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Comparative Study Between Transcutaneous Bilirubin With Serum Bilirubin In Clinically Icteric Neonates.

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ABSTRACT

Newborn jaundice due to severe hyperbilirubinemia, with its potential for producing brain damage, remains a continuing problem for pediatricians. A prevailing understanding is that newborn jaundice is mostly benign and that the occurrence of kernicterus is extremely unusual. Recent reports and evaluation of safety data have demonstrated visual assessment of jaundice as an unreliable and unsafe indicator to initiate a concern for severe hyperbilirubinemia. To study the correlation between Trans Cutaneous Bilirubin measurement and serum bilirubin measurement in clinically icteric neonates. The study was conducted in the Department of Pediatrics at the newborn ward in Sri Muthu Kumaran Medical College and Hospital and Research Institute, Chennai in the year 2024. The study population included 100 newborns of term babies. There are a total of 53 males and 47 females. Clinically icteric newborns that fulfilled the inclusion criteria were included in the study, and the level of jaundice based on Kramer's rule was assessed. Transcutaneous bilirubin (TcB) measurements were taken using a Draeger JM 105. Transcutaneous bilirubinometer over the mid-sternum area and forehead and the mean of 3 values was considered as the final value. TcB recorded in 100 babies was 9.0-20.2 mg/dl and TSB was 8.3- 22mg/dl. The mean TcB and TSB were 14.11 and 14.06 mg/dl. There was a significant correlation between TcB and TSB with a correlation coefficient of 0.961. Transcutaneous bilirubinometry is a useful non-invasive screening tool in detecting hyperbilirubinemia in newborns and should be used routinely before discharging the baby from the hospital

Keywords: Bilirubinometer, Hyperbilirubinemia, Jaundice, Neonate

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INTRODUCTION

Newborn Jaundice is a very common condition in newborns, affecting up to 60% of term newborns and 80% of preterm newborns in the first week of life. Jaundice is caused by increased bilirubin in the blood from the breakdown of red blood cells [1]. The gold standard for measuring bilirubin levels is obtaining a blood sample and processing it in a laboratory. However, noninvasive transcutaneous bilirubin (TcB) measurement devices are widely available and used in many settings to estimate total serum bilirubin (TSB) levels. In recent years, however, new methods have been developed to evaluate the severity of neonatal jaundice, involving transcutaneous bilirubinometry (TcB), which is easy and non-invasive and also minimizes blood loss to an infant through more invasive blood assays [2]. Hence, knowledge of the infant at risk of developing hyperbilirubinemia allows early intervention before critical levels are reached [3]. Several pre-discharge screening strategies based on total serum bilirubin, transcutaneous bilirubin, or clinical risk factor scoring have now been suggested as strategies to identify an at-risk group of infants to be tracked more closely [4]. In addition, there have been calls to adjust the recommendations for interventions with phototherapy or exchange transfusions to include lowered total serum bilirubin (TSB) thresholds in the more vulnerable population: near-term (<38 weeks' gestation) infants, those at earlier postnatal ages (<72 hours), and those who have hypoalbuminemia or presence of comorbidities [5]. The transcutaneous bilirubinometer is a device that measures the spectral reflectance of bilirubin by determining the difference between optical densities for light in the blue (450 nm) and green (550 nm) wavelengths—a dual optical path system [6]. The measurement of bilirubin accumulated primarily in the deeper subcutaneous tissue should decrease the influence of other pigments in the skin, such as melanin and hemoglobin. The device gives a direct TcB measurement in terms of mmol/l or mg/dl, which allows direct interpretation. Some degree of jaundice is seen in 60-70% of term and about 80% of preterm newborns. Chemical jaundice (serum bilirubin level 2mg/dl) is universal in newborns. 6.1% of well-term newborns have a maximum serum bilirubin over 12.9mg/dl. Serum bilirubin level >15mg/dl is seen in 3% of normal-term newborns [7]. Many newborns who are clinically doing well at the time of discharge, may develop hyperbilirubinemia at a later date. Ignorance on the part of parents may result in late reporting and thereby lead to complications inherent to hyperbilirubinemia [8]. Hence, at the time of discharge, there is a need to adopt a method to predict the likely development of hyperbilirubinemia [9]. Early prediction facilitates the use of effective preventive measures, early treatment and thereby reducing mortality and morbidity. As such, from the obvious need to design and implement a follow-up program, the present study was conducted to measure bilirubin levels using a transcutaneous bilirubin meter, which could help diagnose neonatal hyperbilirubinemia in the early stages, thus enabling timely intervention and better outcome in newborns with hyperbilirubinemia [10].

