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Comparative study of strip (stool color for triage of infants for phototherapy) score and transcutaneous bilirubinometer with serum bilirubin in predicting accuracy of neonatal hyperbilirubinemia.

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ABSTRACT

INTRODUCTION: Neonatal hyperbilirubinemia, marked by elevated bilirubin levels in newborns, can arise from various factors such as sepsis, ABO and Rh incompatibility, polycythemia, cephalhematoma, and dehydration. These conditions lead to hemolysis, liver dysfunction, or hindered bilirubin excretion. Preterm infants are particularly at risk due to immature liver function, and parity can influence outcomes through breastfeeding practices and hemolytic disease risks in subsequent pregnancies. Clinical assessment is essential for distinguishing physiological from pathological jaundice.

AIM & OBJECTIVES: This study aims to evaluate the effectiveness of the STrIP score and transcutaneous bilirubinometer against serum bilirubin levels in predicting neonatal hyperbilirubinemia. We seek to determine their accuracy and reliability and assess associated risk factors to enhance early detection and management of hyperbilirubinemia in newborns.

MATERIALS & METHODS: The study will include neonates over 35 weeks gestational age with clinical jaundice, obtaining parental consent. Serum bilirubin levels will be measured at 72 hours of life, and a clinical assessment will be conducted using the Kramer scale. The STrIP score will be calculated from stool samples and compared to transcutaneous bilirubin readings to assess accuracy using Bland-Altman analysis.

RESULTS: Among 290 newborns, 73.8% were term. Clinically significant jaundice was 2.03 times more common in primiparous mothers and significantly associated with gestational age, birth trauma, pregnancy complications, Rh status, and ABO incompatibility. Dehydration and polycythemia were strongly linked to neonatal hyperbilirubinemia, with males slightly more prevalent among participants.

CONCLUSION: The STrIP score provides enhanced predictive accuracy and a better correlation with serum bilirubin levels than the transcutaneous bilirubinometer. The study identifies significant associations between various factors and clinically significant jaundice, highlighting the importance of STrIP as a non-invasive option for managing neonatal jaundice.

INTRODUCTION:-

The health of many newborns is impacted by hyperbilirubinemia, with approximately 80% of term infants experiencing

physiologic unconjugated hyperbilirubinemia, which is usually transient and harmless for the majority[1]. However, a small but significant portion may develop severe neonatal hyperbilirubinemia (SNH). Globally, around one million newborns are affected by SNH each year, requiring intensive treatment to lower the risk of death or kernicterus spectrum disorders (KSD)[2]. The incidence of SNH ranges from 2 to 42 per 100,000 live births in high-income countries (HIC), with variations partly due to different thresholds of total serum bilirubin (TSB) used for diagnosis[3]. In contrast, the rate of SNH is higher in low- and middle-income countries (LMIC), where limited access to healthcare and treatment endangers many newborns[4]. The combined impact of SNH and Rhesus disease contributes to a rate of 73 KSD cases per 100,000 live births, and a mortality rate of 119 per 100,000 in regions such as Eastern Europe, Latin America, sub-Saharan Africa, and Asia. In India, the mortality rate from neonatal jaundice reaches 730 per 100,000 live births[5]. Annually, approximately 114,000 infants may die worldwide due to these conditions. These statistics emphasize the importance of screening methods for early identification of SNH, with the main goal being to detect infants at risk for KSD, while diagnostic tests provide precise confirmation of jaundice severity[6].

Various methods are available for screening for neonatal hyperbilirubinemia:

Visual Assessment: Clinicians assess jaundice by examining the skin and sclera, but this method is subjective and less reliable, particularly in infants with darker skin tones.

Transcutaneous Bilirubin (TcB) Measurement: A non-invasive device estimates bilirubin by measuring skin pigment. It's quick and painless but may need confirmation through serum tests for high levels.

