Transcutaneous Bilirubinometer in Assessment of Neonatal Jaundice in Northern India

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This study was undertaken from April 2002 to March 2003 to find out the correlation of transcutaneous bilirubinometer index with serum bilirubin levels in term, pre-term, small for gestation age babies, with and without phototherapy in neonates with jaundice. Another aim was to evaluate the transcutaneous bilirubinometer as a screening device for neonatal hyperbilirubinemia by finding the action levels for TcBI at forehead and sternum at which sample for serum bilirubin estimation should be taken. A total of 104 neonates were evaluated. Mean (SD) age (hours), birth weight (grams) and gestational age (weeks) were 100.4 (37.90), 2264.9 (634.4) and 36.8 (2.9) respectively. Mean serum bilirubin was 16.6 (6) mg/dL. Overall a correlation coefficient of 0.878 at forehead and 0.859 at sternum was observed. On excluding infants receiving phototherapy coefficients of 0.900 at forehead and 0.908 at sternum were noted. Correlation coefficient over forehead and sternum was found to drop from 0.85 to as low as 0.33 with duration of phototherapy exceeding 48 hrs. Lastly the determined action levels had a sensitivity of 77.8 to 100 % in assessing the need for serum bilirubin estimation in various groups.

Key words: *Hyperbilirubinemia, Neonatal jaundice, Transcutneous bilirubinometery.*

Transcutaneous bilirubinometry measures the intensity of yellow color in the skin and subcutaneous tissue and correlates it with the serum bilirubin concentration in newborn infants(1). It is reported to be safe, simple, objective, reproducible, cost effective, noninvasive modality in the screening and monitoring of jaundiced newborn infants. A significant correlation has been found between serum bilirubin and TcB index (TcBI) in various ethnic groups by various authors. But the correlation is affected by gestational age, use of phototherapy, birth weight, color of skin, degree of jaundice and race(2-6).

Previous studies of this region either have comparatively limited number of observations or lack mention of range of bilirubin observed(5,6). Moreover, considering variations in reported intercept in regression lines for different races(3), there is a need for separate regression equation for different regions. We evaluated transcutaneous bilirubin (TcB) over a wide range of bilirubin, to find out the correlation of TcBI with serum bilirubin levels in term, pre-term, small for gestation age babies, with and without phototherapy in neonates with jaundice in Shimla region. Another aim was to evaluate the TcB as a screening device for neonatal hyperbilirubinemia by finding the action levels for TcBI at forehead and sternum at which sample for serum bilirubin estimation should be taken.

Subjects and Methods

The present study was undertaken at our centre from 1st April 2002 to 31st March

2003. The study group included both inborn and out born term and preterm neonates developing clinical jaundice within first 10 days of life. Babies with major congenital malformations, blood group group incompatibility, conjugated hyperbilirubinemia, post exchange transfusion and those dying during the study were excluded from the study group. Serum bilirubin estimation and TcBI readings were taken as soon as a baby with jaundice was admitted or as soon as jaundice appeared in an already hospitalized baby. Thereafter, daily serum bilirubin estimation and TcBI readings were taken in each case till jaundice subsided. TcBI reading and bilirubin estimation was done by different observers who were unaware of each others results and the instruments were standardized according to the manufacturer's guidelines.

Detailed history and examination of babies enrolled in the study was carried out and provisional clinical diagnosis was assigned. After obtaining informed consent from parents blood samples were drawn from a peripheral vein. Blood samples for serum bilirubin estimation were taken into heparinized capillaries and were placed in labeled dark colored tubes and kept in light proof box until the moment of bilirubin determination. Blood samples were taken within half hour of taking TcBI and were analyzed by Wako Bilirubin tester Model SE 101 D II. Using the Minolta Air-shields Jaundicemeter 101 two readings at forehead just above the glabella and two at mid sternum were taken in a quite child and mean of each was recorded. Eyes were shielded while taking the readings at forehead and the probe was disinfected with 70% isopropyl alcohol after using it on each baby.

Clinical assessment of jaundice was done in each baby at least twice a day in diffuse natural light. When indicated phototherapy was given using Atom Phototherapy unit PIT-220ST which was stopped while taking TcBI reading.

For analysis the study group was divided into the following groups: term AFD (appropriate for date); term SFD(small for date); preterm AFD; and preterm SFD

In each of the above groups, subgroup analysis was done based on exposure to phototherapy.

