NEONATAL MORTALITY AND NEURODEVELOPMENTAL OUTCOME OF VERY LOW BIRTH WEIGHT (VLBW) NEWBORNS ATTENDING A RURAL TERTIARY CARE HOSPITAL, PREDICTED BY CLINICAL RISK INDEX FOR BABIES SCORE II (CRIBS II)

Kausik Patra¹, Balai Chandra Karmakar²

¹Ex-Postgraduate Trainee, Department of Paediatric Medicine, North Bengal Medical College and Hospital, Darjeeling, West Bengal, India.

²Associate Professor, Department of Paediatric Medicine, North Bengal Medical College and Hospital, Darjeeling, West Bengal, India.

ABSTRACT

BACKGROUND

Mortality and various neuro-developmental sequelae among very low birth weight babies (VLBW) are a common problem in Indian scenario. Most of them are delayed diagnosed and there is no enough research work available regarding magnitude and pattern of disability in Indian scenario. Data which is available from developed countries is not reflecting the real picture of developing countries. In contrast to western population, our hands are bound by various problems including poor nutrition of mother during antenatal period, anaemia, poor hygiene, infection, unhealthy environment and inadequate health-care infrastructure. Several studies have reported high incidence of growth failure and poor neurological outcome during infancy and childhood. There have been a few studies from India, reporting growth and neurodevelopment of low birth weight infants. We wanted to assess the efficacy of CRIBS II as a tool for assessing the mortality and long-term neuro-developmental outcome of VLBW babies.

METHODS

This prospective cohort study included 143 VLBW babies admitted in Sick New Born Care Unit (SNCU) of North Bengal Medical College & Hospital, Darjeeling, West Bengal from June 2016 to August 2017 and discharged babies were followed up.

RESULTS

A total of 143 neonates were studied at SNCU. Among them, 82 (57.3%) were male and 61 (42.7%) were female. Birth weight ranged from 500 to 1500 grams with a mean of 1199.6 ± 244.14 and the median was 1240 gm. CRIB II score ranged from 1-18 with mean of 8.021 ± 3.883 , and median of 7.734 %. 105 out of 143 were discharged alive. Significant positive correlations were found among birth weight, gestational age, temperature, excess base, and progressive increase in mortality with increasing CRIB II score ($p < 0.001$). Adverse neonatal outcome associated with CRIB II score ≥ 10 . Cut off value of CRIB II score (> 10) at which maximum sensitivity of 97.5% and specificity of 50% is 9.5 for predicting mortality of VLBW babies. The value under the ROC curve was 0.986 (95 % CI: 0.000 – 1.000) with a standard error of 0.0029.

CONCLUSIONS

CRIB II score was found to be a very good tool for VLBW babies with regard to mortality and neuro-developmental assessment. It is easily applicable and can replace the traditional models as a predictor of neonatal outcome.

HOW TO CITE THIS ARTICLE: Patra K, Karmakar BC. Neonatal mortality and neurodevelopmental outcome of very low birth weight (VLBW) newborns attending a rural tertiary care hospital, predicted by clinical risk index for babies score II (CRIBS II). J. Evolution Med. Dent. Sci. 2019;8(19):1521-1527, DOI: 10.14260/jemds/2019/338

BACKGROUND

Globally, prematurity is the leading cause of neonatal death (babies < 4 weeks) and now the second leading cause of death after pneumonia in children under five years of age. In low-income settings, half of the babies born at 32 weeks die due to a lack of feasible, cost-effective care, such as warmth, breast feeding support, and basic care for infections and breathing difficulties. In high-income countries, almost all of these babies survive.⁽¹⁾

More than 20 million infants worldwide, representing 15.5% of all births are born with low birth weight, 95.6% of them in developing countries. The number of low birth weight babies in developing countries (16.5%) is more than double in developed countries (7%). In India it is estimated that incidence of LBW is about 30%. (Resourced by DHS on 1999 and reanalysed on June 2003).⁽²⁾ In 2005 it was 28% and in 2010 it was nearly 20% of new-borns were LBW. The North-east zone has the lowest prevalence of LBW while the north zone has the highest.^(3,4)

