ORIGINAL ARTICLE

ROLE OF TRANSCUTANEOUS BILIRUBINOMETRY IN A HETEROGENOUS POPULATION OF JAUNDICED NORTH INDIAN NEONATES

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Abstract

Objectives: To evaluate serum bilirubin by Bilicheck™ (Transcutaneous Bilirubin- TcB) and by a standard biochemical method (Total serum bilirubin- TSB) and correlate the results of the two techniques in neonatal hyperbilirubinemia

Methods: All neonates admitted in neonatal unit having clinical jaundice requiring estimation of serum bilirubin irrespective of gestational age, birth weight, sex and race were enrolled in the study. Bilirubin levels were estimated by standard biochemical method (Automated Jendrassik and Grof method) and simultaneously with a noninvasive transcutaneous bilirubinometer. The clinical and demographic characteristics of the neonates were recorded. Statistical analysis was done for comparison between total serum bilirubin (TSB) and transcutaneous bilirubin by Bilicheck™.

Results: TcB values had a high correlation with TSB (r=0.96, r2= 0.92, TSB=11.9 5.5 mg/dl, Tcb=11.7 4.6, p value= 0.072). This correlation coefficient was higher in preterm neonates (0.97) than term neonates (0.95). This Bilicheck™ was more accurate for assessing neonates with TSB of 13 mg/dl or less. It tends to underestimate TSB when TSB levels were more than 15mg/dl.

Conclusion: The Bilicheck™ is a very useful noninvasive device to assess TcB in term as well as preterm neonates. It works best at TcB levels less than 15 mg/dl.

Key words: Neonates, Transcutaneous Bilirubin, TcB, Total serum bilirubin, TSB.

Introduction

Jaundice is the most common problem of the neonatal period. Between 25 and 50 % of all term newborns and a higher percentage of premature infants develop clinical jaundice. (1). In Indian experience, 5 % of newborn babies develop pathological jaundice or hyperbilirubinemia (2). The immature brain is susceptible to toxicity from unconjugated bilirubin resulting in kernicterus or bilirubin induced brain damage. Since the visual assessment of jaundice is inaccurate, a large number of neonates need to be screened. This requires drawing of blood for the estimation of serum bilirubin. Moreover a serial estimation of bilirubin is often required which makes matters worse. In recent years there has been a trend for early discharge of neonates from the hospital. This often causes readmission for the jaundice. To prevent these readmissions neonates are serially screened for jaundice in the first few days of life to determine the trend of their bilirubin levels and categorize them into the low, intermediate, high risk zone for developing severe hyperbilirubinemia later on. Fortunately a number of noninvasive devices for the measurement of transcutaneous bilirubin have been developed. One of them is Bilicheck™. The Bilicheck™ works by directing white light into the skin of the newborn and measuring the intensity of the specific wavelengths which are returned. The major skin components which impact the spectral reflectance in the newborn are dermal maturity, melanin, hemoglobin and bilirubin. The correlation coefficient of total serum bilirubin and transcutaneous bilirubin is quite variable as reported in various studies from different parts of the world. (3-6)

We therefore conducted a study on a heterogeneous population of clinically jaundiced Indian neonates including term, preterm, healthy as well as sick babies to evaluate the usefulness of Bilicheck™.

Methods and Materials

This was a hospital based prospective observational study conducted in the Neonatal Intensive Care Unit (NICU) over a period of one year, after seeking approval from the Ethical committee of the institute and after obtaining informed consent from the parents. All neonates having clinical jaundice irrespective of the gestational age, birth weight, sex or race, requiring estimation of serum bilirubin formed the study subjects. Neonates who had received phototherapy, after an exchange transfusion and neonates with conjugated hyperbilirubinemia were excluded. The enrolled neonates were investigated for total serum bilirubin (TSB) by automated Jendrassik and Grof method from a single laboratory and simultaneously with a noninvasive transcutaneous measurement of bilirubin (TcB) by Bilicheck™. The blood sample for total serum bilirubin was collected within half hour of transcutaneous bilirubin estimation by Bilicheck™. Before each measurement Bilicheck was calibrated to a standard reference. Baby was placed in supine position. The calibration tip was placed over the forehead when baby was quiet. This area over forehead was kept away from hairline, free of any bruising, local nevus, haemangioma or melanotic patch. Light pressure over the forehead was applied till the Bilicheck™ showed green light. The light source in the Bilicheck™ was triggered for 5 spectral readings that were then averaged by Bilicheck™ to provide TcB. The Bilicheck™ calibration tip was changed after every 10 readings. All measurements by Bilichek were done by resident doctors trained in using the device. Demographic details of the mother and neonate was collected.

