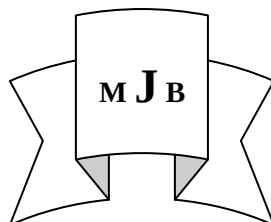


Transcutaneous Bilirubin Testing: A Screening Tool for Jaundiced Term and Near- Term Neonates

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Abstract

Objective: To evaluate the transcutaneous bilirubin (by Minolta JM-103 Jaundice Meter) as a screening tool in near term (≥ 35 weeks) to term neonates with jaundice who presented to our hospital.

Methods: This prospective study which was done in Karbala teaching hospital for children, during the period from April 1, 2010 through December 31, 2010, studied the correlation between the total serum bilirubin (TSB) measurements by (APEL BR-501 BILIRUBIN METRE) and the paired transcutaneous bilirubin (TcB) measurements (by Minolta JM-103 Jaundice Meter).

Result: Transcutaneous bilirubin showed a good correlation with TSB ($r=0.827$) in 107 neonates aged between 1 to 13 days old. The mean difference between TcB and TSB was -1.15.

Conclusion: Transcutaneous bilirubin (measured by JM-103) cannot be considered a substitute for laboratory measurement of TSB, but appears to be useful as a screening tool.

تقييم جهاز فحص البليروبين عن طريق الجلد

الخلاصة

اهداف البحث: لمعرفة كفاءة عمل جهاز فحص البليروبين عن طريق الجلد وامكان استخدامه في متابعه مرضى اليرقان الولادي. الطرق: لقد اجريت هذه الدراسة المستقبلية لمئة وسبعة طفل من حديثي الولادة الذين لديهم يرقان ولادي في مستشفى الاطفال التعليمي في كربلاء للفترة من بداية نيسان ٢٠١٠ الى نهاية كانون الاول ٢٠١٠ وتمت اخذ القراءات بواسطة جهاز فحص البليروبين عن طريق الجلد ومقارنتها بنتائج الاجهزة المستخدمه في المختبرات الكيميائية في المستشفى.

النتائج: لقد وجد ان خمسة وستون (٥٧%) طفلا كانوا من الذكور مقابل (٤٣%) من الاناث وان نسبة الذكور للاناث كانت (١:٣٢). وان معدل عمر الاطفال كانت (٥.٨) ايام مع مدى من (١-١٣) يوم. كان معدل الوزن عند الولادة كان (٣.٠٣٦) كغم بمدى من (٢.٠٠ - ٤.٢٠٠) كغم وان (٧١%) ولدوا ولادة طبيعية بينما (٢٩%) كانت ولادتهم قيصرية. لقد كانت رضاعة (٦٩%) منهم طبيعية وكانت معدل النسبة بين نتائج الفحص عن طريق الجلد لنتائج المختبرات الكيميائية هي (٠.٨٢٧).

الاستنتاج: نسبة المقارنه جيده بين نتائج جهاز فحص البليروبين عن طريق الجلد والاجهزة المستخدمه في المختبرات الكيميائية في المستشفى لذلك من الممكن استخدام جهاز فحص البليروبين عن طريق الجلد لمتابعه الاطفال حديثي الولادة المصابين باليرقان.

Introduction

Noninvasive techniques for transcutaneous measurement of bilirubin (TcB) that are linearly correlated with serum levels may be used to screen infants [1,2], but determination of serum bilirubin level is indicated in patients with elevated age-specific transcutaneous bilirubin

measurement, progressing jaundice, or risk for either hemolysis or sepsis [3].

Transcutaneous bilirubin (TcB) measurement devices use multiwavelength spectral reflectance from the skin surface and can be used to estimate total serum/plasma bilirubin (TB), and, thus, avoid blood sampling. However, TcB measurements are not reliable in

infants undergoing phototherapy [2]. In addition, controversy still exists as to whether TcB testing is affected by skin pigmentation [4,5]. As a result, TcB measurements may be limited in these neonates (ie, infants treated with phototherapy, or darkly skinned), as the magnitude of hyperbilirubinemia cannot be accurately ascertained.

In several reports of racially and ethnically diverse groups of term and late preterm newborns, a close correlation between TcB and TB measurements was demonstrated [4]. However, at high levels of TB (>15 mg/dL [257 micromol/L]), TcB measurements underestimate TB and need to be confirmed by standard laboratory methods [6,7]. As a result, TcB can replace TB in most circumstances when TB is <15 mg/dL (257 micromol/L) [2,6].