Total Serum Bilirubin (TSB) Measurement: The gold standard for diagnosing hyperbilirubinemia, requiring a blood test to measure bilirubin concentration. While accurate, it is invasive and requires lab resources.

Bilirubin Nomograms: TSB or TcB values are plotted on age-specific charts to predict the risk of severe hyperbilirubinemia, aiding in deciding further testing or treatment.

Hour-Specific Bilirubin Monitoring: Tracking bilirubin levels at specific intervals during the first days of life helps identify trends and risks for severe jaundice.

End-Tidal Carbon Monoxide (ETCOc) Measurement: A non-invasive method estimating bilirubin production via exhaled carbon monoxide, though less commonly used due to equipment needs.

Genetic Screening: Identifies genetic risk factors like G6PD deficiency that increase the likelihood of severe hyperbilirubinemia.

STrIP Score:

1. **Risk Prediction**: Combines factors like gestational age and bilirubin levels to estimate the risk of severe hyperbilirubinemia, aiding in early intervention.
2. **Non-invasive Monitoring**: Can be calculated using transcutaneous bilirubin measurements, minimizing the need for invasive testing.

The main aim of the present study is to compare the STrIP score (stool colour for triage of infants for purpose of phototherapy) and transcutaneous bilirubinometer with serum bilirubin and its effectiveness in predicting Neonatal Hyperbilirubinemia.

AIMS AND OBJECTIVES

AIM:

The aim of the present study is to compare the STrIP score (stool colour for triage of infants for purpose of phototherapy) and transcutaneous bilirubinometer with serum bilirubin and its effectiveness in predicting Neonatal Hyperbilirubinemia.

OBJECTIVES:

Primary Objective:

The objective of the study is to compare the STrIP score (stool colour for triage of infants for purpose of phototherapy) and transcutaneous bilirubinometer with serum bilirubin and its effectiveness in predicting Neonatal Hyperbilirubinemia.

Secondary Objective:

To assess the risk factors for Neonatal Hyperbilirubinemia.

MATERIALS AND METHODS:-

The current study is a hospital based cross sectional study conducted in the Department of Pediatrics, Sree Balaji Medical College and Hospital, Chrompet, Chennai. A total of 290 participants are taken up for the study amongst the babies who were >35 according to New Ballard Score and with clinical jaundice delivered at Department of Pediatrics at Sree Balaji Medical College and Hospital using Purposive sampling method

SAMPLE SIZE CALCULATION:

The sample size was calculated according to **Bindu et al,** Considering the prevalence of predicting serum bilirubin in clinically significant jaundice babies as 22% with an alpha error of 5% a precision of 5% and 95% CI the sample size was calculated as

sample size was calculated as, $N = Z^2 \times p \times q / L^2$

$Z1-\alpha/2$ - two tailed probability for 95%

Confidence interval = 1.96

p (%) - prevalence of of predicting serum bilirubin in clinically significant jaundice babies in infants =22%

q = 78

d (%) - precision or allowable error for of predicting serum bilirubin in clinically significant jaundice babies = 5

Sample size calculation = $N = (1.96 \text{ X } 1.96) \text{ X } 22 \text{ X } 78 / (5)^2$

Total number of study participants = 264

25% has been added as the neonates should pass stool within 3 hours of detection of clinical jaundice, when blood for serum bilirubin is drawn, where there is an addition of 66 babies making the total sample size to 330.

N = 330.

ELIGIBILITY CRITERIA:-

Inclusion criteria:

- Neonates who have crossed 35 weeks of gestation according to the New Ballard Score.
- Neonates with Clinical jaundice.

Exclusion criteria:

- Neonates who were clinically unstable.
- Neonates who had received phototherapy based on clinical assessment were excluded.
- Neonates who did not pass stool during the observation time of three hours were not included in the study.
- Neonates with less than 35 weeks of gestation according to the New Ballard Score.
- Neonates with respiratory distress syndrome.
- Neonates with necrotizing enterocolitis.

