

Minolta JM-103 Jaundice Meter: A Screening Tool for Neonatal Jaundice in Chinese Neonates in Maternal and Child Health Centres

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Abstract

Objective: To evaluate the reliability of Minolta JM-103 Jaundice Meter as a screening tool for healthy near term (≥ 35 weeks) to term neonates who presented to the Maternal and Child Health Centres (MCHCs) because of jaundice on day 3-14. **Methods:** This retrospective observational study studied the correlation between the total serum bilirubin (TSB) measurements and the paired transcutaneous bilirubin (TcB) measurements obtained in the MCHCs between January 2008 and July 2009. **Findings:** Transcutaneous bilirubin showed a low correlation with TSB ($r=0.392$) in 253 neonates aged between 3 to 7 days old. The corresponding correlation was moderate ($r=0.674$) in 95 neonates aged between 8 to 14 days old. The mean difference between TcB obtained in the MCHCs and TSB was $15.6 \mu\text{mol/L}$ and $18.6 \mu\text{mol/L}$ in the first and second weeks, respectively; indicating a uniform tendency for JM-103 to overestimate TSB. The corresponding limits of agreement were between -42.9 and $73.1 \mu\text{mol/L}$ in the former group and -42.1 and $79.4 \mu\text{mol/L}$ in the latter group. **Conclusion:** JM-103 cannot be considered a substitute for laboratory measurement of TSB, but appears to be useful as a screening tool in the studied population.

Key words

Maternal-child health centres; Neonatal jaundice; Neonatal screening; Transcutaneous bilirubinometer

Introduction

The American Academy of Pediatrics (AAP) issued clinical practice guidelines in 2004 on the management of hyperbilirubinaemia in the near-term newborn infants and stated that in most newborn populations, noninvasive transcutaneous bilirubin (TcB)-measurement devices generally provide measurements within 2 to 3 mg/dL (34-

51 $\mu\text{mol/L}$) of the total serum bilirubin (TSB) and may replace a measurement of TSB when TSB levels are less than 15 mg/dL (257 $\mu\text{mol/L}$).¹

A new device, Minolta JM-103 Jaundice Meter (Draeger Medical Systems Inc, Telford, US) was introduced into the Paediatric Department of Tuen Mun Hospital (TMH) in January 2008. This new model determines the yellowness of the subcutaneous tissue of a newborn infant by measuring the difference between optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions.² Using two optical paths, the parts that are common to the epidermis and dermis are deducted. As a result, the difference between optical densities of the two wavelength regions can be obtained for subcutaneous tissue only.

Yasuda et al found an excellent correlation ($r=0.94$) between the JM-103 and TSB for all Japanese subjects.² The mean gestational age was 37.8 weeks (range, 25.4-41.4 weeks) and the mean postnatal age was 4 ± 3 days (range, 0-19) in the term infants.² Local studies evaluating term or near-term healthy Chinese neonates within the first week of life have also shown that this new device

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demonstrated good correlation (correlation coefficient was 0.83; $P < 0.001$).^{3,4} In Ho et al's study, the paired TSB readings were taken within 30 minutes of the TcB measurement at the postnatal nursery in Pamela Youde Nethersole Eastern Hospital.³ In Lam et al's study, the paired TSB readings were taken within 5 minutes of the TcB measurement in the Accident and Emergency Department (AED) of TMH.⁴ Transcutaneous bilirubinometer has been routinely used in the Maternal and Child Health Centres (MCHCs) for the past two to three decades as a direct result of local studies.⁵ When the TcB measurements were obtained in the MCHCs but the TSB readings were obtained in the hospital, will such good correlation persist after the lag time in traveling and waiting?

Our primary objective is to evaluate how this lag time will affect the correlation between the JM-103 and TSB readings. Two different time-frame will be studied, namely from day 3 to 7 and from day 8 to 14. Our secondary objective is to assess will this lag time affect the usefulness of JM-103 to act as a screening tool for near term (≥ 35 weeks) to term neonates who presented to the MCHCs because of neonatal jaundice.

Patients and Methods

The Family Health Service (FHS) under the Department of Health is run by the Government of the Hong Kong Special Administrative Region. Under the FHS, 31 MCHCs are distributed throughout five regions in Hong Kong. All child health services including monitoring of jaundice in newborn babies and childhood vaccination provided at MCHCs are free of charge to Hong Kong citizens. Tuen Mun Hospital (TMH) is the only regional hospital in the New Territories West Cluster (NTWC) and it serves a population of over one million. In the NTWC, TMH works with four MCHCs to provide health service to newborn babies.

Since January 2008, the JM-103 Jaundice meter has been used in the Paediatric Department of TMH and one out of the four MCHCs in the NTWC. For the other three MCHCs, the JM-103 has been used since February 2009.

This retrospective study was conducted in the Neonatal Early Discharge Program (NEDP) Clinic in TMH. Under a joint, regional neonatal jaundice referral protocol, newborns aged between 3-14 days having TcB reading ≥ 230 $\mu\text{mol/L}$ in the MCHCs are directly referred to the Department of Paediatrics bypassing the need of AED attendance. The NEDP Clinic runs from Monday to Friday from 9 am to

1 pm. For late attendance, they need to be triaged by the AED to attend the Paediatricians. This NEDP Clinic also accepts in-hospital referral from the postnatal and neonatal nurseries for monitoring jaundice and other medical conditions like feeding problems, cardiac conditions and maternal thyroid diseases.

