

Diagnostic Validity of Kramer's Scale as Compared to Total Serum Bilirubin Neonates with Hyperbilirubinemia

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ABSTRACT

Background: Neonatal Jaundice (NNJ) is a physiological condition characterized by increase in total bilirubin concentration in the blood. High levels can lead to brain damage that causes cerebral palsy, visual and hearing loss hence early detection and appropriate management of neonatal jaundice is very important in preventing kernicterus. Visual assessment of jaundice using Kramer's scale has proved to be highly effective. The objective of this study was to validate the diagnosis of jaundice using Kramer's scale.

Methods: This hospital based study was done in 107 neonates delivered and diagnosed with neonatal jaundice at Dhulikhel Hospital. Visual assessment of jaundice was done by two observers, result compared with that of transcutaneous bilirubinometer and total serum bilirubin.

Results: The result of the study showed that the sensitivity and specificity of the Kramer scale were 94.3% and 31.9% respectively with 40.2% positive predictability and 92% negative predictability value against the TSB measurement. Similarly, there was 83.8% sensitivity, 44.4% specificity, 81.7% positive predictability and 48% negative predictability against transcutaneous Bilirubinometer.

Conclusion: Kramer's scale has high sensitivity and low specificity as compared to total serum bilirubin and transcutaneous bilirubinometer. Therefore it can be used as an alternative method to assess bilirubin level if there is no facility for total serum bilirubin (TSB) and Transcutaneous Bilirubinometer (TcB) measurement.

Keywords : Hyperbilirubinemia; Kramer's Scale; Total serum Bilirubin.

INTRODUCTION

Neonatal Jaundice (NNJ) is a physiological condition characterized by increase in total bilirubin concentration in the blood. This occurs in 60-80% termed neonate worldwide.¹ It appears as yellowish discoloration of skin and mucus membrane due to bilirubin accumulation.² Neonatal jaundice is the seven leading cause of neonatal death worldwide.^{3,4} In some infants, jaundice may become severe enough to cause bilirubin induced mortality or long term neuro-developmental impairments requiring effective evaluation and treatment.³ In most of the conditions, physiological jaundice in neonates is harmless but multiple risk factors might contribute to severe neonatal jaundice, such as prematurity, low birth weight, sepsis, inadequate breast feeding and high risk

mother. High bilirubin level can lead to brain damaged which causes cerebral palsy, visual and hearing loss.^{4,5} Early detection and appropriate management of neonatal jaundice is very important in preventing comorbid conditions associated with it. For the better management of neonatal jaundice, measuring bilirubin levels is vital; which is usually done by visual, cutaneous, and serum evaluations.⁶

Total serum bilirubin (TSB) measurement is the gold standard method of measurement for jaundice.⁷ Transcutaneous Bilirubinometer (TcB) monitoring is a useful clinical screening tool to evaluate the risk of clinically significant jaundice.⁸ Visual assessment of

jaundice using Kramer's rule is simple and possible estimations of jaundice are based on the cephalo-caudal trend.^{5,6,9} To assess the bilirubin levels in neonate, it is best to have a simple, cost effective and easy method which is noninvasive, follows the principles of non-traumatic care and is based on infection prevention too. For developing countries like Nepal, cost effective and easy method should be instituted for better assessment. Therefore this study aims to find out the diagnostic validity of Kramer's scale in comparison with transcutaneous bilirubinometer (TcB) and total serum bilirubin (TSB) among neonates after 24 hours to 28 days of life in Dhulikhel hospital.

METHODS

We conducted a cross-sectional descriptive study from July 2018 to August 2018 at Dhulikhel Hospital (KUSMS). Dhulikhel hospital is a 375 bedded tertiary care hospital in the vicinity of capital of Nepal which acts as a catchment to a large number of rural population of the region. We selected all neonates admitted in neonatal ward (NIMCU), postnatal ward (PNC) and pediatric outpatient department who had developed jaundice after 24 hours of life, whose birth weight was more than or equal to 1000 grams, gestational age above 32 weeks. Neonates admitted for other conditions having jaundice were also included in the study. Neonates having congenital malformation, sepsis, extreme low birth weight (<1000gms) and below 32 weeks of gestation were excluded from the study in order to prevent excess manipulation and invasive procedure in neonates since they are already susceptible to health deficits.

