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Diagnostic Accuracy of Kramer Visual Assessment of Jaundice in Term Neonates Taking Total Serum Bilirubin Levels as the Gold Standard

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ABSTRACT

Objective: To determine the Diagnostic accuracy of Kramer's visual assessment of jaundice in term neonates by taking total serum bilirubin levels as a gold standard.

Study Design: Cross-sectional study.

Place and Duration of Study: Neonatology Department, Pak Emirates Military Hospital, Rawalpindi Pakistan, Mar to Sep 2019.

Methodology: The study was based on examining and investigating 300 neonates. Kramer scale was used to examine jaundice in all neonates, and results were compared to total serum bilirubin levels.

Results: A total of 300 patients were included in this study. The mean bilirubin level was 229.1±74.5mol/L**.** The sensitivity and specificity of visual assessment of jaundice using the Kramer visual scale were 83.84% and 73.53%, respectively, for neonates who were not jaundiced below the abdomen and thighs included in Kramer zones 1 to 3.

Conclusion: Kramer visual assessment can be used as a noninvasive screening method in neonates jaundiced up to the abdomen and thighs, which is included in Kramer zones 1 to 3 but for markedly jaundiced neonates Kramer scale is not a reliable noninvasive method of bilirubin estimation.

Keywords: Kramer visual assessment, Neonates, Total serum bilirubin.

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INTRODUCTION

Jaundice is the yellow discolouration of skin and sclera and is a problem which is seen commonly in up to 60% of term neonates during the first week of life. Most cases are found to be benign and happen to resolve spontaneously, while 20% of cases require medical intervention to treat significant jaundice.[1] Jaundice presents within the first 2-7 days of life in most neonates.[2] Neonates discharged from the hospital within 48 hours after birth is likely to return to the hospital with complaints of jaundice which may require treatment. In the early days, jaundice was assessed by visual examination of the neonates; however, this was subjective, inaccurate and often confounded by skin pigmentation. The gold standard used for measuring bilirubin level in the neonate is total serum bilirubin estimation.[3,4] In most of the postnatal wards, the decision whether to perform total serum bilirubin is dependent on the age of the neonate and the assessment of jaundice by using the Kramer visual scale.[5] However, total serum bilirubin levels and Kramer visual scale correlate poorly in various studies.[6] In most neonates, jaundice due to unconjugated hyperbilirubinemia is found to be a normal transitional phenomenon. However, in some neonates, unconjugated bilirubin levels may excessively rise, which can cause kernicterus resulting in cerebral palsy, hearing loss, gaze abnormality and mental retardation.[7] Therefore, early jaundice detection is of utmost importance and requires stringent examination and evaluation, which can be done in invasive serum bilirubin levels or non-invasive and cost-effective screening. The bilirubin levels may be measured noninvasively by physical examination using Kramer visual scale. This scale is used to estimate the severity of hyperbilirubinemia by examining the zone of skin discolouration in the neonate to five specific dermal zones, which were labelled as the face (zone 1), chest and upper abdomen (zone 2), lower abdomen and thighs (zone 3), arms and legs (zone 4) and finally palms and soles (zone 5). The Kramer visual scale concludes that an increasing zone of yellowish discolouration from zone1 to zone 5 corresponds with progressively increasing total serum bilirubin levels.[8,9]

Early detection of jaundice is important to prevent multiple complications of high bilirubin levels. Therefore, this study was conducted to determine the

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diagnostic accuracy of physical examination of jaundice using the Kramer scale, keeping laboratory serum bilirubin levels as the gold standard.

METHODOLOGY

This comparative cross-sectional study was carried out from March 2019 to Sep 2019 in the Neonatology Department of Pak Military Emirates Hospital, Rawalpindi. Ethical approval was taken from IERB (A/28/Ec/214/2020) and formal consent from the parents of the children after providing them with all the information regarding the study.

Inclusion Criteria: All visibly jaundiced neonates who were more than 7 days of age of either gender and weight of more than 2.0 kg were included in the study.

