COMPARISON OF TWO TRANSCUTANEOUS BILIRUBINOMETERS - MINOLTA AIRSHIELDS JAUNDICE METER JM103 AND SPECTRX BILICHECK - IN THAI NEONATES

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Abstract. Transcutaneous bilirubin (TcB) has been reported to have a high correlation with serum bilirubin. The objectives of this study were: 1) to compare the accuracy of two transcutaneous bilirubinometer (Minolto AirShields Jaundice Meter, JM103 (JM) and SpectRx, Bilicheck (BC) in estimating total serum bilirubin (TSB) levels; and 2) to assess the predictive ability of transcutaneous bilirubin in relation to specific selected TSB levels. A total of 154 measurements of TcB, using JM and BC, and TSB were recruited from 134 term and near-term infants. Postnatal ages ranged from 19 to 160 hours ($\bar{\chi}$ = 64.7, SD = 25.6). TSB levels ranged from 4.5 to 17.5 mg/dl ($\bar{\chi}$ = 10.4, SD = 2.5). The correlation coefficients between TcB (JM and BC) and TSB measurements were significant and similar (r 0.80 and 0.82, respectively). The errors of distribution were, for TSB and TcB-JM, the mean difference of 0.7 mg/dl [SD 1.6 mg/dl and 95% confidence interval of the mean (CI) 0.4 and 1.0]; and, for TSB and TcB-BC, the mean difference of -0.6 mg/dl (SD 1.5 mg/dl and 95% CI -0.4 and -0.8). TcB-JM had a tendency to underestimate TSB levels, and TcB-BC had a tendency to overestimate TSB levels. The sensitivity of BC was higher, but specificity was lower, than JM in corresponding to different TSB levels, except at a TSB level of 15 mg/dl when both instruments yielded 100% sensitivity. The accuracy of JM in predicting TSB was higher than BC at all TSB levels. Operating the JM was simple and uncomplicated. It would be suitable for clinical use when a number of personnel perform the measurement.

INTRODUCTION

Neonatal jaundice is one of the most common problems encountered in newborn infants, and infants with significant hyperbilirubinemia are at risk of developing kernicterus. To prevent this devastating condition, practice parameters for management [American Academy of Pediatrics (AAP), 1994] and nomograms to predict the severity of hyperbilirubinemia (Bhutani *et al*, 1999; Sarici *et al*, 2004) have been recommended. Total serum bilirubin (TSB) is usually determined in clinical practice to identify significant hyperbilirubinemia. The decision to obtain a blood sample for TSB relies on the subjective judgement by visual inspection of the yellowness of the skin. Transcutaneous bilirubin (TcB) measurement is more objective than visual estimation, and the TcB level has been shown to correlate well with serum bilirubin (Bhutani *et al*, 2000; Rubatelli *et al*, 2001; Brisco *et al,* 2002; Engle *et al*, 2002; Wang *et al,* 2002). Two transcutaneous instruments (Minolta AirShields Jaundice Meter, JM102; Bilicheck, SpectRx Inc, Norcross, GA) have been studied extensively (Bhutani *et al*, 2000; Rubatelli *et al*, 2001; Brisco *et al*; 2002; Engle *et al*, 2002; Wong *et al*, 2002). The JM102 had the disadvantages of reading jaundice indexes and not bilirubin levels, and taking measurements that were affected by race, birth weight, and gestational age (Maisels *et al*, 1997). Recently a new device, the Minolta AirShields Jaundice Meter (JM103) has been introduced that measures in numerical units and would be less influenced by the skin maturation level and melanin density (Yasuda *et al*, 2003). To understand the full potential of various bilirubinometers, a study was undertaken to compare them. Specifically, the aims of this study were to compare the accuracy of two transcutaneous bilirubinometers [JM103 (JM) and Bilicheck (BC)] in estimating total serum bilirubin level, and to assess the predictive ability of transcutaneous bilirubin

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of both devices in relation to specific serum bilirubin levels.

