Original Article

First day Predictors of Mortality in Neonates with Early onset Sepsis: A Case–control Study from Baghdad

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Abstract

Context: Early-onset neonatal sepsis (EONS) is one of the leading causes of death in the neonatal period. **Aims:** To identify maternal and neonatal risk factors in the 1st day of life that predicts mortality in neonates with EONS. **Patients and Methods:** A case–control study included neonates with an EONS who were admitted to the neonatal intensive care unit in tertiary hospital in Baghdad-Iraq from May 2023 to May 2024. All patients included in the study have had blood withdrawn for septic screening in the 1st day of life and subsequently carried the diagnosis of EONS by positive blood culture results. According to the fate of the patients, the study sample was divided into two groups: a case group composed of newborns with early sepsis who died and a control group made up of newborns who survived hospital care. Neonatal and maternal factors with possible influence on the fate of neonates were analyzed and compared between both groups. **Results:** A total of 168 neonates were included in the study, 50 neonates died with reported death rate of (42.4%). The deceased neonates had a significantly earlier time of blood withdrawal for investigation than the survived neonate $P = 0.008$. The clinical presentation was significantly different between the two groups, $P = 0.005$. Lower maternal hemoglobin showed a protective effect against neonatal mortality from EONS $P = 0.031$. Apgar scores on 1 and 5 min were both significantly lower in deceased neonates $P = 0.011$, <0.001, respectively, and on multivariate analysis score ≤3 was the only predictive factors for death. **Conclusions:** Mortality rates from EONS are an alarmingly high and closely related to maternal and neonatal factors. Apgar scores ≤3 at 1st and 5th min can serve as the early predictors of death in neonates with EONS.

Keywords: Apgar score, C-reactive protein, mortality, neonatal sepsis

Introduction

Early-onset neonatal sepsis (EONS) is the type of neonatal sepsis that typically manifests during the first 72 h following birth.[1] It carries a high risk of mortality for neonates, with estimated rates reaching 54%.[2] Global incidence and mortality of early-onset neonatal sepsis are varied with neonates disproportionately affected in low-income and middle-income countries (LMICs).[3] Despite the significant improvement in the management of EONS, it is still the third leading cause of neonatal mortality in the neonatal intensive care units (NICUs).[4]

Based on these elevated death rates, an increased effort is crucial for its prevention and management. This can be achieved by assessing the risk factors associated with increased risk of death and implementing interventions to modify these factors.[5] Several neonatal factors have been implicated as risk factors for mortality in EONS, including prematurity, low birth weight, and low Apgar score,[6] and since maternal microorganism that colonize the genitourinary tract namely Group B streptococcus is the main causative agent for EONS, this incorporates maternal factors as an important role player for a fatal outcome in EONS.[7,8] However, studies regarding risk factors for neonatal sepsis and sepsis-related mortality in EONS in LMICs are sparse.[3] The rationale from the current study was to identify the potential risk factors for fatal outcome in EONS enables physicians to develop appropriate risk management strategies which in turn helps to apply timely and appropriate treatment for those neonates with a risk of

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fatal outcomes. This study aims to identify maternal and neonatal risk factors in the 1st day of life that predict mortality in neonates with EONS.

Patients and Methods

Study design and study population

A case–control study included neonates with a diagnosis of early-onset neonatal sepsis who were admitted to the NICU in AL Yarmouk Teaching Hospital Baghdad-Iraq from May 2023 to May 2024. All patients included in the study have had blood withdrawn for septic screening in the 1st day of life and subsequently carried the diagnosis of EONS by the positive blood culture results. Blood samples were collected within 24 h of birth, under strict aseptic techniques by trained neonatal nurse at NICU. The venipuncture site (the peripheral vein) sterilized by povidone-iodine and allowed to dry fully before venipuncture. A sterile syringe and needle were used to collect blood sample, then promptly transferred to blood culture bottle which were send to the microbiology laboratory in the same hospital.

According to the fate of the patients, the study sample was divided into two groups:

- Case group: Newborns who died during hospital admission from EONS
- Control group: Newborns with early-onset sepsis who survived with hospital care.