In each of the above mentioned groups Pearson's correlation analyses and linear regression analyses were performed using the SPSS statistical software. Usefulness of TcBI as a diagnostic tool was evaluated by sensitivity, specificity, positive predictive value and negative predictive values as per standard methodology.

Results

A total of 104 neonates with grossly uniform skin color were evaluated .The mean age in hours was 100.4 (37.9) (SD) range (36 - 200), mean birth weight in grams 2264.9 ± 634.4 (SD) range (1000-3600) and gestational age varied from 28 to 42 weeks with mean of 36.8 ± 2.9 (SD) weeks. The mean serum bilirubin in mg/dL was 16.6 ± 6.1 (SD) range (7.0-34.0), the mean TcBI reading over forehead and sternum was 22.7 ± 4.99 (SD) range (14.0-37.0) and 21.2 ± 4.9 (SD) range (12.0-36) respectively.

The correlation co-efficient ranged from 0.468-0.954 for the various groups (*Table I*) and all but one (Preterm SFD with phototherapy) were statistically significant ($P < 0.05$).

In babies who received phototherapy for a duration of 12 to 48 hrs, correlation coefficient ranged from 0.829 to 0.857 ($P < 0.001$) at the forehead and 0.793 to 0.839 ($P < 0.001$) at sternum. Those who received

TABLE I–*Correlation of TcBI and Total Serum Bilirubin in Various Groups.*

Group and range of serum bilirubin	Number n/N	Photo-therapy	TcBI site	Slope	Intercept	r
Term AFD	52/28	No	F/S	0.761 / 0.697	9.468 / 9.242	0.934***/ 0.914 ***
(7.5-34.0) mg/dL	32/20	Yes	F/S	0.809 / 0.881	7.782 / 3.481	0.871 ***/ 0.904 ***
Term SFD	24/8	No	F/S	0.745 / 0.745	10.185 / 8.709	0.943 ***/ 0.954 ***
(7.7-32.5) mg/dL	23/12	Yes	F/S	0.616 / 0.670	11.448 / 7.613	0.806 ***/ 0.799 ***
Preterm AFD	25/14	No	F/S	0.686 / 0.629	12.154 / 11.575	0.874 ***/ 0.879 ***
(9.0-31.2) mg/dL	20/14	Yes	F/S	1.104 / 1.065	4.898 / 3.212	0.920 ***/ 0.894 ***
Preterm SFD	7/3	No	F/S	0.872 / 0.825	11.616 / 9.651	0.865*/ 0.896 **
(7.0-20.0) mg/dL	7/4	Yes	F/S	0.577 / 0.342	13.255 / 12.057	0.468 / 0.499
ALL (term & preterm)	108/54	No	F/S	0.710 / 0.680	11.000 / 10.032	0.900 ***/ 0.908***
(7.0-34.0) mg/dL	82/50	Yes	F/S	0.704 / 0.697	9.913 / 7.119	0.836 ***/ 0.832 ***
	190/104	Yes + No	F/S	0.735 / 0.743	10.112 / 7.911	0.878 ***/ 0.859 ***

n: Number of TcB readings, N: Number of babies, F: Forehead, S: Sternum.
* P <0.05, ** P <0.01, ***P = 0.001.

phototherapy for more than 48 hr, poor correlation coefficient of 0.329 (P >0.05) was found at the forehead and a fair correlation coefficient of 0.539(P <0.05) was found at sternum. *Table II* depicts the action levels determined for our infant population.

Discussion

If every visibly jaundiced neonate had serum bilirubin estimation done, unnecessary skin puncture would be performed on close to half of them. If only jaundiced neonates at risk for bilirubin encephalopathy were sampled, a large number of unnecessary skin puncture could be avoided. The use of TcB reading as a screening device for neonatal hyperbilirubinemia is based on the assumption that serum and tissue bilirubin are in constant equilibrium. Skin pigmentation has a profound effect on TcBI and this has been illustrated by marked differences of the 'y'-intercept in the regression formula for the various racial groups. The darker is the skin, the greater the 'y'- intercept. In the present study, Minolta Air-shields Jaundicemeter 101 was evaluated in jaundiced babies during first 10 days of life and a good correlation was found between total serum bilirubin level and TcBI over forehead and sternum in almost all groups (*Table II*). Further, action levels for TcBI at forehead and sternum were found at which sample for serum bilirubin estimation could be taken.