METHODS

The study was done in the full-term nursery of the Department of Pediatrics, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. Term and near-term neonates were recruited with verbal consent from their parents when visual observation of jaundice raised concern for hyperbilirubinemia and necessitated the determination of serum bilirubin. TcB measurement was then performed within 10-15 minutes of blood sampling for TSB. A repeat measurement was done, as clinically dictated, at an interval of more than 24 hours. The specific age in hours at the time of assessment were recorded, along with birth weight and gender. All infants weighed more than 2,000 g, had a gestational age of more than or equal to 36 weeks, and were clinically healthy. Infants who were receiving phototherapy and who had exchange transfusion were excluded.

All TcB measurements were performed by one investigator, using the JM103 and the Bilicheck devices. The measurements were obtained from the foreheads of the infants, while lying in a supine position in their bassinets. The JM103 (JM), the device was calibrated before use daily, in accordance with the manufacturer's instructions. Gentle pressure was applied, while the fiber optic probe was placed against the forehead, to exert even contact by the probe with the skin. Three consecutive scans were taken before a computerized mean value in mg/dl was displayed on the screen (TcB-JM).

An additional TcB measurement, using the Bilicheck device (TcB-BC) was performed within a few minutes of each JM measurement. The device was calibrated before each measurement. The fiber optic probe was placed approximately at the same place as the previous JM measurement. The average reading of TcB in mg/dl was obtained after five consecutive scans were taken. The procedure was repeated if an "error" sign indicated that an erroneous measurement was taken.

TSB measurements were done in the neonatal unit using a direct spectrophotometer (Leica Unistat Bilirubinometer, Buffalo, NY). Calibration verification and quality control procedures were done according to the manufacturer's recommendations.

The study was approved by the Ethics Committee of the Faculty of Medicine, Chulalongkorn University.

Data and statistics

Demographic data, TcB and TSB values were analyzed using Excel. The correlation coefficient between TcB and TSB was determined using Pearson linear regression analysis. Error distribution, mean difference, and 95% confidence interval of the differences were evaluated. TcB levels of more than 8, 9, 10, and 12 mg/dl, which were used as cut-off points to indicate blood sampling (Sanpavat *et al*, 2004), were chosen as demarcations in predicting TSB levels of 10, 12, 13 and 15 mg/dl, respectively. At those points, treatment of hyperbilirubinemia would be initiated (Praisuwanna, 2001). The sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio, and accuracy of TcB were determined. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 154 TcB-TSB specimens, from 134 infants, were recruited in this study, from October to November 2003. Birth weights ranged from 2,080 to 3,950 g ($\bar{x}$ 3077.40, SD 413.74). The male to female ratio was 1.35:1. Demographic characters by gender, number of infants at different postnatal ages when assessed, and distribution of TSB levels are shown in Table 1. Postnatal age ranged from 19 to 160 hours ($\bar{x}$ 64.7, SD 25.6). TSB levels ranged from 4.5 to 17.5 mg/dl ($\bar{x}$ 10.4, SD 2.5).

The correlation between TcB using JM103 (TcB-JM) and TSB was significant ($r = 0.80$, $p < 0.05$). Similar result was also observed between TcB using BC (TcB-BC) and TSB ($r = 0.82$, $p < 0.05$) (Fig 1). The error of distribution using a Bland and Altman plot (Bland and Altman,1986) showed that the mean difference between TSB and TcB-JM was 0.7 mg/dl [SD = 1.6 mg/dl, and 95% confidence interval of the mean (CI) of 0.4

