

Original Research Article

Kramer's scale or transcutaneous bilirubinometry: the ideal choice of a pediatrician? can we trust our eyes?

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ABSTRACT

Background: Neonatal hyperbilirubinemia, though benign in 80% cases, can lead to kernicterus if not diagnosed and treated early. The golden method of estimation is measuring serum bilirubin levels. Both Kramer's scale and Transcutaneous bilirubinometer are non-invasive methods. Its high time the pediatricians choose an ideal non-invasive and reliable method to detect hyperbilirubinemia. Objective of this study is to find out which has a better correlation with serum bilirubin - transcutaneous bilirubinometer reading (TcB) or Kramer's scale.

Methods: The study was conducted in a tertiary newborn center from November 2014 to June 2016. The inclusion criteria included all babies above 34 weeks gestation and exclusion criteria included babies with established direct hyperbilirubinemia, neonatal septicemia, major congenital/ gastrointestinal malformations and those on phototherapy. The sample size was 450 and the correlation was analyzed using ROC curves and plots of agreement was done using Bland Altman charts.

Results: The incidence of significant Hyperbilirubinemia is 12%. Transcutaneous bilirubin level had a better correlation and prediction level compared to Kramer at both 24 hours and 48 hours. Bland Altman analysis showed that transcutaneous values were closer to the total serum bilirubin level compared to Kramer values.

Conclusion: Transcutaneous bilirubinometry is a better and more ideal choice to replace serum bilirubin levels. In settings where TcB is not feasible, it's always best to screen for jaundice using Kramer's scale rather than estimating serum bilirubin values in all babies. In babies where TcB levels are above the cut off range, it's better to do serum bilirubin levels.

Keywords: Hyperbilirubinemia, Jaundice, Kramer scale, Newborns, Serum Bilirubin, Transcutaneous bilirubinometry

INTRODUCTION

Neonatal hyperbilirubinemia is one of the most common issues in neonatal period that leads to increased hospitalization and undue stress to the parents. The problem of finding an accurate and specific method of bilirubin assay has for 50 years occupied the attention of many workers. In the early days, jaundice was assessed by the visual examination of the babies. But this was

subjective and inaccurate, often confounded by skin pigmentation.¹ The conventional method of measuring serum bilirubin requires repeated blood sampling, which is invasive, costly and leads to increased blood loss with multiple sampling.²

Over the last few decades, transcutaneous bilirubinometry has emerged as a safe, simple, cost effective non-invasive modality in the screening and

monitoring of jaundiced new-borns.^{3,4} But its clinical utility is limited to a screening method rather than a replacement for invasive blood sampling.

Our study is to see which of the two non-invasive methods- Kramer's scale or transcutaneous bilirubinometry is a better modality to assess the risk of neonatal hyperbilirubinemia.

The ideal choice will be the one which is more reliable and correlates better with the serum bilirubin levels. The primary outcome was to assess whether transcutaneous bilirubin correlates better with total serum bilirubin when compared to Kramer's scale readings.

METHODS

STUDY POPULATION: This was a prospective observational study on inborn babies above 34 weeks gestational age, from November 2014 to June 2016 in a neonatal unit of a medical college hospital in South India.

The inclusion criteria included all babies above 34 weeks gestation. The exclusion criteria included babies with established direct hyperbilirubinemia, septicemia, major congenital/ gastrointestinal malformations and those started on phototherapy.

Sample size was calculated using the formula:

$$N = (TP+FN)/p \quad TP+FN = (Z^2 * \{SN(1-SN)\})/d^2$$

SN = sensitivity of the new test, TP = true positive, FN = false negative, d= error margin or precision, p = prevalence of the disease under study

In the present study 450 samples were collected. The study protocol was approved by the institutional review board and ethics committee. Written informed consent was obtained from the mothers for using their baby's de-identified data. Confidentiality was maintained throughout the study. The clinical and dimorphic profile of the mother and the baby was collected using a proforma.

