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BiliCheck transcutaneous bilirubinometer: a screening tool for neonatal jaundice in the Chinese population

BiliCheck經皮膽紅素計：一種篩檢華人新生兒黃疸的工具

Objective. To verify the usefulness of the BiliCheck transcutaneous bilirubin meter as a screening device for neonatal jaundice in a Chinese population compared with the Minolta bilirubin meter.
Design. A prospective correlation study that compared transcutaneous bilirubin measurements with serum bilirubin levels.
Setting. Obstetric ward and a neonatal unit of a regional hospital in Hong Kong.
Patients. Neonates with gestation above 32 weeks with neonatal jaundice who were admitted between April 2001 and February 2002.
Main outcome measures. Transcutaneous measurements of serum bilirubin obtained from the forehead and the sternum with two instruments: BiliCheck and Minolta Airshields JM 102.
Results. A total of 77 term and six near-term babies (gestation, 32-37 weeks) were recruited. The mean age at the time of data collection was 3.96 days (range, 2-9 days). The correlations between serum bilirubin and transcutaneous bilirubin measurements of the two devices at the two sites were high, with a coefficient of 0.718 (95% confidence interval, 0.610-0.800; n=100) for forehead measurements, and 0.814 (95% confidence interval, 0.740-0.870; n=99) for sternum using the Minolta Airshields JM 102; and a coefficient of 0.757 (95% confidence interval, 0.657-0.827; n=98) for forehead measurements, and 0.794 (95% confidence interval, 0.700-0.862; n=92) for sternum using the BiliCheck. For BiliCheck, a cut-off point of 250 μmol/L at the forehead and 260 μmol/L at the sternum had a specificity of 61.9% and 70.0%, respectively with a sensitivity of 100% for the detection of serum bilirubin concentrations of 250 μmol/L or higher. This level is commonly used as the level for initiation of treatment such as phototherapy.
Conclusion. BiliCheck is a useful screening tool for neonatal jaundice in the Chinese population and is comparable with the Minolta Airshields JM 102.

目的：比較BiliCheck經皮膽紅素計和Minolta膽紅素計在篩檢華人新生兒黃疸的有效程度。
設計：比較經皮膽紅素測量和血清膽紅素的關係研究。
安排：香港一所地區醫院產科病房和兒科部門。
患者：2001 年 4 月至 2002 年 2 月期間接收患有黃疸的新生兒。
主要結果測量：使用BiliCheck和Minolta Airshields JM 102兩種儀器在患者前額和胸部經皮量度膽紅素。
結果：研究期間共接收 77 位滿月嬰兒和 6 位接近滿月的嬰兒（妊娠期為 32-37 星期），收集資料時嬰兒的平均年齡為 3.96 天（介乎 2-9 天）。分別在兩個部位用兩種儀器經皮量度的膽紅素值，與血清膽紅素有很大的相關性。用 Minolta Airshields JM 102 在前額量度的相關係數為 0.718（95% 可信區間為 0.610-0.800，n=100），在胸骨量度的相關係數為0.814 (95%可信區間為0.740-0.870，n=99)。用BiliCheck在前額量度的相關係數為0.757(95%可信區間為0.657-0.827，n=98)，在胸骨量度的相關係數為0.794(95%可信區間為0.700-0.862，n=92)。以BiliCheck量度前額的切斷點達 250 μmol/L 時，特異性為 61.9%，量度胸骨的切斷點是 260 μmol/L時，特異性則為70.0%，偵測250 μmol/L或以上的血清膽紅素濃度的敏感性則達 100%，光照療法等治療措施經常以此作為治療的起始水平。

Key words:
Bilirubin/blood;
Comparative study;
Infant, newborn;
Jaundice, neonatal;
Neonatal screening

關鍵詞：
膽紅素／血液；
比較研究；
嬰兒，新生；
黃疸，新生兒；
新生兒篩檢

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結論：BiliCheck 經皮膽紅素計是一種篩檢華人新生兒黃疸的有效儀器，效果與 Minolta Airshields JM 102 相若。

Introduction

BiliCheck (SpectRx, Inc, Norcross [GA], US) has been available for 5 years and offers an alternative means to the Minolta Airshields JM 102 (Hill-Rom Air Shields, Ashby de la Zouch, UK) of transcutaneous measurement of bilirubin. Its usefulness as a screening test for neonatal jaundice has been well tested in various groups of patients: term or near-term babies,[1-4] preterm babies,[5,6] sick babies[7] in neonatal intensive care units, and in multi-racial populations.[3,8,9] The results of previous studies all confirm a good correlation between transcutaneous bilirubin (TcB) and serum bilirubin levels with reasonable sensitivity and specificity.