MATERIALS AND METHODS

The study was conducted in the Department of Pediatrics at the newborn ward in Sri Muthukumuran Medical College and Hospital and Research Institute, Chennai in the year 2024. The study population included 100 newborns of term babies. There are a total of 53 males and 47 females. Inclusion criteria: Term Newborns with clinical icterus, Newborns < 10 days. Exclusion criteria: Newborns with birth asphyxia, Newborns with major congenital malformations, Newborns who received phototherapy, Newborns with more than 10 days. Newborns who have conjugated hyperbilirubinemia. The information collected regarding all the selected cases was recorded in a Master Chart. Clinically icteric newborns that fulfilled the inclusion criteria were included in the study, and the level of jaundice based on Kramer's rule was assessed. Transcutaneous bilirubin (TcB) measurements were taken using a Draeger JM 105. Transcutaneous bilirubinometer over the mid-sternum area and forehead and the mean of 3 values was considered as the final value. The recorded value was compared with the standard TcB nomogram. Total serum bilirubin (TSB) levels were done using the diazo method. If TcB levels were above the 50th centile level on the nomogram. TSB was measured within 30 min of checking TcB levels.

Statistical analysis

The Statistical software namely SAS-9.4M8 2023 version was used for the analysis of the data, a 'p' value less than 0.05 is taken to denote a significant relationship. Correlation coefficient and percentiles were calculated using Excel Software. If the value of 'r' between two variables is more than $\pm$ 0.5. then those two variables are taken to be correlated.

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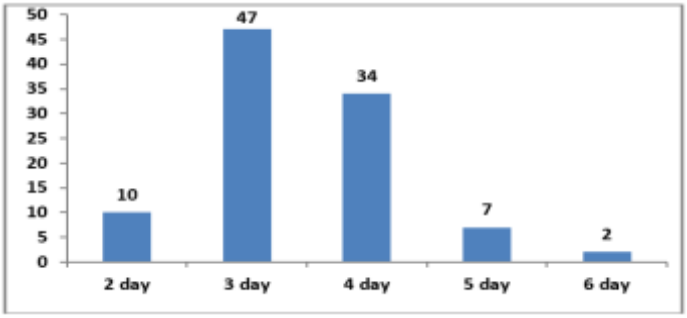
RESULTS

Graph 1: Distribution of age on babies



Graph 1: In the present study the babies included were from Day 2 to Day 6 of life, majority (47%) of the babies were included on Day 3 of life.

Table 1: Comparison of TSB values according to age

Age (in days)	Serum bilirubin (mg/dl)	
	Mean	SD
2	12.06	±1.21
3	13.64	±2.68
4	14.79	±2.50
5	16.56	±3.33
6	12.62	±2.80
P Value	0.003 Significant	

Table 1 In this present study there was a significant correlation between age and mean TSB values with p value 0.003. With the highest mean TSB recording on day 5 being 16.56 mg/dl.

Table 2: Comparison of TSB values according to gestational age

Gestational Age (in weeks)	N	Total Serum Bilirubin (mg/dl)	
		Mean	SD
37-38(Early term)	65	14.01	±2.79
39-40(full-term)	35	14.14	±2.67
P Value		0.827 Not Significant	

Table 2: In this present study there was no significant correlation between gestational age and TSB. The highest mean TSB of 14.14 mg/dl was recorded at 39 to 40 weeks gestation and the least of 14.01 mg/dl at 37 to 38 weeks.