The study period was from January 2008 to mid July 2009. During this study period, 2585 babies had attended our NEDP Clinic. For those that were referred from the MCHCs for jaundice, their TcB readings over the forehead and mid-sternum obtained in the MCHC were recorded. The same set of TcB measurements were then repeated in the NEDP clinic and recorded. Usually within an hour on arrival to the NEDP clinic, the paired TSB would be checked. Correlation tests were then performed on the higher TcB readings obtained in the MCHC (MCH_higher) and the NEDP Clinic (TM_higher) respectively.

The TSB assay was performed in the hospital chemical laboratory, using the Unistat Bilirubinometer, Model 10311C (Leica Inc, Buffalo, New York), a direct spectrophotometer subjected to daily quality testing and having an upper measurable value of 684 $\mu\text{mol/L}$. Total serum bilirubin at the level of 250 $\mu\text{mol/L}$ was taken as a threshold for admission and initiation of phototherapy.⁶

Statistical Analysis

Statistical Package for the Social Sciences (Windows version 15.0; SPSS Inc, Chicago [IL], US) was used for statistical analysis. The correlation between TcB values and TSB measurements was determined by Pearson's linear regression analysis. As the correlation coefficient between TSB and TcB alone can be misleading, the magnitude of the error of distribution (mean difference (d) between TSB and TcB) as well as the 95% limits of agreement ($d + 1.96$ SD, $d - 1.96$ SD) were determined using the Bland and Altman method.⁷

Results

Among the 2585 babies that had attended the NEDP Clinic during the study period, only 381 babies were eligible for inclusion. Patients aged less than 3 days or more than 14 days were excluded, as were preterm, sick-looking and in-hospital referral. Though the new model JM-103 jaundice meter was introduced into all four MCHCs in February 2009, the old model of the jaundice meter, JM-102 were

still in use in the MCHCs. Thus, only about 15% of the babies had both MCH_higher and TM_higher readings available and were eligible for inclusion.

Demographics

This cohort of patients was the usual attendance of the four MCHCs in the NTWC, namely Madam Yung Fung Shee MCHC (99 babies provided 121 pairs of TcB readings), Tuen Mun Wu Hong MCHC (103 babies provided 113 pairs of TcB readings), Yan Oi MCHC (84 babies provided 100 pairs of TcB readings) and Tin Shui Wai MCHC (41 babies provided 47 pairs of TcB readings). A total of 327 jaundiced near term or term healthy appearing infants (180 males, 147 females) were included. Fifty-two babies were referred to NEDP more than once within the study period. For these repeated NEDP visits, one was on day 3-7 and another was on day 8-14 in 21 babies. While 50 out of 52 babies were referred to us twice, 2 babies had been referred to NEDP for 3 times during the study period. Together, this made up the 381 sets of paired TcB and TSB data. The mean birthweight of all neonates was 3.1 ± 0.8 kg, ranging from 2.3 kg to 4.3 kg, mean gestational age was 38.2 ± 2.5 weeks, ranging from 35 to 41 weeks. The mean postnatal age was 6.6 ± 4.2 days, ranging from 3 to 14 days.

Among them, 2 were Nepalese and one was an Indian. The rest (99.1%) were of Chinese race. Other epidemiological data were listed in Table 1.

Day 3-7

From January 2008 to mid July 2009, 279 pairs of TcB-TSB data obtained between 3 to 7 days from 253 babies were included. The mean age at the time of data collection was 5.5 days; the age distributions of the 279 pairs of TcB-TSB data were shown in Figure 1. The TSB concentrations ranged from 176 to 369 $\mu\text{mol/L}$. One hundred and six TSB data (38%) measured 250 $\mu\text{mol/L}$ or higher.

The higher TcB readings obtained in the MCHCs (MCH_higher) showed a low correlation with the paired TSB reading; the highest correlation coefficient was 0.392 ($P < 0.01$). The equation for the best-fit line was $93.84 + 0.58 \times \text{MCH_higher}$ (Figure 2). The higher TcB readings obtained in TMH (TM_higher) showed a moderate correlation with the paired TSB reading; the highest correlation coefficient was 0.533 ($P < 0.01$).

A Bland-Altman plot for all these 279 pairs of TcB_TSB data is shown in Figure 3. The bias, which was estimated as the mean of the differences between MCH_higher TcB and TSB (i.e. MCH_higher TcB minus TSB) was equal

Table 1 The epidemiological characteristic of the studied subjects

	ALL	Day 3-7	Day 8-14	<i>p</i> -value*
No. of data sets	381	279	102	---
No. of babies**	327	253	95	---
Non Chinese, no. of babies	Indian, 1 Nepal, 2	Nepal, 2	Indian, 1	---
Sex, male : female	180 : 147	130 : 123	65 : 30	---
Maturity (weeks)	38.2 ± 2.5	38.3 ± 2.4	37.9 ± 2.8	0.07 NS***
Birth weight (kg)	3.1 ± 0.8	3.2 ± 0.7	3.1 ± 0.8	0.157 NS***
Mode of feeding:				
- Exclusively breast fed;	144 / 381 (37.8%);	96 / 279 (34.4%);	48 / 102 (47.1%);	<0.05
- Partially breast fed;	155 / 381 (40.7%);	120 / 279 (43.0%);	35 / 102 (34.3%);	0.126 NS***
- Formula fed	82 / 381 (21.5%)	63 / 279 (22.6%)	19 / 102 (18.6%)	0.406 NS***
Excessive weight loss, >7%	19 / 381 (4.99%)	18 / 279 (6.45%)	1 / 102 (0.98%)	<0.05
History of phototherapy	84 / 381 (22.1%)	39 / 279 (14.0%)	46 / 102 (45.1%)	<0.05
G6PD deficiency	14 / 327 (3.7%)	8 / 253 (3.2%)	6 / 95 (6.3%)	0.166 NS***
ABO incompatibility	4 / 327 (1.1%)	2 / 253 (0.8%)	2 / 95 (2.1%)	---

* *p*-value, *p*-value between the day 3-7 group and the day 8-14 group.

