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Comparison of Transcutaneous Bilirubinometery and Total Serum Bilirubin in Icteric Newborns

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ABSTRACT

Background: Hospitalization, follow-up, and total serum bilirubin (TsB) testing are required in instances with a high risk of kernicterus, including day-one icter, hepatosplenomegaly, and other similar conditions. For non-invasive testing, transcutaneous bilirubinometry (TcB) is one option.

Objective: Assessment of the accuracy of transcutaneous bilirubinometry in comparison to serum total bilirubin level.

Subjects and methods: This hospital-based study was carried out at the Neonatal Care Unit of Zagazig University Teaching Hospital on 108 healthy neonates suspected on clinical grounds of having neonatal jaundice, of whatever etiology, admitted to the unit for hyperbilirubinemia. Gestational age was estimated from obstetric history and new Ballard Score method.

Result: TsB mean ± SD and TcB differed significantly from each other. At the 2-day, 3-day, 4-day, and 5-day points after the initial measurement, there was a statistically significant difference between the total serum bilirubin and transcutaneous bilirubin levels, when categorized by age. There were extremely significant differences between preterm and full-term newborns in terms of platelet count, C-reactive protein, total serum bilirubin, and transcutaneous bilirubin level. Levels of total serum bilirubin and transcutaneous bilirubin were stratified from 2nd to 5th day of measurement according to age as follows: TcB average, TcB over sternum, and TcB over forehead, and were significantly different.

Conclusion: The great sensitivity of TcB makes it a potential tool for the prediction of neonatal icter. Nevertheless, in newborns who are at high risk of jaundice, it should not be used as a replacement for TsB measurement.

Keywords: Total serum bilirubin (TsB), Transcutaneous bilirubinometry (TcB), Hepatosplenomegaly, Bilirubin level.

INTRODUCTION

Nearly 65% of full-term infants and over 85% of preterm infants experience neonatal jaundice, also known as hyperbilirubinemia, an issue frequently seen in the neonatal nursery [1]. Babies with bilirubin levels below the 95th percentile are very unlikely to develop hyperbilirubinemia complications including acute bilirubin encephalopathy and kernicterus [2]. Acute bilirubin encephalopathy and kernicterus are extremely rare conditions that can cause serious health problems or even death [3]. It is critical to promptly identify jaundiced newborns in need of specific intervention, such as phototherapy or exchange transfusion, and to precisely measure jaundice levels in order to avert such serious sequelae of hyperbilirubinemia [4].

There is no objective way to visually assess jaundice. The results of an objective approach for assessing total serum bilirubin (TsB) levels in a clinical laboratory, however, are not supplied in real-time. Not only is it costly, but there is also a great deal of variation both within and between laboratories. Painful and potentially infectious, blood sampling is a necessary evil. The gold standard for screening for newborn jaundice is transcutaneous bilirubin concentration measurement [5-7].

A device that measures light transmission through newborns' skin can noninvasively estimate TsB levels, allowing for the determination of TcB levels. You can choose from a variety of TcB meters. Immediate, inexpensive, painless, and linked to less parental discomfort, transcutaneous readings are a great option [8,9]. Measurement of transcutaneous bilirubin (TcB) has completely transformed the way icteric neonates are cared for. TcB is a quick, easy, and non-invasive way to measure bilirubin levels, which helps find babies at risk of hyperbilirubinemia early on. In order to avoid the potentially fatal neurological consequence known as kernicterus, this allows for prompt action, like phototherapy. In the first several hours after delivery, when standard serum bilirubin levels are unavailable, TcB tests are invaluable. Additionally, TcB monitoring enables customized treatment regimens, with regular evaluations to modify the length and intensity of phototherapy according to the specific requirements of each newborn. Optimal bilirubin management for the newborn is guaranteed by this dynamic strategy, which reduces interventions that are not necessary. Ultimately, TcB improves infant outcomes in icteric infants by allowing early detection, personalized therapy, and a decreased risk of problems [6].

Objectives: To assessment of the accuracy of transcutaneous bilirubinometry in comparison to serum total bilirubin level.