There are significant variations among different instruments for TcB measurement. When TcB is used clinically as a substitute for TB, values of new instruments should always be compared to TB performed by the laboratory to ensure good correlation [8].

The use of TcB screening reduces the number of blood tests for bilirubin determination compared to visual assessment without compromising detection of infants with significant TB values (eg, >75 th percentile) [9,10]. The aim of this work is to evaluate a non invasive new transcutaneous jaundice meter JM-103 as screening test and decrease unnecessary blood sampling in follow up of jaundice in neonatal period.

Patient and Methods

A prospective study was performed in Karbala teaching hospital for children. Term and near-term neonates presenting for jaundice during the period from April 1, 2010

through December 31, 2010 were included in this study with verbal consent from their parents.

Transcutaneous bilirubin (TcB) and capillary bilirubin assays were performed just once for each patient, with a maximum interval of 30 min between them. The age in days was recorded, along with gestational age, body weight, type of feeding, type of labor and gender. All infants weighed more than 2,000 g, had a gestational age of more than or equal to 35 weeks, and were clinically healthy and jaundiced. Infants who were receiving phototherapy or who had exchange transfusion were excluded.

All TcB measurements were performed by one investigator, using the bilirubinometer (jaundice meter Minolta JM-103, Drager). The measurements were obtained from the foreheads of the infants, while lying in a supine position. Gentle pressure was applied, while the fiber optic probe was placed against the forehead to exert even contact by the probe with the forehead skin.

The TSB assay was performed in the hospital chemical laboratory, using a direct spectrometer (APEL BR-501 BILIRUBIN METRE).

Both devices were calibrated before use daily, in accordance with the manufacturer's instructions

Demographic data, TcB and TSB values were analyzed using SPSS v12.0. The correlation coefficient between TcB and TSB was performed using Pearson Linear Regression Analysis. Error distribution, mean difference, and 95% confidence interval of the difference were evaluated.

Results

During the study period, a total of 107 TcB and TSB measurements were taken from term and near term neonates.

Their body weight ranged from 2.00 to 4.2 kg (mean= $X=3.03$, $SD=0.50$), gestational age ranged from 35 to 41 weeks ($X=38.18$, $SD=1.4$), the age

(figure1) ranged from 1 to 13 days ($X=5.8$ $SD=2.6$).

TcB ranged from 5.9 to 18.8 ($X=11.45$ $SD=2.8$), TSB ranged from 6 to 19.7 ($X=12.6$ $SD=3.37$).

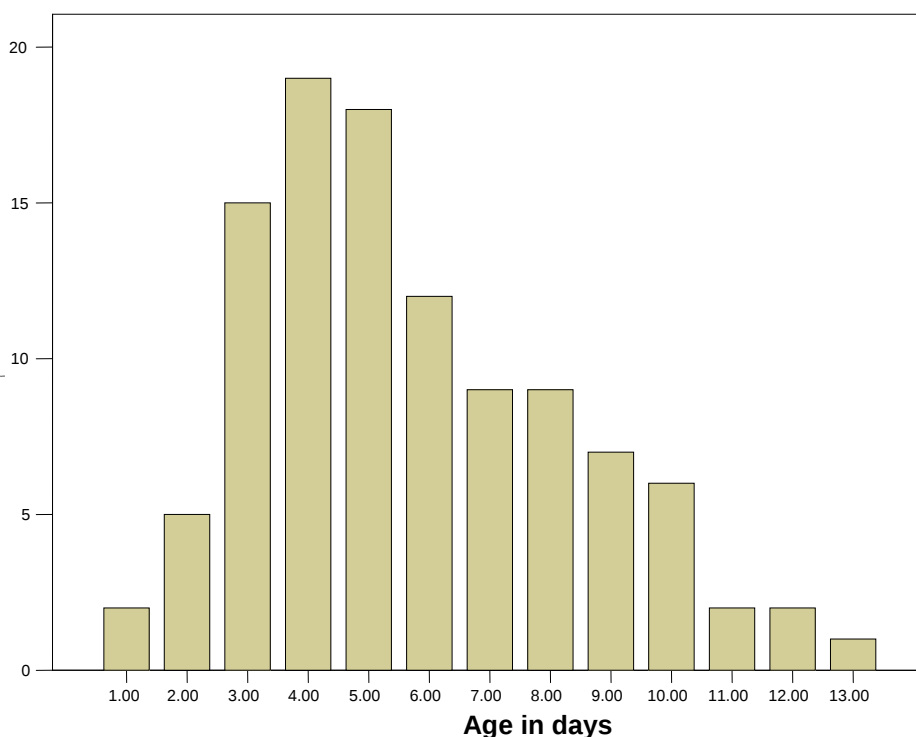


Figure 1 Age distributions

Male to female ratio 1.32:1 (Males 61, female 46). Feeding is by breast in majority (74, bottle feeding 29, mixed feeding is only 4). Seventy

six has been delivered by normal vaginal route (cesarean section 46).