Exclusion Criteria: Neonates who had jaundice with the history of previous hospital admission were excluded from the study.

WHO calculator was used to calculate sample size with a confidence level of 95% and anticipated population proportion of 31.8% with absolute precision of 7%.[10] A trained physician visually examined each baby to assess the level of jaundiced skin. Blood for the serum bilirubin sample was collected under aseptic measures within one hour of clinical examination. To determine the diagnostic accuracy of the Kramer scale as a screening test, we divided the dermal zones 1, 2 and 3 into First Group and the remaining two zones, 4 and 5, into the Second Group. A serum bilirubin level of 250µmol/L was taken as positive for a Kramer scale of 1 to 3. Serum bilirubin levels of more than or equal to 250 were taken as positive for marked hyperbilirubinemia as labelled by Kramer scale 4 and 5.

Statistical Package for Social Sciences (SPSS) version 25.0 was used for the data analysis. Frequency and percentages were calculated for qualitative variables. Mean and standard deviation were calculated for quantitative variables. Diagnostic parameters were calculated using a 2 x 2 table. Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy were determined by using the standard formulae.

RESULTS

A total of 300 neonates were included in this study. The mean gestational age was 38.67±1.17 weeks. Of 300 patients, 211(70.3%) were between 37-39 gestational weeks, and 89(29.7%) were at 40-42 weeks of age. The mean total serum bilirubin (TSB) level calculated was 229.3±74.5µmol/L. Mean TSB values based on the Kramer index were faced (zone-1) 163±11.6µmol/L, chest and upper abdomen (zone-2) 207±9.21µmol/L, lower abdomen and thighs (zone-3) 247.0±9.22µmol/L, arms and lower legs (zone-4) 254± 8.66µmol/L and palms and soles (zone-5) 291.0±11.89 µmol/L as shown in Table-I.

Table-I: Kramer Scale according to Serum Bilirubin Level (n=300)

Kramer scale	Total Serum Bilirubin (µ mol/L) Mean±SD
Face (zone 1)	163.0±11.6 µmol/L
Chest and upper abdomen (zone 2)	207.0±9.21 µmol/L
Lower abdomen and thighs (zone 3)	247.0±9.22 µmol/L
Arms and lower legs (zone 4)	254.0±8.66 µmol/L
Palms and soles (zone 5)	291.0±11.89 µmol/L

Among 300 neonates, 193 were given Kramer scale from 1 to 3. Of these, 166 had serum bilirubin levels less than 250µmol/L, and 27 had serum bilirubin levels more than or equal to 250umol/L. Out of 107 neonates with Kramer scale 4 and 5, 75 neonates had serum bilirubin levels more than or equal to 250µmol/L, and 32 had serum bilirubin levels less than 250µmol/L. 2x2 table revealed that neonates who were jaundiced up to abdomen and thighs included in Kramer zones 1 to 3 had a sensitivity of 83.84% and specificity of 73.53%. In addition, it had a positive predictive value of 86.01% and a negative predictive value of 70.09% (Table-II).

Table-II: Total Serum Bilirubin Levels in Kramer Scale 1-3 (n=300)

	Total Serum Bilirubin Levels	
	Less than 250 µmol/L (n=198)	Equal to or more than 250 µ mol/L (n=102)
Kramer Scale 1-3		
Positive	166(83.83%)	27(26.47%)
Negative	32(16.16%)	75(73.53%)

However, for neonates who had jaundice up to extremities and below the knees, which were included in zones 4 and 5, the Kramer scale may not accurately predict severe hyperbilirubinemia as 29.9% of neonates amongst this Group had serum bilirubin levels less than 250µmol/L (Table-III).