PATIENTS AND METHODS

This hospital-based study was carried out at the Neonatal Care Unit of Zagazig University Teaching Hospital. This study was conducted on 108 healthy neonates suspected on clinical grounds of having neonatal jaundice, of whatever etiology, admitted to the unit for hyperbilirubinemia. Gestational age was estimated from obstetric history and new Ballard Score method[10].

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Inclusion criteria: Healthy term and preterm neonates' population who were: with gestational age 32-41 weeks, with birth weight > 1200 gm, free from exclusion criteria or clinically jaundiced and who needed follow up and/or management.

Exclusion criteria: Newborn infant with: Gestational age less than 32 weeks, gestational age > 41 weeks**,** weight less than 1200 gm**,** infant of diabetic mother, newborn with family history of blood disease or blood transfusion, small or large for gestational age, severely bruised or ecchymosed baby, rh –ve mother or mother with blood group (o), or suspected cases of polycythemia. These groups of neonates were excluded from the study to avoid any fallacies in course of TCB measurement.

Prenatal history: Including maternal illness during pregnancy, congenital viral or toxoplasmosis infection, diabetes mellitus, maternal drugs that may interfere with bilirubin binding to albumin such as (Sulfonamides) or may cause hemolysis in G6PD-deficient such as (Sulfonamides, nitrofurantoin, antimalarials) or drugs that interfere with metabolism, uptake, conjugation or excretion of neonatal bilirubin or history of blood transfusion.

Natal History: Such as history of trauma, history of asphyxiated infant, delayed cord clamping or oxytocin use.

Postnatal history: as respiratory distress, cyanosis, change of color of urine and stool, convulsions, scanty breast milk, delayed passage of meconium, day of start of jaundice, duration of NICU admission, history of bleeding tendency in form of umbilical bleeding, history of delayed or infrequent stooling, poor caloric intake, vomiting.

Family history: Such as consanguinity, congenital anomalies, previous abortion, sibling death, still birth jaundice, anemia, history of previous sibling with jaundice in neonatal period, splenectomy, early gall bladder disease, liver disease.

II- General Examination:

Gestational age assessment according to modified Ballard Score [10].

III. Systemic examinations: Chest examination, cardiac examination. Followed by echocardiography scan, abdominal examination, neurological examination.

IV- Laboratory investigations:

- Blood group of mother and baby.
- Complete blood picture was done on admission to determine hemoglobin and reticulocyte count.
- C-reactive protein to exclude sepsis.
- Serum bilirubin (total and direct) was done on admission and after start of phototherapy daily.

V- Transcutaneous bilirubin measurement

Methods:

We obtained TcB readings for 108 infants (gestational age: > 32 weeks). This was convenience sample, obtained in cross-sectional manner. TcB measurement were obtained by researcher from the forehead and chest and may be back with the Konica Minolta/Air Shields JM 103, Jaundice Meter (JM103), which was calibrated on a regular basis in accordance with the manufacturer's instructions, and was used to measure all TcB levels. Infants Forehead and front of chest were covered by opaque patch if the infant was under phototherapy to guard against effect of phototherapy. Because total serum bilirubin concentration decreases before subcutaneous tissue bilirubin concentration does during phototherapy, this device was only used in conjunction with phototherapy equipment; otherwise, a light-blocking patch was applied to the measuring point on the chest or forehead.

The JM-103 ascertains the neonate's subcutaneous bilirubin content by gauging the discrepancy between the skin's optical densities at 450 and 550 nm. A measuring probe with two optical pathways is used in this approach to reduce the impact of skin maturation and melanin. Returned light from shallow subcutaneous tissue scatters in the inner core, where it follows the fiber's short optical journey, whereas light from deeper subcutaneous tissue scatters in the outer core, where it follows the fiber's long optical path. It is possible to estimate the TsB from the difference in absorbance because of the linear association between the two variables [11].

Within 30 minutes after the transcutaneous measurement, blood was collected from a peripheral vein. Laboratory measurements of TsB levels were taken using direct spectrophotometry.

Ethical approval:

The Ethics Committee of the Faculty of Medicine at Zagazig University approved the study. Parents provided written informed consent before participating in the study. After being told about the study's goals, process, and relevant objectives. The Helsinki Declaration was followed at all stages of the inquiry.