** No. of babies include 21 babies with NEDP Clinic visits during both study periods, on day 3-7 and on day 8-14.

*** NS, not significant

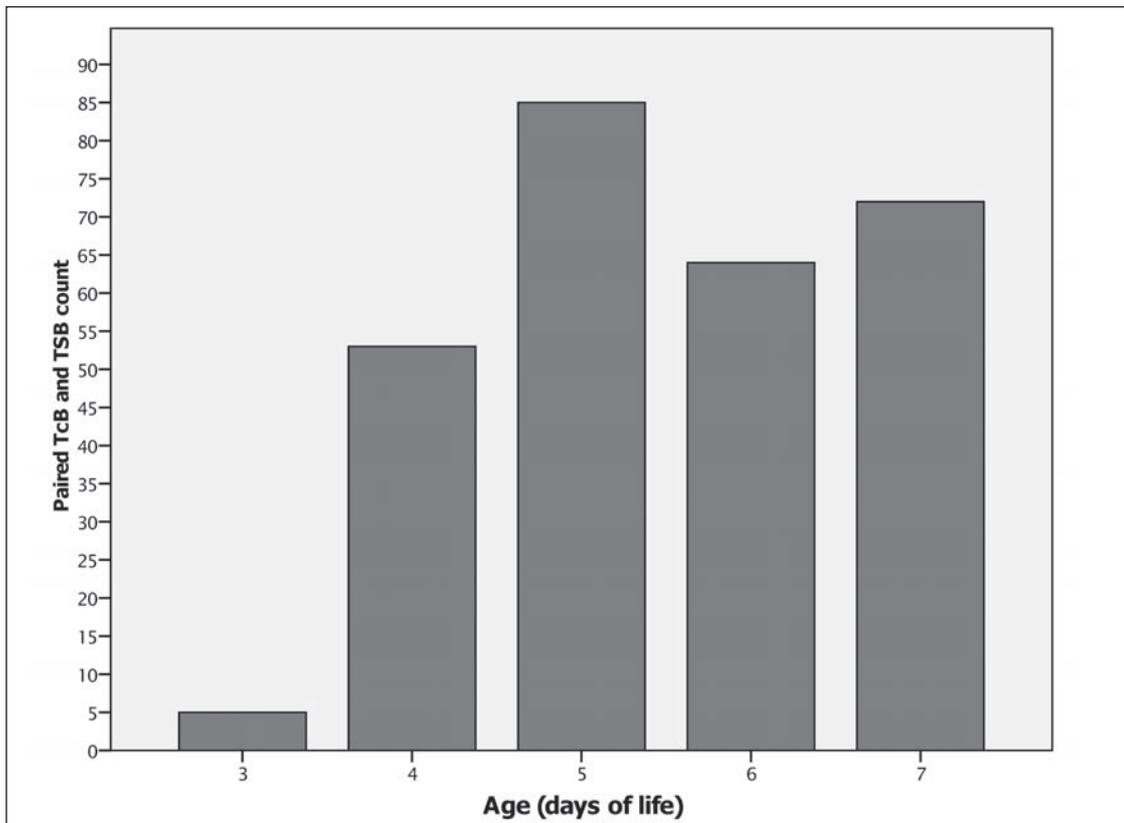


Figure 1 Age distribution of neonates aged between 3 to 7 days. TcB denotes transcutaneous bilirubin and TSB denotes total serum bilirubin.

