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## **Original Research Article**

# A comparison of serum and transcutaneous methods for diagnosis of neonatal hyperbilirubinemia

#### Mehran Hesaraki\*

Department of Pediatrics, Medicine School, Zabol University of Medical Science, Zabol, Iran

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#### \*Correspondence: Dr. Mehran Hesaraki,

E-mail: mehranhesaraki2@gmail.com

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#### **ABSTRACT**

**Background:** Bili-Check is a simple test for non-invasive, quick, and painless estimation of the total serum bilirubin. This research aimed to compare serum and transcutaneous methods for the diagnosis of neonatal hyperbilirubinemia. **Methods:** In this descriptive study, a sample of 120 neonates diagnosed with hyperbilirubinemia was selected using convenience non-probability. They were hospitalized in Amir Al-Momemin Hospital of Zabol, Iran in 2013. The extent of neonatal bilirubin was measured by NINGBO DAVID and lab test. Then, they were compared. The data were analyzed using correlation and t-test in SPSS 22.

**Results:** In this descriptive study, a sample of 120 neonates diagnosed with hyperbilirubinemia was selected using convenience non-probability. They were hospitalized in Amir Al-Momemin Hospital of Zabol, Iran in 2013. The extent of neonatal bilirubin was measured by NINGBO DAVID and lab test. Then, they were compared. The data were analysed using correlation and t-test in SPSS 22.

**Conclusions:** The results showed that Bili-Check can be recommended as an appropriate tool for screening and monitoring phototherapy process. The serum method can be replaced by Bili-check.

Keywords: Bilirubin meter, Neonatal hyperbilirubinemia, Serum bilirubin, Transcutaneous bilirubin

#### INTRODUCTION

Jaundice is common in infancy. Most infants develop visible jaundice within a few days after birth. However, 10% of term and 25% of preterm infants require treatment.<sup>2,3</sup> Hyperbilirubinemia is the major cause of severe injury in preterm neonates. Detecting neonates at risk for jaundice and preventing encephalopathy caused by bilirubin are two important priorities by public health providers.<sup>4</sup> American academy of pediatrics (AAP) has proposed Bhutan's nomogram to measure the total serum bilirubin from the newborn population to detect hyperbilirubinemia.<sup>5</sup> Yet, measuring TSB requires blood sample from the heel of newborns, which is an invasive, stressful and time-consuming procedure. Measuring transcutaneous bilirubin requires less time and can be

used as screening. Since blood sample is not required in this method, TSB use declines.<sup>5,6</sup> Transcutaneous bilirubin measurement uniqueness was depicted in a nomogram based on hours after birth to forecast hyperbilirubinemia of term and preterm neonates. A review study focused on screening neonates using TCB in order to help the physician make a better and quicker decision for starting phototherapy in patients diagnosed with hyperbilirubinemia.<sup>7</sup> This research aimed to investigate the Bili-Check accuracy by comparing the serum and transcutaneous methods of neonates.

#### **METHODS**

This is a descriptive-analytical study on neonates diagnosed with hyperbilirubinemia hospitalized in

Pediatric Ward or NICU of Amir Al-Momemin hospital of Zabol, Iran from March 21st to September 20th 2013. In this study, 120 neonates were investigated. The exclusion criterion was the need for exchange transfusion. According to the previous studies and the number of patients, a sample of 120 was selected using convenience non-probability. NINGBO DAVID, manufactured by David Co. China, was used to determine the transcutaneous bilirubin. We gently put the optic head on infant's skin and preferably tangent to the forehead. Then, gentle pressure was applied. Light was radiated to infant's skin and the back wavelength was measured. The wavelength was analyzed by the photocell in the optic head and converted to e-signals. The beep after 3-4 seconds showed the end of measurement. The figure then appeared on the LCD screen. Serum sample was sent to the laboratory after 10 minutes from transcutaneous measurement. Serum bilirubin was measured based on the auto-analyzer method by SELECTRA, manufactured by Iranian Teb Gostar Co., and Total Bilirubin diagnostic kit by photometric test, manufactured by Pars Azmoon Co. The unit of measurement was mg/dl. Individuals who determined the serum bilirubin were unaware of the bilirubin by the device. The data were analyzed in SPSS by descriptive-analytical statistical tests, t-test, and ANOVA. Significance level was considered P≤0.05.

#### **RESULTS**

Out of 120 neonates diagnosed with hyperbilirubinemia, 64 (53.3%) were male and 56 (46.7%) were female. The mean gestational age was  $35.4\pm2.8$  weeks and the mean weight of neonates was  $2.4\pm0.7$  kg (P>0.05). Mean transcutaneous and serum bilirubin was  $14.4\pm2.8$  and

