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Survival of Premature and Low Birth Weight Infants: A Multicenter, Prospective, Cohort Study in Iran

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ABSTRACT

***Background*:** The survival rate of preterm and low-birth-weight (LBW) infants depends on various factors such as birth weight, gestational age, and quality of care. The present study aimed at evaluating the survival rate of preterm and LBW infants, predictive factors, and the risk of mortality in three training hospitals of Mashhad and Tabriz cities.

***Methods*:** This prospective, cohort study was conducted during six months from 2013 to 2014. Infants with birth weight ≤1500 g or gestational age ≤32 weeks were enrolled. Their information was gathered by using data collection forms and clinical risk index for infants (CRIB II) was calculated for each participant. Infants were followed up until discharge from the hospital and their outcomes were determined. Kaplan-Meier and Log rock tests were used for survival analysis. Cox regression was also applied in order to find out the factors associated with infants' survival.

***Results*:** Among the 338 followed up infants, 97 (28.7%) died and 241 (71.3%) remained alive. The median of preterm and LBW infants' overall survival rate was 76 days (CI: 60.4-91.5). Multivariate Cox regression analysis indicated that three factors of birth weight, base excess, and fifth minute Apgar score had a significant relationship with the survival rate of infants (P<0.05).

Conclusion: The survival rate of preterm and low-weight infants was acceptable in this study (71%). Birth weight, fifth minute Apgar score, and base excess were important items that affected infants' survival and could be considered in predicting it in neonatal intensive care units.

Keywords: Low birth weight, NICU, Premature infant, Survival

Introduction

Neonatal period associated with high level of risks, in which completion of setting occurs outside of the uterus. The mortality rate is high due to vulnerability and fragility of neonates in this period. Therefore, two-thirds of all death incidents, which occur during the first year of life, are associated with neonatal period. Structural and functional immaturity of various body organs poses numerous risks to newborns and causes developmental functional and neurological complications or ultimately leads to mortality (1, 2). Most preterm infants have a higher risk of death compared to the term ones and those who survive are often physically, cognitively, and/or emotionally impaired (3). Studies indicated that 50% of the cases of neonatal mortality were related to very low weight infants, while their proportion was about 1% (4).

One of the studies in the United States revealed that although the rate of infants' mortality had decreased from 1995 to 2005, this reduction was not significant because of the increase in the proportion of LBW births (5). During a 12-year follow-up (1996 -2008) in Switzerland, it was determined that while the mortality rate was relatively stable, there was a significant increase in very preterm and LBW births (6). Among all the global different patterns of survival, preterm birth is the most common

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cause of neonatal death with about 3.1 million infants per year dying due to the direct results of premature birth (3).

Preterm is defined as neonates born alive before 37 completed weeks of pregnancy (1). LBW and low gestational age are two important factors that create complications in preterm infants. They are also the main cause of death during neonatal period and the first year after birth (7). In general, the survival rate of preterm infants depends on several factors such as birth weight, gestational age, diseases, congenital malformations, and quality of care (8). Infection, prematurity, and asphyxia are the leading global causes of infant mortality (9). Some studies reported that the mortality rate of preterm infants, especially the infants born at less than 25 weeks with curative interventions in health centers, is predictable (10). Therefore, the survival chance and outcome of LBW infants depends on the quality of care during delivery and neonatal period and is different from hospital to hospital and one country to another (11).

Receiving steroids and other types of advanced care before birth and effective treatment after birth such as surfactant therapy and strategies of well-ventilation can increase infants' survival (9, 11). Despite all improvements in the quality of care, the mortality rate of preterm and very LBW infants is still high (8).

In some studies, prematurity was reported as the main cause of most deaths in Iran (9). According to the statistics in this country, about 12% of infants, i.e., one in every 10 infants, are born preterm (12). The present statistics indicate the necessity of more attention to this vulnerable population. Improvement of care in preterm infants will be possible if scientific and reliable data become available on this issue (13). A systematic review carried out in 2011 referred to the existence of different models for predicting death in infants. Birth weight and gestational age were considered as the two main factors in most of these models. However, these two variables create two sides and uncertain prognosis of mortality or survival.