The Kramer's scale is based on a 1969 study of 108 full term infants which found that bilirubin concentrations were correlated to five specific dermal zones. At 24 and 48 hours, the infant's skin was blanched using thumb pressure and the level where the yellow color ended was marked and Kramer's zone assigned. Observations were taken under florescent lighting augmented during daylight hours by the principal investigating officer to avoid the chances of investigator bias.

Table 1 shows different dermal zones (I to V)- head and neck, upper trunk, lower trunk, arms and legs and finally palms and soles divided by the bilirubin levels according to the Kramer scale.⁵

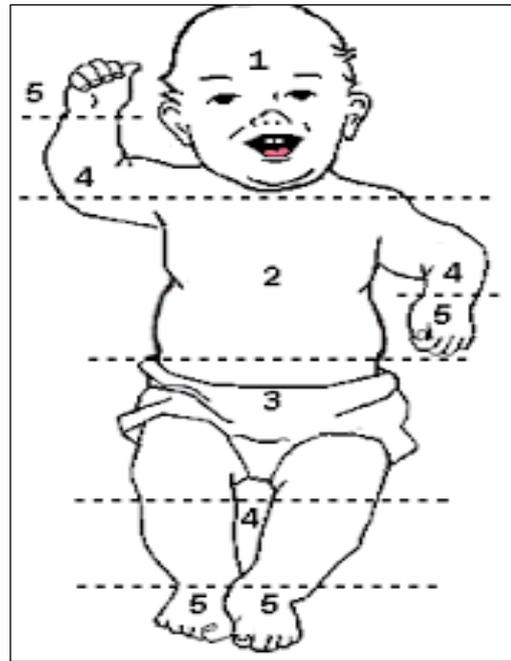


Figure 1: Kramer scale and the different dermal zones according to the bilirubin levels (© Image from Szabo P, Wolf M, Bucher HU, Fauchère J-C, Haensse D, Arlettaz R. Detection of hyperbilirubinemia in jaundiced full-term neonates by eye or by bilirubinometer? *Eur J Pediatr.* 2004 Dec;163(12):722-7).⁵

Table 1: Kramer scale and the different dermal zones according to the bilirubin levels.

Zone	1	2	3	4	5
Definition	Head and neck	Upper trunk	Lower trunk and thighs	Arms and lower legs	Palms and soles
TSB (micro moles/l)	100	150	200	250	>250
TSB (mg/dl)	5.85	8.77	11.70	14.62	>14.62

Transcutaneous bilirubin levels (TcB) were estimated with Drager Jaundice Meter JM-105 by placing the instrument on the baby's sternum. Sternum was taken as the principal site of measurement as several studies have shown excellent correlation with TSB compared to the other sites.^{6,7} An average of three readings was taken as the TcB value.

Approximately 1 ml of venous blood was collected in a microtainer clot activator tube for assessing total serum bilirubin (TSB) level under strict aseptic precautions and measured using the Diazo method in the automated analyzer Cobas Integra 400 plus from Roche Diagnostics.

The maximum interval of time between the transcutaneous measurement and the collection of blood for total serum bilirubin was 30 minutes.

All babies were visually examined every 6 hours on the first day of life by a trained physician and twice a day thereafter. At 24 hours TSB and TcB was done on all babies and later repeated as per attending clinician's discretion. Data was entered in Microsoft Excel and analyzed using the SPSS version 20.0. Pearson's correlation and Bland Altman analysis were used for studying the data.

RESULTS

Demography of the cohort is given in Table 2. The males were 245(54.4%) while female babies were 205(45.6%).

Out of 450 babies, 293(65.1%) babies were delivered by vaginal delivery, 23(5.1%) by instrumental delivery and 134(29.8%) were delivered by Cesarean section. According to growth, 396(88%) babies were AGA, 52(11.6%) babies were SGA and only 2(0.4%) babies were LGA. According to birth weight, 40(8.9%) babies were <2000g, 167(37.1%) babies had 2000-2499g, 187(41.6%) babies had 2500-2999g, 45(10%) babies had weight from 3000-3499g and finally 11(2.4%) babies had weight more than 3500g.