The ability of BiliCheck to distinguish, by means of spectral subtraction theory, the light absorption of bilirubin from that of other factors such as haemoglobin and melanin enables unbiased measurement independent of race, age, and weight of newborns.[10] In practice there are nonetheless some exceptions. The correlation between TcB and serum bilirubin level becomes progressively poor in babies younger than 30 weeks and in those who have received phototherapy.[6] Hence, it remains important to test whether the basic assumption of its accuracy, regardless of numerous variables, is true. To date, all studies have been based on principally Caucasian populations. In two studies with higher proportions of Asians, they still comprised only 13% to 15% of the study samples.[3,8] The aim of this study was to verify usefulness of BiliCheck in a Chinese population and compare it with the older Minolta Airshields JM 102.

Methods

This was a prospective study on term and near-term babies with gestation above 32 weeks admitted to our unit between April 2001 and February 2002. The study was conducted in our hospital with an obstetric unit that delivers 3000 to 4000 babies each year. The babies were recruited from the postnatal ward or neonatal ward if serum bilirubin was to be checked for neonatal jaundice. The TcB was taken on the forehead and the sternum with both instruments (BiliCheck and Minolta Airshields JM 102) within half an hour of blood sampling for serum bilirubin. Blood samples were processed within 1 hour. If the blood sample was only for serum bilirubin determination, a direct spectrophotometric method using an AO Unistat Bilirubinometer (American Optical, New York, US) was used at the bedside or an automated system based on Diazo reaction used in the hospital laboratory. Both machines underwent daily quality testing and were calibrated against samples with known values. Both methods have been shown to highly correlate (r=0.988) with high-performance liquid chromatography, the gold standard for serum bilirubin concentration determination.[11] All these measurements were carried out for babies not yet receiving phototherapy as this would influence the accuracy.[6]

Reproducibility of test results was checked by repeating the measurement 5 times on the same patient: a total of seven patients were recruited for this purpose. The study was approved by the hospital ethics committee and informed consent was obtained.

Statistical analysis

At r=0.1 with a power of 0.8 and significance level of 0.05, a sample size of 83 babies was needed. The TcB taken by BiliCheck and that by Minolta Airshields JM 102 were correlated with serum bilirubin levels by calculating the Pearson's product moment correlation coefficient. Sensitivity and specificity of the two instruments in predicting serum bilirubin concentrations of higher than 250 μmol/L were calculated at different cut-off points of TcB.

Results

Of 83 babies, 46 were male and 37 were female. Six were near-term (gestation, 32-37 weeks) and the rest were term babies. The mean gestational age was 38.84 weeks (standard deviation [SD], 1.52 weeks; range, 34.29-41.86 weeks); mean birth weight was 3.12 kg (SD, 0.49 kg; range, 1.95-4.58 kg); and the mean age at the time of data collection was 3.96 days (SD, 1.69 days; range, 2-9 days). Serum bilirubin concentrations ranged from 68 to 387 μmol/L. Most (86%) babies developed jaundice after 48 hours of life, only 12 babies developed jaundice earlier and none was jaundiced before 24 hours of life.

For reproducibility of tests performed on seven newborns, coefficients of variation for Minolta Airshields JM 102 ranged from 0.61% to 2.85%, slightly better than that of BiliCheck (2.63-6.85%). Hence, the reproducibility of the two instruments was satisfactory.

The correlations between serum bilirubin and TcB of the two devices at the two sites were all high, with a coefficient of 0.718 (95% confidence interval [CI], 0.610-0.800; n=100) for TcB at the forehead, and 0.814 (95% CI, 0.740-0.870; n=99) at the sternum taken by Minolta Airshields JM 102; a coefficient of 0.757 (95% CI, 0.657-0.827; n=98) for TcB at the forehead, and 0.794 (95% CI, 0.700-0.862; n=92) at the sternum taken by BiliCheck. The relationships were positive and were significant at the level of 0.01 (2-tailed). Serum bilirubin had higher correlations with TcB at the sternum than at the forehead. Among all, the highest correlation coefficient was obtained for TcB at the sternum using the Minolta Jaundice Meter. The scatterplots of the relationship between serum bilirubin concentration and TcB

