

Diagnostic Accuracy of Kramer's Scale and Transcutaneous Bilirubinometer Compared with Serum Bilirubin Levels Among Neonates with Hyperbilirubinemia: A Cross-Sectional Study in a Tertiary Care Hospital, Mandya

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ABSTRACT

Background: Neonatal hyperbilirubinemia is a common clinical condition affecting approximately 60% of term and 80% of preterm neonates during the first week of life. Although serum bilirubin measurement is the diagnostic gold standard, it requires invasive sampling. Non-invasive methods such as Kramer's scale and Transcutaneous Bilirubinometer (TcB) are commonly used but their accuracy remains debated. This study aimed to evaluate the correlation and diagnostic performance of Kramer's scale and TcB compared with serum bilirubin levels.

Methods: This cross-sectional study was conducted over 3 months in the Paediatrics wards of Mandya Institute of Medical Sciences, Mandya. A total of 100 neonates ≥ 34 weeks gestation presenting with clinical jaundice were enrolled. Kramer's zones were assessed by a trained observer under natural light. TcB measurements were recorded using the Dräger JM-105 jaundice meter. Total serum bilirubin (TSB) values were obtained from laboratory reports.

Results: A total of 100 neonates were assessed, 60% delivered vaginally; most were appropriate for gestational age (85%). Kramer's scale significantly underestimated serum bilirubin across all zones, whereas TcB showed no significant difference from TSB ($p = 0.103$). Correlations analysis demonstrated a moderate relationship between Kramer's and TSB ($r = 0.644$) while TcB showed a stronger correlation ($r = 0.851$). Receiver Operating Curve (ROC) analysis showed superior diagnostic accuracy for TcB (AUC= 0.952) as compared to Kramer's scale (ACU=0.819).

Conclusion: TcB demonstrated strong correlation with serum bilirubin levels and outperforms Kramer's scale in detecting significant hyperbilirubinemia. TcB provides a more reliable, objective, and non-invasive method for neonate's jaundice assessment.

Keywords: Neonatal jaundice, hyperbilirubinemia, Transcutaneous Bilirubinometer, Kramer's scale, serum bilirubin, diagnostic accuracy.

INTRODUCTION

Neonatal hyperbilirubinemia is one of the most common clinical conditions encountered during the early neonatal period, occurring in approximately 60% of term infants and 80% of preterm infants during the first week of life. It occurs due to an imbalance between bilirubin production and elimination and typically presents as visible as jaundice. Although most cases are physiological and self-limiting, untreated significant hyperbilirubinemia can progress to acute bilirubin encephalopathy or kernicterus, resulting in permanent neurological injury. [1] Early recognition and accurate assessment of bilirubin levels are therefore essential for timely intervention and improved neonatal outcome.

Serum bilirubin measurement remains gold standard for diagnosing and monitoring hyperbilirubinemia. However, it requires invasive blood sampling and laboratory processing, which can be painful for neonates, increase the risk of infection and additional healthcare cost. [2] These limitations have revived the use of non-invasive screening tools such as Kramer's rule and Transcutaneous Bilirubinometer (TcB) in routine clinical practice. [3]

Kramer's rule estimates bilirubin levels based on the cephalocaudal progression of dermal jaundice, providing a rapid bedside assessment. Nevertheless, its accuracy is limited by subjectivity, varying lighting conditions and interobserver variability. [3] TcB devices, in contrast measure bilirubin by analysing skin reflectance, offering a more objective and reproducible method with the advantage of being completely non-invasive. [4]

Despite their widespread use, concerns persist regarding the diagnostic accuracy of these non-invasive methods across different

skin tones, gestational ages, and clinical settings. A direct comparison of Kramer's rule and TcB with serum bilirubin levels is therefore essential to evaluate their validity and determine their reliability for neonatal jaundice screening.

Objectives

- To determine the correlation between bilirubin values obtained using Kramer's scale, Transcutaneous Bilirubinometer and total serum bilirubin levels among neonates with hyperbilirubinemia.
- To compare the diagnostic accuracy of Kramer's scale and the Transcutaneous Bilirubinometer in identifying significant hyperbilirubinemia.

