International Journal of Contemporary Pediatrics
Rajmeena A et al. Int J Contemp Pediatr. 2025 Sep;12(9):1487-1491
http://www.ijpediatrics.com
pISSN 2349-3283 | eISSN 2349-3291

DOI: https://dx.doi.org/10.18203/2349-3291.ijcp20252597

Original Research Article

Validation of transcutaneous bilirubinometer with Kramer's scale in term babies with neonatal jaundice

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Received: 17 June 2025
Revised: 08 July 2025
Accepted: 15 July 2025

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ABSTRACT

Background: Neonatal jaundice affects a significant proportion of newborns globally and, if unrecognized or inadequately managed, may lead to severe neurological complications. In low-resource settings, clinical assessment using Kramer's scale is often the initial approach, though its subjective nature and limited accuracy warrant further evaluation. Transcutaneous bilirubinometry (TcB) offers a non-invasive, objective alternative for estimating bilirubin levels.
Methods: Across-sectional observational study was conducted involving 98 term neonates aged over 24 hours with clinical jaundice. Kramer's zones were recorded and simultaneously TcB measurements were obtained using a handheld bilirubinometer. Data were analyzed using descriptive statistics, Pearson correlation, and one-way ANOVA
Results: The majority of neonates were classified under Kramer's zones 2 (35.7%) and 3 (32.7%). Mean TcB levels increased progressively from zone 1 (4.06 mg/dl) to zone 5 (17.65 mg/dl), with the difference being statistically significant ($p=0.01$). A strong positive correlation was observed between Kramer's zone and TcB ($r=0.894$, $p<0.01$), indicating a reliable association between clinical grading and bilirubin levels.
Conclusions: Kramer's scale correlates strongly with TcB values and can be used as a reliable initial screening tool in term neonates. However, in neonates with higher Kramer's zones, confirmatory testing using TcB or Total serum bilirubin (TSB) is recommended.

Keywords: Neonatal jaundice, Kramer's scale, Transcutaneous Bilirubinometry, Bilirubin screening, Term neonates

INTRODUCTION

Neonatal jaundice is one of the most commonly encountered conditions in the early neonatal period, affecting nearly 60-80% of term and preterm neonates worldwide.[1] It is primarily caused by elevated levels of unconjugated bilirubin due to the physiological immaturity of hepatic conjugation and elimination mechanisms. Although most cases are benign and self-limiting, early identification and monitoring are crucial as severe hyperbilirubinemia may progress to acute bilirubin encephalopathy or kernicterus, leading to irreversible neurological damage. Timely and accurate assessment of bilirubin levels is therefore a critical component of neonatal care.[2-4]

In many low- and middle-income countries, especially in rural and semi-urban settings, access to laboratory-based TSB testing is limited.[5] Delays in obtaining results and the invasiveness of repeated blood sampling pose significant challenges. Consequently, there is a continued reliance on visual methods such as Kramer's scale, which grades jaundice based on the cephalocaudal progression of yellowish discoloration of the skin. While practical and cost-effective, Kramer's scale is known to be subjective and influenced by factors such as lighting, skin pigmentation, and observer experience.[6-8]

TcB has emerged as a non-invasive, rapid, and reproducible alternative to visual assessment. TcB devices use multi-wavelength optical sensors to estimate bilirubin concentration in subcutaneous tissues and have shown promising accuracy when validated against TSB. Numerous international studies have demonstrated that TcB correlates well with TSB values, particularly before phototherapy, and can significantly reduce the number of unnecessary serum bilirubin estimations and blood draws in neonates.[9-12]

Despite the availability of TcB devices in select healthcare settings, Kramer's scale continues to be widely used as an initial screening tool, especially in government hospitals and peripheral health centres. However, there remains a paucity of local validation data comparing Kramer's grading with TcB values in Indian populations. Assessing the degree of correlation between the two methods can help determine whether Kramer's scale is sufficiently reliable to be used as a standalone tool or whether it should be supplemented or replaced by TcB in standard protocols. [13-16]

Recent studies have reported variable correlations between Kramer's zones and TcB or TSB levels, with correlation coefficients ranging from moderate to high. Some authors have concluded that Kramer's scale has good sensitivity but poor specificity and is more useful as a screening rather than a diagnostic tool.

Others suggest that TcB provides a closer approximation to TSB, supporting its utility in decision-making regarding phototherapy initiation. However, findings are not always consistent across different geographic, ethnic, and healthcare settings, reinforcing the need for contextual validation.[5,7,12,13,16]

This study aims to bridge the evidence gap by validating Kramer's scale against TcB readings in term neonates at a tertiary care hospital in Cuddalore. By analyzing the correlation between Kramer's zones and TcB values and evaluating the distribution of mean TcB levels across different zones, the study seeks to provide objective evidence on the utility of Kramer's scale in real-world clinical settings. The findings are expected to inform neonatal screening protocols and guide appropriate use of non-invasive methods in resource-limited healthcare environments.