A modified, pre-structured questionnaire was utilized to gather socio-demographic information, including gestational age, gender, birth weight, place of residence, Clinical examinations centered on identifying symptoms, breastfeeding habits, birth weight, and any weight loss. The study enrolled neonates over 35 weeks gestation (assessed via the New Ballard Score) who exhibited clinical jaundice. Parental consent was obtained before participation. Blood samples were collected for serum bilirubin at 72 hours of life or sooner if clinically necessary. Jaundice was evaluated using the Kramer scale, and stool color was assessed using the STrIP score. Additionally, transcutaneous bilirubin measurements were taken from the forehead, with comparisons made between the STrIP score, transcutaneous bilirubin, and serum bilirubin via Bland-Altman analysis. A total of 290 neonates participated, with prior approval from the Institutional Review Board and Ethics Committee. The study spanned 12 months, from July 22 to June 23,

and received ethical clearance from Sree Balaji Medical College's Institutional Human Ethics Committee. Data were analyzed using SPSS version 27, employing chi-square and odds ratio tests to determine associations, while Bland-Altman analysis assessed the agreement between different measurement methods.

RESULTS

Table 1: Socio-demographic details of the Study Participants.

Socio-demographic details	Frequency (N=290)	Percentage (%)
Gestational age		
Term	214	73.8
Pre term	76	26.2
Gender		
Male	148	51
Female	142	49
Residence		
Urban	152	52.4
Rural	138	47.6
Mothers' education		
Illiterate	5	1.7
School	184	63.4
Graduate	101	34.8
Socio-Economic Status		
Class- I	15	5
Class-II	47	16
Class- III	116	40
Class- IV	84	29
Class- V	28	10
Birth weight (Kg)		
<2.5	62	21.4
≥2.5	228	78.6
Weight loss (%)		
<10	220	75.8%
≥10	70	24.1%

Table 1repesents the Socio-demographic details of the Study Participants.

Of the 290 participants, 214 (73.8%) were term and 76 (26.2%) were pre-term. The gender breakdown included 148 males (51%) and 142 females (49%). Among the participants, 152 (52.4%) resided in urban areas, while 138 (47.6%) lived in rural areas. In terms of maternal education, 5 (1.7%) were illiterate, 184 (63.4%) had attended school, and 101 (34.8%) were graduates. According to the B.G. Prasad classification (Jan 2021), socioeconomic status was distributed as follows: 15 (5%) in Class I, 47 (16%) in Class II, 116 (40%) in Class III, 84 (29%) in Class IV, and 28 (10%) in Class V. Among the neonates, 62 (21.4%) weighed less than 2.5 kg, while 228 (78.6%) weighed more than 2.5 kg. Weight loss of less than 10% occurred in 220 (75.8%) neonates, whereas 70 (24.1%) experienced more than 10% weight loss.