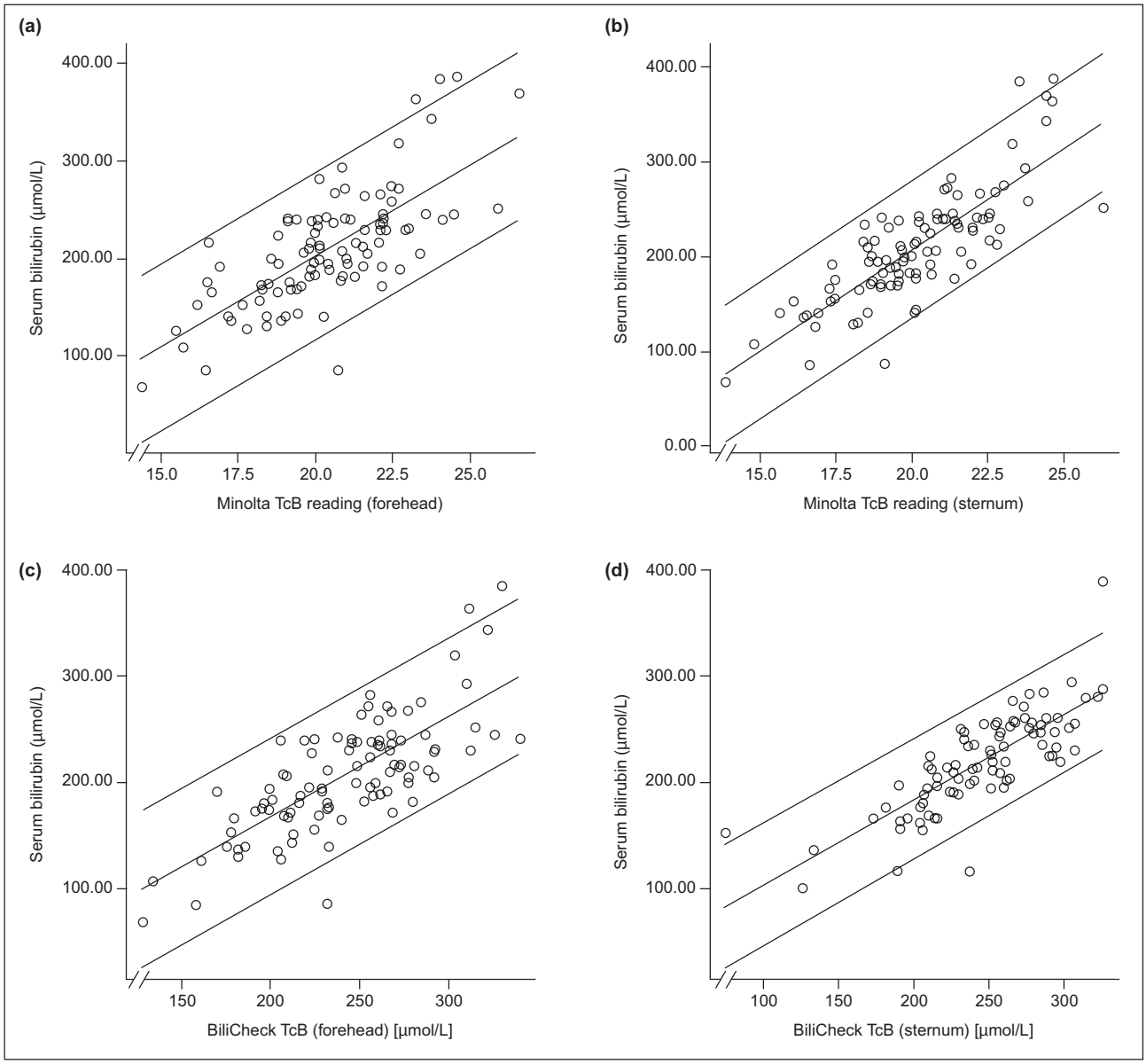

Fig 1. Relationship between serum bilirubin and transcutaneous bilirubin (TcB) meter readings
(a) Minolta Airshields JM 102 (forehead), (b) Minolta Airshields JM 102 (sternum), (c) BiliCheck (forehead), and (d) BiliCheck (sternum)

taken at the two sites by the two devices are shown in Fig 1.