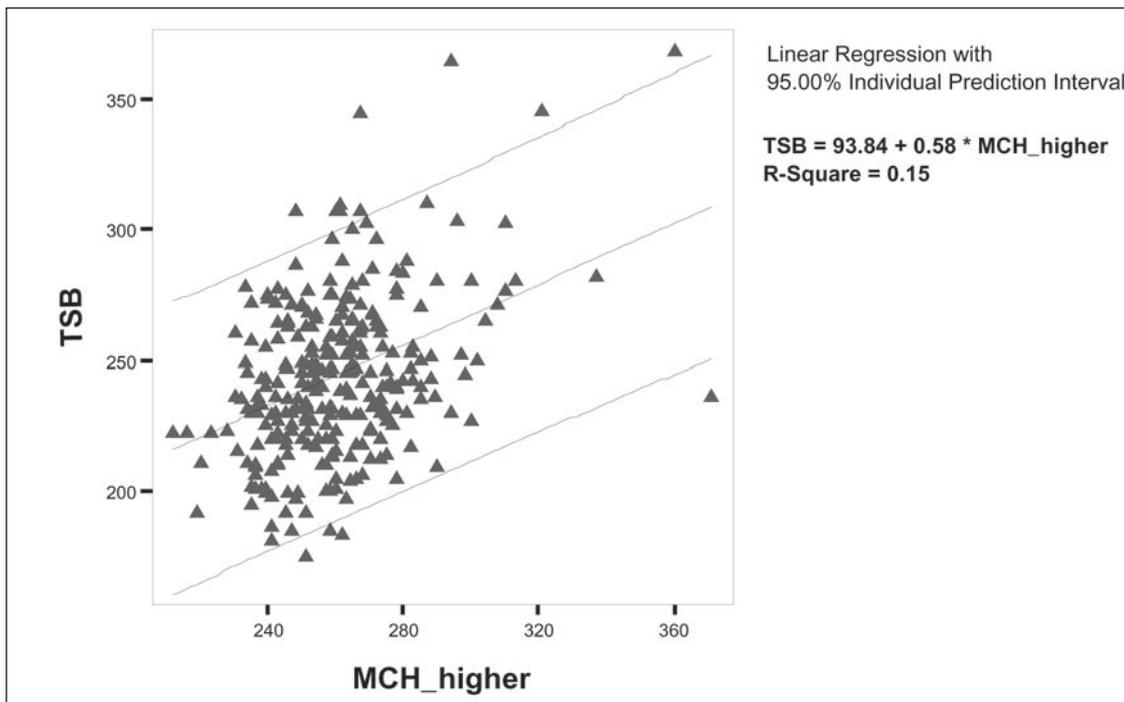


Figure 2 Higher TcB readings obtained in the MCHCs (MCH_higher) vs total serum bilirubin (TSB) scatter diagram for babies aged between 3 to 7 days.

to 15.6 $\mu\text{mol/L}$ (standard deviation, 29.3; $P < 0.001$) indicated a uniform tendency for JM-103 to overestimate TSB. The 95% limits of agreement were between -42.9 and 73.1 $\mu\text{mol/L}$ (Figure 3).

Day 8-14

From January 2008 to mid July 2009, 102 pairs of TcB-TSB data obtained between 8 to 14 days from 95 babies were included. The mean age at the time of data collection was 9.6 days; the age distributions of the 102 pairs of TcB-TSB data were shown in Figure 4. The TSB concentrations ranged from 172 to 546 $\mu\text{mol/L}$. Twenty seven TSB data (26%) measured 250 $\mu\text{mol/L}$ or higher.

The higher TcB readings obtained in the MCHCs (MCH_higher) showed a moderate correlation with the paired TSB reading; the highest correlation coefficient was 0.674 ($P < 0.01$). The equation for the best-fit line was $-45.66 + 1.10 \times \text{MCH_higher}$ (Figure 5). The higher TcB readings obtained in TMH (TM_higher) also showed a moderate correlation with the paired TSB reading; the highest correlation coefficient was 0.671 ($P < 0.01$).

A Bland-Altman plot for all these 102 cases is shown in Figure 6. The bias, which was estimated as the mean of the differences between MCH_higher TcB and TSB (i.e. MCH_higher TcB minus TSB) was equal to 18.6 $\mu\text{mol/L}$ (standard deviation, 31.0; $P < 0.001$) indicated a uniform tendency for JM-103 to overestimate TSB. The 95% limits of agreement were between -42.1 and 79.4 $\mu\text{mol/L}$ (Figure 6).

Discussion

This study was the first to evaluate the use of JM-103 in the MCHCs in Hong Kong. It provided new information on the use of the JM-103 device in South East Asian neonates aged 8 to 14 days who had neonatal jaundice. It has filled the information gap left by previous local studies, which focused on subjects within the first week of life and were performed outside community based setting.^{3,4} It explored the effect of lag time on the validity of the jaundice meter readings at different ages.