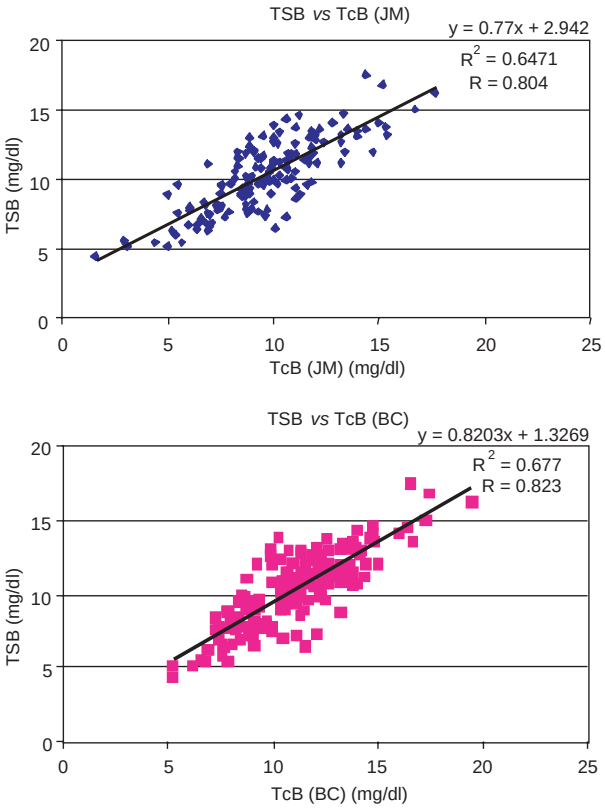

Fig 1–Pearson linear regression analysis between TSB and TcB (JM and BC).

Table 1
Demographic characteristics.

Characteristics	n	%
Male	77	
Female	57	
Age at the time of test (hr)		
<24	5	3.2
24 - 48	37	24.0
49 - 72	73	47.4
73 - 96	23	14.9
> 96	16	10.4
TSB ≤ 10 (mg/dl)	70	45.4
10.1 - 11	18	11.7
11.1 - 12	28	18.2
12.1 - 13	15	9.7
13.1 - 14	14	9.1
14.1 - 15	6	3.9
>15	3	1.9

and 1.0]. The mean difference between TSB and TcB-BC was - 0.6 mg/dl (SD 1.5 mg/dl, 95% CI -0.4 and -0.8) (Fig 2). The sensitivity, specificity, positive and negative predictive values, likelihood ratio, and accuracy of TcB levels of 8, 9, 10, and 12 mg/dl, respectively, in relation to the TSB levels of 10, 12, 13, and 15 mg/dl, respectively, are shown in Table 2.

DISCUSSION

A noninvasive transcutaneous bilirubin measurement has been advocated because of its objectivity when compared to visual estimation of jaundice and its accuracy when compared to serum bilirubin level. Measurement with the Bilicheck device had such a high correlation with TSB levels that its substitution for serum bilirubin was suggested (Rubatelli *et al*, 2001). It was also recommended as a screening test to identify infants at risk for developing hyperbilirubinemia or the need for blood sampling (Bhutani *et al*, 2000). The Bilicheck device was accurate in a multiracial population, including pigmented neonates (Slusher *et al*, 2004). However, there

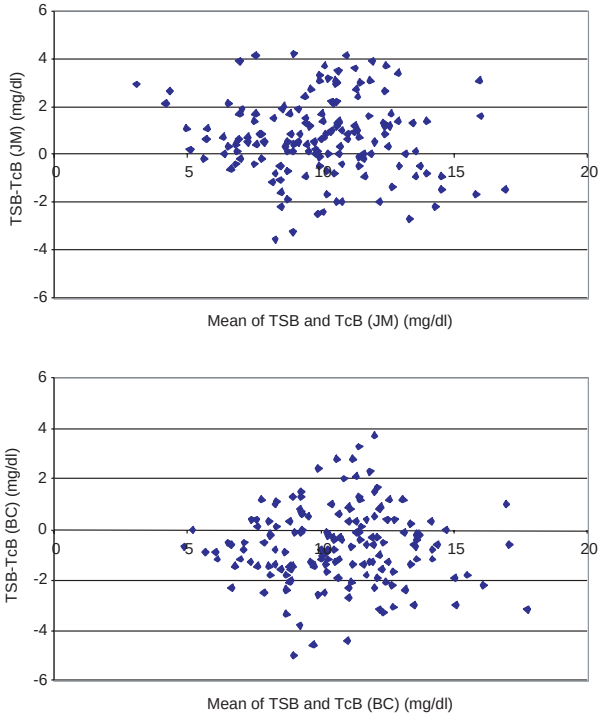

Fig 2–Error distributions of TSB and TcB (JM and BC).

Table 2
Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratio, and accuracy of TcB (JM and BC) in relation to specific TSB levels.