The questionnaire consisted two sections, the first section taking in the socio-demographic information and the second section for detailed assessment of the neonates. We assessed jaundice in the neonates with following three techniques. First was using the Kramer's scale, the finding of which was triangulated by assessment by a second person independently, Then we assessed the neonates with a Transcutaneous Bilirubinometer (JH20-1A) and assessed the serum bilirubin using BA400 model system. We did the data entry and analysis using SPSS version 21. We conducted descriptive analysis and used correlation for the findings between the techniques used to assess the jaundice. We conducted the study after ethical approval from the Institutional Review Board of National Academy of Medical Sciences and Institutional Review Committee from Kathmandu University School of Medical Sciences. The proforma was pre -tested among 11 neonates (10% of the total patient) in the emergency department and Neonatal intermediate care unit (NIMCU) in Kanti Children Hospital, Maharajgunj, Kathmandu.

RESULTS

Table 1 illustrates the demographic information of the total 107 cases included in the study. Out of total 107 neonates, 95 (88.8%) neonates were less than 5 days,

8 (7.5%) were 5-10 days and 4 (3.7%) neonates were more than 10 days. The mean age of the neonates were 3.76 days (SD 4.57). The median age of neonates was 3 days (IQR 2-4). Among them, male female ratio was 3:2. There were 71 (66.36%) neonates who had sufficient breastfeeding and 36 (33.64%) neonates with neonatal jaundice had insufficient breast feeding. There were 36 (33.64%) neonate had blood group "O" positive, "B" positive were 29 (27.10%), and 27 (25.23%) neonates were "A" positive blood group. Among 107 neonates, 105 (98.1%) neonates were term. There were 95 (88.8%) neonates between 2.5kg to 4kg. The mean birth weight was 2.99kg (SD 0.3911).

Table 1: Socio-Demographic Characteristics of the Neonates

Variables	Frequency	Percent
Age (in days)		
24 hours-5 days	95	88.80
5-10 days	8	7.50
10-28 days	4	3.70
Mean age (in days)	3.76±4.57	
Median age (in days)	3 (2-4)	
Sex		
Male	65	60.75
Female	42	39.25
Breast Feeding		
Sufficient	71	66.36
Insufficient	36	33.64
Baby's Blood group		
A Positive	27	25.23
B Positive	29	27.10
O Positive	36	33.64
AB Positive	13	12.15
Negative	2	1.86
Gestational Age		
Term	105	98.10
Preterm	2	1.90
Birth Weight		
Less than 2.5 kg	11	10.30
2.5 kg -4 kg	95	88.80
More than 4 kg	1	0.90
Mean weight (2.99± 0.3911)		

Table 2 shows the correlation among observation of Kramer's scale against Transcutaneous-bilirubinometer and Serum Bilirubin. It was found that there were moderately significant positively correlation among all the tests at p <0.001 level. Similarly, table 3 shows that the sensitivity and specificity of the Kramer scale were 94.3% and 31.9%, respectively with 40.2% positive predictability and 92% negative predictive value.

Table 2: Correlation of Total Observation of Kramer Scale against Transcutaneous Bilirubinometer and Total Serum

Kramer's Scale	Transcutaneous bilirubinometer (TcB)		Total Serum Bilirubin (TSB)	
	Spearman's rho	p-value	Spearman's rho	p-value
Assessment of Hyperbilirubinemia	0.580	<0.001	0.580	<0.001

** Correlation is significant at the 0.01 level (2-tailed).

Table 3: Calculation Summary of Diagnostic Validity of Kramer's Scale with TSB among Neonates

Diagnostic characteristics	Kramer's scale compared with TSB
Sensitivity	94.3 %
Specificity	31.9%
Predictability	
Positive Predictive Value	40.2%
Negative Predictive Value	92%

The table 4 shows that, the sensitivity and specificity of the Kramer scale as compared with transcutaneous bilirubinometer was 83.8% and 44.4% respectively with positive predictive value was 81.7% and 48% negative predictive value against the transcutaneous bilirubinometer measurement.