Statistical analysis

Software developed by SPSS Inc. of Chicago, Illinois, USA, specifically for Windows, version 25.0, was used to analyze all of the data. Quantitative data were presented as mean, standard deviation (SD), median, and range and were compared by the Mann Whitney U test and by paired Student's t-test. Qualitative data were presented as frequency and percentage and were compared by Chi-Square test. Dependent variables were analyzed using binary logistic regressions. Passing-Bablock regression diagram, deming in order to determine the intercept (Y) and slope (ŋ), regression analysis was employed. We used Pearson's correlation coefficient. Statistical significance (S) was denoted by $P < 0.05$, highly statistical significance (HS) by $P < 0.005$, and non-significant (NS) by $P > 0.05$.

RESULTS

No statistically significant difference was found regarding sex when comparing preterm and full-term newborns. When looking at the prenatal and postnatal histories of babies, there was a statistically significant difference between the two groups (Table 1).

Table (1) Comparison between preterm and full-term infants as regard demographic data and history

	Preterm (n=31)		Full-term (n=77)		Test	p
	N	%	N	%		
Gestational age (weeks)					**MW**	
Mean ± SD	34.87 ± 1.92		38.83 ± 1.005		0.000	<0.001 (HS)
Median	35		38			
Range	32 – 37		38 – 41			
Sex					χ^2	
Male	12	38.7%	38	49.4%	1.007	0.316 (NS)
Female	19	61.3%	39	50.6%		

	Preterm (n=31)		Full-term (n=77)		Test	p
	N	%	N	%		
Prenatal history					χ^2	
Free	16	51.6%	50	64.9%	16.786	0.052 (NS)
Rhinitis	1	3.2%	5	6.5%		
Common cold	4	12.9%	7	9.1%		
Influenza	1	3.2%	0	0%		
UTI	5	16.1%	5	6.5%		
Arthritis	2	6.5%	0	0%		
Cervical cerclage	0	0%	2	2.6%		
Rheumatic heart	0	0%	1	1.3%		
Valve lesions	2	6.5%	1	1.3%		
Hypertension	0	0%	6	7.8%		
Mode of delivery					χ^2	
NVD	16	51.6%	46	59.7%	0.597	0.440 (NS)
CS	15	48.4%	31	40.3%		
Natal history					χ^2	
Free	19	61.3%	75	97.4%	33.923	<0.001 (HS)
Difficult labour	0	0%	1	1.3%		
Prolonged labour	0	0%	1	1.3%		
Preterm labour	12	38.7%	0	0%		
Postnatal history					χ^2	
Free	21	67.7%	70	90.9%	8.944	0.003 (HS)
Easy Resuscitation	10	32.3%	7	9.1%		
Family history					χ^2	
Free	28	90.3%	64	83.1%	0.909	0.340 (NS)
Physiological jaundice	3	9.7%	13	16.9%		
Birth trauma					χ^2	
No	30	96.8%	74	96.1%	1.249	0.535 (NS)
Fracture clavicle	0	0%	2	2.6%		
Erb's Palsy	1	3.2%	1	1.3%		

There was statistically significant difference between TsB and TcB of each of forehead, sternum, and TcB average (Table 2).

Table (2): Comparison between total serum bilirubin and transcutaneous bilirubin level

	TsB	TcB forehead	TcB sternum	TcB average	p1	p2	p3
Mean	12.27	10.79	11.22	11.01	<0.01 (HS)	<0.01 (HS)	<0.01 (HS)
SD	3.69	2.21	2.25	2.22			

Paired t test was used to compare between pairs of measurement in the same infant

p1 denote comparison between TsB and TcB forehead

p2 denote comparison between TsB and TcB sternum

p3 denote comparison between TsB and TcB (average)

There was statistically significant difference at 2nd, 3rd, 4th, and 5th days, between TsB and TcB of each of forehead, sternum, and TcB average (Table 3).

Table (3): Comparison between total serum bilirubin and transcutaneous bilirubin level stratified according to age at measurement.