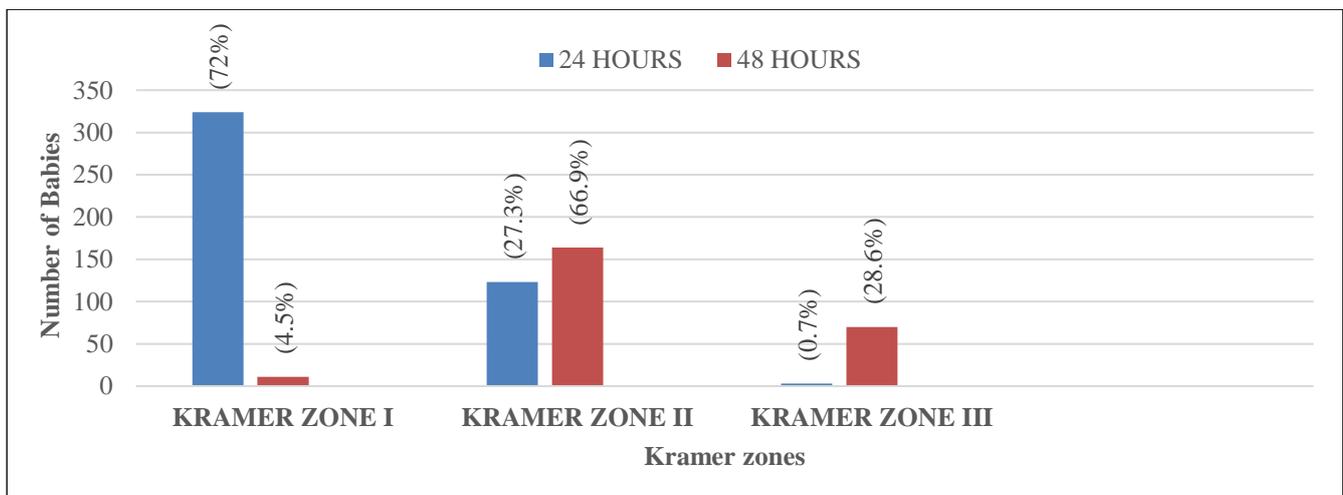
Preterm babies were 38 (8.4%), remaining were term babies. Significant hyperbilirubinemia was seen only in 54(12%) babies, remaining 396(88%) babies had insignificant hyperbilirubinemia.

At 24 hours, serum bilirubin, TcB and Kramer's scale evaluation are done for all 450 babies. The serum bilirubin levels were found to be elevated at 24 hours for 248 babies.

Table 2: Demography of the study population.

