

Transcutaneous Bilirubin Measurements: Variation in Meter Response

The transcutaneous bilirubin meter has been shown to be a useful screening device for the identification of significant neonatal jaundice in full-term infants.¹⁻³ Investigators have, nevertheless, emphasized the necessity for each institution to establish the relationship between the transcutaneous bilirubin index, as measured with a particular instrument, and the serum bilirubin determination obtained from the institution's laboratory.³ This is important, because of the known variation between laboratories in the measurement of serum bilirubin concentration⁴ and because no information has been published regarding the potential variation in the response of different transcutaneous bilirubin meters. To examine the latter question, we studied the response of four transcutaneous bilirubin meters in a neonatal population.

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METHODS

Transcutaneous bilirubin measurements were obtained from 72 white newborn infants in the Neonatal Intensive Care Unit and the Well Baby Nursery of the Hershey Medical Center using four Minolta/Air Shields jaundice meters (transcutaneous bilirubin meter). Single sequential readings were taken in random order from the forehead of each infant using the four meters. The order was randomized using a 4×4 Latin square design.⁵ Each instrument was calibrated by the manufacturer and the calibration was checked against the color standard provided. No change in calibration was noted during the study period. The reliability of the measurements was calculated using the analysis of variance technique described by Winer.⁶

RESULTS

The transcutaneous bilirubin index in the 72 infants ranged from 4 to 29 (see Fig 1). Analysis of variance was used to estimate the reliability of a single meter (r_1) using the formula: $r_1 = (MS_b - MS_w) / (MS_b + [k - 1]MS_w)$, where MS_b = mean square between patients; MS_w = mean square within (meter) measurements; k = number of meters.⁴

The estimated reliability for one transcutaneous

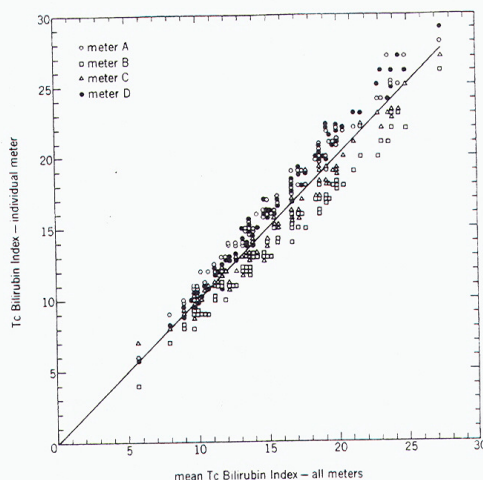


Fig 1. Transcutaneous (Tc) bilirubin index for each of four transcutaneous bilirubin meters plotted against mean transcutaneous bilirubin index of all meters. Line of identity is shown.

bilirubin meter was 0.89, implying that 89% of the variance is common between any two meters (or that one meter accounts for 89% of the variance in any other). This term (r_1) takes into account systematic differences between the instruments as well as interactions between meters and babies. It is an expression of the reliability of a single meter over the range of measurements expected in clinical practice. This value was used to calculate the standard error of estimate (the standard deviation of the deviations from the mean regression line). Two standard errors = 4.24, which implies that in 95% of cases the measurement obtained will be within ± 4.24 transcutaneous bilirubin units of the theoretical true value.

Linear regression lines were plotted by the method of least squares for each transcutaneous bilirubin meter against the mean for the four meters (Fig 2). When all the slopes were compared by analysis of variance they were significantly different ($P < .001$). Individual slopes were compared using the Newman-Keuls multiple-range test.⁶ With the exception of meter B *v* meter C, each slope differed from the other slopes significantly ($P < .001$). The slopes appeared to diverge from the line of identity as the transcutaneous bilirubin values increased. We analyzed the deviation of each transcutaneous bilirubin measurement from the line of identity. For transcutaneous bilirubin values of 5 to 15, the mean deviation was 0.89 ± 0.566 (SD) units and for values ≥ 15.1 , the mean deviation was 1.39 ± 0.531 (SD) units. These differences are highly significant ($t = 6.47$, $P = 0$) and suggest greater potential for abso-