	TsB	TcB forehead	TcB sternum	TcB average	p1	p2	p3
2nd day	10.86±2.66	9.57±2.32	10.02±2.34	9.8±2.32	<0.01 (HS)	<0.01 (HS)	<0.01 (HS)
3rd day	12.56±3.41	11.02±2.96	11.43±2.97	11.23±2.96	<0.01 (HS)	<0.01 (HS)	<0.01 (HS)
4th day	11.6±2.71	10.25±2.31	10.64±2.39	10.44±2.34	<0.01 (HS)	<0.01 (HS)	<0.01 (HS)
5th day	13.64±3.82	12.07±3.16	12.63±3.14	12.35±3.14	<0.01 (HS)	<0.01 (HS)	<0.01 (HS)

Values: mean ± SD
Paired t test was used to compare between pairs of measurement in the same infant
p1 denote comparison between TsB and TcB forehead
p2 denote comparison between TsB and TcB sternum
p3 denote comparison between TsB and TcB (average)

Correlation between total serum bilirubin and transcutaneous bilirubin levels over forehead, sternum, and TcB average were highly statistically significant (Table 4).

Table (4): Correlation between total serum bilirubin and transcutaneous bilirubin level in all studied infants stratified by age at measurements

	Total serum bilirubin (µmol/L) (All infants, n=108)		
	n	**R**	**p**
TcB over forehead			
2nd day	15	+ 0.963	< 0.001 (HS)
3rd day	48	+ 0.974	< 0.001 (HS)
4th day	30	+ 0.960	< 0.001 (HS)
5th day	14	+ 0.976	< 0.001 (HS)
TcB over sternum			
2nd day	15	+ 0.965	< 0.001 (HS)
3rd day	48	+ 0.981	< 0.001 (HS)
4th day	30	+ 0.963	< 0.001 (HS)
5th day	14	+ 0.983	< 0.001 (HS)
TcB average			
2nd day	15	+ 0.965	< 0.001 (HS)
3rd day	48	+ 0.979	< 0.001 (HS)
4th day	30	+ 0.965	< 0.001 (HS)
5th day	14	+ 0.981	< 0.001 (HS)

Regarding TcB over forehead as screening test for detection of high-risk hyperbilirubinemia (TsB>14 mg/dl), sensitivity was 100%, specificity was 85.53%, PPV (positive predictive value) was74.4 %, NPV **(**negative predictive value) was100%, area under curve was 0.988. Regarding TcB over sternum as screening test for detection of high-risk hyperbilirubinemia (TsB>14 mg/dl) at cut-off values> 11.3, sensitivity was 100%, specificity was 77.63%, PPV was 65.3%, NPV was100 %, area under curve was 0.984. Regarding TcB over sternum as screening test for detection of high-risk hyperbilirubinemia (TsB>14 mg/dl) at cut-off values> 11.8, sensitivity was 100%, specificity was 85.53%, PPV was 74.4%, NPV was100 %, and area under curve was 0.990. There was highly statistically significant difference regarding mean differences (Δ) between TsB and TcB and their CI 95% for particular measurement sites as p value <0.001.