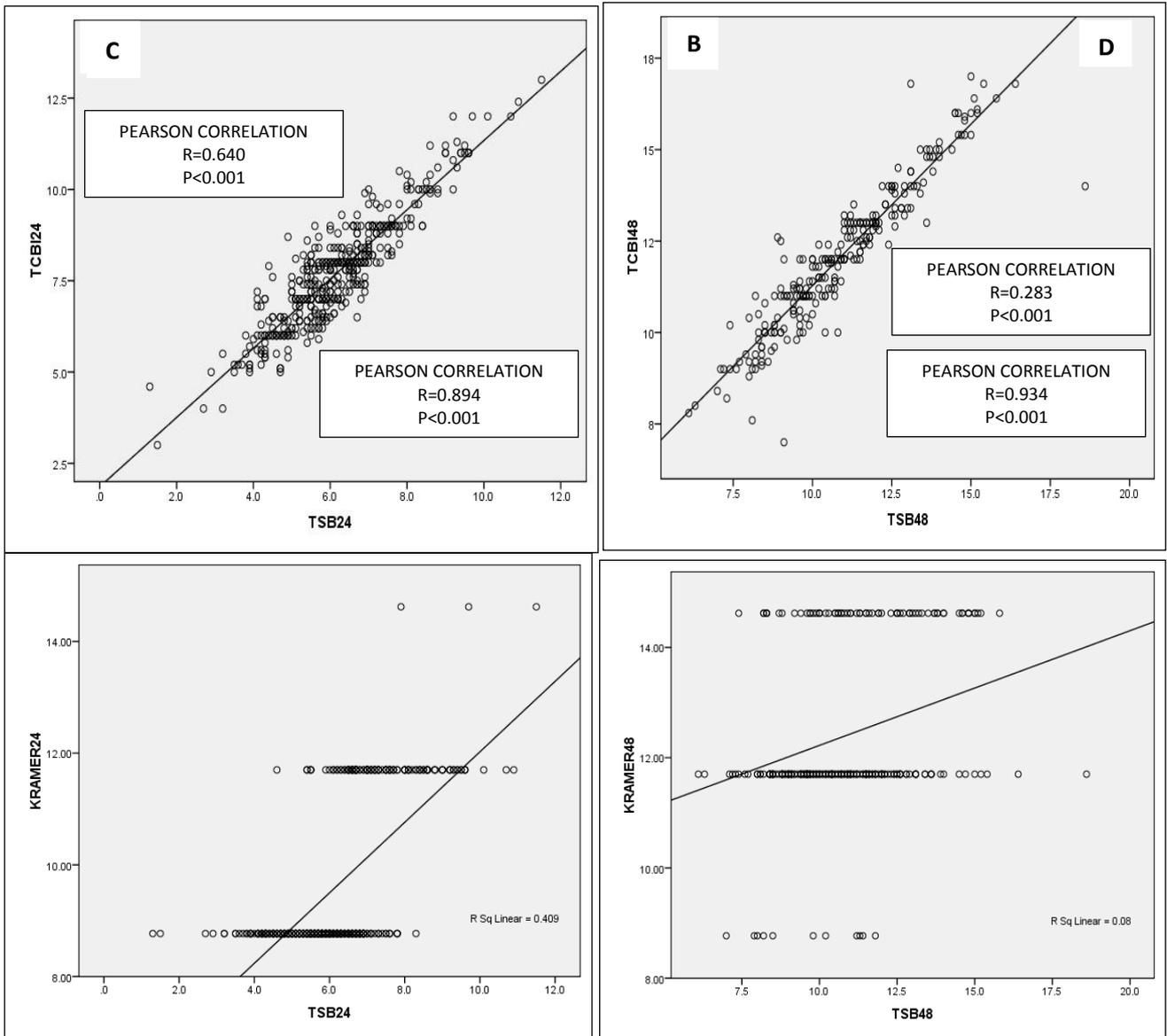
Characteristics	Number (n=450)	(%)
SEX		
Male	245	54.4
Female	205	45.6
Birth Weight		
<2000g	40	8.9
2000-2499g	167	37.1
2500-2999g	187	41.6
3000g-3499g	45	10.0
>3500g	11	2.4
Mode of delivery		
Normal vaginal delivery	293	65.1
Instrumental delivery	23	5.1
Caesarean delivery	134	29.8
Gestational Age		
34-36 ⁶ weeks (late preterm)	38	8.4
37- 39 ⁶ weeks (term)	355	78.9
>40 weeks	57	12.7
Growth		
Small for gestational age	52	11.6
Approximate for gestational age	396	88
Large for gestational age	2	0.4
Hyperbilirubinemia		
Significant	54	12
Not significant	396	88

Hence serum bilirubin levels were repeated at 48 hours, along with Kramer's evaluation and TcB for these babes.



In figure 2, at 24 hours, 72% babies were in Kramer Zone I, 27.3% babies were in Kramer zone II and only 0.7% babies were in Kramer zone III. By 48 hours, 66.9% babies were in Kramer zone II and 28.6% babies were in Kramer zone III.

Figure 2: Number of babies at 24 and 48 hours in different Kramer zones.



Transcutaneous bilirubin (TCB) comparatively better correlated with total serum bilirubin (TSB) values at 24 hours ($r=0.894$) and 48 hours ($r=0.934$) as shown in Figure 3A and 3B, compared to Kramer's value with at 24 hours ($r=0.64$) and at 48 hours ($r=0.283$) as shown in figure 3C and 3D.