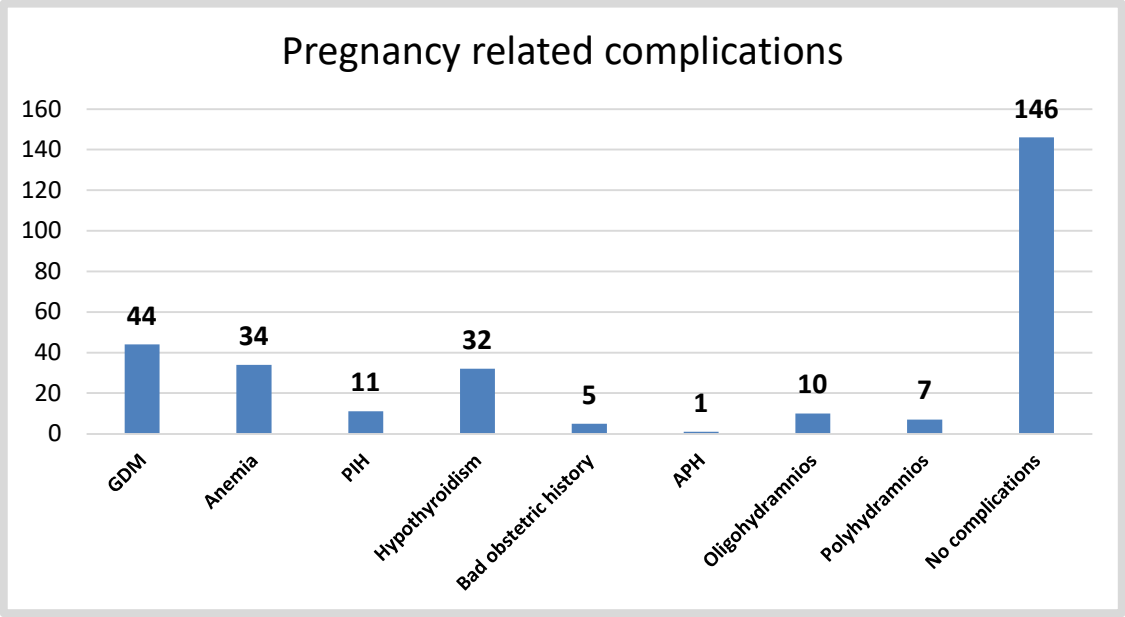

Fig 1: Distribution According Pregnancy Related Complications in Mothers

Table 2 : Association Of Socio-demographic details with Clinically Significant Jaundice

Socio-demographic details		Clinically significanceJaundice		ODDS RATIO	95 % CI	P VALUE
		YES N (%)	**NO N (%)**			
Residence	Urban	27(17.8)	125(82.2)	1.353	0.71-2.56	0.352
	Rural	19(13.8)	119(86.2)			
Gender	Male	25 (16.9)	123 (83.1)	1.17	0.62-2.20	0.624
	Female	21 (14.8)	121 (85.2)			
Parity	Primiparous	31(20.1)	123(79.9)	2.03	1.04-3.96	**0.036***
	Multiparous	15 (11)	121 (89)			
Complication related to pregnancy	Yes	37 (25.7)	107 (74.3)	5.26	2.43-11.38	**<0.0001***
	No	9(6.2)	137 (93.8)			
Gestational age(weeks)	35-37	22 (28.9)	54 (71.1)	3.23	1.68-6.19	**<0.0004***
	≥37	24 (11.2)	190(88.8)			
Birth trauma	Yes	24 (46.2)	28 (53.8)	8.42	4.18-16.94	**<0.00001***
	No	22 (9.2)	216 (90.8)			

Rh status of mother	Negative	26 (70.3)	11 (29.7)	27.5	11.89-63.78	**<0.0001***
	Positive	20 (7.9)	233 (92.1)			
ABO Incompatibility	Yes	15(24.2)	47 (75.8)	2.03	1.01-4.06	**0.045***
	No	31 (13.6)	197 (86.4)			
Sepsis	Yes	10 (66.6)	5 (33.4)	13.28	4.29-41.07	**<0.0001***
	No	36 (13.1)	239 (86.9)			
Dehydration (Weight loss >10 %)	Yes	34 (48.6)	36 (51.4)	16.37	7.75-34.56	**<0.0001***
	No	12 (5.5)	208 (94.8)			
Polycythemia	Yes	5 (83.3)	1(16.7)	29.63	3.38-260.16	**<0.002***
	No	41 (14.4)	243(85.6)			

P value <0.05- statistically significant

Table 2 shows the Association Of Socio-demographic details with Clinically Significant Jaundice