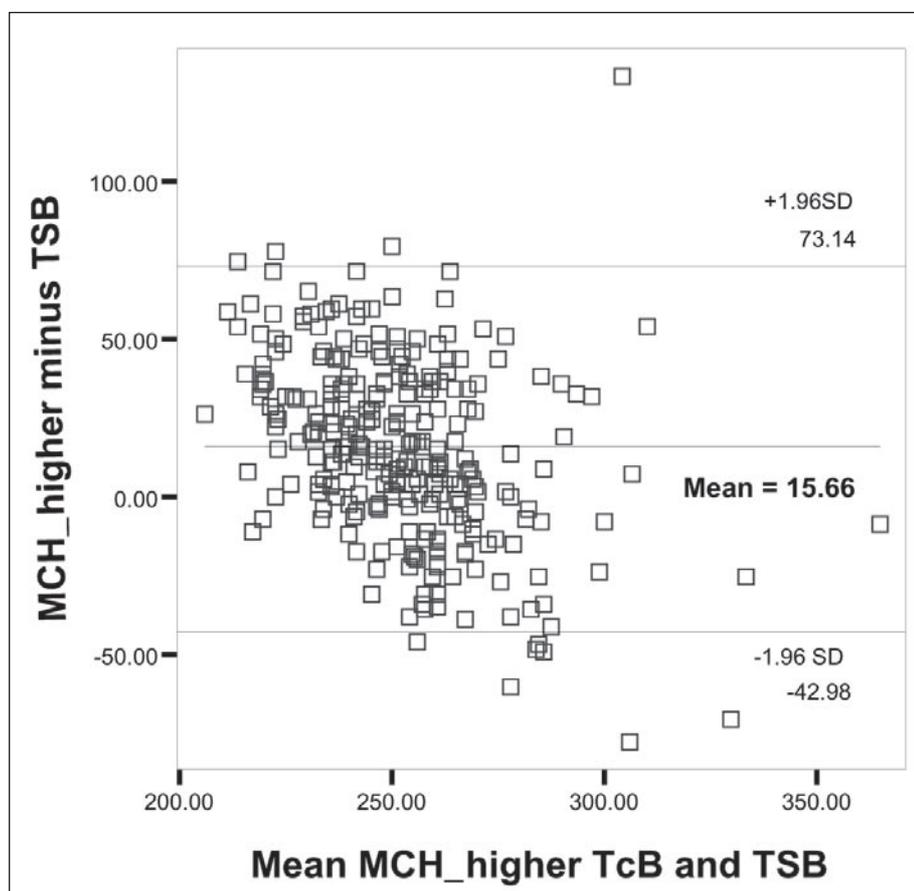


Figure 3 The Bland-Altman plot of transcutaneous bilirubinometer (TcB) and total serum bilirubin (TSB) for babies aged between 3 to 7 days.

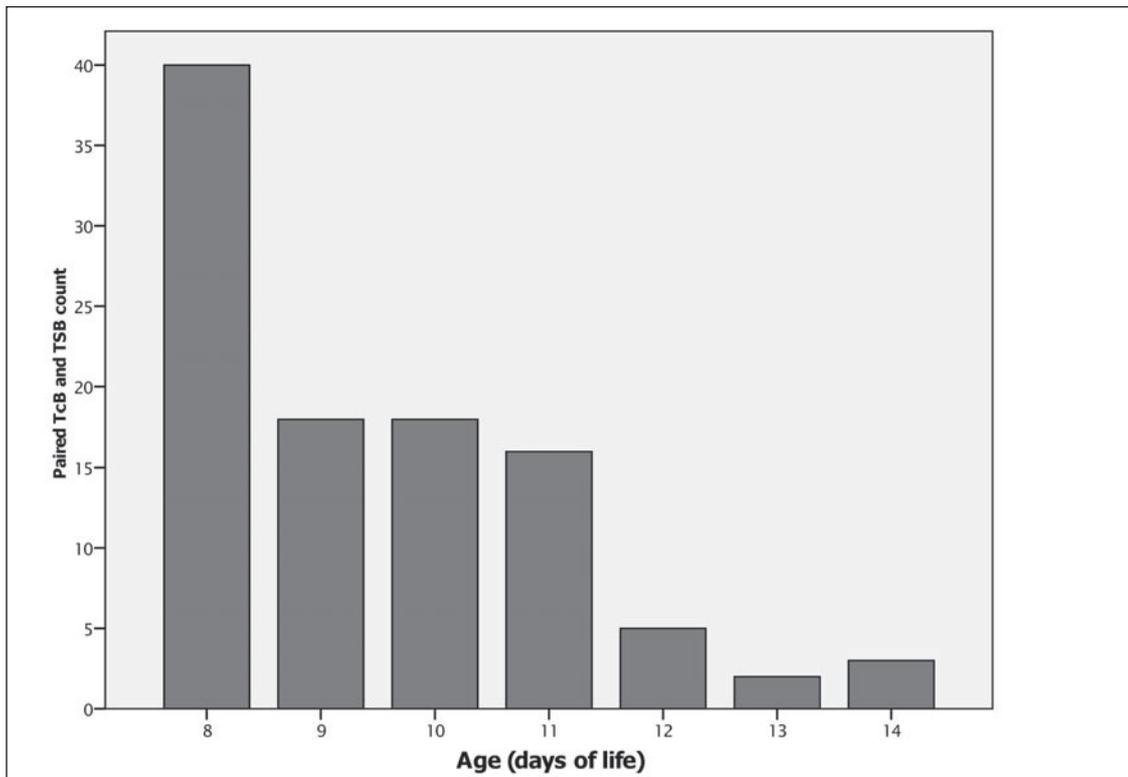


Figure 4 Age distribution of neonates aged between 8 to 14 days. TcB denotes transcutaneous bilirubin and TSB denotes total serum bilirubin.