Figure 3: Graph showing correlation of TsB with TcB and kramer at 24 and 48 hours

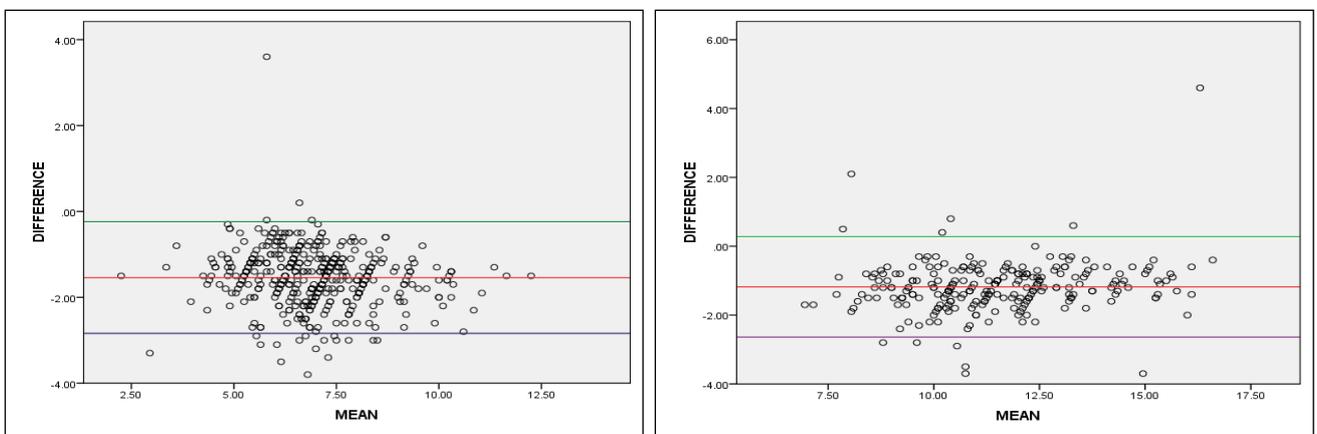


Figure 4: Bland altman plot with TsB and TcB at 24 hours and 48 hours.

Table 3: Significant hyperbilirubinemia at 24 and 48 hours in different TsB percentiles.

At 24 hours									
TsB Percentile	Significant Hyperbilirubinemia	Insignificant Hyperbilirubinemia	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	LR	Accuracy (%)	P value
>40	53 (20.5%)	205 (79.5%)	98.2	48.2	20.5	99.5	1.9	54.2	<0.001
<40	1 (0.5%)	191 (99.5%)							
>75	45 (42.9%)	60 (57.1%)	83.3	84.9	42.9	97.4	5.5	84.7	<0.001
<75	9 (2.6%)	336 (97.4%)							
>95	19 (95%)	1 (5%)	35.2	99.8	95	91.9	139.3	92.0	<0.001
<95	35 (8.1%)	395 (91.9%)							
At 48 hours									
>40	45 (30.2%)	104 (69.8%)	88.2	47.2	30.2	93.9	1.7	55.7	<0.001
<40	6 (6.1%)	93 (93.9%)							
>75	36 (58.1%)	26 (41.9%)	70.6	86.8	58.1	91.9	5.4	83.5	<0.001
<75	15 (8.1%)	171(91.9%)							
>95	10 (100%)	0 (0%)	19.6	100	100	82.8	-	83.5	<0.001
<95	41 (17.2%)	197 (82.8%)							

Table 3 shows that at lower TsB percentiles, the sensitivity of detecting significant hyperbilirubinemia is significantly higher at both 24 and 48 hours with sensitivity of 98.2% and 88.3% respectively. As the TsB percentile increases, the sensitivity decreases, but specificity increases. All the values are significant.

Table 4: Mean serum bilirubin levels at 24 and 48 hours in different kramer zones.

Kramer Zone	TsB at 24hr (Mean±SD)	TsB At 48hr (Mean±SD)
>4-<6 (zone I)	5.6±1.0	9.6±1.7
>6-<8 (zone II)	7.5±1.2	10.6±1.9
>8-<12 (zone III)	9.7±1.8	11.7±2.1
Total	6.2±1.4	10.9±2.1
F value	155.2	10.555
P value	P<0.001	P<0.001

Table 4 shows that at 24 hours, Kramer zone 1 had mean TsB 5.6±1.0, zone II 7.5±1.2 and zone III had 9.7±1.8. At 48 hours, Kramer zone 1 had mean TsB 9.6±1.7, zone II had 10.6±1.9 and zone III had 11.7±2.1.