MATERIALS & METHODS

This cross-sectional study was conducted in the Paediatrics wards of Mandya Institute of Medical Sciences (MIMS), Mandya, over a six months period from July 2025 to December 2025. The study population consisted of neonates admitted with clinical hyperbilirubinemia. Neonates with gestational age ≥ 34 weeks, clinical evidence of jaundice requiring bilirubin assessment and whose parents given informed consent were eligible for included in the study. Neonates with direct (conjugated) hyperbilirubinemia, sepsis, congenital anomalies, edema, haemangioma, ecchymosis of the skin, or with a prior history of phototherapy or blood transfusion were excluded.

The sample size was calculated using the formula $N = [(Z_{1-\alpha/2})^2 * S_n + (1-S_n)] / (pd)^2$, where $Z_{1-\alpha/2} = 1.96$ (standard normal variable), $S_n = 67\%$ (sensitivity of Kramer's scale from a similar study), $d = 2.5\%$ of $p = 1.3775$, and $p = 55.11\%$ (prevalence of hyperbilirubinemia from a similar study) [5].

The minimum required sample size was estimated to be 81 neonates. A convenience sampling technique was used and a total of 100 neonates were ultimately included in the study.

The study protocol was approved by the Institutional Ethics Committee of MIMS. Written informed consent was obtained from the mothers. Participants confidentiality was strictly maintained throughout the study.

Kramer's Scale Assessment

Kramer's scale originally described in 1969 in a cohort of 108 full-term infants, correlates dermal zones of jaundice with underlying serum bilirubin levels. The body is divided

into five sequential dermal zones according to the Kramer scale, with the extent of cephalocaudal progression of jaundice correlating with increasing serum bilirubin concentrations. These zones include Zone I (head and neck), Zone II (upper trunk), Zone III (lower trunk and thighs), Zone IV (arms and legs), and Zone V (palms and soles), with progressive involvement generally corresponding to higher bilirubin levels. The distribution of jaundice across these five dermal zones is presented in Table 1. [3]

The highest dermal zone of jaundice observed in each neonate was recorded as the Kramer score (I–V).

Table 1. Kramer scale and the different dermal zones according to bilirubin levels. [5]

Kramer Zone	Definition	TSB ($\mu\text{mol/L}$)	TSB (mg/dL)
Zone 1	Head and neck	100	5.85
Zone 2	Upper trunk	150	8.77
Zone 3	Lower trunk and thighs	200	11.70
Zone 4	Arms and lower legs	250	14.62
Zone 5	Palms and soles	>250	>14.62

Data were collected using a structured proforma, that included demographic and clinical details such as the neonatal age (in hours), gestational age, and maternal blood group. Visibly jaundiced neonates were identified in the postnatal wards or NICU by a single trained observer. Kramer's zones were determined by applying gentle pressure to blanch the skin and marking the level to which the yellow discoloration extended. To minimize observer bias, all assessments were performed by the same examiner under natural sunlight.

TcB measurements were obtained using the Dräger Jaundice Meter JM-105, with the probe placed on the sternum. Three consecutive readings were taken, and the mean value was recorded as the TcB.

Serum bilirubin levels (TSB) were obtained from routine laboratory investigations performed according to departmental protocols. These results were noted in the proforma for subsequent comparison with Kramer scores & TcB values.

Statistical Analysis

Data was entered in Microsoft Excel and statistical analysis done using SPSS version 30. Descriptive statistics such as mean, standard deviation, frequencies, and proportions, were used to summarize demographic and clinical characteristics. The correlation between TcB and total serum bilirubin (TSB), as well as between Kramer's scale scores and TSB was assessed using Pearson's correlation coefficient (r). Correlation between non-invasive methods (TcB and Kramer's scale) and TSB was evaluated using Bland–Altman analysis, plotting the differences against the mean of paired measurement. The Diagnostic performance of TcB and Kramer's scale in predicting significant hyperbilirubinemia was assessed using Receiver Operating Characteristic (ROC) curve analysis, with sensitivity, specificity, and Area Under Curve (AUC) reported. Comparisons of mean bilirubin levels across Kramer's zones were performed using paired t-tests or analysis of variance (ANOVA), as

appropriate. A p-value <0.05 was considered statistically significant.

A total of 100 neonates with clinical hyperbilirubinemia were included in the study.