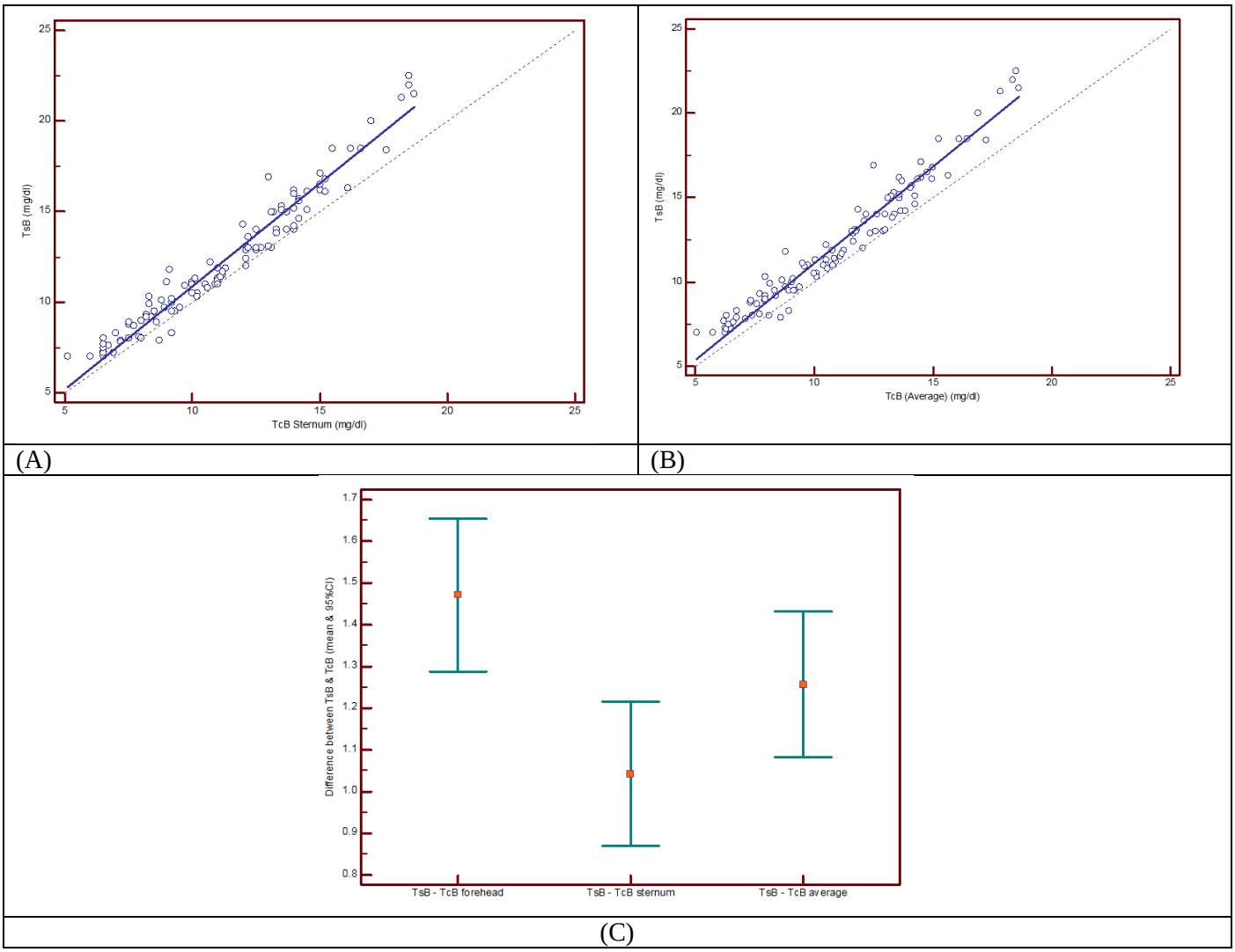

Figure (1): Number of cases was 108. (A) Comparing total serum bilirubin with transcutaneous bilirubin measured over the sternums. Dotted lines indicate lines of equivalence (TcB = TsB). The equation that best represents the least squares fit is TsB = 0.018 + 1.09 (TcB), and the solid line represented this. (B) Comparison of total serum bilirubin with the average measurement of transcutaneous bilirubin. Dotted lines indicate lines of equivalence (TcB = TsB). The solid line represents the best-fitting line according to the equation of least squares, which was TsB = 0.111 + 1.109 (TcB). The mean differences (mg/dl) and 95% confidence intervals between total serum bilirubin (TsB) and transcutaneous bilirubin (TcB) readings, broken down by transcutaneous measurement site, are shown in (C).

Comparison between preterm and full-term infants as regard correlation between total serum bilirubin and transcutaneous bilirubin level, there was highly statistically significant correlations (Table 5).

Table (5): Comparison between preterm and full-term infants as regard correlation between total serum bilirubin and transcutaneous bilirubin level.