DISCUSSION

Neonatal hyperbilirubinemia has always been a matter of concern for paediatricians worldwide. Visual examination by the Kramer scale has been used for many decades for screening for hyperbilirubinemia, and total serum bilirubin is the gold standard for measurement of jaundice [7,8]. Neonatal hyperbilirubinemia is one of the most common and preventable

Table-III: Diagnostic Parameters of Kramer Scale 1-3 with Serum Bilirubin Level (n=300)

Diagnostic accuracy of Kramer index 1-3	
Sensitivity= True Positive/(True Positive+False Negative)	83.84%
Specificity= True Negative/(True Negative + False Positive)	73.53%
Positive Predictive Value=True Positive/(True Positive + False Positive)	86.01%
Negative Predictive Value=True Negative/(True Negative +False Negative)	70.09%
Diagnostic Accuracy=(True Positive +True Negative)/All Patients	80.33%

problems in term and near-term neonates during their early postnatal period. Since the reduced duration of hospital stay for newborns has been established in the last decade, neonatal readmission due to hyperbilirubinemia has seen an increase in Turkey, along with many other developed and developing countries. [9-12]

There have been differences in opinion among many paediatricians regarding the usefulness of the Kramer scale. It is, however, true that in poor resource settings, the Kramer scale continues to be effective in diagnosing hyperbilirubinemia when examined by trained professional.[13] In healthy-term babies, if jaundice has not reached the abdomen or the extremities, included in Kramer zones 3 to 5, hyperbilirubinemia can be easily and safely ruled out by visual assessment.[14] This is similar to our study that showed that as Kramer's score increases, bilirubin value also increases. Madlon-Kay found that nursing staff trained in the clinical assessment of jaundice could adequately identify neonates with total serum bilirubin levels <205µmol/L and those with serum bilirubin levels >290µmol/L. Therefore satisfactorily referring neonates to the hospital who were at greater risk.[15] Another study by Aprilia *et al*. showed that visual assessment of neonatal jaundice had a sensitivity value of 76.92%, a specificity value of 89.47%, and an accuracy value of 86.27%.[16] In a comparison of our study, the sensitivity and specificity of the Kramer scale were 83.84% and 73.53%, respecti-vely, in Kramer zones 1 to 3. Riskin *et al*. labelled bilirubin level of 6mg/dL (102.6µmol/L) as the cut-off point, which had a positive predictive value of 26.2%, whereas the negative predictive value was found to be 97.9%. The predicted serum bilirubin levels based on the Kramer scale were significantly correlated with total serum bilirubin levels (r=0.682, p<0.001).[17] Another study was conducted in Iran, in which the bilirubin cut-off point was 6 mg/L (102.6 µmol/L) with a negative predictive value of 97.7% and specificity of 76.60%.[15] Another Study by Strauss *et al*. debated the reliability and accuracy of Kramer's scale and found an insignificant correlation between physician's observations and total serum bilirubin levels. Despite these shortcomings, they concluded that clinical observations made by physicians were 97% specific in identifying infants who were not likely to have bilirubin levels >205µmol/L, based on the identifi-cation that jaundice did not extend beyond the nipple line.[18] However, in our study, physicians were 73.53% specific in identifying infants with jaundice extending up to the abdomen and legs. Different studies in tertiary care hospitals in Pakistan revealed that Kramer scale 1 and 2 and transcutaneous bilirubinometer were dependable tools to rule out significant hyperbilirubinemia after 24 hours of age in term babies.[19,20]

CONCLUSION

Kramer visual estimation of bilirubin levels for the degree of jaundice is a non-invasive, cost-effective screening method with 83.84% sensitivity and 73.53% specificity in neonates who are jaundiced from face to abdomen and thighs, which is included in the Kramer scale 1 to 3. Serum bilirubin levels should always be measured in neonates who are jaundiced below the abdomen or up to extremities to contemplate the decision of phototherapy and exchange transfusion.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

SM & MFS: Data acquisition, critical review, approval of the final version to be published.

KAK & MH: Conception, Study design, drafting the manuscript, approval of the final version to be published.

AR & SS: Data analysis, data interpretation, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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