Table 1 demonstrates demographic character for 107 neonates.

Table 1 Demographics characters

	Minimum	Maximum	Mean	Std. Deviation
Gestational age	35.00	41.00	38.1869	1.44804
B W in Kg	2.00	4.20	3.0360	.50159
Age in days	1.00	13.00	5.8037	2.60058
TcB in mg/dl	5.90	18.00	11.4561	2.88098
TSB in mg/dl	6.00	19.70	12.6065	3.37103

The Pearson correlation between TcB using JM-103 (TcB-JM) and TSB was significant ($r = 0.827$, $p < 0.01$). The mean difference between TSB and TcB-JM was -1.15 mg/dl [$SD = 1.8$

mg/dl, and 95% confidence interval of the mean (CI) -1.5 and -0.7].

The linear regression and curve estimations are seen in figures 2 and 3).

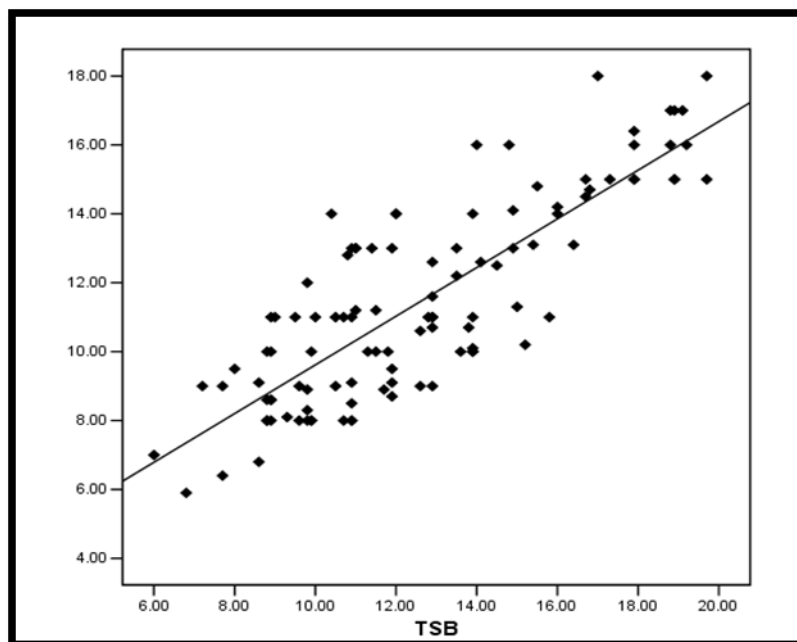


Figure 2 linear regression.

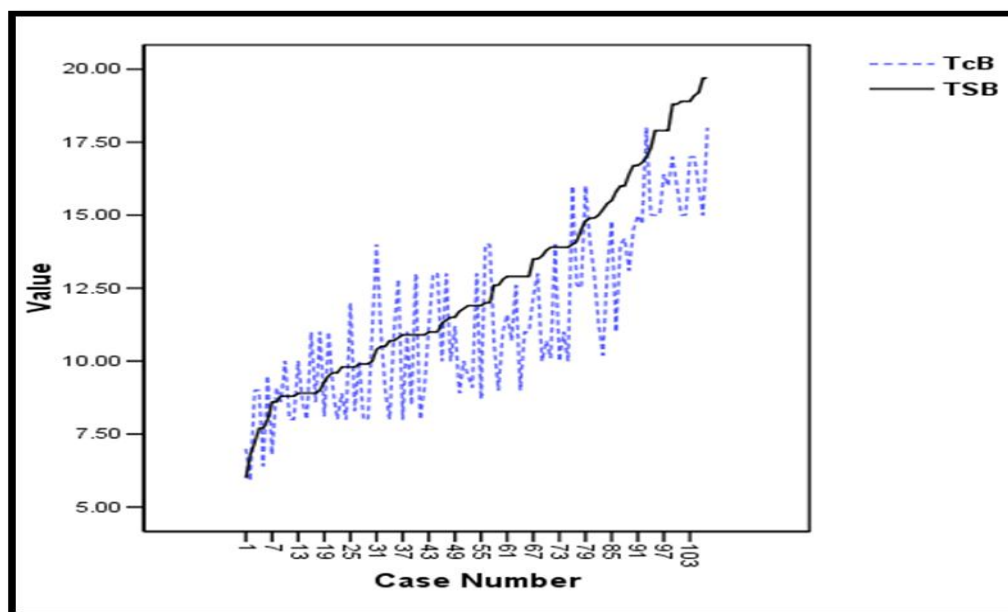


Figure 3 Linear curve.