RESULT

Table 2. Demographic Characteristics of the Study Cohort (n = 100)

Variable	Category	Frequency (n)	Percentage (%)
Sex	Male	37	37
	Female	63	63
Mode of Delivery	Vaginal	60	60
	Instrumental	5	5
	Caesarean section	35	35
Growth Status	Appropriate for gestational age (AGA)	85	85
	Small for gestational age (SGA)	12	12
	Large for gestational age (LGA)	3	3
Birth Weight (g)	< 2000	10	10
	2000–2499	30	30
	2500–2999	35	35
	3000–3499	15	15
	≥ 3500	10	10
Gestational Age (weeks)	Late preterm (34–36)	10	10
	Term (37–41)	80	80
	Post-term (≥ 42)	10	10

Of the 100 neonates, 37 (37%) were male and 63 (63%) were female. Most neonates were delivered vaginally (60%), followed by caesarean section (35%) and instrumental delivery (5%). Based on growth status, 85% were appropriate for gestational age (AGA), 12% were small for gestational age (SGA),

and 3% were large for gestational age (LGA). The majority of neonates were term (37–41 weeks) (80%), while 10% each were late preterm and post-term. Birth weight distribution showed that 60% of neonates weighed ≥2500 g.(table-2)

Table 3: Distribution of Mother's & Babies Blood Groups (n = 100)

Blood Group	Mothers Blood Group		Babies Blood Group	
	Frequency (n)	Percent (%)	Frequency (n)	Percent (%)
A+	20	20.0	23	23.0
B+	27	27.0	25	25.0
B–	1	1.0	2	2.0
AB+	1	1.0	1	1.0
O+	50	50.0	45	45.0
O–	1	1.0	4	4.0
Total	100	100	100	100

The most common blood group among mothers was O+ (50%), followed by B+ (27%) and A+ (20%). A similar distribution

was observed among neonates, with O+ being the most frequent (45%), followed by B+ (25%) and A+ (23%). (table-3)

Table 4: Distribution of Kramer's Zones (n = 100)

Kramer's Zone	Frequency (n)	Percent (%)	Valid Percent (%)	Cumulative Percent (%)
Zone 1	1	1.0	1.0	1.0
Zone 2	26	26.0	26.0	27.0
Zone 3	43	43.0	43.0	70.0
Zone 4	25	25.0	25.0	95.0
Zone 5	5	5.0	5.0	100.0
Total	100	100.0	100.0	100.0

The majority of neonates were classified as Kramer zone 3 (43%), followed by zone 2 (26%), zone 4 (25%), zone 5 (5%), and zone 1 (1%). (table-4)

Table 5: Paired Samples Statistics – Kramer's Bilirubin vs Serum Bilirubin (n = 100)

Kramer Zone	Variable	Mean (mg/dL)	N	SD
1	Kramer's bilirubin	5.85	1	—
	Serum bilirubin	8.20	1	—
2	Kramer's bilirubin	8.77	26	0.00
	Serum bilirubin	12.87	26	2.30
3	Kramer's bilirubin	11.70	43	0.00
	Serum bilirubin	15.72	43	2.81
4	Kramer's bilirubin	14.62	25	0.00
	Serum bilirubin	17.07	25	1.65
5	Kramer's bilirubin	16.80	5	1.10
	Serum bilirubin	21.42	5	3.41

The comparison between Kramer's estimated bilirubin levels and total serum bilirubin (TSB) values across different Kramer zones. Kramer's scale consistently underestimated serum bilirubin levels across all zones. (table-5)

Table 6: Paired t-Test Comparison of Kramer's Bilirubin and Serum Bilirubin

Parameter	Mean (mg/dL)	N	Std. Deviation	Std. Error Mean
Kramer's bilirubin value	11.8647	100	2.46742	0.24674
Serum bilirubin value (TSB)	15.5250	100	3.25190	0.32519

The mean Kramer's bilirubin level was 11.86 ± 2.47 mg/dL, while the mean serum bilirubin level was 15.53 ± 3.25 mg/dL (Table 6). The mean difference between Kramer's bilirubin and TSB was statistically significant ($p < 0.001$), indicating systematic underestimation by Kramer's scale.