Nearly 24% or one in four children born prematurely across the globe in 2010 were from India. Around one million children die each year due to complications of preterm birth. Significant progress has been made in the care of premature infants, but not in reducing the prevalence of preterm birth.⁽⁵⁾ In 2010, an estimated 32.4 million infants were born small for gestational age in low-income and middle-income countries (27% of live births), of whom 10.6 million infants were born at term and low birth weight. Of 18 million low-birth weight babies, 59% were term-SGA and 41% were preterm-SGA. Two-thirds of small-for-gestational-age infants

'Financial or Other Competing Interest': None.

Submission 26-02-2019, Peer Review 24-04-2019,

Acceptance 30-04-2019, Published 13-05-2019.

Corresponding Author:

Dr. Balai Chandra Karmakar,

30H Harey Krista Sett Lane,

P. S. Sinthi, Kolkata-700050,

West Bengal,

India.

E-mail: balaikarmakar75@gmail.com

DOI: 10.14260/jemds/2019/338

were born in Asia (17.4 million in south Asia). Preterm-SGA babies totalled to 2.8 million births in low-income and middle-income countries. Most small-for-gestational-age infants were born in India, Pakistan, Nigeria, and Bangladesh.⁽⁶⁾

Therefore in past years various scoring system have been developed to predict neonatal morbidity and mortality and these neonatal scores have been developed in order to assume a more accurate evaluation. Unfortunately mortality rates, even if are risk adjusted, can no longer be the only index of the performance of neonatal intensive care unit. During last two decades various scoring system for assuming neonatal mortality risk were introduced as follows:

The national institute of health neonatal network model,⁽⁷⁾SNAP (Score for Neonatal Acute Physiology),⁽⁸⁾SNAP-PE(Score for Neonatal Acute Physiology-Perinatal Extension)⁽⁹⁾and CRIBS (Clinical Risk Index for Babies).⁽¹⁰⁾Then SNAP-II (Simplified New-born Illness Severity and Mortality Risk Score) and CRIBS II(An Update of CRIBS) were developed later in NICU and introduced as robust indices of neonatal risk, to predict mortality and morbidity in new-borns.^(10,11)

CRIB II scoring system has five variables: (i) Birth weight (ii) Gestational age (iii) Base deficit (iv) Temperature on admission and (v) Sex.

It is a risk index for newborn weighing less than 1500 grams. The score is divided according to gender and weight are compared with gestational age. The range of score for weight compared with gestational age in male is 0-15 and in female is 0-14 and for temperature the score is 0-5 and for base excess 0-7. At the end the scores are totalled. Better prognosis with lower scores attained the best favourable results with score of one.

METHODS

Settings and Design

A Prospective cohort study among 143 VLBW babies admitted in Sick New Born Care Unit (SNCU) of North Bengal Medical College & Hospital, Darjeeling, West Bengal from June 2016 to August 2017 and discharged babies were followed up.

Inclusion Criteria

All preterm newborn of both sexes admitted in SNCU 23 to 32 weeks of gestational age and birth weight <1500 grams.

Exclusion Criteria

All preterm newborn Less than 23 weeks of gestation, Birth weight <500 grams, Gross congenital malformation, genetic disorder, delivery room death, admission after 12 hours of birth.

Study Tools

The study was conducted by using Measuring tape, Torch, Cubes, Percussion hammer, Infantometer, DDST chart, Growth chart, Proforma, SPSS V 20, EpiCalc 2000 v 1.2 statistical software and Analyse-it for method validation in MS excel ultimate edition.

