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RESEARCH ARTICLE

KRAMERS RULE AS A SCREENING TEST TO ASSESS NEONATAL HYPERBILIRUBINEMIA

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Abstract

Background: Neonatal jaundice is a frequently encountered condition in the postnatal ward. If not treated properly, it can lead to permanent neurological sequelae. The gold standard investigation for diagnosis is total serum bilirubin (TSB)level. Transcutaneous bilirubinometers and visual assessment of cephalo-caudal progression of yellowish discoloration of neonatal skin by Kramer's rule are commonly used non-invasive methods to predict jaundice. If correctly applied, these methods can help in minimising the number of blood samples to be drawn for TSB testing.

Aims/Objectives:1. To assess the reliability of Kramer's rule in predicting TSB in healthy neonates admitted in postnatal ward**.** 2**.** To assess theusefulness of Kramer's rule in deciding which neonates require testing of TSB levels.

Methods: This is a cross sectional study conducted on 100 healthy neonates admitted in the post-natal ward of a tertiary care hospital. Data was collected in pre-designed case record sheets. Sensitivity and specificity of Kramer's rule in correct prediction of serum bilirubin was identified by using true and false outcomes**.**

Results: The mean age at which neonates were examined was at 72 hours of life. 41% of the neonates were male and 59% were female.79% of the total babies were born via normal vaginal delivery and 21% via caesarean section.The sensitivity of Kramer's rule in predicting serum bilirubin levels was 83.33% with a specificity of 54.55% (P value 0.015).

Conclusion: Kramer's rule is a fairly reliable method for predicting serum bilirubin levels and can help in avoiding unnecessary blood testing in neonates, especially in resource limited settings where such facilities might not be available.

Introduction:-

Jaundice in neonates refers to yellowish discoloration of skin and sclera of the eye caused due to accumulation of bilirubin in skin and mucous membrane. It is the most common morbidity in the first week of life, occuring in up to 60% of term and 80% of preterm neonates and the most common cause of readmission after discharge at birth. [1] It is usually benign and is termed as physiological jaundice. It occurs due to increased breakdown of red blood cells in neonates along with immature hepatic clearance mechanism. Jaundice is clinically visible in neonates at serum bilirubin levels of more than 5 to 7 mg/dl. [2] Although most cases of neonatal jaundice are physiological and do not have serious consequences, high levels of bilirubin can cause bilirubin induced neurological dysfunction (BIND)

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leading to acute bilirubin encephalopathy, kernicterus, athetoid cerebral palsy, cognitive dysfunction, sensorineural hearing loss. [3] Prolonged jaundice or any jaundice occurring within first 24 hours of life is considered pathological and requires urgent medical attention. The American academy of pediatrics (AAP) recommends that all infants should be routinely monitored for progression of jaundice. [4,5] A simple tool to assess the level of jaundice in neonates is the Kramer's scale. [6] The scale is based on a 1969 study of 108 full term infants which found that bilirubin concentrations were correlated to 5 specific 'dermal zones' (i) head and neck, (ii) upper trunk, (iii) lower trunk and thighs, (iv) arms and legs below the knees, (v) hands and feet. (Fig 1) Lowest serum bilirubin levels were associated with yellow discoloration of the head and neck only and highest levels where the discolouration extended to the hands and feet.

Site	Serum bilirubin levels
Head and neck	4-8 mg/dl
Upper trunk	5-12 mg/dl
Lower trunk and thighs	8-16 mg/dl
Arms & lower legs	11-18 mg/dl
Palms & soles	>18 mg/dl

Fig 1:- Kramer's criteria (Indian Academy of Paediatrics, April 2016)

While Kramer's scale is a safe non-invasive method to estimate the level of jaundice in a neonate, the gold standard still remains analysis of TSB level by blood sampling. Use of transcutaneous bilirubinometers is another non-invasive method available for assessing jaundice, however, it may not be feasible in developing countries with resource limited settings. This study aims at assessing the reliability of Kramer's rule in predicting the level of TSB in neonates and thereby reducing the number of blood tests needed to be done.