Table 4: Calculation Summary of Comparison of Kramer's Scale with TcB among Neonates

Characteristics (Kramer's scale)	Compared with Transcutaneous Bilirubinometer (TcB)
Sensitivity	83.8%
Specificity	44.4%
Positive Predictive value	81.7%
Negative Predictive Value	48%

DISCUSSION

Most of the studies have compared transcutaneous bilirubinometer with total serum bilirubin, but this study is conducted to identify the diagnostic validity of Kramer's scale as compared with total serum bilirubin and transcutaneous bilirubinometer. It was found that there was moderate positive correlation between findings of Kramer's scale and transcutaneous bilirubinometer and also with total serum bilirubin. The study found that Kramer's scale had 94.3% sensitivity, 31.9% specificity, 40.2% positive predictive value and 92% negative predictive value as compared to total serum bilirubin. On comparing Kramer's scale with transcutaneous bilirubinometer, it was found that there were 83.8% sensitivity, 44.4% specificity, and 81.7% positive predictability and 48% negative predictability. This shows that Kramer's scale has relatively higher

sensitivity values than specificity values in both total serum bilirubin (TSB) and transcutaneous bilirubinometer (TcB). Besides that Kramer's scale has comparatively high negative predictive value as compared with TSB than positive predictive value, and the other hand high positive predictive value in transcutaneous bilirubinometer (TcB). This means that Kramer's scale is able to identify true negative cases more than true positive cases in Total Serum Bilirubin and to identify the more true positive cases in transcutaneous bilirubinometer.

Similar study of Kramer examination of neonatal jaundice comparison with total serum bilirubin proved that the Kramer test was good for determining neonatal jaundice among neonates. The sensitivity, specificity and accuracy were (76.92%, of 89.47% and 86.27%. respectively). That study recommended that the Kramer test is a good method for obtaining accurate result in neonatal jaundice examination.²

Another study by Lauer BJ, showed an appraisal of the use of the Kramer's scale in predicting hyperbilirubinemia in a healthy full term infants. The positive and negative predictive value were 4% and 98% respectively. Because 49 and 72 hours, the sensitivity was 89% and specificity was 54% with a positive predictive value 99% of the 111 infant who had blood drawn for testing, who were over 72 hours of age, none required phototherapy.¹⁰ Another study conducted on accuracy of bilicare transcutaneous bilirubinometer, showed correlation between TcB and TSB was significant correlation with TSB $r = 0.84$, $r^2 = 0.7$. The sensitivity, specificity, positive predictive value, negative predictive value were 78.3%, 94.2%, 62.1%, and 97.3% respectively. The conclusion was bilicare TcB and TSB measurement were well correlated.¹¹ These studies show that bilirubin level findings with transcutaneous bilirubinometer is significant with total serum bilirubin findings. Our study shows that Kramer's scale is significant with both transcutaneous bilirubinometer values. Thus, Kramer's scale can also be used as significant tool to estimate hyperbilirubinemia in neonates.

CONCLUSION

The Kramer scale has high sensitivity and low specificity as compared to total serum bilirubin and bilirubinometer therefore can be used as an alternative method to assess bilirubin level if there is no facility for TSB and TcB measurement.

Implications

The findings of the study have implications for nursing practice, nursing education, administration and nursing research.

Nursing Service

Nurses may use Kramer's scale to identify early neonatal jaundice and timely start its management.

Nurses can reduce further complication of neonatal jaundice by early identifying the levels using Kramer scale. (Kernicterus).

Nursing Education

The validity of Kramer's scale and finding of this study will provide information to develop clinical teaching and in-services education programs for all nursing students on management of neonatal jaundice.

Nursing student can be assessed cephalo caudal direction of progression of neonatal jaundice.

Nursing Administration

The nurse administrator could encourage the use of the study finding in daily clinical practice.

The study finding may contribute to the development of evidence based protocols on management of neonatal jaundice.

Nursing Research

The study finding may be used to conduct other similar studies in different settings.

This study may encourage other researchers to investigate the problem further to facilitate further generalization of the results.

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