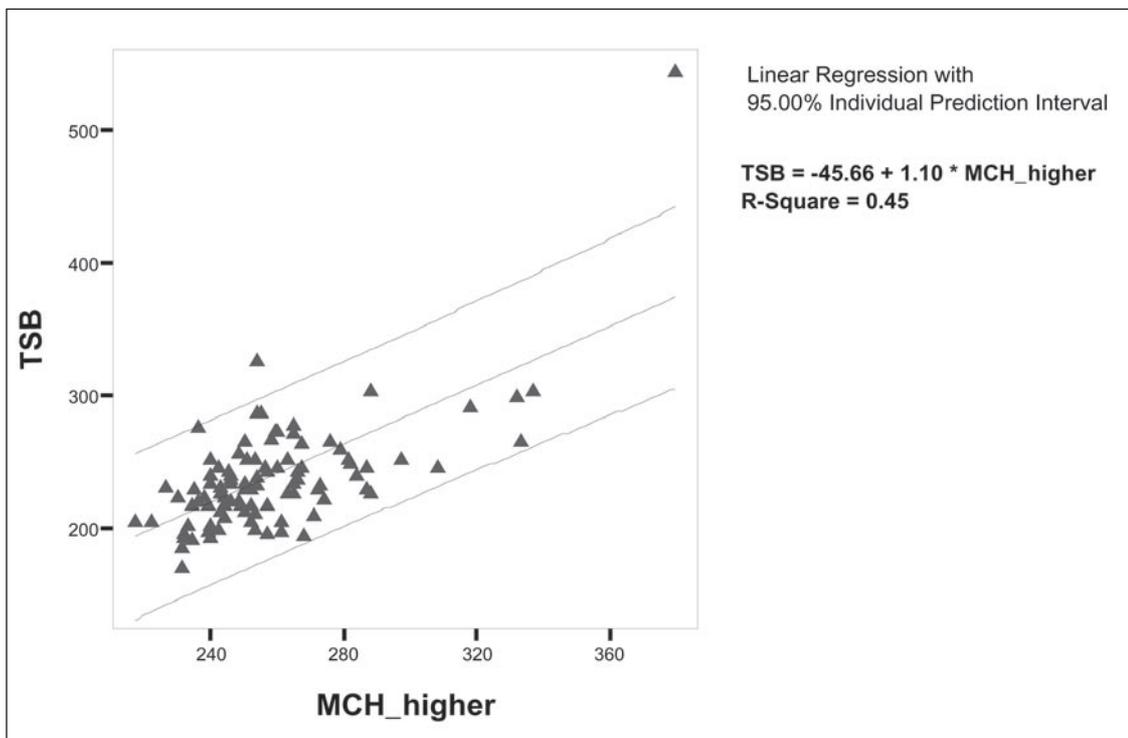


Figure 5 Higher TcB readings obtained in the MCHCs (MCH_higher) vs total serum bilirubin (TSB) scatter diagram for babies aged between 8 to 14 days.

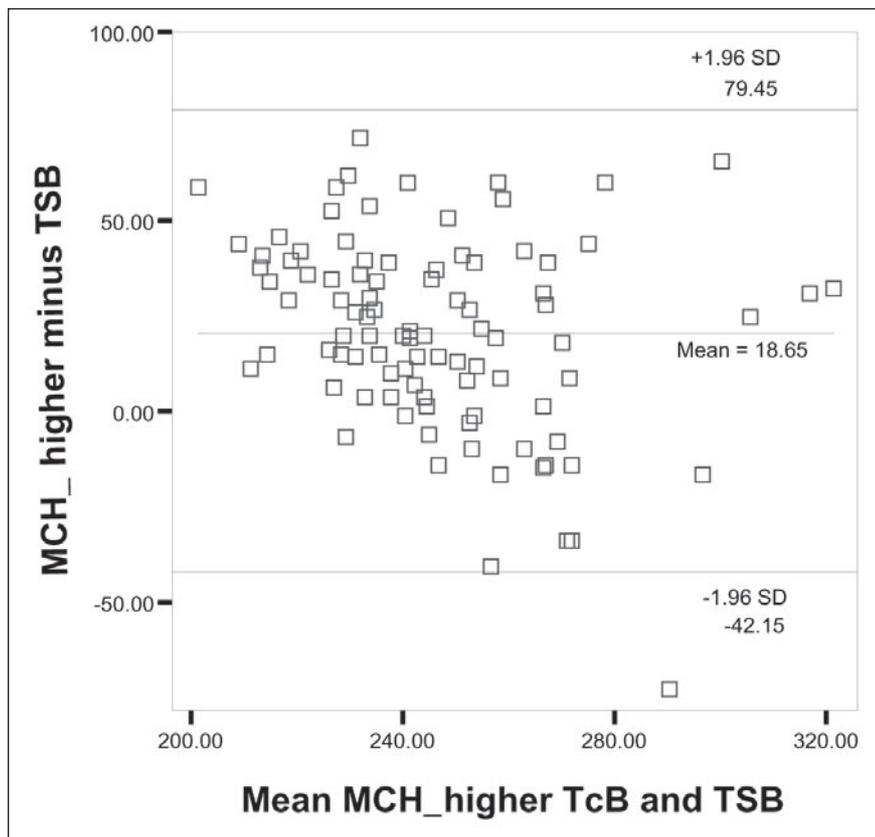


Figure 6 The Bland-Altman plot of transcutaneous bilirubinometer (TcB) and total serum bilirubin (TSB) for babies aged between 8 to 14 days.

Demographics

Ethnicity

In the previous local studies by Ho et al³ and Lam et al,⁴ only Chinese neonates were included. In this study, we have not excluded other East Asians, namely Indian & Nepalese just as in the multiracial study performed by Maisels et al,⁸ in which the East Asians, Indian/Pakistani were counted as a group and found to have a close correlation between TSB and TcB values of 0.926.

Mode of Feeding

Our study is the first of this kind to report the mode of feeding among the studied population. In this cohort, 77.4% of the babies were on breast milk during the first week of life and by the second week of life, this figure increased to 81.4%. More importantly, there was a significant increase in the proportion of babies that were on exclusive breast feeding.

Excessive Weight Loss

The cutoff point of 7% was set according to AAP

recommendation.⁹ In this cohort, among the 18 episodes of excessive weight loss during the first week of life in 17 babies, 12 episodes were associated with exclusive breast feeding, 3 episodes were associated with mixed feeding and the rest 3 were associated with formula feeding. The single baby with excessive weight loss that was repeatedly referred to NEDP Clinic on day 4 and 5 was on exclusive breast feeding. By the second week of life, none of them was referred back again. In the second week of life, the single episode of excessive weight loss belonged to a newly attended exclusively breast fed baby.