METHODS

This study was done in the department of pediatrics, government Cuddalore medical College and hospital. The study populations are preterm and term neonates with clinically diagnosed neonatal jaundice.

Study period

The study carried out from January 2024 to December 2024.

Study design

It was a cross-sectional observational study.

Sample size

Term neonates with clinical jaundice were enrolled in the study. The sample size was calculated based on an expected sensitivity of 83.3% for 1, Kramer's scale, as reported by Varughese et al with a 95% confidence level and an allowable absolute precision of 8%.[1] Using the standard formula for estimating a single proportion, the required sample size was calculated to be 83. After accounting for a 15% non-response rate, the final sample size was adjusted to 98 neonates.

Sampling technique

Consecutive sampling technique was used.

Inclusion criteria

Neonates were eligible for inclusion if they term babies (≥37 weeks to 42 weeks of gestational age) and fulfilling the criteria for term babies in modified Ballard's score, presenting with clinical jaundice after 24 hours of life.

Exclusion criteria

Preterm neonates (<37 weeks of gestation), post term (>42 weeks of gestation) and neonates who developed jaundice within first 24 hours of life were excluded.

After obtaining informed consent from parents, each neonate was clinically assessed for jaundice using Kramer's scale by trained healthcare personnel. Kramer's zones were recorded based on the cephalocaudal distribution of yellowish skin discoloration and simultaneously a TcB reading was obtained using a handheld bilirubinometer placed on a consistent site (typically the sternum or forehead) to avoid variability.

Analysis

Total of 98 term neonates with jaundice were entered into Microsoft excel and analyzed using SPSS software version 26. Descriptive statistics such as means and standard deviations were computed for TcB levels. Frequencies and percentages were calculated for Kramer's zones. The correlation between Kramer's grading and TcB values was evaluated using Pearson correlation analysis. One-way ANOVA was used to compare the mean TcB values across different Kramer's zones. A p value of less than 0.05 was considered statistically significant.

Ethical considerations

Approved by institutional human ethics committee, government medical college and hospital, Cuddalore

district (Erstwhile Rajah Muthaih Medical College) on 21/07/23 Ref No. IHEC/1155/2023.The registration number of IEC is EC/NEW/INST/2020/1249.

RESULTS

A total of 98 term neonates fulfilling the inclusion criteria were included. The distribution of participants according to Kramer's scale is presented in Table 1. Among the enrolled neonates, the majority were classified in Kramer's zone 2 (35.7%, n=35), followed by zone 3 (32.7%, n=32). Zone 1 included 16 neonates (16.3%), while zone 4 and zone 5 comprised 11 (11.2%) and 4 (4.1%) neonates, respectively. This distribution indicates that most cases of neonatal jaundice in the study population were identified in the moderate Kramer's zones (2 and 3), suggesting mid-level cephalocaudal progression of jaundice at the time of clinical assessment.

The mean transcutaneous bilirubin levels increased progressively with higher Kramer's zones, indicating a positive association between the clinical assessment of jaundice and bilirubin concentration. As shown in Table 2, the mean TcB level in neonates categorized under Kramer's zone 1 was 4.06 mg/dl (SD=1.09), while zone 2 recorded a mean of 7.09 mg/dl (SD=1.54). In zone 3, the mean TcB rose to 9.85 mg/dl (SD=2.01), and further increased to 13.98 mg/dl (SD=1.55) in zone 4. The highest mean TcB was observed in zone 5 at 17.65 mg/dL (SD=2.05). The overall mean TcB for the entire study cohort was 8.70 mg/dl (SD=3.75), with values ranging from 2.4 to 20.7 mg/dl. The differences in mean TcB levels across the Kramer's zones were found to be statistically significant (p=0.01), supporting a strong gradation pattern between visual assessment and objective bilirubin measurement.

A strong positive correlation was observed between Kramer's zone grading and transcutaneous bilirubin values, as shown in Table 3. Pearson's correlation coefficient was r=0.894, indicating a high degree of linear association between the clinical assessment of jaundice and the TcB measurement. This correlation was found to be statistically significant (p<0.01), suggesting that as the Kramer's zone increased, the TcB values also increased consistently. These findings validate clinical relevance of transcutaneous billirubinometer as a potential screening tool for jaundice severity, particularly in settings where access to biochemical testing may be limited.

Table 1: Frequency distribution of Krammer's zone among term neonates with jaundice, (n=98).