Table 7: Mean Difference Between Kramer's Bilirubin and Serum Bilirubin Across Zones

Kramer's Zone	Mean Difference (mg/dL)	Std. Deviation	Significance (p-value)
Zone 2	-4.10308	2.30123	0.000
Zone 3	-4.01628	2.81009	0.000
Zone 4	-2.44800	1.64690	0.000
Zone 5	-4.62000	3.33047	0.036

Also, a paired t-test was conducted to compare Kramer's bilirubin estimates and serum bilirubin levels across different Kramer's zones. The mean difference between Kramer's and serum bilirubin was statistically significant in all zones, indicating that Kramer's scale significantly underestimates true serum bilirubin levels. (table-7)

Table 8: Paired t-Test Comparison of TcB and Serum Bilirubin

Parameter	Mean (mg/dL)	N	Std. Deviation	Std. Error Mean
Transcutaneous bilirubin (TcB)	15.8060	100	2.75801	0.27580
Serum bilirubin (TSB)	15.5250	100	3.25190	0.32519

The mean transcutaneous bilirubin (TcB) level was 15.81 ± 2.76 mg/dL, which was comparable to the mean serum bilirubin level of 15.53 ± 3.25 mg/dL (Table 8). The difference between TcB and TSB was not statistically significant ($p = 0.103$), indicating good agreement between the two methods.

Table 9: Correlation Between Bilirubin Estimation Methods

Variables Correlated	Pearson's Correlation Coefficient (r)	p-value	Interpretation
Kramer's B vs TSB	0.644	<0.001	Moderate positive correlation
TcB vs TSB	0.851	<0.001	Strong positive correlation
Kramer's B vs TcB	0.725	<0.001	Strong positive correlation

TcB correlates better with serum bilirubin ($r = 0.851$) than Kramer's scale does ($r = 0.644$), which was found to be statistically significant ($p < 0.001$). These findings indicate that TcB correlates more strongly with serum bilirubin than Kramer's scale (Table 9). Therefore, TcB is a more reliable

non-invasive screening tool for hyperbilirubinemia compared to Kramer's visual assessment.

Scatter plot analysis demonstrated greater variability between Kramer's and TSB values, whereas TcB showed closer agreement with TSB measurements.

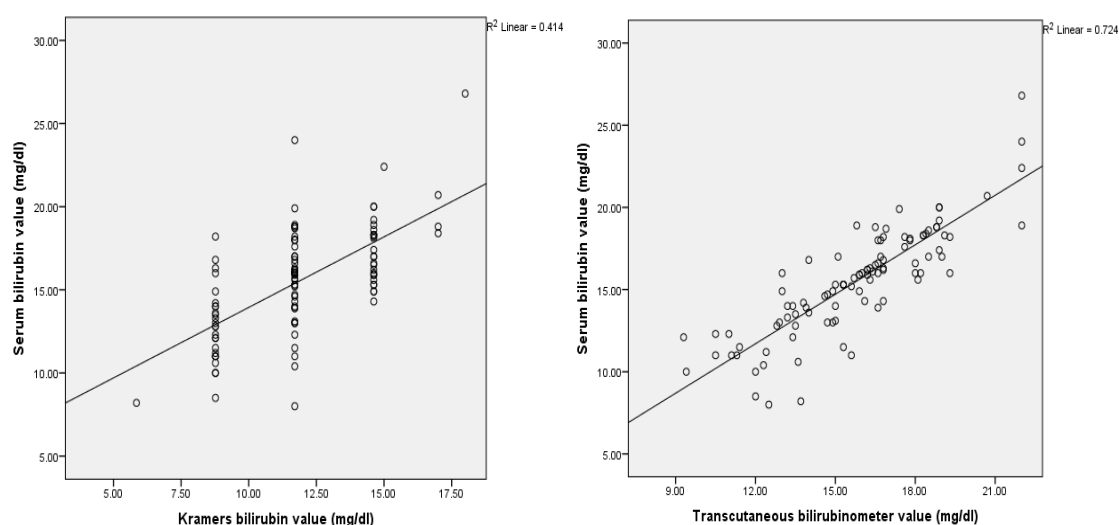


Fig 1: Scatter plot showing correlation between Kramer's bilirubin values and TSB levels among neonates with hyperbilirubinemia.

A moderate positive correlation ($r = 0.644$, $p < 0.001$) was observed between Kramer's bilirubin and serum bilirubin values. However, considerable variability is observed within each Kramer's zone, indicating limited precision of the Kramer's scale in estimating true bilirubin levels. A

strong positive correlation was observed between TcB and TSB values ($r = 0.85$, $p < 0.001$).