Table 5: Mean Kramer values at 24 hours and at 48 hours among significant hyperbilirubinemia infants.

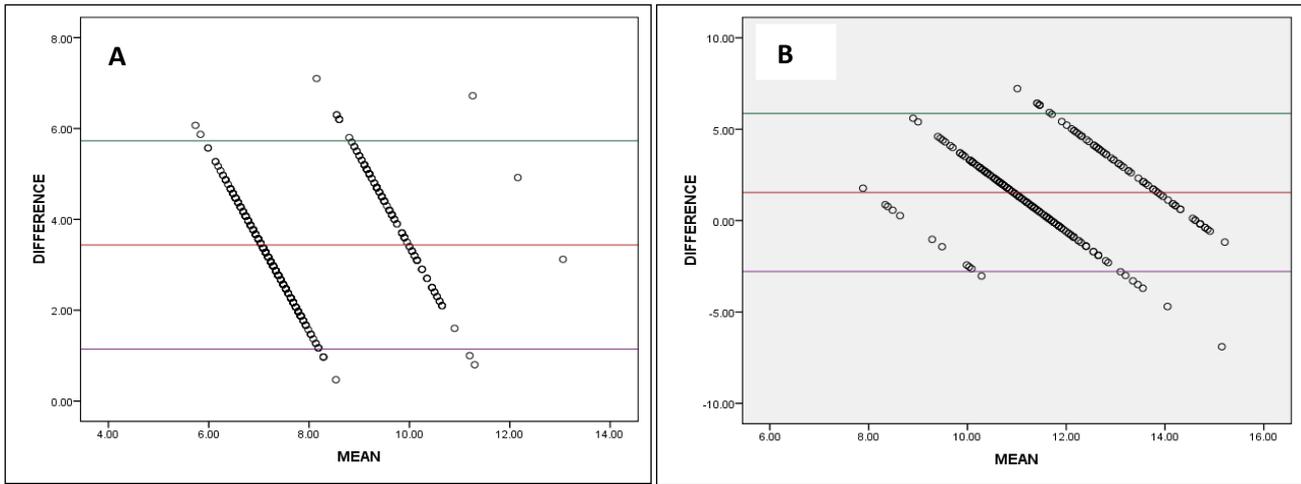
Time	Photo	N	Mean Kramer	Std. Deviation	T value
At 24 hrs.	Significant hyperbilirubinemia	54	11.6	1.0	13.93
	Insignificant hyperbilirubinemia	396	9.3	1.2	P <0.001
At 48 hrs.	Significant hyperbilirubinemia	50	13.0	1.5	3.39
	Insignificant hyperbilirubinemia	195	12.2	1.5	P=0.001

Table 5 shows that at 24 hours, significant hyperbilirubinemia was seen in 54 babies with mean Kramer value of 11.6 ±1.0, while insignificant hyperbilirubinemia was seen in 396 babies with mean Kramer value of 9.3 ±1.2. At 48 hours, 50 babies had significant hyperbilirubinemia with mean Kramer value of 13 ±1.5. All the values were significant.

Table 6: Roc analysis to predict significant hyperbilirubinemia.

Variable	Area under the curve	95% confidence interval		P value
		Lower bound	Upper bound	
TCBI 24 hour	0.908	0.862	0.953	<0.001
TCBI 48 hour	0.824	0.748	0.900	<0.001
TSB 24 hour	0.938	0.904	0.971	<0.001
TSB 48 hour	0.856	0.788	0.923	<0.001
Kramer 24 hrs	0.872	0.825	0.919	<0.001
Kramer 48 hrs	0.625	0.537	0.712	0.007

It is evident from the above table 6; the prediction of significant Hyperbilirubinemia was better by total serum bilirubin followed by trans-cutaneous bilirubin and least by Kramer scale values. The area under the curve was maximum for TSB (0.938), followed by TCBI (0.908) and last by Kramer (0.872) at 24 hours. The area under the curve was more for TSB (0.856), followed by TCBI (0.824) and last by Kramer (0.625) at 48 hours All the values are significant.