Clinical characteristics and hematological indices of the neonates, as well as prenatal characteristics of mothers were compared between both case and control groups to identify the factors that predict mortality from EONS.

All neonates matched the following inclusion criteria during the study period were recruited in the study: (1) Newborns had sepsis workup in the first 24 h of life (2) neonates carried the diagnosis of early-onset sepsis based on positive blood culture results. Patients were not included in the study if they met any of the following exclusion criteria (1) major congenital anomalies or (2) missing data. The study sampling was done by convenient sample and for reduction of the possibility of researcher bias the sample was consecutive, i.e., it recruited all neonates who met the inclusion criteria and were treated in the period from 1 May 2023 to 1 May 2024. A written informed consent was obtained from the parents of patients enrolled in the study and the ethics committee of Mustansiriyah University issued the study approval with a number (IRB 20) dated 12 of January 2023.

Variables measured in the study

The following maternal factors with a possible significant influence on the outcome of interest were analyzed: age, last hemoglobin level before delivery, diseases (chronic or gestational diabetes and hypertension), premature rupture of membrane (PROM), mode of delivery (caesarean section or vaginal delivery), whether mother received prenatal steroid or not before delivery. Neonatal factors included in the study were the time of blood withdrawal for septic screen, gestational age at birth, birth weight, and gender. Clinical characteristics of neonate: Apgar score at 1 and 5 min, clinical presentations, duration of hospitalization. In addition, laboratory tests included blood culture, C-reactive protein (CRP), blood parameters normally obtained by complete blood counts (total white cell count and differential with absolute neutrophil and lymphocytes count, hemoglobin level and mean corpuscular volume, red blood cell (RBC) count, platelets count and RBC distribution width and platelet distribution width and mean platelet volume).

Statistical analysis

Statistical analyses were performed by using SPSS software version 25.0 (SPSS, Chicago, IL, USA). The continuous data were subject to a normality test (Shapiro–Wilk test), presented as mean and standard deviation and analyzed with a student *t*-test. The categorical variables were expressed as numbers and percentages and analyzed with Chi-square or Fischer exact test for the low frequency of certain categories. Logistic regression was constructed to estimate the odds ratio (OR) for neonatal outcomes versus Apgar scores. A $P < 0.05$ was considered to indicate a statistically significant difference.

Results

A total of 168 neonates diagnosed with EONS were included in the study, of which 50 neonates died (42.4%), while the remaining 118 newborns (47.6%) survived. Male had slight predominance in the study sample with male-to-female ratio = 1.2:1. The deceased neonates presented with the signs of sepsis significantly earlier than the surviving neonates, as indicated by an earlier time of blood sample collection ($P = 0.008$). There were insignificant differences between both groups regarding gender, gestational age, and birth weight. Three clinical characteristics were significantly lower in deceased neonate than survived neonates: Apgar score at 1 and 5 min and hospital stay ($P = 0.011$, <0.001, and 0.001, respectively), while presenting with apnea was seen exclusively in the deceased neonates with significant statistical difference ($P = 0.005$) [Table 1].

None of the studied hematological indices of the neonates with EONS exert a statistically significant difference between both groups, as shown in Table 2.

A lower maternal hemoglobin level was found to have protective effect in relation to neonatal mortality from EONS. All other maternal factors were not significantly different between the survived and died neonates, as shown in Table 3.

By logistic regression test, only Apgar score were found to carry higher odds of death from EONS: Apgar score on 1 min ≤3 ($P < 0,0001$; OR: 10.165; Confidence interval [CI]: 2.48–41.58) and Apgar score 5 min ≤3 ($P < 0.0001$; OR: 10.80; CI: 3.79–30.76) which means that neonates with Apgar score ≤3 on 1st and 5th min had more than 10 folds risk

Table 1: Demographic and clinical characteristics of the neonates with early-onset neonatal sepsis