Our data reveals a good correlation coefficient of 0.878 at forehead and 0.859 at sternum and was comparable to results of other workers(4,8). On excluding infants receiving phototherapy we found an increase in correlation coefficient to 0.900 at forehead and 0.908 at sternum. This was better than that found by Bhat, *et al.*(9) (r = 0.70) and Guha, *et al.*(7) (r = 0.84).On evaluating infants who received phototherapy, the coefficient of 0.836 at forehead and 0.832 at sternum was comparable to that found by Aroor, *et al.*(4).

TABLE II–*Suggested Action Levels for Different Groups in the Present Study.*

Group	Photo therapy	TcB site	TcBI	S. Bil. (mg /dL)	Sensitivity (%)	Specificity (%)	PPV(%)	NPV(%)
Term AFD	No	F/S	21/20	15.0	93.9/ 94.1	73.6/ 88.9	86.1/ 94.1	87.5/88.9
	No	F/S	19/17	12.9	92.8/ 97.6	90.0/ 66.7	97.5/ 93.3	75.0/85.7
	Yes	F/S	20/17	15.0	82.3/ 88.2	80.0/ 80.0	82.3/ 83.3	80.0/85.7
	Yes	F/S	17/15	12.9	100.0/ 96.1	33.3/ 83.3	86.6/ 96.1	100.0/83.3
Term SFD	No	F/S	22/20	15.0	100.0/ 100.0	83.3/ 100.0	85.7/100.0	100.0/100.0
	No	F/S	18/17	12.9	94.7/ 94.7	40.0/ 40.0	85.7/ 85.7	66.7/66.7
	Yes	F/S	22/20	15.0	77.8/ 77.8	92.8/ 100.0	87.5/100.0	86.5/87.5
	Yes	F/S	19/17	12.9	100.0/ 80.0	62.5/ 62.5	83.3/ 80.0	100.0/62.5
Pre term	No	F/S	18/17	10.0	92.5/ 96.3	40.0/ 40.0	89.2/ 89.6	50.0/66.6
	Yes	F/S	17/15	10.0	85.7/ 85.0	50.0/ 71.4	85.7/ 89.4	50.0/62.5
	Yes	F/S	16/14	10.0	100.0/ 90.5	42.8/ 33.3	83.3/ 82.6	100.0/50.0

All percentages have been rounded off to the nearest first decimal point.
NPV: Negative predictive value; PPV: Positive predictive value.

For all the above groups slope and intercept of the regression line in the present study were different from those of other studies. This is because of the laboratory variation in serum bilirubin estimation, variation in TcB instrument and ethnic differences in the basal yellowness of the skin, the more the confounding variables present the poorer the correlation.

In our study, as the duration of phototherapy increased correlation coefficient over forehead and sternum was found to drop from 0.85 to as low as 0.33 with duration exceeding 48 hr. For infants undergoing phototherapy this relationship between TcB and serum bilirubin level appears to be disrupted as bleaching as well as tanning of the skin may affect the accuracy of the TcB and the TcBI will be lower than expected for the same serum bilirubin value.

The action levels determined for our population correctly assessed the need for serum bilirubin estimation in most cases. For neonatal hyperbilirubinemia a screening procedure should have a high sensitivity and low rate of false negative observations , so that no neonate with the cut off level is missed by the procedure even if a few cases are falsely picked up . In our study a small number of cases were missed by the action levels we determined but the levels studied by us do not pose serious danger to a healthy newborn. We agree with other workers that it should be used for screening and not as an alternative to serum bilirubin estimation(10,11).

In the present study, specificity was low in some groups due to the fact that very few babies with low serum bilirubin levels were included in the study group. If the babies with low serum bilirubin levels had been included in the study group, specificity would have increased. Cut off levels of TcBI for action levels at various serum bilirubin could not be compared with those found by other authors, since these are different for different institutions. Small number of preterms in our study preclude any meaningful assessment in this subgroup and larger studies in preterms of

Key Messages

- Good correlation exists between TcBI at forehead/sternum and serum bilirubin level in infants not exposed to phototherapy.
- This correlation gets insignificant for neonates under phototherapy for greater than 48 h.
- Action levels determined in the present study correctly assessed the need for serum bilirubin estimation in most cases.

various maturity and nutritional states are needed. Studies are also required to evaluate this device for screening jaundiced neonates in primary health care setting in regions with homogenous ethinic background.

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