Krammer's zone	N	Percent (%)
1	16	16.3
2	35	35.7
3	32	32.7
4	11	11.2
5	4	4.1
Total	98	100

Table 2: Descriptive statistics of transcutaneous bilirubin by Krammer's zone, (n=98).

Krammer's zone	N	Mean TCB with SD (mg/dl)
1	16	4.06±1.09
2	35	7.09±1.54
3	32	9.85±2.01
4	11	13.98±1.55
5	4	17.65±2.05

DISCUSSION

The present study aimed to validate transcutaneous billirubinometer by comparing it with Kramer's scale in term neonates with jaundice. A statistically significant positive correlation (r=0.894, p<0.01) was observed between Kramer's zones and TcB values, indicating that higher Kramer grades were strongly associated with higher bilirubin levels. This finding reinforces the utility of transcutaneous billirubinometer as a useful screening tool for jaundice in clinical settings, particularly in resource-constrained environments.

Our findings align with those of Esmaelzadeh et al who reported a high correlation between serum bilirubin and TcB values (r=0.915) and a substantial agreement between Kramer's scale and bilirubin measurements before phototherapy.[2] Similarly, Kurnianto et al reported a correlation coefficient of 0.897 between TcB and TSB, supporting the accuracy of non-invasive methods in estimating bilirubin.[7] Gupta et al also found that Kramer's scale correlated well with TSB (r=0.757) and that TcB performed slightly better (r=0.801).[5] Varughese et al demonstrated that TcB was more accurate than Kramer's scale, particularly at 24 and 48 hours, as evidenced by ROC analysis and Bland-Altman plots.[1]

The progressive increase in mean TcB values across Kramer's zones in our study (from 4.06 mg/dL in zone 1 to 17.65 mg/dL in zone 5) is consistent with the craniocaudal progression of jaundice described in classical literature. Siluwal et al also reported high sensitivity (94.3%) but low specificity (31.9%) of Kramer's scale against TSB, highlighting its value for screening rather than diagnostic confirmation.[3] In our study, the significant difference in mean TcB levels across Kramer's zones (p=0.01) further strengthens the scale's clinical applicability when interpreted with caution. Mumtaz et al found that Kramer's scale had acceptable accuracy in neonates jaundiced up to the abdomen (Zones 1-3), supporting our observation that the majority of cases clustered in mid-range zones.[4]

While the present study supports the use of Kramer's scale in settings where TcB is unavailable, it also emphasizes the limitations of subjective assessment. Szabo et al reported that clinical assessment performed when compared to two transcutaneous bilirubinometers and was influenced by gestational age, skin color, and

ambient light.[9] Similarly, Shariati et al showed that the accuracy of TcB varies slightly depending on the site of measurement but still outperforms visual inspection.[15] Ercan et al demonstrated that TcB could reduce the need for serum sampling by up to 40% when appropriate cut-offs were used, suggesting that combining both TcB and Kramer's scale may optimize neonatal jaundice screening.[6]

The current study provides strong evidence that Kramer's scale correlates well with TcB values and can serve as a practical screening tool in term neonates. However, it should be complemented with TcB or serum bilirubin testing, especially in neonates with higher Kramer zones or those with risk factors for severe hyperbilirubinemia. Our findings are consistent with those of Lim et al who showed that integrating TcB with Kramer's rule reduced unnecessary serum bilirubin testing without increasing adverse outcomes.[8] Future studies with larger sample sizes and inclusion of TSB values are recommended to further validate and optimize neonatal jaundice screening protocols in diverse clinical settings.

Limitations

Being a single-center study, the findings may not be generalizable to all settings. The study did not include serum bilirubin levels for comparison, limiting validation to TcB alone.

CONCLUSION

In this study, Transcutaneous bilirubinometer demonstrated a strong positive correlation with Kramer's zone in term neonates, supporting its validity as a clinical tool for jaundice assessment. The mean TcB values showed a consistent increase across ascending Kramer's zones, indicating good clinical reliability of the cephalocaudal progression model in estimating bilirubin levels. Therefore, Transcutaneous bilirubinometer can be used as a screening method, particularly in settings where Serum Bilirubin testing is not available

While TcB and Kramer's zone is useful for initial evaluation, confirmatory serum bilirubin testing is recommended for neonates presenting with higher transcutaneous bilirubin values and Kramer's zones to ensure accurate diagnosis and appropriate management.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee Ref No. IHEC/1155/2023.The registration number of IEC is EC/NEW/INST/2020/1249.

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Cite this article as: Rajmeena A, Chidambaranathan S, Rajaselvan R, Divya E. Validation of transcutaneous bilirubinometer with Kramer's scale in term babies with neonatal jaundice. Int J Contemp Pediatr 2025;12:1487-91.