methods. If a systematic bias between JM-103 and TSB measurements is identified at a hospital, then an evaluation of the clinical laboratory technique is appropriate, and if this is satisfactory, then the clinicians might want to apply a correction to the TcB measurement. To this extent, our study reflects data obtained in a "real world" setting and includes any biases (known or unknown) introduced by interlaboratory variation.

Third, TSB measurements were obtained only on jaundiced infants. The distribution of TSB values shown in Fig 1 is close to that obtained in a population in which TSB levels were measured in every infant on the second or third hospital day,[27] and the prevalence of higher bilirubin levels does not seem much greater than expected in the general population. Thus, these data could be applied to a normal nursery population in which a TcB was routinely measured once or several times in each infant.

Fourth, with the exception of 40 infants, tested as outpatients, all of the TcB measurements were obtained by research nurses or technicians. In clinical practice, where measurements are performed by a large number of nursing staff, accuracy and precision are likely to be poorer.

Bilirubin measurements are currently interpreted in 2 different situations. In the first, a measurement of the TSB level is compared with the infant's age in hours, and, given the narrow range of umbilical cord TSB, this represents a close approximation of the rate of rise of TSB. This provides a very useful assessment of the risk (or lack of risk) of subsequent severe hyperbilirubinemia.[16,28–31] At age 24 hours, the 50th percentile for TSB levels is ~5 mg/dL (86 μmol/L) and the 95th percentile is 8 mg/dL (137 μmol/L).[16] Thus, small differences between the TcB and TSB at that age could lead to an infant's being placed in a significantly different risk category. This is much less likely at older ages, when the difference between the 50th and 95th percentiles increases. Because measurements with the JM-103 are so easy to perform, however, an infant could easily have 4 or 5 measurements obtained over a 24- to 36-hour period. This should reduce the effect of random error (from a single measurement) and should also provide an excellent indication of the rate of rise of the bilirubin. (This assumes that the differences between TcB and TSB measurements in a single infant at different TSB levels are likely to be relatively constant, but we do not yet have the data to confirm this.) Plotting this information on a nomogram[16] will soon reveal whether an expected (and therefore reassuring) course of the TcB is occurring or whether TcB levels are rising and crossing percentiles and therefore must be followed more carefully.

The other application of TSB measurements is to identify TSB levels at which intervention with phototherapy or exchange transfusion is indicated. Be-

cause phototherapy "bleaches" the skin, the JM-103 cannot currently be recommended for use in infants who receive phototherapy, although TcB measurements in an area of the skin that is protected from light might still be useful.[32] Thus, when phototherapy is indicated, a TSB must be obtained, and these infants will also require subsequent TSB measurements. We do not know how long it is necessary to wait after phototherapy has been discontinued before JM-103 measurements can be used, but a recent study suggests that TcB measurements are valid 18 to 24 hours after cessation of phototherapy.[32]

A TcB is not a serum bilirubin, and although the TcB measurement provides a good estimate of the TSB level, as with any laboratory measurement, TcB levels should not be considered in isolation, and critical decisions should not be made on the basis of a single measurement. If there is concern about a value, then it is easily repeated, and it is always important to consider the relevant risk factors for jaundice when making decisions about follow-up or intervention.[33,34]

We conclude that TcB measurements using the JM-103 Jaundice Meter correlate closely with TSB levels over the range of TSB encountered in this study. The correlation between TSB and TcB levels in the black population is not as close as in nonblack infants, but the tendency in this population is for the TcB to overestimate rather than underestimate the TSB level. This could lead to unnecessary measurements of TSB levels in these infants, but it is unlikely that significant elevations of the TSB will be missed. Decisions to implement phototherapy or exchange transfusion should be made only after confirmation by a TSB measurement and should almost never be based on a single measurement. Because the measurement technique is so simple, repeated measurements can be performed over time. This should significantly reduce the likelihood of error. The ability to measure the TcB in the office or other outpatient setting, including the home, noninvasively and instantaneously, should prove of inestimable value in the monitoring and management of the jaundiced newborn infant and will avoid the potential errors associated with clinical estimation of bilirubin levels.

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