According to recommendations in this study, complementary studies are necessary to validate the available models (14). Recognizing predictive models and risk factors relevant to mortality of preterm and LBW infants can be effective in increasing their survival. Regarding the high rate of preterm or LBW in Iran and variety of infants' outcomes in different centers, it is necessary to conduct multicenter studies in order to comprehensively investigate the survival of these infants. The present study was carried out in three training hospitals of Tabriz and Mashhad cities with the aim of evaluating the survival rate of preterm and LBW infants and its related predictors.

Materials/Patients and Methods

Study design and population

This prospective, cohort study was conducted from October 2013 to March 2014 (for six months) in three neonatal intensive care units (NICUs) of Tabriz and Mashhad cities, Iran. The qualified infants, who were hospitalized in NICUs, were included in the study through consecutive method (infants who had the inclusion criteria were enrolled in the study during a six-months sampling period consecutively). The study setting included Alzahra and Taleqani hospitals of Tabriz and Omolbanin Hospital of Mashhad. These NICUs were selected based on their similarity in equipment and facilities in NICUs, as well as care provide for the preterm and LBW infants.

Methods

The sample size of the study was calculated by using the following formula. It was based on the results from a study conducted by Fuladinejad (15) in Gorgan Province, Iran, in which the mortality rate was 37%. Considering d=7.4 and a 95% confidence interval, the required sample size was at least 164 cases, while in our study, 338 infants were included during six months of sampling period.

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Measuring tools/ checklist

To gather the infants' data, we used a researcher-made data collection form. Face and content validity of the form was determined by seven professors of School of Nursing and Midwifery and three neonatologists of Tabriz University of Medical Science (school of medicine). The collected data included gender, type of delivery, gestational age, body weight, Apgar score at 1 and 5 minutes of life, base excess, body temperature on admission, need of positive pressure ventilation (PPV) at birth, need for mechanical ventilation, using T-Piece (to give positive pressure to infant's airway) at birth, and receiving corticoids by the mother. These data were obtained from infants' cases and hospital records available for the researcher and they were recorded in a data collection form. Afterwards, based on the collected data (including gender,

gestational age, body weight, base excess,, and body temperature on admission), Clinical Risk Index For Babies II (CRIB II) score was calculated for each infant and recorded in data collection form by the researcher. Revised index of mortality risk in LBW infants (CRIB II) is a simple scoring system to predict mortality of LBW infants using the five mentioned items.

Inclusion criteria

The inclusion criteria were gestational age ≤32 weeks or birth weight ≤1500 g .

Exclusion criteria

The exclusion criteria consisted of severe fetal malformations and gestational age < 23 weeks or birth weight < 500 g. These criteria were considered because of poor viability of infants less than 23 weeks and 500 g birth weight, which could affect survival rate.

Ethical considerations

After submitting the study in Tabriz Pediatric Health Research Center and getting permission from Ethics Committee to do the study in vulnerable groups (letter No 5.4.12258), informed written consent was obtained from parents of the qualified infants.

Data analysis

The outcome in the current study was defined as infant's death during hospitalization period and survival was defined as being alive up to discharge from hospital. Statistical analysis was performed using SPSS, version 13. Overall and stratified survival rates based on length of hospital stay were calculated via Kaplan–Meier analysis and life tables. The prediction rate of CRIB II on infants' death was determined by receiver operating characteristics (ROC) and area under the curve (AUC). Independent and adjusted relationship of different factors with infants' survival was assessed with log-rank and Cox regression tests, respectively. The risk of mortality was explored and presented with hazard ratios and 95% confidence interval. P-value less than 0.05 was considered significant.