Transcutaneous bilirubin over estimated serum bilirubin values at 24 hours and 48 hours by 1.5 units and 1.2 units respectively as shown in Figure 4A and 4B and these differences were statistically significant. Kramer values under estimated serum bilirubin values at 24 hours and 48 hours by 3.4 units and 1.5 units respectively as shown in Figure 5A and 5B and these differences were statistically significant.

Figure 5: Bland altman plot with TsB and Kramer at 24 hours and 48 hours.

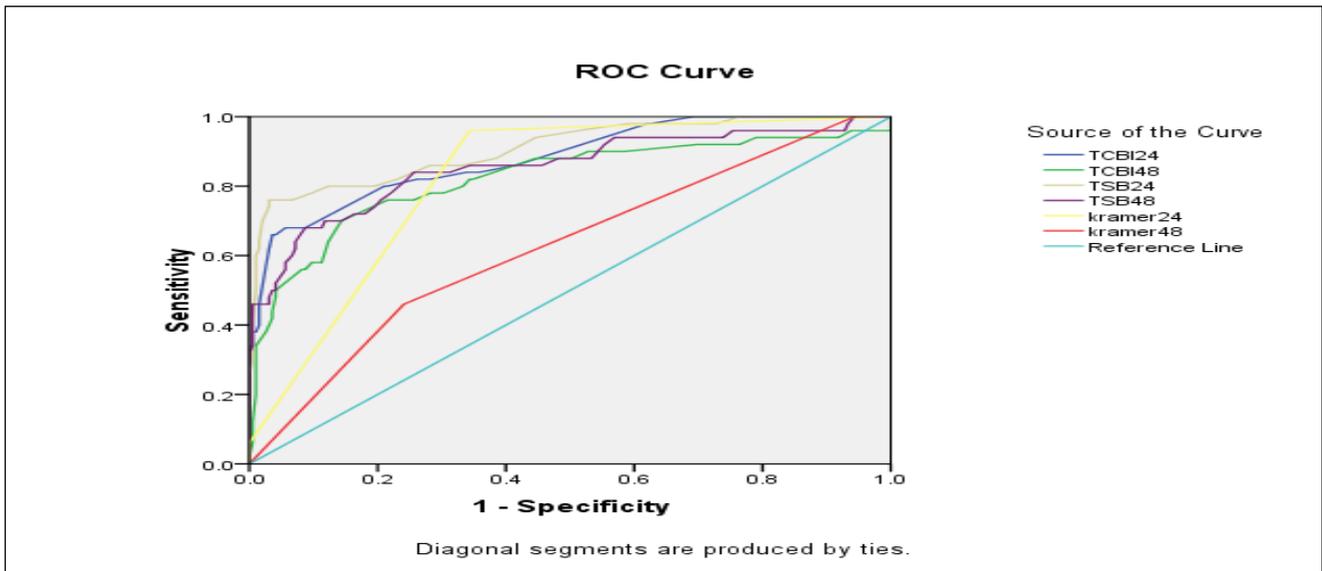


Figure 6: Roc curves showing TsB, TcB and Kramer at 24 and 48 hours with significant hyperbilirubinemia.

DISCUSSION

Neonatal hyperbilirubinemia has always been a matter of concern for pediatricians worldwide. Visual examination by Kramer’s scale has been used from many decades for screening of hyperbilirubinemia in new-borns. Being non-invasive and cost-free evaluation, it is of valuable assistance to health personnel where laboratory facilities are not readily available.⁸ With the introduction of measuring serum bilirubin in the diagnosis of hyperbilirubinemia, babies were being pricked multiple times to check for the rise or fall of serum bilirubin levels. This not only adds to the worry and stress of parents and pain and blood loss for babies.

Transcutaneous bilirubinometry has come a long way as an effective tool for assessing bilirubin levels in new-borns since its introduction about 4 decades ago.