Data Collection

1. Obstetrical history of mother for time of birth, gestational age in week calculated from the first day of last menstrual Period (LMP).
2. Neonatal Data-
 - a) Gestational age by obstetrical ultrasonography and Expanded New Ballard Score where LMP is unknown.
 - b) Gender and Birth weight by digital weighing scale.
 - c) Base excess on admission by arterial blood gas analysis.
 - d) Temperature (Celsius) on admission by digital thermometer.
 - e) Anthropometry (height, weight, head circumference) using WHO growth chart/foetal-infant growth chart/CDC growth chart accordingly.
 - f) Developmental and neurological score using DDST chart and standard neurological examination procedure.
 - g) Ophthalmological and BERA examination report.

Growth and developmental assessment and neurological examination on follow up of discharged babies at 1st, 3rd, 6th, 9th, 12th months.

All the parameters along with the Gender of baby were assigned scores according to CRIBS II. The final CRIB II score (ranged from 0 to 27) was obtained by the arithmetic sum of the individual scores. The scores were further classified into four levels as follows; Level 1:0 to 5, Level 2:6 to 10, Level 3:11 to 15, Level 4 above 15.⁽¹²⁾

Statistical Analysis

Independent t test and Pearson's chi-square test were used to analyse the data. The analysis of specificity and sensitivity of the studied variables for mortality prediction was carried out through Receiver Operating Characteristics (ROC) curves, and the areas under the curves (AUC) were compared to define the differences with statistical significance with selection of the most suitable cut-off point of each parameter with the best sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and overall accuracy. All tests were tailed with p value < 0.05 as significant and performed by SPSS v 20, Chicago. Pearson correlation was used for calculation between CRIB II score and Predicted Death Rate.

RESULTS

143 babies were studied, 82 (57.3%) were males and 61(42.7%) were females. Non-survivors represented 38 (26.6%) while survivors represented 105 (73.4%). According to CRIB II score babies were classified into 4 groups:

Male infant												Female infants											
2751 to 3000												2751 to 3000											
2501 to 2750												2501 to 2750											
2251 to 2500												2251 to 2500											
2001 to 2250												2001 to 2250											
1751 to 2000												1751 to 2000											
1501 to 1750												1501 to 1750											
1251 to 1500												1251 to 1500											
1001 to 1250												1001 to 1250											
751 to 1000												751 to 1000											
501 to 750												501 to 750											
251 to 500												251 to 500											
22 23 24 25 26 27 28 29 30 31 32												22 23 24 25 26 27 28 29 30 31 32											
Birth weight (g) and gestation (weeks)																							
Cribs II Scoring System																							

<= 29.6	5	< -26	7
29.7 to 31.2	4	-26 to -23	6
31.3 to 32.8	3	-22 to -18	5
32.9 to 34.4	2	-17 to -13	4
34.5 to 36	1	-12 to -8	3
36.1 to 37.5	0	-7 to -3	2
37.6 to 39.1	1	-2 to 2	1
39.2 to 40.7	2	>= 3	0
>=40.8	3		
Temperature on Admission (°C)		Base Excess (mmol/L)	

CRIB II Score Level	Distribution of Samples according to Total Score		Outcomes				p Value
			Discharged (N= 105)		Expired (N=38)		
Level I (0-5)	52	36.4%	52	49.5%	0	0	< 0.001
Level II (6-10)	56	39.2%	53	50.5%	3	7.9%	
Level III (11-15)	27	18.9%	0	0	27	71.1%	
Level IV (>15)	8	5.5%	0	0	8	21.1%	
Table 1. The Mean Total Score (Mean± SD) was 8.021±3.883 with Range 3-18 and the Median was 7. The Mean Birth Weight (Mean ± SD) was 1199.6 ±244.14 gm with Range 580-1490 gm and the Median was 1240 gm. The Mean Gestational Age (Mean± SD) was 29.65 ±2.032 Weeks with Range 24-32 Weeks and the Median was 30 Weeks. The Mean Temperature (Mean± SD) was 33.54±1.61° C with Range 30-37 ° C and the Median was 34 ° C. The Mean Base Excess (Mean± SD) was -5.68 ±4.37 with Range -20 to +2.0 and the Median was -4.5.							