Among the participants, 27 (17.8%) in urban areas and 19 (13.8%) in rural areas had clinically significant jaundice, with urban participants 1.353 times more likely to experience jaundice; however, this association was not statistically significant (OR=1.353; 95% CI= 0.71-2.56; p=0.352). Clinically significant jaundice was present in 25 (16.9%) males and 21 (14.8%) females, showing no statistically significant association (OR=1.71; 95% CI= 0.62-2.26; p=0.642). Primiparous mothers had 31 (20.1%) cases compared to 15 (11%) in multiparous mothers, with a statistically significant association (OR=2.03; 95% CI= 1.04-3.96; p=0.036). In cases of pregnancy complications, 37 (25.7%) had jaundice versus 9 (6.2%) without complications, showing a strong association (OR=5.26; 95% CI= 2.43-11.38; p=0.0001). Jaundice was found in 22 (28.9%) of mothers with gestational ages 35-37 weeks, compared to 24 (11.2%) with gestational ages over 37 weeks (OR=3.23; 95% CI= 0.71-2.56; p=0.352). Among neonates with birth trauma, 24 (46.2%) had jaundice, while 22 (9.2%) without birth trauma had jaundice, indicating a significant association (OR=8.42; 95% CI= 4.18-16.94; p=0.00001). Clinically significant jaundice was observed in 26 (70.3%) of Rh-negative mothers and 20 (7.9%) of Rh-positive mothers, with a significant association (OR=27.5; 95% CI= 11.89-63.78; p=0.00010). Among those with ABO incompatibility, 15 (24.2%) had jaundice compared to 31 (13.6%) without it, showing a statistically significant association (OR=2.03; 95% CI= 1.01-4.06; p=0.045). In participants with sepsis, jaundice was found in 10 (66.6%), compared to 36 (13.1%) without sepsis, indicating a significant association (OR=13.28; 95% CI= 4.29-41.07; p=0.0001). Among those with dehydration, 34 (48.6%) had jaundice, while only 12 (5.5%) without dehydration had jaundice, also showing a significant association (OR=16.37; 95% CI= 7.75-34.56; p=0.0001). Lastly, 5 (83.3%) of those with polycythemia had jaundice compared to 41 (14.4%) without polycythemia, showing a significant association (OR=29.63; 95% CI= 3.38-260.18; p=0.002).

Table 3: Mean, Median, Standard Deviation of Transcutaneous Bilirubinometer, Strip, Serum Bilirubin

	Transcutaneous Bilirubinometer	STRIP	S. bilirubin
Mean ± SD	12.93 ± 3.43	12.50 ± 3.21	11.58 ± 3.28
Median	13.20	12.95	12.15
Range	18.6	15.2	5.8

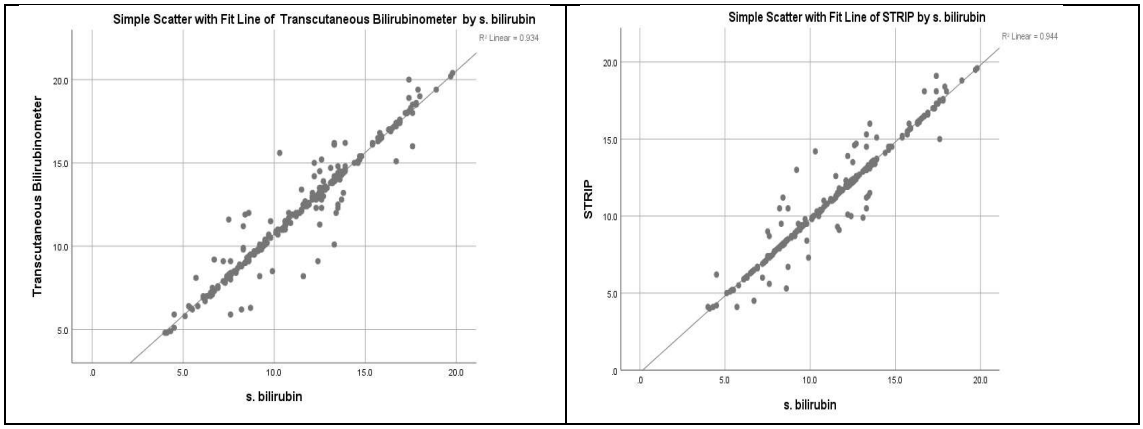

Fig 2 (a) Fig 2 (b)

Fig 2 (a) represents the corelation between transcutaneous bilirubin and S.bilirubin with correlation coefficient (r) of 0.934 and p value of 0.001 which is clinically significant.