	Total serum bilirubin in Preterm Infants (n=31)		**Total serum bilirubin in Full-term infants (n=77)**		**Total serum bilirubin in All infants (n=108)**	
	r	**p**	**r**	**p**	**r**	**p**
TcB over forehead	+ 0.948	<0.001 (HS)	+ 0.978	<0.001 (HS)	+ 0.971	<0.001 (HS)
TcB over sternum	+ 0.962	<0.001 (HS)	+ 0.978	<0.001 (HS)	+0.974	<0.001 (HS)
TcB average	+ 0.957	<0.001 (HS)	+ 0.980	<0.001 (HS)	+0.974	<0.001 (HS)

Comparison between preterm and full-term infants as regard correlation between total serum bilirubin and transcutaneous bilirubin level stratified as (TcB average, TcB over sternum TcB, over forehead) according to age at measurement from 2nd day to 5th day. There were highly statistically significant correlations (Table 6).

Table (6): Comparison between preterm and full-term infants as regard correlation between total serum bilirubin and transcutaneous bilirubin level stratified according to age at measurement.

	Total serum bilirubin in Preterm infants (n=31)		Total serum bilirubin in Full-term infants (n=77)		Total serum bilirubin in All infants (n=108)	
	r	p	r	P	r	p
TcB over forehead						
2nd day	+ 0.948	< 0.001	+ 0.973	< 0.001	+ 0.963	< 0.001
3rd day	+ 0.978	< 0.001	+ 0.972	< 0.001	+ 0.974	< 0.001
4th day	+ 0.888	0.001	+ 0.984	< 0.001	+ 0.960	< 0.001
5th day	+ 0.993	0.007	+ 0.981	< 0.001	+ 0.976	< 0.001
TcB over sternum						
2nd day	+ 0.958	< 0.001	+ 0.973	< 0.001	+ 0.965	< 0.001
3rd day	+ 0.981	< 0.001	+ 0.979	< 0.001	+ 0.981	< 0.001
4th day	+ 0.925	< 0.001	+ 0.974	< 0.001	+ 0.963	< 0.001
5th day	+ 0.999	0.001	+ 0.986	< 0.001	+ 0.983	< 0.001
TcB average						
2nd day	+ 0.954	< 0.001	+ 0.974	< 0.001	+ 0.965	< 0.001
3rd day	+ 0.982	< 0.001	+ 0.977	< 0.001	+ 0.979	< 0.001
4th day	+ 0.909	< 0.001	+ 0.982	< 0.001	+ 0.965	< 0.001
5th day	+ 0.998	0.002	+ 0.984	< 0.001	+ 0.981	< 0.001

DISCUSSION

Babies often have hyperbilirubinemia. During the first week of life, jaundice affects 60% of term neonates and 80% of preterm neonates. Some of the problems that might arise from hyperbilirubinemia include transient encephalopathy and kernicterus [12-13].

Risk factors for kernicterus include hepatosplenomegaly, day-one icter, and other conditions that necessitate TsB monitoring, follow-up, and hospitalization. In an effort to alleviate patient anxiety, cut down on laboratory costs, and eliminate the need for blood samples, noninvasive bilirubin tests have been introduced in the past few decades. TcB is one of these noninvasive techniques [14].

Transcutaneous bilirubinometry (TcB) involves pressing the bilirubinometer against the skin, which causes a pale appearance, and then measuring bilirubin levels using various light wave techniques [15]. There has been conflicting evidence from studies that have looked at the relationship between TsB and TcB. The researchers **Briscoe and colleagues**[16] discovered a strong relationship between TsB and TcB.

The findings of the two assessments were not clearly related, according to **Janjindamai and Tansantiwong** [17]. The researchers noted in the subsequent study that TcB can replace TsB because it is just as accurate.

In terms of gestational age, our findings revealed a mean ± standard deviation of 37.69 ± 2.23. In terms of sex, 53.7% were female and 46.3% were male, and the rate of full-term maturity was 71.3%.

We discovered the same range of gestational ages as **Mohamed *et al.*** [18]; 38.4 (1.31) weeks, with a range of 35–42 weeks. They also discovered that the average TsB level was 232 (72) µmol/L, with values varying between 74 µmol/L and 419 µmol/L, which aligns with our findings.