Parameter/Variables	Description n= 143		
Gender	Number	%	Male mortality is higher than females.
Male	82	57.3	
Female	61	42.7	
Birth Weight (in gm)	Number	%	The mean birth weight (Mean ± SD) was 1199.6 ±244.14 gm with range 580-1490 gm and the median was 1240 grams and mean gestational age (Mean± SD) was 29.65 ±2.032 weeks with range 24-32 weeks and the median was 30 weeks.
500-≤1000	34	23.8	
1001-≤1500	109	76.2	
Gestational Age (weeks)	Number	%	
24-≤28	37	25.9	
29-≤32	106	74.1	
Temperature (in °C)	Number	%	The mean temperature (Mean± SD) was 33.54±1.61° C with range 30-37 ° C and the median was 34 ° C.
30.0 - 32.0	34	23.8	
32.1 - 34.0	60	42	
34.1 - 36.0	48	33.6	
36.1 - 37.0	1	0.7	
Base excess (mmol/L)	Number	%	The mean base excess (Mean± SD) was -5.68 ±4.37 with range -20 to +2.0 and the median was -4.5.
-20.4 to -10.0	20	14	

-9.9 to 0.0	117	81.8	
0.1 to 2.0	6	4.2	
Distribution of Samples According to Score for BW & GA			
Score for BW & GA	Number	%	The mean score for BW & GA (Mean± SD) was 3.78±2.71 with range 1-12 and the median was 3.
1 – 4	90	62.9	
5 – 8	45	31.5	
9 – 12	8	5.6	
Distribution of Samples According to Score for Temperature			
Score for temperature	Number	%	The mean score for temperature (Mean± SD) was 2.11 ±0.93 with range 0-4 and the median was 2
0-2	106	74.1	
3-4	37	25.9	
Distribution of Samples According to Score for BE			
Score for BE	Number	%	The mean score for BE (Mean± SD) was 2.15 ±0.91 with range 1-5 and the median was 2
1-2	108	75.5	
3-5	35	24.5	
Table 2. Descriptive Data of The Studied Neonates			

Parameter/variables	Outcomes	N	Mean	Std. Dev	P value
Birthweight (in gms)	Discharged	105	1306.2	155.42	< 0.001
	Expired	38	900	194.01	
Gestational age (in weeks)	Discharged	105	30.56	1.229	< 0.001
	Expired	38	27.08	1.605	
Score for BW GA	Discharged	105	2.63	1.71	< 0.001
	Expired	38	7.0	2.4	
Temperature at admission (°C)	Discharged	105	34.26	0.981	< 0.001
	Expired	38	31.52	1.278	
Score for Temp	Discharged	105	1.69	0.58	< 0.001
	Expired	38	3.3	0.7	
Base excess (mmol/L)	Discharged	105	-3.66	2.0	< 0.001
	Expired	38	-11.3	4.26	
Score for BE	Discharged	105	1.75	0.5	< 0.001
	Expired	38	3.27	0.87	
Table 3. Comparison of Parameters of Crib II Scores Between Discharged Alive and Expired					

CRIB II Score	Pearson Correlation	Outcomes
Total CRIB II score	Pearson Correlation	0.823**
	Sig. (2-tailed)	< 0.001
	N	143
Predicted Death Rate	Pearson Correlation	0.819**
	Sig. (2-tailed)	< 0.001
	N	143
Table 4. Pearson Correlation was Statistically Significant with Positive Correlation Between Higher Total CRIB II Score and Predicted Death Rate (%) i.e. Higher Score was Associated with High Predicted Death Rate Values.		
**. Correlation is significant at the 0.01 level (2-tailed).		