Data analysis

Data was entered in visual fox pro 6.0 data base management software and data was analyzed using statistical software package 8.0. We found coefficient of correlation with the help of Pearson's coefficient correlation and mean difference between TSB and TcB is tested by Paired t test.

Results

A total of 250 neonates were enrolled in the study. Demographic details of the study patients were as given in table 1.

Table 1: Demographic details of the patients

Variable	Patients
Post natal age	5.02±3.46 days
Birth weight <1000 grams 1000-1499 grams 1500-2499 grams >2500 grams	2069±648.4 days 8(3.2%) 52(20.8%) 120 (48%) 70(28%)
Gestational age Preterm(<37 wks) Term(≥37 wks)	35±5.49 weeks 132 (52.8%) 118 (47.2%)
Male: Female	2.8: 1
Hemoglobin	17±3.01 gm/dl
Blood group Incompatibility Rh AO BO None	 21(8.4%) 11(4.4%) 30(12%) 188 (75. 2%)

As shown in table 2, Coefficient of correlation (r) between TSB and TcB in preterm neonates was 0.97 and in term neonates 0.95. Out of 250 neonates, 169 had TSB level < 13 and Bilicheck™ detected 161 (95%) correctly, 27 had TSB level between 13-15 mg/dl and Bilicheck™ detected 17 (62.9%) correctly, 29 had TSB level between 15.1-18 and Bilicheck™ detected 22 (75%) while 25 had TSB more than 18 and Bilichek detected 20 (80%) correctly. According to Kappa statistics, agreement between levels of TcB and TSB was 88%. In this study, 93.6% neonates the difference between TcB and TSB was less than 2 mg/dl. For TSB levels of less than 15 mg/dl TcB values tend to be overestimated while for TSB levels of more than 15.1 mg/dl, TcB tends to underestimate.

Discussion

Most studies on TCB conducted from various parts of the world included term or near term neonates who were healthy, did not have any hemolysis, were not exposed to phototherapy and were less than 7 days old (3-6). The only study from India evaluating the Bilicheck™ conducted by Lodha et al was also the same (7). In our study we have taken a heterogenous population of north Indian neonates including term/ preterm and well/sick neonates (including those with hemolysis due to ABO/Rh in compatibility). The overall correlation coefficient "r" for our neonates was 0.96 which is similar to those reported previously suggesting good correlation between TcB and TSB.

In our study we had term and preterm neonates in the ratio of 118:132. Jangaard et al found that the instrument was not as sensitive in the small sample of preterm infants (8). However, Rubaltelli et al found that, Bilicheck™ accuracy was independent of race, birth weight, gestational age and post natal age of newborn. It could not only be used for screening but also as a substitute for TSB (9). William et al, found Bilicheck™ to be reliable for very premature neonates (< 30 weeks) especially that group of neonates which had good skin condition. We also found that correlation of TcB and TSB in preterms was good with correlation coefficient 'r' of 0.97 and thus it could be used for screening in preterms. This could be because preterm babies have lower values of TSB as compared to term neonates and in our study we found TcB values to be in better agreement with TSB values when the latter were < 13mg/dL.

In our study we found mean TcB of sick and healthy neonates was similar to TSB levels. Thus Bilicheck™ measures TCB as accurately as TSB in sick neonates. We included neonates upto the age of 30 days in our study as most workers had evaluated the Bilicheck™ only during the first week of life. Rubaltelli et al. 2001 also included neonates upto < 28 days of age and found post natal age not to affect the correlation between TSB and TcB significantly (9). In our study group of 250 neonates, 104 (41.6%) neonates were more than 7 days old but the overall correlation coefficient was not affected. This clearly indicates that Bilicheck™ can be used for assessing jaundice in>7 days old neonates reliably.

