Neonatal Transcutaneous Bilirubin Measurements: An Opportunity to Enhance Laboratory Utilization and Improve Patient Care

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By far the most common clinical problem addressed by family practitioners and pediatricians in the first weeks of an infant’s life is hyperbilirubinemia. With the exception of the standard metabolic screen, the measurement of a total serum bilirubin (TSB) concentration is the most common laboratory test ordered for a newborn infant. That is not surprising because the clinical sign, jaundice, is seen in approximately 80% of infants in a well-baby nursery during the first few days (1). The process of observation, clinical monitoring, and laboratory testing that continues throughout the infant’s first week of life has a single objective—to prevent extreme hyperbilirubinemia [a TSB concentration >25–30 mg/dL (>428–513 μmol/L)] and its rare but dreaded consequence, bilirubin encephalopathy. Data from most of the Western world suggest that chronic bilirubin encephalopathy, or kernicterus, is currently occurring at an incidence of approximately 0.5–2 per 100 000 live births (2). Thus, of approximately $4 \times 10^6$ infants born annually in the US, perhaps 20–40 will develop kernicterus, a permanently disabling condition characterized by athetoid cerebral palsy, severe sensorineural hearing loss, paralysis of upward gaze, and dental dysplasia. For decades practitioners have relied on the appearance and intensity of jaundice as a means of deciding when to obtain a TSB measurement, but recognizing that estimating TSB by eye is difficult and on occasion grossly misleading (3) has prompted the development of transcutaneous bilirubinometry.

The instruments that measure the transcutaneous bilirubin (TcB) concentration operate by transmitting light that penetrates the blanched skin and transilluminates the subcutaneous tissues. The scattered light returns through a fiber optic filament, and the yellowness of the reflected light—corrected for the contribution of hemoglobin, melanin, and dermal thickness—is measured in a spectrophotometric module and converted into an estimate of the TSB concentration (3). Transcutaneous bilirubinometers measure the yellowness of the skin and subcutaneous tissues, and the contribution of the serum bilirubin to this measurement is minimal (4). Thus, a TcB measurement is not the equivalent of measuring TSB. Nevertheless, TcB and TSB measurements are highly correlated, and there are substantial data to confirm that TcB assessment, when used as a screening measurement, provides noninvasive, instantaneous, and clinically relevant information about the infant’s TSB concentration that cannot be obtained in any other way. Although many studies have evaluated the use of TcB in the immediate postdelivery hospital stay, the data are limited regarding the use of this technique at the doctor’s office or in the home.

In a recent report, Wainer et al. (5) made an important contribution to our understanding of how TcB measurements can improve the care of newborn infants. These investigators studied 14 796 newborn infants ≥35 weeks of gestation and who were discharged from 3 newborn nurseries in Calgary, Canada. They assessed the impact of universal TcB screening combined with routine follow-up in the home or community clinic, and they compared the outcomes in this population with a historical cohort of 14 112 infants who had their bilirubin assessed by visual inspection alone. Wainer et al. used an existing public health nurse program that ensures that every infant born at one of the Calgary Health Region nurseries is seen within 1 to 2 days of discharge. The public health nurses, trained in newborn assessment and armed with a TcB device, obtained TcB measurements at the follow-up visit for all infants. Using a nomogram developed in their nurseries, the visiting public health nurse was able to decide whether a TSB measurement was necessary, whether the TcB assessment should be repeated within 24 h, or whether subsequent routine care was appropriate.

Compared with the previous experience with visual inspection alone, the implementation of routine TcB measurements produced a 55% reduction (odds ratio, 2.219; 95% CI, 1.543–3.193; $P < 0.0001$) in the incidence of TSB values $>20$ mg/dL ($>342 \mu$mol/L).
The total number of TSB draws was also reduced by 23%, from 134.4 to 103.6 per 1000 live births (odds ratio, 1.332; 95% CI, 1.226–1.446; P < 0.0001), and the overall phototherapy rate decreased from 5.27% to 4.3% (odds ratio, 1.241; 95% CI, 1.122–1.374; P < 0.001), although other studies of universal TSB screening, but without the follow-up provided in the Calgary study, have reported an increase in phototherapy use. Wainer et al. concluded that the implementation of their program significantly enhanced patient safety while it reduced demands on both laboratory and hospital resources, although they recognized that it might require an increase in community health services.

Unfortunately, replication of this type of community service in the US and many other parts of the world is difficult if not impossible, but it is certainly an example that we should strive to emulate. The use of TcB measurements both in the hospital and in the outpatient setting will certainly increase in the next several years. The advantages of such measurements are substantial. Instead of requiring a painful heel stick and waiting an hour or more for the laboratory result, TcB measurements provide noninvasive, instantaneous information about the infant’s bilirubin concentration. They offer the possibility of performing multiple measurements over a single day, allowing the calculation of the rate of increase in the bilirubin concentration, and alerting the clinician to the need for additional surveillance and evaluation. TcB measurements substantially reduce the number of TSB measurements required in the well-baby nursery, as well as in the neonatal intensive care unit, and they have been shown to reduce costs and the use of resources while improving patient safety. Although some studies have reported that implementation of TcB screening has reduced costs, the overall economic impact of this intervention has not been evaluated systematically. The variation among institutions regarding the indications for phototherapy, length of stay in the nursery, timing and frequency of follow-up visits, indications for readmission, and so forth makes it difficult to obtain a meaningful assessment of the economic impact.

As with any point-of-care test, quality control is essential, and Wainer et al. have developed their own rigorous system of quality control (5). They emphasize the central role of the clinical laboratory in device evaluation and point out that “25% of devices did not perform within allowable limits of our quality control procedures . . . in spite of passing the manufacturer’s standard wave-length calibration.” More than 60% of their instruments were “returned for repair or recalibration” during the period of their study. There is clearly a need for more-rigorous calibration methods and quality controls for these instruments, and although clinical laboratories in the US are involved in the quality control of other point-of-care measurements, they are not involved in the evaluation of these devices. They should be. Our clinical laboratories still struggle to standardize serum bilirubin measurements and reduce the variation found among laboratories and different measurement techniques (6). Given that TcB measurements reduce the need for TSB measurements and have other important benefits for newborns and their families, they should be welcomed and supported by our laboratory pathologists.

References