Variables	Survived (*n*=118), *n* (%)	Deceased (*n*=50), *n* (%)	Total (*n*=168), *n* (%)	*P*
Time of blood withdrawal (h), mean±SD	20.65±7.03	15.4±7.46	19.1±7.5	0.008
Gender				
Male	70 (59.32)	22 (44)	92 (54.76)	0.197
Female	48 (40.68)	28 (56)	76 (45.24)	
Term/preterm				
Term	34 (28.81)	16 (32)	50 (29.76)	0.770
Preterm	84 (71.19)	34 (68)	118 (70.24)	
Gestational age (weeks), mean±SD	34.86±2.57	33.56±3.42	34.48±2.89	0.058
Birth weight (kg), mean±SD	2.38±0.7	2.18±0.82	2.32±0.74	0.247
Apgar score 1 min, mean±SD	5.0±1.32	4.09±1.54	4.71±1.45	0.011
Apgar score 5 min, mean±SD	7.84±0.97	6.74±1.51	7.49±1.27	<0.001
Hospital stays (days), mean±SD	8.59±4.82	5.04±3.17	7.47±4.65	0.001
Presentation				
Grunting	72 (61)	28 (56)	100 (59.52)	0.005
Tachypnea	40 (33.9)	10 (20)	50 (29.76)	
Apnea	0	10 (20)	10 (5.95)	
Cyanosis	6 (5.1)	2 (4)	8 (4.76)	

SD: Standard deviation

Table 2: Hematological indices of infants

Variables (mean±SD)	Survived (*n*=118)	Deceased (*n*=50)	Total (*n*=168)	*P*
CRP (g/dL)	23.68±21.9	43.42±50.78	29.63±34.23	0.35
Total WBC (×10^9/L)	11.88±6.41	10.61±7.8	11.5±6.83	0.202
ANC (×10^9/L)	9.36±12.47	11.3±18.78	9.94±14.54	0.676
ALC (×10^9/L)	3.68±1.6	3.85±2.15	3.73±1.77	0.902
RBC (×10^9/L)	4.74±0.64	4.61±0.56	4.7±0.62	0.390
Hb (g%)	16.25±2.12	16.14±1.95	16.22±2.06	0.826
MCV (fL)	102.3±5.45	103.8±5.5	102.7±5.5	0.263
MCH (pg)	34.29±2.07	35.43±3.55	34.63±2.55	0.061
MCHC (g%)	33.5±1.15	33.66±1.13	33.55±1.14	0.579
Packed cell volume (%)	48.45±6.23	47.83±5.39	48.26±5.97	0.668
Platelet ×10^9/L	205.85±85.82	189.28±85.82	200.93±86.4	0.424
RDW-CV (%)	18.0-1.26	18.3±2.54	18.1±1.73	0.467
PDW	13.0±2.37	12.5±1.8	12.85±2.22	0.406
MPV (fL)	10.26±0.86	9.98±0.87	10.18±0.87	0.217

ALC: Absolute lymphocyte count, ANC: Absolute neutrophil count, Hb: Hemoglobin, RBC: Red blood cell, CRP: C-reactive protein, WBC: White blood cell, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, RDW: Red cell distribution width, PDW: Platelet distribution width, MPV: Mean platelet volume, SD: Standard deviation, CV: Coefficient of variation

of death from EONS compared to neonates with >3 score, as shown in Table 4.

Discussion

The early recognition of neonates at higher risk of fatal outcomes can help pediatricians and neonatologists to identify high-risk neonates which can lead to the early implementation of high level of care for those neonates.[9]

The mortality rate in EONS in the present study is (42.4%) which is high compared to rates reported from previous studies,[5,10,11] this can be attributed to inadequacy of neonatal care facilities, as a high resource setting typically report a lower rate of mortality due to access to mechanical ventilation, parenteral nutrition, and advanced hemodynamic monitoring. Neonatal mortality following sepsis is higher in LMICs compared to high-income countries,[12] this high mortality rates had been attributed to low resources available in addition to different bacterial profile seen in EONS in LMIC.[13] Data in the current study showed that died neonates had earlier blood withdrawal than survived neonates $P = 0.008$ which may indicate that earlier presentation carries a higher risk for mortality. Although this factor has never been evaluated as predictor for mortality in EONS or neonatal sepsis in general, previous study by Montaner Ramón *et al*. compared the time of assessment and management of EONS that used by three different strategies and indicated that earlier implementation of septic screen in neonatal sepsis may predispose the neonate to unnecessary investigation and antibiotic therapy that alter the normal flora