Results

Among the 338 followed infants, 168 (49.7%) were female and 170 (50.3%) were male. One hundred and twenty (35.5%) infants were born through normal vaginal delivery (NVD) and 217 (64.2%) by cesarean section (C/S). Sixty-two mothers (18.3%) received and 259 mothers (76.6%) did not receive any corticosteroids during the prenatal period. T-Piece was used for 136 (40.2%) infants at the moment of birth, while for 196 (58%) of them this device was not needed. Fifty-three cases among the expired infants (54.6%) and 69 (28.6%) of alive ones needed positive pressure ventilation (PPV) at birth. Mechanical ventilation was also required for 92 (94.8%) of the expired and 184 (76.3%) of alive infants during hospitalization.

The mean duration of the infants' hospital stay was 27.33±20.49 days (33.4±17.8 and 12.3±18.5 days for the alive and dead infants, respectively). During this period, 97 (28.7%) infants died and 241 (71.3%) ones remained alive. The major reasons of infants' death were prematurity (32%), respiratory distress syndrome (29.9%), and LBW (10.3%).

The median of preterm and LBW infants' overall survival was 76 days (CI: 60.4-91.5), that is, half of the hospitalized infants were alive for at least 76 days. The survival pattern of the infants according to length of hospitalization is presented in both Table 1 and Figure 1. The prediction rate of CRIB II score in infants' death by using ROC and AUC showed that CRIB II score with cut-off point of 8.5, sensitivity of 62%, and specificity of 81% could predict 0.77% of infants' death (Table 2 and Figure 2).

Table 1. Survival pattern of preterm and low birth weight infants

Interval times(days)	Cumulative proportion surviving at end of interval
0-7	0.82
8-14	0.79
15-21	0.77
22-28	0.73
29-35	0.73
36-42	0.72
43-49	0.71
50-56	0.69
57-63	0.66
64-70	0.51
71-77	0.46
78-84	0.46
85-91	0.35
92-98	0.35
99-105	0.35

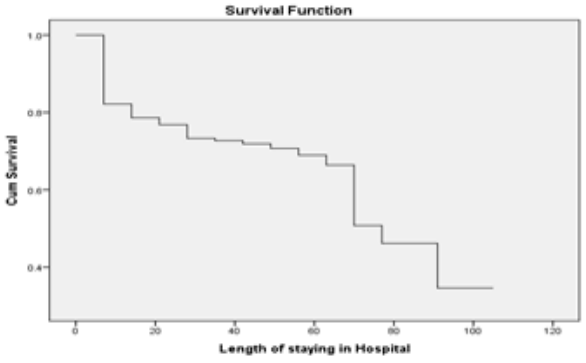

Figure 1. Survival pattern of preterm and low birth weight infant

Table 2. Sensitivity and specificity of clinical risk index for babies (CRIB II)

Variables	95% CI	Estimate
Sensitivity	0.52 – 0.71	0.62
Specificity	0.75 – 0.85	0.81
PPV *	0.46 – 0.65	0.55
NPV **	0.79 – 0.88	0.84
LR+ ***	2.4 -4.44	3.27
LR- ****	0.35 – 0.6	0.46

*PPV:Positive predictive values
**NPV: Negative predictive values
***LR+: Likelihood ratio Positive
**** LR-: Likelihood ratio Negative

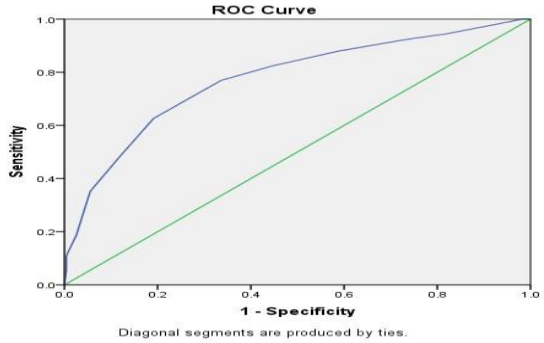

Figure 2. Sensitivity and specificity of CRIB II in ROC

Assessing the related factors with infants' survival rate by using log-rank test, revealed that gestational age, birth weight, base excess, CRIB II, and fifth minute Apgar score were significantly related to the survival rate (P<0.05). However, the relationship between variables such as gender, type of delivery, body temperature on admission, and receiving corticoids by mothers in prenatal period with infants' survival was not statistically significant (P>0.05; Table 3). Multivariate analysis with Cox regression indicated that regarding the mutual effect of all factors and adjusting them, three factors of birth weight, base excess, and fifth minute Apgar score had a statistically significant relationship with infants' survival rate (P<0.001). The results of Cox regression and hazard ratios are presented in Table 4.

