Correlation between Transcutaneous Bilirubin and Serum Bilirubin Measurements in Neonates in Tertiary Care Hospital

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ABSTRACT

BACKGROUND: Transcutaneous bilirubinometry (TCB) is a simple method for estimation of bilirubin level in neonates. This method is based on the principle of spectral reflectance. This method is noninvasive, quick and painless. While total serum bilirubin (TSB) method is accepted worldwide for estimation of bilirubin level. AIM AND OBJECTIVES: We aimed to compare transcutaneous and serum bilirubin concentration in full term neonates. Our objective is to evaluate the transcutaneous bilirubin and analyse its correlation with serum bilirubin values and find out whether transcutaneous bilirubin measurement could replace invasive serum bilirubin measurement. METHODOLOGY: This cross sectional study was conducted on 80 full term neonates, admitted in neonatal ward of S.S.G Hospital, Vadodara. TCB was measured using transcutaneous bilirubinometer. Mean and SD levels were calculated. TSB estimation was performed within 30 minutes of doing TCB, for the same patients. The data was tabulated and paired T test was used to find the significance of difference between 2 methods using Med Cal software. r value is calculated by using the Pearson correlation coefficient (r).

OBSERVATION & RESULT: The mean and SD for TCB was 11.09, ±3.93mg/dl (3.2 - 20.0). The mean and SD of TSB was 9.16, SD ±3.11mg/dl (2.9 - 17.0). P value is <0.0001. There seems to be a close correlation between TCB estimation and TSB estimation. CONCLUSION: The study demonstrates clearly that there is good correlation between the TCB and TSB estimation, when the bilirubin values are low. The TCB values were higher than the TSB values.

Key words: Transcutaneous bilirubin, Total serum bilirubin, Transcutaneous bilirubinometer.

INTRODUCTION

Hyperbilirubinemia is one of the common problem in neonates. An estimation of the bilirubin value is essential for decision making in jaundiced babies. Transcutaneous bilirubin screening (TcB) is a quick and noninvasive technique to measure bilirubin level in neonates. Many previous studies have shown that transcutaneous bilirubin measurement provides a close estimate of total serum bilirubin levels. This test is easy to perform and obviates the need for pricking the baby for blood sample for total serum bilirubin measurement (TSB) and sending to lab and waiting for the report. Serum bilirubin estimation is one of the essential investigation done to assess the severity and type of Jaundice. Serum bilirubin estimation is traditionally done on serum sample drawn by venipuncture which is invasive and painful. Hence there was need for a non invasive and reliable method to assess the bilirubin level. The objective of the study was to find out whether Transcutaneous bilirubin measurement could be reliably used to assess jaundice and avoid veni puncture for serum bilirubin estimation.

MATERIAL AND METHODS

This cross sectional study was conducted in the clinical chemistry laboratory of biochemistry department and neonatal unit of SSG hospital and Medical college baroda. Neonates who were clinically diagnosed to have jaundice were included in this study. 80 neonates who met the inclusion criteria during the period of September 2016 to November 2016 were enrolled in this study. TcB measurement was done using the Drager Transcutaneous Bilirubinometer JM 103 which is based on the principle of spectral reflectance. Measurement was obtained by keeping the bilirubinometer over the sternum of the
Transcutaneous Bilirubin & Serum Bilirubin Measurements in Neonates

Further the statistical analysis showed paired mean difference between the group I is 0.93 ($P < 0.0001$), group II is 2.1 ($P < 0.0001$) and group III is 4.1 ($P = 0.004$). (Table 1)

Table 1: Statistical analysis

<table>
<thead>
<tr>
<th>Group (TSB values)</th>
<th>No</th>
<th>Paired Mean Difference</th>
<th>$P$ value and Significance</th>
<th>Correlation (r)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no of patients</td>
<td>80</td>
<td>1.93</td>
<td>&lt;0.0001</td>
<td>0.928</td>
</tr>
<tr>
<td>Group I (&lt;9.9mg/dl)</td>
<td>30</td>
<td>0.93</td>
<td>&lt;0.0001</td>
<td>0.910</td>
</tr>
<tr>
<td>Group II (10.0-14.9 mg/dl)</td>
<td>40</td>
<td>2.1</td>
<td>&lt;0.0001</td>
<td>0.614</td>
</tr>
<tr>
<td>Group III(&gt;15mg/dl)</td>
<td>10</td>
<td>4.1</td>
<td>0.004</td>
<td>0.816</td>
</tr>
</tbody>
</table>

Table 2: TCB and TSB Relationship

<table>
<thead>
<tr>
<th>TSB VS TCB</th>
<th>TSB&lt;9.9</th>
<th>Group 2 TSB 10-14.9</th>
<th>Group 3 TSB &gt;15</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCB more than TSB</td>
<td>29(96.66%)</td>
<td>37(92.5%)</td>
<td>10(100%)</td>
</tr>
<tr>
<td>TCB less than TSB</td>
<td>1(3.33%)</td>
<td>3(7.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>30(100%)</td>
<td>40(100%)</td>
<td>10(100%)</td>
</tr>
</tbody>
</table>

Pearson’s correlation coefficient($r$) for all neonates is 0.928 with significant $P <0.0001$ (Table-1 & graph 1), for Group I it was 0.910 with a 95% confidence interval of 0.8195 to 0.9571 with a significant $P$ value of < 0.0001 (graph 2), for Group II it was 0.614 with a 95% confidence interval of 0.3739 to 0.7769 with a significant $P$ value of < 0.0001 (graph 3), for Group III it was 0.816 with a 95% confidence interval of 0.3830 to 0.9549 with $P$ value of 0.004 (graph 4) which was statistically moderately significant (Table-1).