Table 3: Prenatal characteristics of the mothers

Variables	Survived (*n*=118), *n* (%)	Deceased (*n*=50), *n* (%)	Total (*n*=168), *n* (%)	*P*
Age (years), mean±SD	26.78±5.68	27.24±6.8	26.92±6.0	0.753
Hb (g%), mean±SD	11.37±1.08	11.94±0.9	11.56±1.06	0.031
Past medical history				
Hypertension	14 (11.86)	12 (24)	26 (15.48)	0.170
Diabetes mellitus	12 (10.17)	4 (8)	16 (9.52)	0.740
PROM				
No	94 (79.66)	42 (84)	136 (79.76)	0.619
Yes	24 (20.34)	8 (16)	32 (19.05)	
Delivery				
Vaginal delivery	40 (33.9)	20 (40)	60 (35.71)	0.594
Cesarean section	78 (66.1)	30 (60)	108 (64.29)	
Prenatal steroids				
No	60 (50.85)	26 (52)	86 (51.91)	0.923
Yes	58 (49.15)	24 (48)	82 (48.81)	

Hb: Hemoglobin, PROM: Premature rupture of membrane, SD: Standard deviation

Table 4: Odds ratios for neonatal death by 1- and 5-min Apgar scores

Variables	Outcome		OR 95% CI	*P*
	Survived (*n*=118), *n* (%)	Dead (*n*=50), *n* (%)		
1st min Apgar score				
≤3	26 (22)	41 (82)	10.16 (2.48–41.58)	0.001
>3	92 (78)	9 (18)	Reference	
5th min Apgar score				
≤3	18 (15.3)	30 (60)	10.80 (3.79–30.76)	<0.001
>3	100 (84.7)	20 (40)	Reference	

OR: Odds ratio, CI: Confidence interval

and predispose to serious infections and herby increase the overall mortality.[14]

Previous studies indicates that higher birth weight and gestational age had protective effect against death from EONS,[15] such effect is not proved in the present sample. Although neonates died from EONS in the present study had lower mean birth weight and gestational age at birth than survived neonates, it fails to show a statistically significant (P = 0.247, 0.058), respectively. This difference could be attributed to the difference in sample characteristics which is obvious in that the mean birth weight in the deceased neonates in the current study is (2.18 ± 0.82 kg) which is much higher than the mean weight reported in other studies by (882.8 ± 372.2 g).[15]

Male gender is a known risk factor for EONS.[16,17] However, gender has a conflicting role as the predictor for mortality in neonatal sepsis. Several studies indicated that male gender associated with increased fatal outcome in neonatal sepsis,[18,19] while others found a nonsignificant correlation between gender and mortality from neonatal sepsis,[15] which matches the results of the current study.

Not surprisingly, the duration of hospital stays for died neonates were significantly lower than survived one, P = (0.001), this also noted in previous studies.[18-20] The average time to death in neonates due to EONS was 5.04 ± 3.17 days, this matches duration of hospitalization reported by Turhan *et al*. study in turkey,[20] and both are higher than results reported by Meshram *et al*. in India 4.68 ± 3.86 days.[18] However, a much higher mean of stay reported in Egypt by Abdel Haie *et al*. 12.48 ± 5.13 days[19] and Jibro *et al*. in Ethiopia with time to death in neonatal sepsis regardless of type is 14 days.[9] The time to death in neonatal sepsis is reported to be related to multiple factors including home delivery, premature delivery, respiratory distress syndrome, presence of lethargy, and use of continuous positive airway pressure and thrombocytopenia as all of this had been associated with shorter time to death in neonatal sepsis.[9]

From the clinical presentations of neonates with EONS, apnea was reported exclusively in neonate who died and none of the survived neonate presented with apnea. However, the clinical presentation of the neonates with EONS did not serve as the predictors for mortality in EONS, while previous studies identify a number of clinical presentations including cyanosis, delayed capillary refill, and hypothermia to be associated with fatal outcome in EONS.[10,18,19] This discrepancy could be related to different sample demographics.