Diagnostic Performance for Kramers and TcB

Table 10: Crosstabulation of Kramer's Scale vs Serum Bilirubin (Cut-off: 15 mg/dL)

Kramer's Scale	Hyperbilirubinemia (HB)	No Hyperbilirubinemia (No-HB)	Total
Kramer ≥ 15 mg/dL (Positive)	4	0	4
Kramer < 15 mg/dL (Negative)	56	40	96
Total	60	40	100

Parameter	Formula	Substitution	Result
Sensitivity	$TP / (TP + FN)$	$4 / (4 + 56)$	6.7%
Specificity	$TN / (TN + FP)$	$40 / (40 + 0)$	100%
Positive Predictive Value (PPV)	$TP / (TP + FP)$	$4 / (4 + 0)$	100%
Negative Predictive Value (NPV)	$TN / (TN + FN)$	$40 / (40 + 56)$	41.7%
Accuracy	$(TP + TN) / \text{Total}$	$(4 + 40) / 100$	44.0%

Table 11: Crosstabulation of TcB vs Serum Bilirubin (Cut-off: 15 mg/dL)

Transcutaneous bilirubin	TSB $\geq$ 15 mg/dL (HB)	TSB < 15 mg/dL (NOHB)	Total
TcB = Hyperbilirubinemia ($\geq$ 15 mg/dL)	58	8	66
TcB = NO Hyperbilirubinaemia (<15 mg/dL)	2	32	34
Total	60	40	100

Parameter	Formula		Result
Sensitivity	TP / (TP + FN)	58 / (58 + 2)	96.7%
Specificity	TN / (TN + FP)	32 / (32 + 8)	80.0%
Positive Predictive Value (PPV)	TP / (TP + FP)	58 / (58 + 8)	87.9%
Negative Predictive Value (NPV)	TN / (TN + FN)	32 / (32 + 2)	94.1%
Accuracy	(TP + TN) / Total	(58 + 32) / 100	90.0%

TcB demonstrated higher sensitivity and specificity in detecting significant hyperbilirubinemia.

Diagnostic Accuracy of TcB and Kramer's Scale- ROC curve analysis.

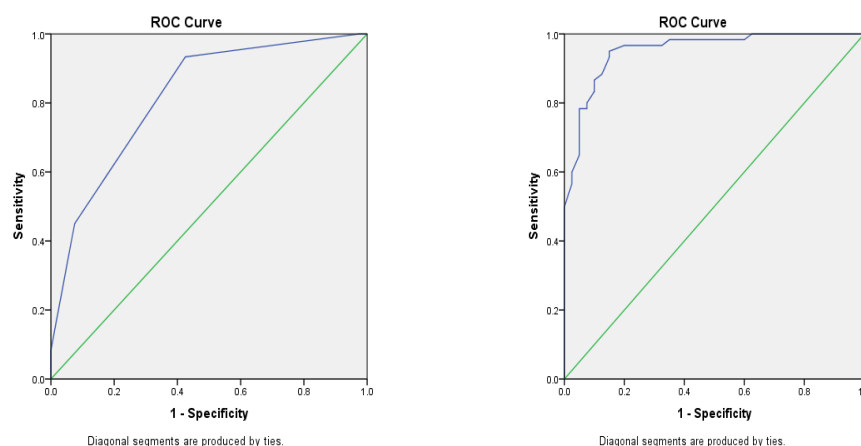


Fig 2: ROC Curve for Kramer's Scale and TcB

Using serum bilirubin $\geq$ 15 mg/dL as the cutoff for significant hyperbilirubinemia, ROC curve analysis showed:

Transcutaneous bilirubinometer (TcB):

- Area under curve (AUC): 0.952
- 95% Confidence Interval: 0.913–0.992
- $p < 0.001$

This indicates excellent diagnostic accuracy.

Kramer's scale:

- Area under curve (AUC): 0.819
- 95% Confidence Interval: 0.734–0.904
- $p < 0.001$

This indicates good diagnostic accuracy, but lower than TcB. Overall, TcB demonstrated superior diagnostic performance compared to Kramer's scale in detecting significant hyperbilirubinemia.