The strength of our study was that we used truly heterogenous population of neonates within a single ethnic group. We had both term, preterm, sick, well, less than 7 days old as well as more than 7 days old neonates in our study. The limitations of our study were the values of TcB were not compared with the High

Table2 : Comparison of mean TSB and TcB & Coefficient of correlation(r) between TSB and TcB

	TSB(mg/dl) Mean ±SD	TcB(mg/dl) ± Mean SD	P value	Coefficient of correlation(r)
Term (118)	13.4 ± 6.5	13.0 ± 5.4	0.0562	0.95
Preterm(132)	10.5 ± 3.9	10.5 ± 3.5	0.8751	0.97
Healthy (200)	9.8 ± 3.9	9.8 ± 3.56	0.8392	0.93
Sick (50)	12.4 ± 5.69	12.17 ± 4.75	0.6612	0.91
All cases (250)	11.9 ± 5.5	11.7 ± 4.6	0.0718	0.96

Performance Liquid Chromatography (HPLC) value of TSB which is the gold standard for estimation of TSB. The calibration tip was not changed for every neonate as recommended by the manufacturer. The same tip was used for 10 neonates due to financial constraints. We did not get Bland - Altman plots for the analysis of the data.

Conclusion

The Bilicheck™ is a very useful noninvasive device to assess TcB in term as well as preterm neonates. The Bilicheck™ is more accurate for assessing neonates with TSB of 13mg/dl or less. It tends to underestimate TSB when levels are more than 13mg/dl. Thus there is danger of inadequately treating these neonates.

Contributors:

MK designed the study, helped in patient management, analyzed the data and edited the manuscript. SA helped in designing the study, management of patients and writing the manuscript. RC collected the data and analyzed it.

Funding : none

Competing interest : none

References

1. Martin CR, Cloherty JP. Neonatal Hyperbilirubinemia. In: Cloherty JP, Eichenwald EC, Stark AR. Manual of Neonatal Care. 5th Edition. Philadelphia: Lippincott Williams and Wilkins; 2004:181-212
2. Singh M. Care of the newborn, 6th edition. Sagar Publications, New Delhi. 2009; 239-255
3. Bhutani VK, Gourley GR, Adler S, Kreamer B, Dalin C, Johnson LH. Noninvasive measurement of total serum bilirubin in a multiracial predischarge newborn population to assess the risk of severe hyperbilirubinemia. Pediatrics. 2000; 106: E17
4. Janjindamai W, Tansantiwong T. Accuracy of transcutaneous bilirubinometer estimates using BiliCheck in Thai neonates. J Med Assoc Thai. 2005; 88: 187-190
5. Maisels MJ, Ostrea EM Jr, Touch S, Clune SE, Cepeda E, Kring E, et al. Evaluation of a new transcutaneous bilirubinometer. Pediatrics. 2004; 113: 1628-1635
6. Kolman KB, Mathieson KM, Frias C. A comparison of transcutaneous and total serum bilirubin in newborn Hispanic infants at 35 or more weeks of gestation. J Am Board Fam Med. 2007; 20: 266-271
7. Lodha R, Deorari AK, Jatana V, Paul VK. Non-invasive estimation of total serum bilirubin by multi-wavelength spectral reflectance in neonates. Indian Pediatr. 2000; 37: 771-775
8. Jangaard K, Curtis H, Goldbloom R.. Estimation of bilirubin using BiliChek, a transcutaneous bilirubin measurement device: Effects of gestational age and use of phototherapy. Paediatr Child Health 2006; 11: 79-83
9. Rubaltelli FF, Gourley GR, Loskamp N, Modi N, Roth-Kleiner M, Sender A, Vert P. Transcutaneous bilirubin measurement: a multicenter evaluation of a new device. Pediatrics. 2001; 107: 1264-1271

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E-published: 1st March 2011. **Art**#15