Fig 2 (b) represents the co relation between STRIP score and S.bilirubin with correlation coefficient (r) of 0.972 and p value of 0.001 which is clinically significant.

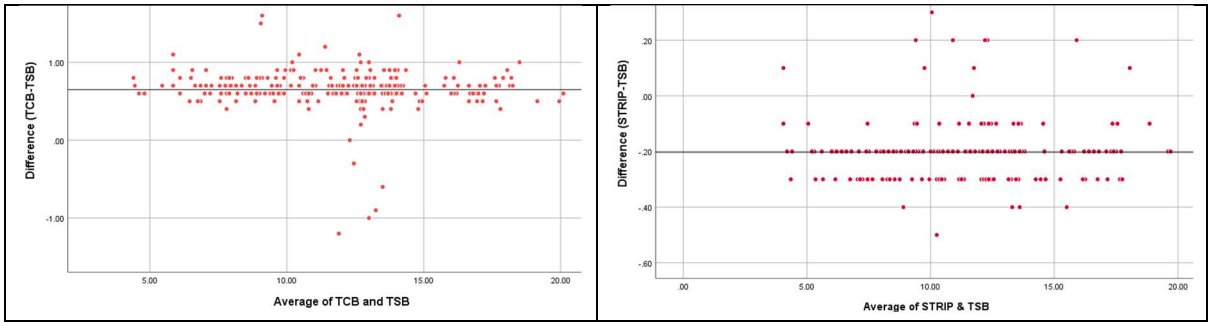

Fig 3 (a) Fig 3 (b)

Fig 3 (a) : Bland–Altmann plots depicts the difference between transcutaneous bilirubin TCB and TSB on Y-axis against mean of TSB and TCB on X-axis. The mean difference is 0.652 and 95% limit of agreement between TCB and Serum Bilirubin is 0.691 to 0.684.

Fig 3 (b) : Bland–Altmann plots depics the difference between STrIP Score and TSB on Y-axis against mean of STrIP and TSB on X-axis. The mean difference is -0.202 and 95% limit of agreement between STrIP and Serum Bilirubin is -0.213to -0.191.

DISCUSSION:-

The current study demonstrates that the STrIP score is more accurate in predicting serum bilirubin levels compared to other non-invasive methods, such as the transcutaneous bilirubinometer, at three days of age, with a mean difference of -0.202 mg/dL. This value is significantly lower than those from alternative non-invasive techniques. A study by Sushma et al. (2015) corroborated this, reporting a mean difference of 0.9 mg/dL, which supports the reliability of the STrIP score[7].

Joan et al. found that the modified Kramer score, which is frequently used for jaundice screening in neonates, was ineffective, achieving a sensitivity of 89% and a specificity of 54%[8]. Factors such as skin color, birth weight, and observer variability affect its accuracy, indicating that it should not be the sole method for jaundice detection.

Gestational Age of Neonates:

Among the 290 participants, 73.8% were term neonates, while 26.2% were preterm. This aligns with findings by Wu et al. (2022), who reported that 76.3% of term neonates had hyperbilirubinemia[9].

Parity:

The occurrence of clinically significant jaundice was 2.03 times higher in primiparous mothers compared to multiparous mothers (OR=2.03; 95% CI=1.04-3.96; p=0.036). This finding is consistent with Brucker et al. (2014), who reported a similar relationship[10].