13.4±3.1 mg/dl, respectively. The correlation was r=0.722 (P<0.0001). In male neonates, transcutaneous bilirubin was reported 14.3±2.8 mg/dl and serum bilirubin was 13.2±3.2 mg/dl. The correlation was r=0.667 (P<0.0001). In female neonates, transcutaneous bilirubin was reported 14.4±2.9 mg/dl and serum bilirubin was 13.6±3.0 mg/dl. The correlation was r=0.791 (P<0.0001). Mean transcutaneous bilirubin was reported 15.1±2.8 mg/dl and mean serum bilirubin was 14.6±3.1 mg/dl among neonates with gestational age of over 37 weeks. The correlation was r=0.885 (P<0.0001). However, in neonates with gestational age of fewer than 37 weeks, mean transcutaneous bilirubin was reported 13.7±2.7 mg/dl and mean serum bilirubin was 12.2±2.8 mg/dl. The correlation was r=0.502(P<0.0001). Among neonates with weight over 2.5kg, mean transcutaneous bilirubin was reported 15.2±2.9 mg/dl and mean serum bilirubin was 14.7±2.8 mg/dl. The correlation was r=0.822(P<0.0001). However, among neonates with weight less than 2.5kg mean transcutaneous bilirubin was reported 13.7±2.6 mg/dl and mean serum bilirubin was  $12.3\pm3.0$  mg/dl. The correlation was r=0.593(P<0.0001) which was statistically significant (Table 1). According to transcutaneous bilirubin, the neonates were assigned in two groups: Need for phototherapy and no-need for phototherapy. Transcutaneous bilirubin accuracy was investigated by serum bilirubin as the golden standard method. The following results were also found: Transcutaneous bilirubin sensitivity, 97.3%; specificity, 70%; Positive predictive value (PPV), 97.3%; and Negative predictive value (NPV), 70%. According to the statistical investigation, the greatest sensitivity was found in transcutaneous bilirubin of 10-16.

Table 1: Comparing transcutaneous and serum bilirubin of neonates using pearson correlation test.

|                 | Bilirubin  | Number | Serum    | Transcutaneous | Correlation | P-Value  |
|-----------------|------------|--------|----------|----------------|-------------|----------|
| Gender          | Male       | 64     | 13.2±3.2 | 13.2±3.2       | 0.667       | P<0.0001 |
|                 | Female     | 56     | 13.6±3.0 | 13.6±3.0       | 0.791       | P<0.0001 |
| Gestational Age | Term       | 58     | 14.6±3.1 | 14.6±3.1       | 0.885       | P<0.0001 |
|                 | Preterm    | 62     | 12.2±2.8 | 12.2±2.8       | 0.502       | P<0.0001 |
| Weight          | Normal     | 54     | 14.7±2.8 | 14.7±2.8       | 0.822       | P<0.0001 |
|                 | Low Weight | 66     | 12.3±3.0 | 12.3±3.0       | 0.593       | P<0.0001 |

#### **DISCUSSION**

In this research, we compared the serum and transcutaneous methods. A high correlation was found between these two methods. Bili test managed to accurately diagnose the neonatal bilirubin diagnosed with hyperbilirubinemia. The study by Kaynak-Türkmen et al, in Turkey showed that the correlation was 0.85 between these two methods. Due to low false-positive results and high sensitivity, Bili Check was advised to be used a complete replacement for measuring serum

bilirubin. Which is consistent with ours. However, the correlation was slightly higher. The study by Yu et al, in China on investigated 9174 healthy children. Out of them, 972 developed hyperbilirubinemia. Their results showed that transcutaneous bilirubin coupled with clinical factor risk can increase hyperbilirubinemia diagnosis accuracy. The study by Panburana et al, showed that the correlation was 0.81 between these methods. Their results showed that TCB can accurately forecast TSB in cut off and various gestational ages. The study by Hemmati and Kiyani Rad showed that the

correlation was 0.96 between these two methods. Gestational age, gender and weight at birth had no effect on the correlation. Bili-check sensitivity was 96.6%. The results showed that Bili-check is a simple, non-invasive, and reliable method to measure the bilirubin.11 The results of this study were also consistent with ours and the sensitivity was equal with that of this research. Despite the study by Hemmati and Kiyani Rad, in this study, gestational age, gender and weight at birth had an effect on the correlation. Term female neonates with normal weight had greater correlation compared to others. Despite the previous study, the study by Ebbesen in the USA showed that serum and transcutaneous methods had close correlation. In this transcutaneous method was proven to be dependent on race, gestational age, and weight at birth and was limited in heterogeneous populations. <sup>12</sup> Therefore, it is consistent with this study. The study by Hegyi showed that transcutaneous sizes were not much of different in preterm neonates in every age group. A high correlation was observed among black and white races between the serum and transcutaneous methods in neonates who did not undergo phototherapy. The study showed that phototherapy decreased the correlation coefficient. At the moment, it is not advised in neonates undergoing phototherapy.<sup>13</sup> The study by Keshishjan et al, in Russia revealed that the serum and transcutaneous methods had a linear relationship. Their results showed that measuring by transcutaneous method during phototherapy does not estimate the serum bilirubin concentration correctly. This method is only appropriate for monitoring the bilirubin level, its changes in skin, and screening neonates.<sup>14</sup> The study by Saeedi et al, showed that measured serum bilirubin in laboratory had a high correlation with the results by TCB using Bili-check (r=0.766).1

#### **CONCLUSION**

According to the results and other studies, it seems that Bili Check has the essential accuracy to measure and assess the neonatal jaundice. It can be an appropriate replacement for measuring serum bilirubin in neonates diagnosed with jaundice.

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Institutional Ethics Committee

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