Aims:-

To assess the reliability of Kramer's rule in predicting total serum bilirubin level in healthy neonates admitted in postnatal ward**.**

Objectives:-

1. To assess the reliability of Kramer's rule in predicting TSB in healthy neonates admitted in postnatal ward**.**
2. To assess theusefulness of Kramer's rule in deciding which neonates require testing of TSB levels**.**

Material And Methods:-

Study design-

This was a hospital based cross-sectional descriptive study.

Study site-

Conducted in the post-natal ward of a tertiary care hospital during the month of February 2022.

Sample size-

A time bound sample of 100 healthy neonates admitted in the postnatal ward formed the study.

Inclusion criteria:

All healthy neonates of gestational age more than 35 weeks and weight >1.6kg admitted in post-natal ward.

Exclusion criteria

1. Neonates who have received/ currently receiving phototherapy.
2. Neonates of gestational age <35 weeks and weight < 1.6kg
3. Neonates whose mother did not give consent.

Procedure –

A total of 100 neonates were enrolled in this study. Neonates were examined in broad daylight and visually assessed for clinically visible jaundice using the Kramer's rule by two independent treating pediatricians. Infant's skin was blanched using thumb pressure and the colour of the underlying skin noted. Based on the extent of discoloration, specific Kramer's zone was assigned to each neonate. A parallel blood sample was drawn for TSB and the value obtained was compared with the expected range of TSB level as per assigned Kramer zone.

Statistical analysis –

Primary data was collected in paper based proforma and the data was then entered in Microsoft Excel spreadsheets 2016. Statistical analysis was done on IBM SPSS STATISTICS VERSION 20. Categorical variables were taken in the form of frequencies and percentages. Distribution was represented by pie charts or bar graphs. Continuous variables were expressed in the descriptive statistics tables as means, standard deviation and range. Sensitivity and specificity of Kramer's rule in correct prediction of serum bilirubin was identified by using true and false outcomes. Receiver operating curve was plotted using sensitivity on Y axis and 1- specificity on X axis and Area under the curve was calculated. P value < 0.05 was considered significant and p value < 0.01 was considered highly significant.

Results:-

Table 1:- Demographic data.

Parameters	**N = 100**
Age (Days)	
Mean	03.17
SD	01.17
Range	1 - 17
Gender (%)	
Male	41 (41.0)
Female	59 (59.0)
Type of Delivery (%)	
ND	79 (79.0)
LSCS	21 (21.0)

Table 2:- Profile of Blood group in babies & mothers.

Blood Group	**Babies (N = 100) N (%)**	**Mothers (N = 100) N (%)**
O+ positive	28 (28.0)	27 (27.0)
O- negative	01 (01.0)	-
A+ positive	21 (21.0)	19 (19.0)
A- negative	02 (02.0)	03 (03.0)
B+ positive	33 (33.0)	23 (23.0)
B- negative	03 (03.0)	04 (04.0)
AB+ positive	12 (12.0)	24 (24.0)

Table 3:- Mean Sr. Bilirubin detected per Zone.

Zone	**N**	**Mean Sr. Bilirubin ($\overline{X}$ ± SD) (N = 100)**
1 (Range 4 – 8 mg/dL)	06	06.50 ± 01.33
2 (Range 5 – 12 mg/dL)	19	11.51 ± 02.73
3 (Range 8 – 16 mg/dL)	30	13.39 ± 02.10
4 (Range 11 – 18 mg/dL)	31	15.96 ± 02.77
5 (Range >18 mg/dL)	14	19.89 ± 03.50