Table 3. Predictors of infants' survival in univariate (log-rank) analysis

Prediction Factors	Chi-square	P-value
Gender	0.2	0.64
Type of delivery	0.47	0.49
Receiving corticosteroid	1.87	0.17
Gestational age	2.83	0.04
Body weight	39.42	<0.001
Base excess	6.69	0.01
Body temperature	1.52	0.21
CRIB II score	43.14	<0.001
Fifth minute Apgar	29.39	<0.001
PPV* at birth time	19.65	<0.001

*PPV: positive pressure ventilation.

Table 4. Predictors of infants' survival in multivariate (Cox Regression) analysis

Prediction factors	P-value	Hazard ratio	CI=95%
Gestational age	0.74	1.11	0.57-2.19
Body weight	0.02	0.41	0.23-0.71
Base excess	0.04	0.30	0.09-0.97
CRIB II score	0.83	1.75	0.93-3.3
Apgar min5	0.00	0.45	0.25-0.81
PPV* at birth time	0.07	0.65	0.4-1.04

* PPV: positive pressure ventilation.

Discussion

The aim of this study was to investigate the infants' survival rate and related factors in Tabriz and Mashhad cities, Iran. The results indicated that 71.3% of preterm and LBW hospitalized infants in NICUs of three training hospitals in the mentioned cities remained alive, and the mean duration of hospital stay in alive infants was 33.4±17.8 days.

In a study conducted by Munack et al. (16), 53.1% of the infants born at 23-37 weeks gestation and followed up to the 120th day of their life or their discharge from hospital, were alive. Mean of hospitalization period in alive infants was 104 days. Similarly, in another study by Costeloe et al. (17), median of hospitalization period in alive infants was 102 days and survival rate of 22-26 weeks gestation infants was reported to be 51%. The discrepancy between mortality rate and hospitalization period in these studies and ours could be due to different age range of infants, as infants with lower gestation weeks had lower survival rate and needed longer hospitalization period. Another study, which was carried out in Thailand and had subtle difference with the present study, reported 81% survival rate for infants with less than 25 weeks gestation and lower than 1,500 g weight (11).

In our study, 28.7% of infants died during hospitalization period, which was consistent with a study carried out in Sari, Iran (9), and reported 23.8% of deaths hospitalized infants in NICUs. The reason for the subtle difference in percentage of mortality could be attributed to lack of inclusion criteria in the study conducted by Khani, while in our study infants with gestational age ≤ 32 weeks or birth weight ≤ 1,500 g were enrolled. In a study by Navaei et al. in Isfahan, Iran, among 194 infants aged lower than 30 weeks gestation, 125 (64.4%) expired during hospitalization (18). The reported mortality rate in this study was higher than our result, which could be related to infants' lower gestational age.

In another study by Alleman et al. (10) performed during 2006-2009, 11-26% hospital mortality was reported among infants with ≥ 25 weeks of gestation in various centers. The

difference between this result and ours could be attributed to gestational age and different study settings. Manuck et al. (16) in USA studied mortality and morbidity in 8,334 infants aged 23-37 weeks of gestation between 2008 and 2011. In that study, 119 (1.4%) infants died, which is lower than our finding. This difference in results can be probably due to inclusion of infants with higher gestational age and exclusion of infants who needed resuscitation immediately after birth.

The highest mortality rates in our study were related to the second (16 [4.7%] infants) and third (20 [5.9%] infants) days of hospitalization, which is consistent with the study by Khani (9) in which the most cases of mortality occurred in the second and third days of infants' life.