The hematological indices obtained in the 1st day of life in neonate with EONS does not serve as predictors for mortality

and all the studied blood parameters were not significantly different between both groups. Although CRP show higher trend in died neonate in comparison with survived group, it fails to show statistical significance $P = 0.35$. No previous study evaluates the role of 1st day CRP as prognostic factors as far as we are aware, instead, reports evaluate its use in neonatal sepsis in general without time frame like Abdel Haie *et al*. who reported a statistically significant elevation of CRP in neonates died from neonatal sepsis as compared to survived neonates but did not specify the time of CRP testing.[19] The role of CRP as diagnostic and prognostic factor in EONS remains controversial.[21] The limitation of use of CRP to serve as diagnostic and prognostic marker in the 1st day of life reside in that although it starts to elevate in 4–6 h, its level needs 36 h to peak which undervalues its use in the first 24 h of life.[22]

The low Apgar score is defined by several previous studies to increase the risk of death from EONS.[11,23-26] This aligns with our finding as the Apgar score in 1 and 5 min was significantly lower in neonates who died of early EONS with $P = 0.011$, <0.001, respectively. On multivariate analysis, mortality was strongly associated with one and 5-min Apgar score ≤ 3 (0.001, OR = 10.16, 95% CI 2.48–41.58 and $P < 0.0001$, OR = 10.80, 95% CI 3.79–30.76, respectively) and although align with results by Harum *et al*., but the OR in the present study was much higher as neonates with Apgar score ≤ 3 on 1 or 5 min had more than 10 folds risk of death from EONS compared to neonates with > 3 score while in Harum *et al*. Apgar score ≤ 3 at 1st and 5th min were carried a 4-fold increased risk of death from EONS.[11] The relation of low Apgar scores and EONS has been linked through multiple factors: First, low Apgar scores are seen in birth asphyxia which in turn causes immune modulating effect that predisposes the newborn to infection,[27] Second: neonate with low Apgar score were more likely to receive an interventional procedures like umbilical vein catheterization and assisted ventilation all these increased their risk of contracting a nosocomial infections.[28,29]

Maternal factors studied in the present study including age, PROM, chronic or gestational diabetes, and mode of delivery were not significantly related to the fatal outcome of neonatal sepsis and this disagree with previous studies which found that those factors increase neonatal mortality.[18] This discrepancy may be attributed to temporal and geographic variability which play a critical role in the outcome of neonatal sepsis as regional differences in pathogen prevalence, antimicrobial resistant pattern can result in lead to variable outcome, even among similar maternal risk factors.[30] The only maternal factor that was found to be protective against sepsis-related neonatal mortality was low maternal hemoglobin level. Although the mean maternal hemoglobin level in both groups of survived and died neonates was in nonanemic range, mothers of neonates who died of EONS tend to have higher hemoglobin level just before delivery. This interesting finding has been explained by Brabin *et al*.[31] who concluded that iron supplementation in nonanemic pregnant mothers, can increase susceptibility and subsequent severity of infection.[31] In addition, a Cochrane Review raised a safety concern regarding iron supplementation in pregnant women in relation to neonatal outcomes.[32]

This study is limited by the single hospital settings and small sample size, so the results may not be representative of other hospitals. However, the strength of this study lies in that, none of the previous reports interested in finding 1st day predictors of death in EONS as shown in the present study. We have highlighted the maternal and neonatal parameters linked with higher neonatal mortality rates in EONS and identified a 1st day predictors for death in EONS.

Conclusions

Mortality rates from EONS are an alarmingly high and closely related to maternal and neonatal factors. Apgar scores ≤ 3 at 1st and 5th min can serve as the early predictors of death in neonates with EONS which may help pediatricians identify neonates in needs of intensive care. Low maternal hemoglobin level was noted to be associated with lower neonatal mortality rate due to ENOS.

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Conflicts of interest

There are no conflicts of interest.

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