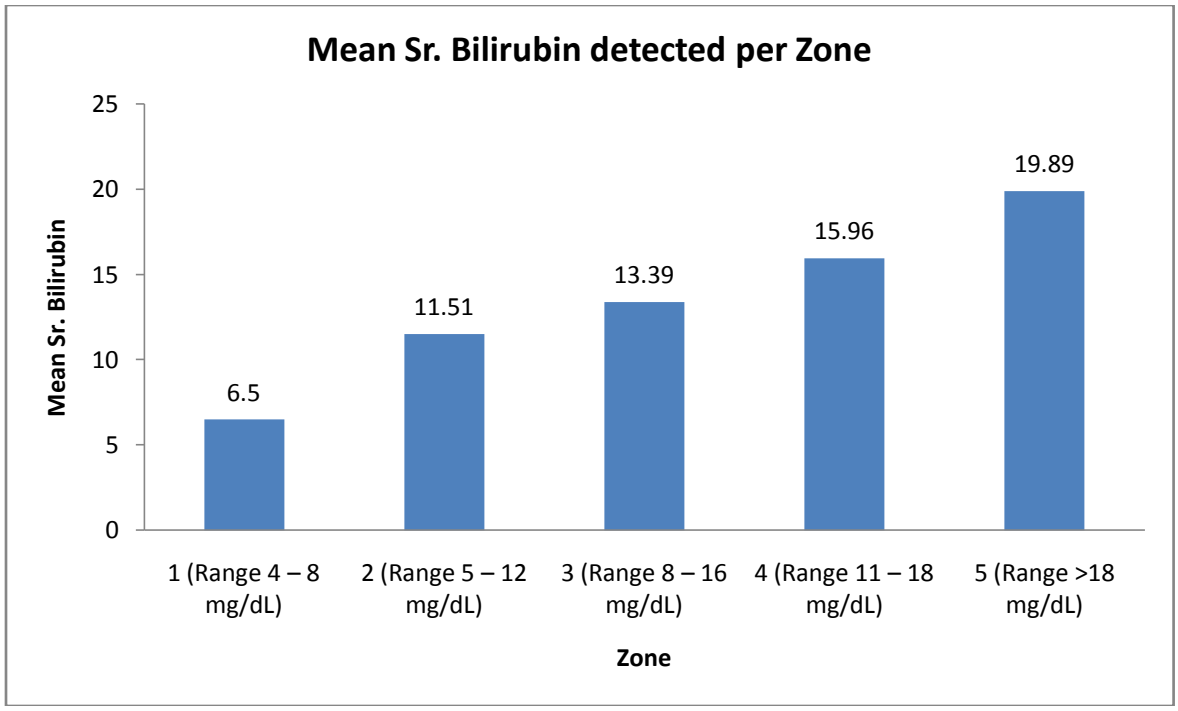

Table 3:- Profile of Sensitivity & Specificity for detection of Sr. Bilirubin.

Parameters	**Value**
Sensitivity	83.33%
Specificity	54.55%
Area under the curve	0.663

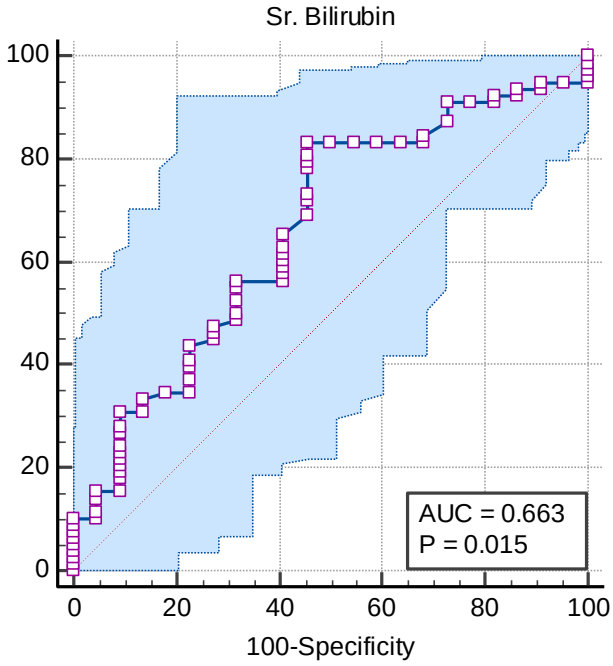

Fig:- ROC curve.