Variables	Cut-off Point	Sensitivity	Specificity	PPV	NPV	Accuracy
CRIB II Score	≥ 10	97.37%	97.14%	92.50%	99.03%	97.20%
GA	≤ 28	76.32%	92.38%	78.38%	91.51%	88.11%
Birth Weight	≤ 1000	73.68%	94.29%	82.35%	90.82%	88.81%
BW & GA	>4	86.84%	80.95%	62.26%	94.44%	82.52%
Temperature	>2	84.21%	95.24%	86.49%	94.34%	92.31%
Score for BE	>2	84.21%	97.14%	91.43%	94.44%	93.71%

Table 4a. Shows Screening Analysis of CRIB II Score, Gestational Age, Birth Weight BW & GA, Temperature and Score for BE in Predicting Mortality Using the Most Suitable Cut-Off Point.

Chi-square (χ^2) test performed among different variables viz total CRIB II score ($\chi^2 = 123.56$; $p = 0.0000001$), Score for BW & GA ($\chi^2 = 54.91$; $p = 0.0000001$), Score for temperature ($\chi^2 = 91.70$; $p = 0.0000001$) and Score for BE ($\chi^2 = 99.67$; $p = 0.0000001$) and showed significant association between score and adverse outcome ($p < 0.01$). The risk of death was more for total score ≥ 10 , score for BW & GA > 4 , Score for temperature > 2 and Score for BE > 2 .

Figure 1. ROC curves of CRIB II Score and different parameters used in the score. With decreasing age, weight, temperature, and excess base, the mortality increased. Highest value of Area Under Curve (AUC) is seen with total score followed by score for temperature.

Growth Parameters		Total CRIB II score				p Value
		Mean	S.D	Minimum	Maximum	
Weight for age (<-2 Z Score)	Yes	7.346	1.765	4	10	< 0.001
	No	5.615	1.752	3	9	
Length for age (<-2 Z score)	Yes	7.543	1.559	4	10	< 0.001
	No	5.298	1.597	3	9	
Weight for length (<-2 Z Score)	Yes	7.346	1.765	4	10	< 0.001
	No	5.615	1.752	3	9	
Head circumference for-age (< -2 Z score)	Yes	8.923	1.44	5	10	< 0.001
	No	5.423	1.608	3	9	
Head circumference (cm)	≤ 40	7.87	1.486	6	10	< 0.001
	> 40	5.531	1.681	3	9	
Weight (kg)	≤ 7	6.906	1.89	4	10	< 0.001
	> 7	5.667	1.792	3	9	
Length (cm)	≤ 70	7.543	1.559	4	10	< 0.001
	> 70	5.29	1.591	3	9	

Table 5. Showing correlation of different growth parameters with total CRIBS II score which shows good statistically correlation with a p value <0.05.

Total CRIB II Score					p Value
	Mean	S.D.	Minimum	Maximum	
Developmental Delay					
Yes	8.21	1.197	5	10	< 0.001
No	5.25	1.434	3	9	
Cerebral Palsy					
Yes	9.00	1.069	7	10	< 0.001
No	5.8	1.745	3	9	
Visual Abnormality					
Yes	8.8	0.919	7	10	< 0.001
No	5.76	1.745	3	10	
Absent ABR					
Yes	8.308	1.251	6	10	< 0.001
No	5.725	1.758	3	10	
Table 6. Showing correlations of Total CRIB II Score with parameters of neuro-developmental delay like developmental delay, cerebral palsy, visual abnormality, absent ABR. All showing good correlations which is statistically significant (p <0.001)					

DISCUSSION

Premature births are outnumbered by males with higher susceptibility of mortality⁽¹³⁾. This finding is consistent with our study where male to female cases were 1.3:1 respectively, with higher mortality in males. A useful and simple method of

risk-adjustment is important to ensure accurate assessment for quality care of newborn⁽¹⁴⁾. Our study revealed positive associations between the gestational age, the birth weight temperature, base excess and the mortality; the lower the gestational age, birth weight the higher the mortality that was

proved to be statistically significant ($p < 0.001$). Survivors had a mean CRIB II score of less than non-survivors. Cut off value of CRIB score at which maximum sensitivity of 97.5% and specificity of 50% is 9.5 for predicting mortality of VLBW babies. Similar results were obtained by Ezz-Eldin ZM et al,⁽¹⁵⁾ Jafrashteh A et al,⁽¹⁶⁾ Jasik BM et al⁽¹⁷⁾ and Heidarzadeh M et al⁽¹⁸⁾