In this study, bland Altman plot was drawn for both TcB and TSB values for all 80 jaundiced neonates. The plot reveals that the difference between two rater is more than 5.0 and less than -1.1 are out liaers (Graph 5). In group I the plot reveals that the difference between two rater is more than 2.52 and less than -0.66 are out liaers (Graph 6). In group II the plot reveals that the difference between two rater is more than 5.0 and less than −0.7 are out liaers (Graph 7). In group III the plot reveals that the difference between two rater is more than 6.2 and less than 2.0 are out liaers (Graph 8).

Graph 1: Pearson’s correlation coefficient showing relationship between TcB and TSB in 80 patients

RESULT

Statistics of paired sample of 80 neonates for TcB and TSB was analysed. The mean and SD for TcB was 11.09 ± 3.93 mg/dl(3.2-20.0) and the mean and SD of TSB was 9.16 ± 3.11 mg/dl (2.9-17.0) ($P < 0.0001$). For group I the mean and SD of TcB was 7.01 ± 1.96(3.2 – 9.9) and mean and SD of TSB was 6.08 ±1.76 (2.4 - 8.5) ($P < 0.0001$). For group II the mean and SD of TcB 12.42 ± 1.47mg/dl(10.1-14.9) and mean and SD of TSB 10.29 ± 1.77mg/dl(6.5-12.5) ($P < 0.0001$). For group III the mean and SD of TcB was 17.30 ± 1.59mg/dl(15.7-20.0) and mean and SD for TSB was 13.16 ± 1.84mg/dl(10.7-17.0) ($P < 0.0001$). The overall the mean difference between the TcB and TSB value was 1.93 mg/dl.

patient. Simultaneously a serum sample was collected and sent to clinical chemistry laboratory at SSG Hospital for bilirubin estimation which is based on Diazo method. Depending on TSB concentration 80 neonates with jaundice were sub divided into three groups. Group I (30 in numbers) having bilirubin < 9.9 mg/dl , group II(40 in numbers) having bilirubin 10.0 - 14.9 mg/dl and group III(10 in numbers) having bilirubin >15 mg/dl. Babies who had received prior phototherapy, exchange transfusion and unstable babies in shock were excluded from this study. The software Med Cal was used for statistical analysis. Paired t test, Pearson’s Correlation coefficient ($r$) is used to show the relationship between 2 variables and Bland - Altman plot were drawn to evaluate the agreement among two different instruments or two measurements techniques.

The Interpretation was done according to $P$ value as follows:

- $P \geq 0.05$ was considered not significant
- $P < 0.05$ was considered significant
- $P < 0.001$ considered highly significant

The Interpretation was done according to $r$ value as follows, which can range in value from -1 to +1.

- $r = 0.5$ to 1.0 considered high correlation
- $r = 0.3$ to 0.5 considered medium correlation
- $r = 0.1$ to 0.3 considered low correlation

In this study, bland Altman plot was drawn for both TcB and TSB values for all 80 jaundiced neonates. The plot reveals that the difference between two rater is more than 5.0 and less than -1.1 are out liaers (Graph 5). In group I the plot reveals that the difference between two rater is more than 2.52 and less than -0.66 are out liaers (Graph 6). In group II the plot reveals that the difference between two rater is more than 5.0 and less than −0.7 are out liaers (Graph 7). In group III the plot reveals that the difference between two rater is more than 6.2 and less than 2.0 are out liaers (Graph 8).

Graph 1: Pearson’s correlation coefficient showing relationship between TcB and TSB in 80 patients
DISCUSSION

The aim of the our study was to assess the difference between TcB – TSB paired values. Out of 80 paired values, 76 paired values show TcB was greater than the corresponding TSB level and only in 4 paired values, TcB level was less than the paired TSB level. The p values in all 3 groups is highly significant (P < 0.0001), which indicates that there is major difference in value given by both the methods (TcB and TSB). Further, Pearson’s correlation coefficient (r) in 2 groups (group I, II ) shows that there is a good correlation between two different methods i.e TcB and TSB (P < 0.0001 ,which means that when one variable is increased, the another variable is also increased correspondingly, while group III does not show very good correlation between 2 methods (P < 0.004). Further, Bland and Altman plot in all 3 groups( group I,II and III) indicates that the bilirubin measurement done by 2 different methods(TcB and TSB) shows no agreement, that means the difference in the values of bilirubin done by two method is clinically significant. So one method can not replaced by another method. Rodriguez-Capote et al. assessed the association between TcB measurements(using Bilicheck JM-103) and TSB and evaluated the predictive accuracy of TcB measurements. They find that there is good correlation between 2 method .

CONCLUSION

Our study in 80 jaundiced patients shows that bilirubin estimation done by TSB method cannot be replaced by TcB method. Therapeutic decisions and interventions should be done on the basis of TSB method, whose value is clinically
different from those of TcB value. Further, as there is a close relationship between both the methods, TcB method can be used for monitoring response to treatment when repeated testing is required.

REFERENCES