The results of the study have been tabulated above. 100 healthy neonates admitted in the postnatal ward were enrolled in this study. The mean age at which neonates were examined was at 72 hours of life. 41% of the neonates

were male and 59% were female. Out of the total babies,79% were born via normal vaginal delivery and 21% were born via caesarean section. There were 3 Rh negative pregnancies in this study. The serum bilirubin levels were compared with the corresponding Kramer's zone for each baby. The mean serum bilirubin levels for each zone have been tabulated above. In this study, the sensitivity of Kramer's rule in predicting serum bilirubin levels was 83.33% with a specificity of 54.55% (P value 0.015).

Discussion:-

Our study is mainly based on evaluating the reliability of visual assessment of jaundice as an indication for the measurement of serum bilirubin levels. Jaundice in newborns progresses in a cephalo caudal direction, it first appears in the face and then progresses downwards to involve the palms and soles.The American Academy of Pediatrics (AAP) recommends that **clinicians should ensure that all infants are routinely monitored for the development of jaundice, and nurseries should have established protocols for the assessment of jaundice. If doctors and nurses are trained properly in visually inspecting the babies, jaundice can be picked up at an early stage and further complications can be avoided.**

Devi et. al conducted a study on detection of jaundice using Kramer's criteria- they concluded that Kramer's criteria is a suitable low-cost and a feasible alternative modality for early detection of neonatal jaundice in a resource poor setting.[7]

However, visual assessment of jaundice is a subjective finding and can vary from one individual to another. Moyer et. Al conducted a study on 122 healthy term newborns on Accuracy of Clinical Judgment in Neonatal Jaundice among experienced paediatric nurses and attending physicians.They concluded that clinical examination with visual assessment for jaundice in newborns is neither reliable nor accurate. The decision to perform serum bilirubin testing should be based on additional factors.[8] A similar study was conducted by L Hatzenbuehleret al on Validity of neonatal jaundice evaluation by primary health-care workers and physicians in Karachi, Pakistan. Primary health-care workers identified hyperbilirubinemic neonates with adequate sensitivity. With proper training and supervision, their assessment could improve the referral of hyperbilirubinemic neonates in low-resource settings in the developing world.[9]

According to a study done by Webster et al among 405 term neonates: An appraisal of the use of the Kramer's scale in predicting hyperbilirubinemia in healthy full-term infants, using Kramer's scale to assess which infants require intervention for jaundice leads to over servicing. They concluded that significant hyperbilirubinemia is present in very few infants and more refined methods are needed for identifying those who are at greatest risk. If the number of unnecessary tests is to be reduced, more accurate methods for identifying infants who may be at risk for hyperbilirubinemia must be used.[10]

Visual assessment of jaundice has its own drawbacks, it being a subjective finding. Also, it is not reliable in babies who are under phototherapy. However, it can be useful as a primary tool of screening in setup where facility for TSB testing is not available. It can help in early identification and prompt referral of babies for further medical management.

Conclusion:-

Kramer's rule is a fairly reliable screening test for prediction of TSB level in neonates. In this study, the sensitivity of Kramer's rule in predicting serum bilirubin levels was 83.33% with a specificity of 54.55% (P value 0.015). Healthcare workers should be trained in visual assessment of jaundice. Kramer's rule can be used as a primary test for predicting serum bilirubin levels, especially in setting where no laboratory facility is available helping in early identification and prompt referral of babies for further medical management. It can help in triaging which neonates require testing for TSB levels and reduce the number of blood tests to be done, thereby reducing the risk of introducing an infection. Awareness regarding visual assessment of jaundice should be created among healthcare workers as well as mothers.

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