In term and near-term babies with physiological jaundice, serum bilirubin concentration at the level of 250 μmol/L or above was a commonly used indicator for initiation of treatment such as phototherapy.[12] This level was used to determine the sensitivity and specificity of the two devices. Because of the potential risk of hyperbilirubinaemia in newborn babies, a lower specificity was accepted to achieve a sensitivity of 100% to ensure all cases were detected. For Minolta Airshields JM 102, a cut-off point of 20 at the forehead and 21 at the sternum produced a specificity of 50% and 78%, respectively with a sensitivity of 100%. For BiliCheck, a cut-off point of 250 μmol/L at the forehead and 260 μmol/L at the sternum produced a specificity of 61.9% and 70.0%, respectively with a sensitivity of 100%.

A graphical presentation using the receiver operating characteristics (ROC) curves was constructed to compare the two devices (Fig 2). The TcB taken at the sternum using the Minolta Airshields JM 102 produced the best ROC curve (area under the curve was 0.881 at cut-off point of TcB >21). The second best was produced by TcB at the sternum using the BiliCheck (area under the curve was 0.845 at cut-off point of TcB >260 μmol/L). The values of area under the curve using the BiliCheck and the Minolta Airshields JM 102 at the forehead were 0.81 and 0.75, respectively.

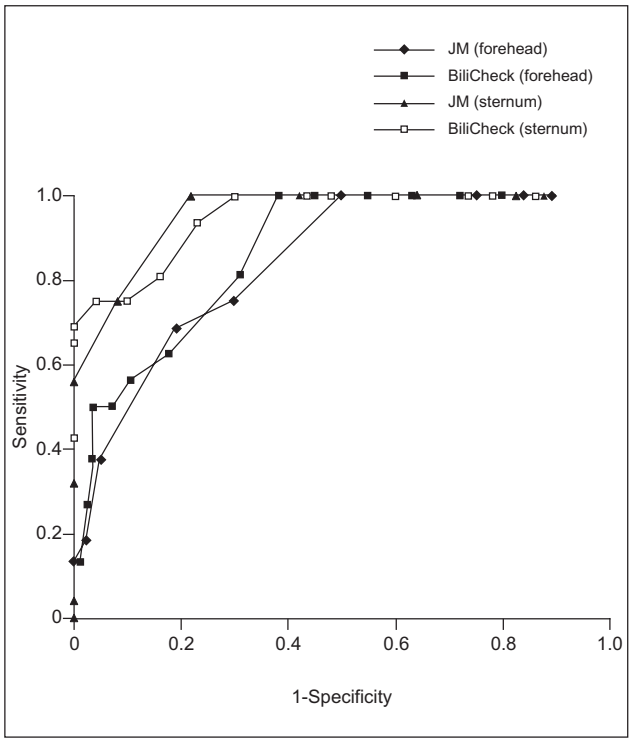

Fig 2. Comparison of receiver operating characteristics curves in predicting serum bilirubin concentration of 250 μmol/L or higher
JM denotes Minolta Airshields JM 102

Discussion

BiliCheck has the theoretical advantage of isolating the light absorption of bilirubin from that of other factors such as haemoglobin or melanin. This is achieved by spectral subtraction and thus generates TcB independent of factors such as race, age, and weight of newborns.[10] Previous studies have confirmed that TcB derived from BiliCheck is not affected by haemoglobin level,[7] gestational age,[7] or ethnicity.[7,8]

This is the first study of the use of BiliCheck in an entirely Asian, in this study, entirely Chinese population. We confirmed that in a Chinese population, the correlation of TcB derived from BiliCheck with serum bilirubin were 0.757 and 0.794 at the forehead and sternum, respectively. For BiliCheck, a cut-off point of 250 μmol/L at the forehead and 260 μmol/L at the sternum produced a specificity of 61.9% and 70.0%, respectively with a sensitivity of 100%. These figures were comparable with those found in a white population.[1-4]

Another characteristic of our studied population is that TcB was taken later in life (3.96 days; range, 2-9 days). This reflects the later development of jaundice in Chinese babies compared with Caucasians.[13]

The differences among the ROC curves of measurements taken at the forehead and the sternum using BiliCheck and Minolta Airshields JM 102 are small. In concordance with the results of previous studies,[1,4,14] we conclude that BiliCheck and Minolta Airshields JM 102 are useful screening tools for neonatal jaundice in Chinese term and near-term babies. The newer BiliCheck device is not superior to the older Minolta device.

Declaration

No conflicts of interest were declared by the authors.

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