DISCUSSION

Neonatal hyperbilirubinemia is one of the most common clinical conditions encountered during the early neonatal period and remains a significant cause of neonatal morbidity in India. Early detection and appropriate monitoring are essential to prevent severe complications such as acute bilirubin encephalopathy and kernicterus, which may result in permanent neurological damage. ^[6]

TSB estimation remains the gold standard for diagnosis and management; however, it requires invasive blood sampling, laboratory infrastructure, and may delay timely intervention, particularly in resource-limited settings. ^[2]

TcB has emerged as a reliable, non-invasive alternative for screening neonatal hyperbilirubinemia. In the present study, TcB demonstrated a strong positive correlation with serum bilirubin levels, supporting its role as an effective screening tool. Similar findings have been reported in recent Indian studies. Kumar and Kumar conducted a prospective observational study among Indian neonates and reported a strong correlation between TcB and TSB measurements, both before and after phototherapy, concluding that TcB is reliable for clinical use and reduces the need for repeated invasive sampling. [7] Likewise, Shaw et al. developed a gestational age-specific TcB nomogram in Indian neonates and demonstrated its usefulness for early detection and monitoring of hyperbilirubinemia, supporting TcB as an effective screening modality. [8]

Recent evidence from Indian tertiary care settings further strengthens these findings. Chandranaik et al. reported excellent agreement between TcB and TSB values among term and late preterm neonates, concluding that TcB can be effectively used for screening and monitoring jaundice in routine neonatal care. [9] Similarly, a study found a strong correlation between TcB and serum bilirubin levels, recommending TcB as a reliable screening tool, particularly in settings where laboratory facilities are limited. [10] These findings are consistent with the present study and confirm that TcB provides accurate and reproducible bilirubin estimation in Indian neonatal populations.

The major advantage of TcB lies in its non-invasive nature, allowing rapid, painless, and repeatable assessment of bilirubin levels without the risks associated with venipuncture. This is particularly important in neonates, where repeated blood sampling may cause pain, anemia, and increased risk of infection. [2] TcB enables frequent monitoring and facilitates early identification of neonates requiring intervention, thereby improving clinical outcomes.

Despite its advantages, TcB should primarily be used as a screening tool rather than a definitive diagnostic method. Serum bilirubin estimation remains necessary for confirmation, particularly when TcB values approach treatment thresholds or when clinical risk factors are present. [3] The American Academy of Pediatrics recommends TcB for screening, with confirmatory TSB testing for clinical decision-making. [11] Indian studies have also emphasized this approach, recommending TcB as an initial screening modality while retaining TSB as the gold standard for diagnosis and treatment. [7,9]

Compared to visual assessment methods such as Kramer's scale, TcB provides objective and quantitative measurements, reducing observer variability. Visual assessment is subjective and influenced by factors such as skin pigmentation, lighting conditions, and examiner experience, which limits its accuracy. Studies have demonstrated that visual assessment alone is insufficient for reliable estimation of bilirubin levels and may lead to underestimation or delayed diagnosis. [5] The present study also supports this observation, highlighting the superior diagnostic accuracy and reliability of TcB compared to clinical assessment methods.

Overall, the findings of the present study are consistent with recent Indian and international literature demonstrating that TcB is a reliable, accurate, and practical screening tool for neonatal hyperbilirubinemia. Its use in routine neonatal care can facilitate early detection, reduce invasive procedures, and improve neonatal outcomes. However, serum bilirubin estimation remains essential for confirmation and management decisions. Wider implementation of TcB screening, particularly in resource-limited settings, can significantly strengthen neonatal care and contribute to improved neonatal health outcomes in India.

Limitations

The present was conducted at a single tertiary care centre, which may limit the generalizability of the results to wider neonatal populations. Skin pigmentation and lighting conditions may have influenced visual assessment, contributing to the underestimation seen with Kramer's scale. Another one could be TcB measurement was taken from one anatomical site, which may not reflect regional skin differences.

CONCLUSION

TcB being non-invasive it demonstrates significantly higher accuracy, stronger correlation with serum bilirubin and better diagnostic performance than Karmer's scale in detecting neonatal hyperbilirubinemia. Whereas Karmer's scale remains useful in the initial assessment. However, performing TcB routinely among newborn as a screening protocol can enhance early detection and improve neonatal outcome.

Declaration

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Conflict of Interest: The authors declare no conflict of interest.

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