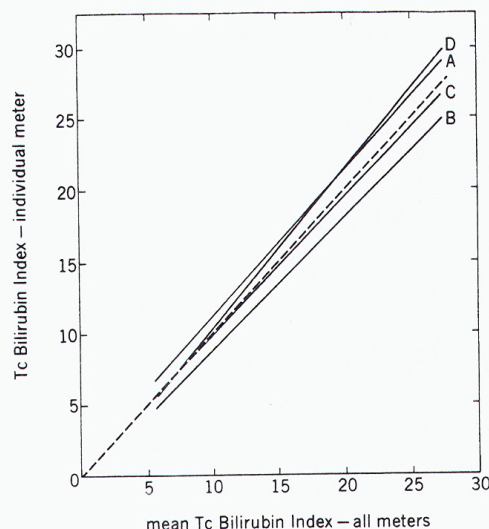


Fig 2. Regression lines for individual transcutaneous bilirubin index. Dotted line is line of identity: meter A, $y = 0.881 + 1.017x$; meter B, $y = -0.471 + 0.927x$; meter C, $y = 0.329 + 0.947x$; meter D, $y = 0.721 + 1.109x$. P values for comparison of slopes are: A *v* B, $< .001$; A *v* C, $< .001$; A *v* D, $< .001$; B *v* C, NS; B *v* D, $< .001$; C *v* D, $< .001$.

lute error at higher transcutaneous bilirubin measurements.² We analyzed this possibility in our previous clinical study³ and did not find significant differences in potential error with increasing serum bilirubin values, although such a trend was apparent. However, the mean transcutaneous bilirubin value in the 5 to 15 range was 11.8 and in the ≥ 15.1 range was 19.67. Thus, when the mean deviations are expressed as percentages of the mean transcutaneous bilirubin values they are 7.5% for the lower, and 7.1% for the upper range, respectively.

DISCUSSION

The comparison of different transcutaneous bilirubin meters requires an assumption regarding the "true" or "correct" transcutaneous bilirubin value. As the transcutaneous bilirubin measurement is an index of the yellowness of the skin and subcutaneous tissues and does not, in fact, measure serum bilirubin, for the purposes of comparing meters, the relationship of the transcutaneous bilirubin measurement to the actual serum bilirubin is irrelevant, and no single true measurement can be obtained. The closest practical approximation to a theoretical true value is calculated by averaging the readings obtained from different instruments that have been similarly calibrated. The calculation of the standard error of estimate (see above) provides the confidence limits about this mean.

When compared with the line of identity, it is apparent that the transcutaneous bilirubin measurements obtained with meters A and D were consistently higher than those obtained with meters B and C (Figs 1 and 2). The fact that these differences are systematic and not random is reassuring. The figure allows a graphic estimate of the reliability of an individual measurement. It should be noted, however, that even when a single instrument is used to make repeated measurements, the coefficient of variation is 3% to 4%.² Thus, some of the variation might be accounted for by differences in the technique of obtaining the individual measurements. Nevertheless, the systematic nature of the differences between meters and the significantly different slopes of the regression lines, suggest that these are real differences in the instruments themselves and are not the result of operator variation.

As calculated above, in 95% of cases, the measurement should provide a transcutaneous bilirubin index that is within ± 4.24 transcutaneous bilirubin units of the true value. If this degree of error was applied to transcutaneous bilirubin measurements on full-term infants in our nursery, it would represent approximately ± 2.8 mg/dL of serum bilirubin. (To convert transcutaneous bilirubin to serum bilirubin we used the regression equation developed from 292 transcutaneous bilirubin measurements made in our well baby nursery: $y = 7.96 + 1.33x$, where y = transcutaneous bilirubin units and x = serum bilirubin concentration.) As the transcutaneous bilirubin measurement should be used as a screening tool only, this degree of error might appear acceptable. However, because of the demonstrated differences between instruments, and the fact that with any individual meter it is not possible to know on which side of the true value it is reading,

optimal accuracy can only be obtained by constructing a regression line for each instrument using the serum bilirubin measurement as the independent variable and transcutaneous bilirubin index as the dependent variable. We, therefore, recommend this kind of in vivo calibration in all hospitals because it appears to be the only way to obtain maximal accuracy and to keep false-positive and false-negative values to a minimum.

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