We detected a strong correlation ($p < 0.0001$) between TcB and TsB measures in newborns, which is in keeping with the findings of **Mansouri *et al.*** [14] who found a strong relationship between TsB and TcB in their investigation. **Gupta *et al.*** [19] demonstrated a similar strong association between TcB and TsB in their study. **Lam *et al.*** [20] found a strong association between transcutaneous bilirubin and total serum bilirubin in a prospective correlation analysis. **Povaluk *et al.*** [21] found a robust relationship between plasma and transcutaneous bilirubin tests. Both the **Leite *et al.*** [22] and the **Mahram *et al.*** [23] studies found similar results. As a result, there is a strong relationship between TcB and TsB readings in neonates, according to multiple research conducted on the subject.

Our findings are in line with those of **Mansouri *et al.*** [14] who measured cutaneous bilirubin levels at 17.85±4.46 mg/dl and serum levels at 18.75±5.38 mg/dl, respectively. The results showed that TsB and TcB were highly correlated.

There was a strong relationship between TcB and TsB readings in newborns (r=0.89), which is in keeping with the findings of **Mansouri *et al.*** [14]. Another study found a strong connection (r=0.91) between TcB and TsB in 490 neonates weighing more than 2.5 kg [24].

This has been the subject of multiple investigations [24-25]. We found a correlation coefficient of 0.8, which is in agreement with another study that looked at 388 term neonates who were healthy [26]. The favorable linear association between TsB and TcB was revealed by **Rubaltelli *et al.*** [27]. The TcB forehead

values (r = 0.89) were found to be better than the TcB sternal values (r = 0.88). Nevertheless, there are studies that have come to opposite conclusions. For example, a study conducted by **Kosarat and Khuwuthyakorn** [28] with 257 newborns indicated that the TcB sternal measurement was more closely related to TsB than the TcB forehead measurement (r > 0.8).

A similar result was also shown by **Chimhini *et al.*** [29]. With a correlation of 0.77 between the TsB and TcB sternum and 0.72 between the TsB and TcB forehead, this study found that the sternum was more useful than the forehead for evaluating newborns with jaundice in Zimbabwean neonates. There was a substantial connection between the TsB and TcB forehead (P-value < 0.05) and between the TsB and TcB sternum (P-value < 0.001) in another Egyptian study by **El-Kabbany *et al.*** [30], with sternal measurements being more accurate than forehead measurements.

The current investigation found that transdermal bilirubin analysis (TcB) across the forehead was a 100% sensitive screening test for high-risk hyperbilirubinemia (TsB>14 mg/dl). The specificity was 85.53 %, the positive predictive value (PPV) was 74.4%, the negative predictive value (NPV) was 100 %, and the area under the curve was 0.988.

It was discovered by **Mohamed *et al.*** [18] that TcB over the forehead can be used as a screening test to detect high-risk hyperbilirubinemia, and our results are in agreement with them. The following statistics were presented: sensitivity: 85.3%, specificity: 76.4%, positive predictive value: 83.1%, negative predictive value: 79.3%.

Our findings demonstrated a highly significant disparity in terms of the mean differences (Δ) and their CI 95% for specific measurement sites between TsB and TcB, with a p value of less than.001.

Consistent with previous research, our findings support the use of TcB on the chest as a cutoff value for TsB >10 mg/dl prediction [30]. This method demonstrated a validity of 96.2% sensitivity and 86.4% specificity. Results from the Iranian study by **Mansouri *et al.*** [14] were similar to these findings; the researchers found a high correlation between TcB on babies' foreheads and TsB, with a validity result of 95.1% sensitivity and 68% specificity at a cutoff value of 8 mg/dl for TcB on the forehead. Since the forehead was exposed to room light while the chest was covered by garments, the underestimating of TcB on the forehead is the reason for the lower cutoff value compared to TcB on the chest.

There was a statistically significant difference in gestational age between preterm and full-term infants in the current study. No statistically significant difference was found regarding sex when comparing preterm and full-term newborns. When it came to factors like family history, birth trauma, mode of delivery, and prenatal history, there was no statistically significant difference.

CONCLUSION

It is possible to employ TcB as a method for neonatal icter prediction due to its great sensitivity. In premature infants who are at high risk of jaundice, though, it cannot replace TsB testing.

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