Gestational Age:

The study found that neonates born at 35-37 weeks had a 3.23 times greater likelihood of clinically significant jaundice than those born after 37 weeks (OR=3.23; 95% CI=1.68-6.19; p=0.0004). This is consistent with the results of Taylor et al. (2015), which highlighted a significant association between gestational age and neonatal hyperbilirubinemia[11].

Birth Trauma:

The incidence of clinically significant jaundice in neonates with birth trauma was found to be 8.42 times greater than in those without trauma (OR=8.42; 95% CI=4.18-16.94; p<0.00001). This is consistent with findings by Maisels et al. (2022), who also established a significant connection between birth trauma and hyperbilirubinemia[12].

Complications Related to Pregnancy:

A positive correlation was observed between pregnancy complications and neonatal hyperbilirubinemia, with 26% of cases reporting an OR of 5.26 (95% CI=2.43-11.38; p<0.0001). These results align with the findings of Mishra et al[13]. (2011).

Rh Status of Mother:

The study indicated that the likelihood of clinically significant jaundice was 27.5 times higher in neonates of Rh-negative mothers compared to those of Rh-positive mothers (OR=27.5; 95% CI=11.89-63.78; p<0.0001), corroborated by Pendse et al. (2017)[14].

ABO Incompatibility:

There was a notable correlation between ABO incompatibility and neonatal hyperbilirubinemia (24.2%), with an OR of 2.03 (p=0.045), consistent with findings from Surana et al[15]. (2017).

Sepsis:

Clinically significant jaundice was found to be 13.28 times more common in neonates without sepsis compared to those with sepsis (OR=13.28; 95% CI=4.29-41.07; p<0.0001), which supports the findings of Mahajan et al[16]. (2005).

Dehydration:

The study revealed a significant correlation between dehydration and neonatal hyperbilirubinemia, with an OR of 16.37 (95% CI=7.75-34.56; p<0.0001), similar to the findings of Olusanya et al[17]. (2015).

Polycythemia:

Clinically significant jaundice was found to be 29.63 times more prevalent in neonates with polycythemia than in those without (OR=29.63; 95% CI=3.38-260.18; p<0.002), which aligns with results from Harish et al[18]. (2021).

Gender:

The study observed a male predominance, with 51% of neonates being male, aligning with findings from Shameen et al., where 62% of neonates with hyperbilirubinemia were male.

Socio-economic status:

In the study, 40% of neonates were from socio-economic class 3, followed by 29% in class 4 and 16% in class 2. This is consistent with findings from Yamauchi et al[19]. (2022). Additionally, 50.3% of mothers in the study did not report any

pregnancy-related complications.

STRENGTH:

This pioneering study conducted in South India assesses the differences between the STrIP score and transcutaneous bilirubin (TcB) across various total serum bilirubin (TSB) ranges. It employs Bland-Altman analysis to evaluate the agreement between the STrIP score and TSB, as well as to examine their correlation. The findings emphasize the limitations of using correlation alone as an indicator of agreement, highlighting that a strong correlation may still coexist with clinically significant discrepancies between the two measurements.

LIMITATION:

As a hospital-based study with a relatively small sample size, the results may not be representative of the general population. While the study included a considerable number of participants, there were relatively few neonates with extremely high TSB levels. This is likely attributable to the early identification of significant hyperbilirubinemia within the inborn neonatal unit.

CONCLUSION:-

The STrIP score offers enhanced predictive accuracy, making it a valuable tool for assessing bilirubin levels in newborns and providing reliable non-invasive options for monitoring neonatal jaundice. It demonstrates a stronger correlation with serum bilirubin compared to the transcutaneous bilirubinometer. While the Modified Kramer Scale and transcutaneous bilirubin methods aim for simplicity and reliability, factors such as the mother's age, place of residence, and gender of the participant show no correlation with clinically significant jaundice. In contrast, parity, pregnancy complications, gestational age, birth trauma, Rh status of the mother, ABO incompatibility, sepsis, dehydration, and polycythemia all demonstrate statistically significant associations with clinically significant jaundice.

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