History of Phototherapy

In our cohort, the proportion of babies with history of phototherapy in the older group (aged 8-14 days) was three-fold than that of the younger group (aged 3-7 days). However, better correlation was seen in the older group. This finding lends further support to Tan et al's findings of recovery of skin colour occurred within 18-24 hours after cessation of exposure.¹⁰ In TMH, we advise the jaundiced babies to visit the MCHC the day after discharge. In this way, by the time the baby was seen in the MCHC, it will be

at least 24 hours after cessation of phototherapy and in accordance with Tan et al's findings, the good correlation should return by then.

Lag Time Effect on Correlation Between TcB and TSB

In previous local studies, good correlation ($r=0.83$) between TcB and TSB could be seen throughout the first week of life no matter the baby was in a postnatal nursery or in the AED.^{3,4} Our NEDP clinic is situated in the same hospital complex as the AED and the same chemical laboratory uses the same method to perform the TSB assay. We should expect similarly good correlation be obtained in our study. However, the correlation between TSB and the TcB readings obtained in the NEDP clinic was just moderate ($r=0.53$) and the correlation between TSB and the TcB readings obtained in the MCHCs was even lower ($r=0.39$). We believe that the low correlation observed was mainly due to the time lag between the TcB check and the corresponding serum bilirubin measurement.

The jaundice assessment sessions start at 9 am in the MCHCs and the NEDP clinic stops seeing babies referred from MCHCs for jaundice if they arrived late after 11:30 am. Usually within an hour on arrival to the NEDP clinic, the paired TSB would be checked. So, the maximal time lag between TcB check in MCHCs and paired TSB check would be within 4 hours.

Ho et al's study³ is a retrospective study and so is ours. However, the former study controlled the paired TSB measurements be checked within 30 minutes but ours were checked at variable times depending on the availability of the phlebotomies. Also, in Ho et al³ & Lam et al's studies,⁴ under controlled setting, prior arrangement was usually made with the laboratory to facilitate the TSB be measured as soon as possible after blood collection. One of the authors in Yasuda et al's study was from the JM-103 manufacturer company, Minolta.² In this study, the authors reported that as photoisomerisation and degradation of bilirubin in the samples will occur during transport and preservation, the TSB should be measured as soon as possible. Our study reflects practical difficulties in view of absence of on-site TSB assay. Under this setting, we can hardly expect the serum bilirubin sample be transported to the laboratory and processed without delay in a busy running hospital, a situation far from ideal.

In our study, as both groups of babies were handled in

the same way during the same period of time, the impact of non-controlled setting should affect both of them to the same extent. However, out of our expectation, the TSB correlation difference between the MCHCs and TMH readings in the younger group was absent in the older group. This finding can only be explained by intrinsic factor difference as the extrinsic factors (environments and handling) are practically identical for both groups of babies.

For the difference in intrinsic factors, a comparison between the younger and older groups had been made and was shown in Table 1. Statistically significant difference existed only in the proportion of babies on exclusive breast feeding, with excessive weight loss and history of phototherapy. These factors are conditional factors, which was present in at most 47% of our studied subjects. One probably universal intrinsic factor difference would be the different natural courses of "physiological" jaundice at different ages.

Natural Course of "Physiological" and Breast Milk Jaundice

At birth, healthy babies do not have jaundice. Over the first few days, serum bilirubin begins to accumulate and the mean age of peak serum bilirubin was 83 hours for "physiological" jaundice⁵ and was later till the end of the first week for breast milk jaundice.¹¹ After reaching the peak, the serum bilirubin begins to decline. The decline in serum bilirubin is rapid initially, especially if the baby is treated with phototherapy.¹ After entering the second week of life, the decline becomes more gradual.¹¹ This phenomenon is indirectly shown in Figures 1 and 4.

Excluding the data on day 3, which was probably biased by not having the babies returned to the community from the delivering hospital, a trend of fluctuations at high levels (range 65-85) was seen in Figure 1 but a predominantly static level below 20 was seen in Figure 4. In our cohort, up to 80% of the babies suffered from breast milk jaundice and about 20% suffered from physiological jaundice. With this composition of population acting in concert with inter-individual variation, it seems adequate to explain the different trends in the two figures. In the second week of life, the slow pace in the decline of TSB may make the effect of lag time less apparent as there may just be a minimal drop in TSB during the lag time. This may help to explain the absence of TSB correlation difference between MCHCs and TMH readings in babies aged 8-14 days.

Lower Correlation Than Previous Studies

Compared with previous TcB-TSB correlation studies that were performed using JM-103, our study yielded the lowest correlation because of the retrospective and observational nature.

In our study, the epidemiological characteristics were obtained from review of the computer record. There was no preset data sheet to fill and recall bias may exist. The recall bias particularly affects the information collected on prior phototherapy. In 34 out of 381 (8.9%) pairs of the data, the information on prior phototherapy was not clearly documented and could not be retrieved from the electronic patient record as the baby was delivered in the private sector. While 27 pairs were contributed by the younger group, 7 pairs were contributed by the older group. For the sake of simplicity, these unconfirmed data were interpreted as no prior phototherapy. If the unconfirmed data were considered as having prior phototherapy, this would constitute up to 23.7% of the younger group and phototherapy would lower the correlation.