Velaphi et al. (19) showed that the survival rates of the infants with 26, 27, and 28 weeks of gestation were 38%, 50%, and 65%, respectively.

In a study carried out by Mohamed et al. (20), the rate of mortality decreased by increasing gestational age, which is consistent with our finding, as gestational age of the expired infants was significantly lower than that of the alive ones. According to our results, CRIB II score, which comprises of the parameters of gestational age, gender, birth weight, base excess deficiency and body temperature on admission, could predict 77% of infants' mortality rate. This result was consistent with the study by Babaei et al. (21) in Kermanshah, Iran, in which 85% of preterm infants' death was predicted with CRIB II. Rastogi (22) claimed that 90% of infants' mortality rate was predicted by using CRIB II, which was better than our study results which predicted 77% of mortalities. Locatelli et al. (23) in Italy could predict 69% of infants' survival utilizing five parameters of gender, gestational age, body weight, Apgar score, and corticosteroid administration.

Investigating the different predictive factors in infants' mortality with Cox regression indicated that through adjusting other effective factors, infants' survival rate could have a significant relationship with birth weight, base excess deficiency, and fifth minute Apgar score. Although gestational age and PPV at birth were significantly related to survival. In log rank test, with interference of other mutual factors in Cox regression, no significant relationship was noted. In spite of 77% prediction of infants' death, CRIB II score did not have a significant association with infants' survival rate. It could be due to variables such as gender and body temperature, which were items of CRIB II score and did not have any significant relationship with survival in log rank test.

Locatelli et al. (23) demonstrated a significant relationship between gestational age, birth weight, fifth minute Apgar score and survival rate by using logistic analysis. Moreover, in a study by Mohamed (20), the risk factors, which were significantly related to the infants' mortality, were vaginal delivery, multiple births, low fifth minute Apgar score, respiratory distress, prematurity, and LBW.

According to the results of a study carried out by Mori et al. (24) in Japan, fifth minute Apgar score was a good predictor of mortality in LBW infants (1,500-2,500 g). The results regarding birth weight and fifth minute Apgar score in our study were similar to that studies, although type of delivery, gender, and receiving corticosteroids by mother did not have any significant relationship with survival rate. These results were consistent with those of the mentioned study conducted by Khani (9), in which no significant relationship was found between receiving corticosteroids by mother and survival. However, Vincer (25) in Canada showed that receiving corticosteroids by mother was one of the predictors in infants. The results of a study by Ravelli et al. (26) in Poland revealed a significant relationship between infants' mortality rate and lack of receiving corticosteroids by mothers, male gender, and old mothers.

Moreover, Velaphi et al. (19) in a study carried out in Africa indicated that cesarean section and female gender were linked with of infants' good survival. Dissimilarity in the results of our study with other studies was probably related to different contextual environments of the countries that affected the variables. There was no study about base excess variable in the national and international databases. The major reasons of infants' mortality, as shown in our study, were prematurity and respiratory distress, respectively. This finding was similar to that of the study by Velaphi et al. (19). Fallahi et al. (27) considered respiratory distress syndrome as the major reason of infants' mortality. This syndrome was also introduced as the most common problem and the most important reason of LBW infants' death in some other studies (11, 18, 28).

Conclusion

The survival rate of preterm and LBW infants in this study was 70%, which was acceptable. The highest risk of death was related to the first days of birth during hospitalization. The survival of preterm and LBW infants can be evaluated by using

key factors, which are easily assessed. In so doing, the findings can be beneficial in promoting infants' quality of care. Our study indicated that birth weight, fifth minute Apgar score, and base excess deficiency were important items that could affect infants' survival. Therefore, they could be considered in predicting preterm and LBW infants' survival in NICUs. This study was conducted in three NICUs, which were similar in equipment and facilities. To examine the performance of different centers and to bridge the gaps among different infants' survival prediction models, it is recommended that effective factors of infants' survival rate be investigated comparatively in different settings through future studies.

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Conflicts of interests

No Conflict.

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