Discussion

Visually determined jaundice may invite to blood sampling for serum bilirubin level. However, visual inspection, being subjective, usually inaccurate and unreliable and will result in a number of unnecessary blood sampling. Transcutaneous bilirubin device may provide an answer for an objective, noninvasive measurement, few skill-demanding, comfortable, fast and painless [10].

A new device, JM 103, introduced in 2003, provides the measurement result in a clinical unit and was reported to have less influence of skin maturation level and melanin than the previous JM 102 [11].

In our study the correlation coefficient between TcB (JM 103) and TSB is significant ($r = 0.827$, $p < 0.01$), in agreement with study done by maisels M J in China [12] ($r=0.83$), Tommy SK Lam [13] ($r.83$) and sanpavat [14] ($r=0.80$) but less so than that of Yasuda et al [15] ($r = 0.93$).

One factor which may account for the difference is different laboratory measurement of TSB due to inter-laboratory variability with a wide range of uncertainty is well documented [16].

According to our results, the mean difference between TSB and TcB-JM was -1.15 mg/dl [$SD = 1.8$ mg/dl, and 95% confidence interval of the mean (CI) -1.5 and -0.7].

The measurement of TcB over forehead had a tendency to underestimate TSB level which in agreement with study of Snapvat [14].

The correlation coefficient does not provide information about clinical significance of diagnostic test, it was found that when TSB level increase the difference between values of TcB and TSB increase as well [17]. However, a lower level of TSB upon which

treatment begins can cause frequent monitoring of blood sampling, a painful procedure with possible complications. TcB can be used as a screening test to determine the need for TSB measurement [18].

Although the accuracy of TSB is not clarified by comparison with high performance liquid chromatography (HPLC), which is considered to be the gold standard for bilirubin assay, the TSB, performed by clinical laboratory method, is the test a physician routinely relies upon to make decision in management of hyperbilirubinemia.

In the majority of studies evaluating TcB measurements, TSB was measured by laboratory instruments using diazo-based methods [19] that have interferences with hemoglobin and other intracellular compounds [20]. Because blood collected from newborns is often hemolysed, this could affect the accuracy of the clinical laboratory methods. Several studies have evaluated the accuracy and precision of TcB measurements compared to HPLC measurements; the HPLC measurement approach, unlike routine laboratory-based methods, is not subject to interference from hemolysis or lipemia[21,22].

These studies suggest that TcB measurements may be used not only as a screening device but also as a reliable substitute for clinical laboratory-based serum bilirubin measurements. This is in line with the recent National Academy of Clinical Biochemistry laboratory medicine practice guidelines, which concluded that the TcB meters currently available for clinical use in the US (BiliChek and JM-103) provide results comparable to laboratory TSB [23,24].

When comparing TcB and TSB measurements, it is also important to

remember that the 2 methods of measurement may be evaluating different physiologic entities. Rubaltelli et al. [25] suggested that TcB methods measure the amount of bilirubin that has moved from the serum into the tissue, possibly mimicking the movement of bilirubin across the blood– brain barrier and into brain tissue, whereas laboratory-based methods measure only bilirubin that is circulating in the blood. Thus, TcB may actually offer additional information not provided by TSB measurements, although this hypothesis remains to be proven.

TSB should be measured if the management plan would be altered by considering the TSB to be equal to TcB + 3 mg/dL (51 micromol/L). Therapy should be initiated while awaiting confirmatory results [26].

This study has few limitations:

The TSB was measured by the electro photometric device in our local chemical laboratory rather than the gold standard HPLC

We didn't measure TcB in preterm < 35 weeks gestation, and we used only the forehead skin for measurement.

Conclusion

Noninvasive transcutaneous bilirubin assessment by JM 103 has demonstrated significant correlation when compared to total serum bilirubin measured by chemical laboratory method. It can be favorably used as a screening test to identify the need for serum bilirubin measurement.

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