TSB	TcB	Type	Sensitivity	Specificity	PPV	NPV	Likelihood ratio	Accuracy
10	>8	JM	98.8	50.7	71.2	97.2	2.0	77.3
		BC	100.0	27.5	63.0	100.0	1.4	67.5
12	>9	JM	92.9	50.0	41.0	94.9	1.9	61.7
		BC	100.0	29.5	34.7	100.0	1.4	48.7
13	>10	JM	92.6	67.7	37.8	97.7	2.9	72.1
		BC	96.3	42.5	22.3	98.2	1.7	51.9
15	>12	JM	100.0	87.3	17.4	100.0	8.0	87.7
		BC	100.0	68.0	71.7	100.0	3.1	68.8

was some discrepancy between studies with Hispanic infants (Engle *et al*, 2002), and with relatively high TSB levels (Beck *et al*, 2003; Nanjundaswamy *et al*, 2004).

Comparison studies between the Bilicheck and JM102 suggested that the Bilicheck was less variable than the JM102 (Robertson *et al*, 2002; Beck *et al*, 2003) in all but one study (Wong *et al*, 2002). The newer Jaundice Meter, JM103, adopted a "two point method," by which different spectrums were obtained from the deep subcutaneous tissue, and from the epidermis and dermis. The difference between optical densities obtained from these two regions eliminated the effect of dermal thickness and of melanin that was distributed in the epidermis (Yasuda *et al*, 2003). Hemoglobin was excluded in the measurement by the intensity of the hemoglobin-corrected yellow density (according to the measurement principle of JM103). TcB measurement, using the JM103, correlated closely with TSB levels (Yasuda *et al*, 2003; Maisels *et al*, 2004). In a previous study, a comparison between the Bilicheck and JM 103, in mostly white infants, showed no difference, with a high correlation coefficient for TSB levels (Bilicheck: r = 0.973, JM: r = 0.971) (Maisels *et al*, 2004). Our study also showed no difference between Bilicheck and JM103, although the correlation coefficients were lower (r = 0.82 and r = 0.80, respectively) than the other studies. We attributed this difference to the interlaboratory variability of TSB measurement. Our study found that TcB-JM had a tendency to underestimate TSB levels, while TcB-BC had a tendency to overestimate TSB levels.

We established cut-off levels for hour-specific TcB-JM that indicated a need for serum bilirubin determination, which were TcB > 8, 9, 10, and 12 mg/dl (Sanpavat and Nuchprayoon, 2004). Using these cut-off levels of TcB for analysis (Table 2), the BC device showed higher sensitivity but lower specificity than the JM device at TSB levels of 10, 12 and 13 mg/dl. For TSB levels >15 mg/dl, both devices yield 100% sensitivity, but specificity in the JM group was still higher than the BC group. Thus, the BC seemed to perform better in identifying all infants for whom serum bilirubin needed to be assessed. However, this was done at the expense of more than 50% of unnecessary blood sampling in false positive infants for TSB levels of 10, 12, and 13 mg/dl; and 32 % for TSB levels of 15 mg/dl. Therefore, the accuracy of the JM device was higher than that of BC at all TSB levels.

Measurement with the JM103 device was simple, and calibration was required only once daily. The number of scans before getting an average result can be selected from a range of one to five. We selected three consecutive scans for one average measurement. A minimal difference between 1 and 3 measurements was reported by Maisels *et al* (2004). This would benefit the user in terms of time saving. Operating the device was easy and convenient, which should be beneficial when the device would be put into clinical use with a number of personnel performing the measurement.

For the BC device, calibration for an individual calibration tip, "Bilical," was required before each measurement. Five consecutive scans were needed to provide one average TcB level, and this meant that there was a longer measurement time for BC than for JM (Maisels *et al*, 2004). Experience was needed to operate the device; an "error" sign indicated an erroneous technique and the measurement would have to be repeated. On the other hand this would have a positive effect in practice by reducing the variability when different personnel use the instrument in real situations.

In conclusion, comparison between transcutaneous bilirubin measured by JM and BC had similar correlation to TSB. The TcB-JM has a tendency to underestimate TSB levels, and TcB-BC had a tendency to overestimate TSB levels. Accuracy in predicting TSB at specific levels for JM was higher than BC. Operating JM was simple and uncomplicated, and would therefore be more suitable for clinical use when a number of personnel perform the measurement.

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