Table 3: Antenatal complications

Antenatal History	Frequency	Percent
Anemia	9	9.0
GDM	6	6.0
Hypothyroidism	10	10.0
Hypothyroid/Gdm	1	1.0
Oligohydramnios	4	4.0
PiH	6	6.0
PiH/Anemia	1	1.0
PiH/Hypothyroid	2	2.0
PROM	1	1.0
No Complications	60	60.0
Total	100	100.0

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Graph 2: showing Visual Assessment Kramer's rule

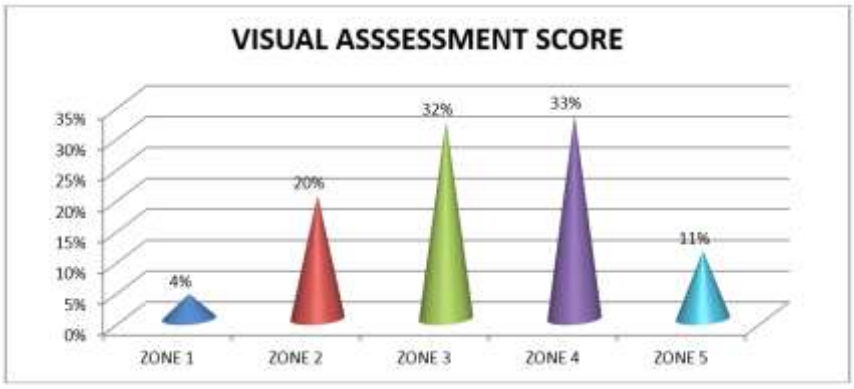
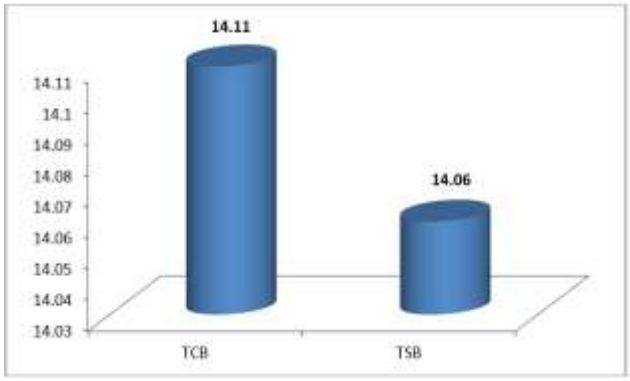


Table 4: Comparison of TSB Values According to Visual Assessment

Visual Assessment Zone	Mean	SD
1	12.80	±1.62
2	10.82	±1.76
3	13.62	±1.61
4	15.10	±1.73
5	18.53	±1.41
Total	14.06	±2.73
P value	<0.001 Significant	

Table 4: In the present study, 33% of babies were in zone 4 when visually assessed by Kramer's rule. There was a significant correlation between TSB and visual assessment (p<0.001)

Table 5: Comparison of TcB and TSB



In the present study, 34% of babies were in zone 3 when visually assessed by Kramer's rule. There was a significant correlation between TcB and visual assessment (p<0.961) **. Correlation is significant at the 0.01 level.

DISCUSSION

Jaundice is a clinical condition that is present in neonatal practice and constitutes one of the major issues within the neonatal period. It occurs in both physiological and pathological processes in newborns. Early discharge of newborns after delivery is a common practice because of medico-social reasons and economic constraints [11]. An association between decreased length of stay and the risk of re-admission during the neonatal period with hyperbilirubinemia has been shown. The potential risk of developing bilirubin encephalopathy or even kernicterus is high in babies with elevated serum bilirubin levels [12]. The