Concerning lag time estimation, the estimated figure of 4 hours has not taken into account of the delay in process in the laboratory as there was no prior arrangement with the laboratory. This waiting time in the laboratory may have further underestimated the correlation.

Ho et al's study³ was performed in a postnatal nursery on the first 3 days. The correlation that they obtained ($r=0.83$) was comparable with that reported in the study by Maisels et al ($r=0.915$), which was mainly of white or black races.⁸ Both studies were conducted in babies on the first 3 days without prior phototherapy.

In our study, the younger group of babies (aged 3-7 days) should be compared with Lam et al,⁴ Engle et al¹² and Tan et al's¹⁰ studies as their studied subjects were of similar ages. In Engle et al's study, 92% of the studied subjects were Hispanic and with high TSB (47% ≥ 15 mg/dl) and had not received prior phototherapy.¹² Overall correlation between TcB and TSB was 0.77 among 121 subjects.¹² This correlation coefficient is comparable with Lam et al's study, which also consisted of subjects with high TSB (48% ≥ 250 $\mu\text{mol/L}$) but had not excluded cases with prior phototherapy.⁴ The highest correlation was 0.83.⁴ Tan et al's study evaluated the reliability of transcutaneous bilirubinometry during and after phototherapy and noted that recovery of skin colour occurred within 18-24 hours after cessation of

exposure.¹⁰ In the post-phototherapy period, correlation recovered on day 1 (chest $r=0.80$; forehead, $r=0.70$), and further improved on day 2 (chest $r=0.84$; forehead, $r=0.80$). From the aforementioned studies, it looks as if prior phototherapy does not have significant effect on TcB correlation provided that phototherapy has been stopped for at least a day.

Overall, above studies seem reflecting a trend. For babies in the first 3 days, the correlation between TcB and TSB was better, ranging from 0.83 to 0.915. From day 2 to 7, the correlation was weaker but still satisfactory, ranging from 0.77 to 0.84.

Moderate Correlation Between TcB and TSB on Day 8-14

The correlation between TcB and TSB in the second week of life has not been well studied and our study is the first to show that moderate correlation exists ($r=0.67$). Moreover, this correlation was shown to be reproducible using different data sets obtained from the MCHCs and the NEDP clinic respectively. This finding is plausible. As the JM-103 Jaundice Meter was designed to reflect the dermal bilirubin only, the limitation posed by the increase in dermal thickness and melanin deposition as the baby matures may be overcome.²

As explained before, the retrospective and observational nature of our study may weaken the correlation between the TcB and TSB readings. So, the moderate correlation that we observed may be an underestimation. Lining up this correlation coefficient of 0.67 with the trend previously mentioned, it will then be 0.83 to 0.915 in the first 3 days, 0.77 to 0.84 from day 2 to 7 and ≥ 0.67 in the second week.

Patient Safety Issue

In daily practice, we always put patient's safety in the first priority. This explains why we use the higher TcB value to process. With the JM-103, we found that the predominant tendency is for the TcB value to overestimate TSB levels. This finding is coherent with what were reported by the two local studies and Maisels et al's study.^{3,4,8} This overestimation is an advantage for the JM-103 to function as a screening tool as dangerous errors may be minimised.

Correlation Versus Agreement

The correlation coefficient is a measure of the strength of the relationship between two variables, not the agreement between them. Agreement is how much the new method, the JM-103 Jaundice Meter in our case, is likely to differ from the old, the TSB assay in our case. If this is not enough to cause problems in clinical interpretation, we can replace the old method by the new or use the two interchangeably.⁷ The plot of difference between two methods of measurements against the average of the two methods was devised by JM Bland and DG Altman in year 1986. Ever after its publication, this statistical method was widely used in studies of this kind, jaundice meter studies.^{3,4} The mean and standard deviation of the differences would enable us to estimate how far apart measurements by the two methods on the same subject were likely to be.

In this study, the mean of the difference between TcB readings obtained in the MCHCs and TSB was 15.6 $\mu\text{mol/L}$ on day 3-7 and 18.6 $\mu\text{mol/L}$ on day 8-14. The consistent positive findings during the two time frame indicate that a uniform tendency for JM-103 to overestimate TSB. Thus, the JM-103 Jaundice Meter is capable in screening but cannot replace the TSB assay.

Limitations of the Study

First, the retrospective and observational nature of this study, coupled with absence of controlled settings was the greatest limitation. Second, the TSB was measured by a direct spectrophotometric method in our chemical laboratory rather than the gold standard high-performance liquid chromatography. Third, different JM-103 devices were used in different MCHCs by different operators that may introduce errors.

Conclusion

When the TcB measurements were obtained in the MCHCs but the TSB readings were obtained in the hospital, the lag time in traveling and waiting was observed to weaken the correlation between the TcB and TSB readings, apparently to greater extent in the first week of life. Despite of this lag time effect, low ($r=0.392$) and moderate

($r=0.674$) correlations remained in the first and second week, respectively. Moreover, uniform tendency for JM-103 to overestimate TSB is present in both time frames. These findings imply that the lag time effect would not affect the usefulness of the JM-103 to act as a screening tool for near term (≥ 35 weeks) to term neonates who presented to the MCHCs because of neonatal jaundice.

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