In new-borns, Knudsen explained that there was a cephalocaudal progression of jaundice which is apparently related to the conformational changes in the newly formed bilirubin-albumin complexes.⁹ Another reason attributed to this direction of progression, is the relative thickness of skin at various parts with the skin being the thinnest at face and thicker over the palms and soles. In the case of preterm babies, as the skin is relatively thinner, jaundice occurs even at lower serum bilirubin levels. With increase in the gestational maturity

and postnatal age, this cephalocaudal color difference is found to decrease.

There have been differences in opinions among many pediatricians regarding the usefulness of the Kramer's scale. It is true that in poor resource settings, Kramer's scale continues to be effective in diagnosing significant hyperbilirubinemia if examined by trained professional.^{5,10,11} In healthy term babies, hyperbilirubinemia can be safely ruled out by visual assessment if jaundice does not reach the abdomen or the extremities (Kramer zones 1 and 2).¹² This is similar to our study that shows that as Kramer scores increase, chances of significant hyperbilirubinemia also increase Table 4.

But the other school of thought remains that the visual estimation of actual bilirubin levels by the yellowness of the skin can be unreliable and can cause errors in judgement and therefore delay in treatment. In darkly pigmented infants' errors are found to be more. In the 1940's, Davidson et al suggested the variability of the skin color and bilirubin values is different in different babies and not observer-dependent.¹³ Later, Kramer et al in the 1960's reported that a single observer noting the presence or absence of jaundice in five dermal zones had poor correlation with serum bilirubin levels in each of the dermal zones.¹⁴ Studies have shown that babies in high risk group were misclassified when visual assessment was used to detect hyperbilirubinemia.^{15,16} Joan et al demonstrated the ineffectiveness of the Kramer scale as a screening instrument with sensitivity and specificity at less than 48 hours being 67% and 47% respectively and between 49-72 hours the sensitivity and specificity being 89% and 54% respectively.¹⁷ The difference between a TSB level of 5mg/dl and 8mg/dl cannot be perceived by eye, yet this is the difference between a TSB level at the 50th and the 95th centile thus again causing potential error in the prompt management of hyperbilirubinemia. The situation gets even more difficult once phototherapy is started as the skin gets bleached and then the severity of the jaundice becomes unreliable. Results of these studies indicate that visual cues alone are not sufficient in detecting jaundice and should not be used as a screening mechanism for further assessment. A more systematic approach to detection of jaundice is, therefore, required.

Transcutaneous bilirubinometer has significantly reduced the need for blood sampling in jaundiced term and late-preterm neonates compared with systematic visual assessment of bilirubin.^{18,19} Studies have shown that routine use of transcutaneous bilirubinometry Mishra et al showed that the need for blood sampling to assess hyperbilirubinemia was 34% lower in the TcB group compared with visual assessment group.²⁰ Kaplan et al did a similar study using 100 paired readings and showed that 49 babies had serum bilirubin samples taken based on TcB compared with 83 serum samples taken as detected by visual assessment.²¹ Gupta et al conducted a prospective study in Manipal over a one year period (2007-2008) and showed poor correlation with clinical

assessment ($r = 0.757$) than with TcB taken at the forehead (TcB(F) $r = 0.798$) and the sternum (TcB(S) $r = 0.801$).²² Szabo et al too showed that transcutaneous bilirubinometer showed better correlation with serum bilirubin levels than visual assessment in preterm babies, but cannot replace serum bilirubin in severe jaundiced preterms.²³ Our study shows that Tcb is better indicator for significant hyperbilirubinemia than Kramer's scale. The Bland Altman plots show that both at 24 and 48 hours, Tcb overestimates and Kramer values underestimate serum bilirubin values respectively, thus Tcb helps to minimize or reduce the possibility of missing any case with neonatal hyperbilirubinemia (Figure 4,5).

A study from Italy concluded that the combined use of visual assessment and icterometer results in improved sensitivity and specificity as compared to serum blood sampling results.²⁴

CONCLUSION

This study was the first of its kind to be done in the South Indian population. But it has some limitations too. Firstly, it is not a population-based study and it represents the data of a single tertiary care hospital in South India. Secondly was the subjectivity of the visual assessment of jaundice.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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