The value under the ROC curve was 0.986 (95 % CI: 0.000 – 1.000) with a standard error of 0.0029. The curve is deviated upwards and to the right, so that it is located in the upper right corner of the graph that means as sensitivity decreases, it is not followed by loss of specificity. Higher scores correlated well with mortality. Therefore, CRIB II scoring turns out to be a reliable discriminative test. Compared to birth weight and gestational age, CRIB II score showed better calibration to predict neonatal mortality. This is in accordance with other studies like Ezz-Eldin et al⁽¹⁵⁾ and Jasik BM et al.⁽¹⁷⁾

Growth Outcome

This study showed incidence of moderate to severe growth retardation (< -2 Z score) like wasting 25.7%, stunting 34.3%, under nutrition 25.7% and microcephaly 24.8% among total study population which is comparable with Pradip k. Sharma et al,⁽¹⁹⁾ and Modi et al,⁽²⁰⁾ study but microcephaly is about 15% more in our study that was due to socioeconomic factors, and significant postnatal morbidities, lack of detailed nutritional history and parental heights and small sample size.

This study also showed that AGA babies had microcephaly 14.8%, stunting 24.7%, wasting 14.8%, under nutrition 14.8% in comparable with SGA babies it were 58.3%, 66.7%, 62.5% and 62.5% for SGA respectively and considerable differences between mean Z score (weight for age, weight for length, length for age, and head circumference for age) in two groups of population ($P < 0.05$) which was consistent with observation done by Ane C. Westerberg et al⁽²¹⁾ that Very low birth weight infants showed catch-up growth during the first year, but their weight and length remained less than full-term peers. Growth deficiencies were more pronounced among infants subjected to early growth restriction, despite increased catch-up growth. Pradip k. Sharma et al,⁽¹⁹⁾ also shown the similar growth difference between VLBW SGA and AGA children.

Neurodevelopment

This study showed major neurological abnormalities are Developmental delay (isolated delay but no CP) 32.4%, Cerebral palsy (CP) 7.6%, Deafness 12.4%, Blindness and/ or ROP 9.5% and more with higher CRIB II score that is comparable with study done by HoJJ et al⁽²²⁾ to estimate the prevalence and pattern of neuro-developmental handicap at 2 years of age in very low birth weight infants (VLBW) admitted in 1993 to a level 3 Malaysian nursery. Functionally 23.3% of the study group had mild handicap, 1.3% moderate, 2.5% severe, 2.5% multiply severe and 70.2% were normal. Most of western literature (Procianoy RS, Koch MS et al,⁽²³⁾ Gutbrod T et al,⁽²⁴⁾ Gabriel J Escobar et al and few eastern literature (Modi et al,⁽²⁰⁾ Pradip k. Sharma et al,⁽¹⁹⁾ Mukhopadhyay K et al⁽²⁵⁾) showed the incidence of neuro-developmental abnormality is lower in comparison to our study. Though the incidence of, hearing and visual

abnormality is higher in our study, developmental delay and cerebral palsy is quite comparable, that, might be due to high rate of post-natal morbidity in VLBW babies and sample size is too small in compare to those studies.

Limitations of The Study

This study was done in small sample size ($n=143$) with one year follow up period so we might miss some delayed neuro-developmental sequelae. Parental height was not taken into consideration during stunting calculation.

CONCLUSIONS

CRIB II score proved to be a good tool for neonatal assessment and for predicting neonatal mortality and neuro-developmental outcome among Indian neonates. It should be implemented as an essential component of routine care to all neonates admitted to SNCUs.

Ethical Considerations

The study was approved by of North Bengal Medical College & Hospital, Darjeeling, West Bengal Ethics Committee. Written consent was taken from the parents of the involved neonates.

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