sequel could be serious as babies may develop cerebral palsy, sensorineural deafness, and mental retardation. Hence, there is a need to adopt a method to predict the likely development of hyperbilirubinemia [13]. Early prediction facilitates the use of effective preventive measures and early treatment, thereby reducing mortality and morbidity. A prospective correlation study with 100 newborns is undertaken to study the correlation of transcutaneous bilirubin and serum bilirubin and its accuracy as a screening tool in detecting hyperbilirubinemia.In the present study there was a strong association between the age of the baby and TcB value ($p<0.01$), the mean TSB was least on Day 6(12.48mg/dl) and highest on Day 5 (16.47mg/dl). Hence this study infers a strong association between age and TSB. [13] TSB measured was plotted and classified as High-risk, Low-risk, and minimal-risk. Results showed a significant association between age and TSB ($p<0.01$) with a high Likelihood ratio >10 in the high-risk category. Hence TSB reading varies steadily as the age increases. In the present study, 86% of babies weighed above 2.5kg with a mean birth weight of 2.93± 0.40 kg, and TSB values recorded were higher in 2-2.49 Kg babies. Hence, there was no significant association between birth weight and hyperbilirubinemia (p value=0.975) [14]. In the present study based on a visual assessment of jaundice by Kramer 33% of cases were in Zone 4 and 32 % were in Zone 3. There was a significant association ($p<0.001$) between visual assessment and TSB. In the present study, all 100 babies included were clinically icteric and all the TcB measurements taken were above the 50th percentile on the TcB nomogram. Therefore, TSB was measured simultaneously and results showed that there was a strong correlation between TcB and TSB with a value of 0.86. When a TcB cut-off level of 13mg/dl was taken, sensitivity was 93.85%. But when cut–off was taken as 15 and 17mg/dl, the sensitivity decreased to 97.14% and 71.43% respectively. Specificity was 82.86%, 95.38%, and 96.51% for 13mg/dl, 15mg/dl, and 17mg/dl respectively for all the babies that were included in our study were clinically icteric babies. There is a significant correlation between TcB and TSB in neonates [15]. Early prediction facilitates the use of effective preventive measures and early treatment, thereby reducing mortality and morbidity. A prospective correlation study with 400 newborns was undertaken to examine the correlation of transcutaneous bilirubin and serum bilirubin and its accuracy as a screening tool in detecting hyperbilirubinemia. Transcutaneous bilirubin measurements are made by the absorption of light caused by the presence of bilirubin in the capillary beds and subcutaneous tissue to be isolated by spectral subtraction. This allows an unbiased measurement that is independent of the race, age, and weight of the newborn. The practical application of these findings is that considering the high sensitivity of TCB, we can predict neonatal icterus using a noninvasive method without spending much time and money. The highest levels of bilirubin are seen on the fifth and sixth days of birth [16]. This is while most neonates are discharged 48 hours after birth. Therefore, they should be followed accurately concerning icter after discharge. TCB is an ideal method for outpatient follow-up and aid the quick diagnosis of icterus to prevent its consequent side effects. We also found that the agreement between TSB and TcB was poor in the subgroup where the TSB was more than 13 mg/dl. Similar results were reported earlier using a different transcutaneous billimeter The sensitivity of clinical judgement for values >13 mg/dl was poor, though the specificity was good. It seems that the TcB estimation reconfirms the clinical judgment, especially for higher bilirubin levels in the pathological range (>13 mg/dl). [14] To prevent this complication and to do appropriate management such as blood exchange or phototherapy as soon as possible, all susceptible neonates with jaundice are checked for serum levels of bilirubin. Once this check-up is merely as a screening test and in some cases, near-critical levels, serial measurements should be done. Besides the traditional method of measurement of Total Serum Bilirubin (TSB) level, today, non-invasive techniques for Transcutaneous Measurement of Bilirubin (TCB) are used [15]. This is recommended to use TCB just to screen infants, and 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 [16, 17]. The variations in the accuracy that predicts significant hyperbilirubinemia can be explained by the differences in the sample size, method of estimation of bilirubin, and duration between the collection and estimation of bilirubin and by their chosen cut-off values for significant neonatal hyperbilirubinemia [18-20].

CONCLUSION

The TcB correlates well with TSB in the TSB range of 10-18 mg/ dL in the Indian population but agreement between the two methods is not good and underestimation by TcB at higher values of TSB is a concern. So TcB is not a substitute for TSB, should be used as a screening tool only and management decisions should be based on TSB.

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