

Predictors of Mortality in Outborns with Neonatal Sepsis: Aprospective Observational Study

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Abstract

Background: Mortality in outborns with Neonatal sepsis result from interaction of maternal-fetal colonization, transplacental immunity and physical and cellular defense mechanisms of neonates. Objective: The objective of this study was to determine risk factors Of mortality in outborn with neonatal sepsis. Materials and Methods: A 6-months prospective observational study was done at neonatal intensive care unit of Benha university hospital and Serselyan General Hospital. All outborn neonates with maternal and neonatal risk factors of sepsis were enrolled. Blood culture, sepsis screen and other needed investigations were performed. Results: The mortality rate among outborn with neonatal sepsis was 42%.The common presentations among outborns with neonatal sepsis were Hypothermia, convulsions, cyanosis and poor suckling. The significant risk factors of mortality include Malesex (p=0.021), gestational age (p=0.027), convulsions(p=0.003), presence of cyanosis(p=0.02), hypothermia(p=0.009), mottling(p=0.001),poor suckling(p=0.001), positive creactive protein(p=0.009),

Anemia(p=0.011)..Maternal factors such as Premature rupture of membranes (p=0.047) and hypertension during pregnancy (p=0.001) and diabetes mellitus (p=0.017) were statistically significant associated with mortality in outborn neonatal sepsis. On multivariate logistic regression temperature on admission and distance during transport to hospital were the predictive factors of mortality in outborn neonatal sepsis. **Conclusion**: Long distance tranelled with neonates during transport to hospital and presentation with hypothermia at admission, were the independent risk factors of mortality in outborn neonatal sepsis.

Keywords: Neonatal sepsis, outborn neonates, mortality predictors.

Introduction

Neonatal mortality is defined as neonate who was born alive after 28 weeks of gestational age and died within the first 28 days. (1) According to the World Health Organization, of the 130 million newborns, four million will die during the neonatal period, and half neonatal deaths (i.e., 50%) occur within the first 24 hours of life. Neonatal mortality rate remains a challenge; the risk factors associated with neonatal mortality are considered quality indicators for improving health care provided in the Neonatal Intensive Care Unit (NICU), as well as an indicator of population health and wellbeing. (2)

A remarkable decline in mortality rates during neonatal period for the past two decades is due to the advances of obstetric practice in term of medical screening and surveillance, and increased neonatal specialization. However, respiratory tract disorders, along with sepsis and other types of infection, are the major causes of neonatal morbidities and mortalities. Consequently, the length of hospital stay, intensive care costs, and burden on the healthcare system have increased. (2,3)

Neonatal sepsis is a clinical manifestation of a systemic infection during the first 28days of life, usually classified as EOS (<48–72h) And LOS (>48–72h), depending on the age at onset of the sepsis.(4)

There are different levels of sepsis: sepsis, severe sepsis, and septic shock. In2016 screening response by syndrome (SIRS) was replaced with quick Sepsis related Organ Failure Assessment (qSOFA) which is two of the following three : increased breathing rate, change in level of consciousness, and low blood pressure . SIRS is the presence of two or more of the following: abnormal body, heart rate, respiratory rate or blood gas, and white blood cell count.

Sepsis is defined as SIRS in response to an infectious process. Severe sepsis is defined as sepsis with sepsis-induced organ dysfunction or tissue hypo perfusion (manifesting as hypotension, elevated lactate, or decreased urine output.

Septic shock is severe sepsis plus persistently low blood pressure despite the administration of intravenous fluids. (5)

Multiple organ dysfunction syndrome (MODS) is a progressive organ dysfunction in an acutely ill patient such that homeostasis cannot be maintained without intervention. It is at the severe end of the severity spectrum of both SIRS and sepsis. The sepsis spectrum begins with infection, which progresses to bacteremia, severe sepsis, septic shock, and death. (6)

In Egypt, neonatal sepsis is considered a big problem due to lack of infection control measures and inadequate nursing staff ,so the incidence range increases more than the documented incidence. (7) Many screening tests lack the capacity to specific pathogens detect and are unavailable at many centers in developing countries. Positive blood culture is the gold standard for the diagnosis of neonatal sepsis, but it is positive in 50%–80% at best; however, negative blood culture does not rule out the disease. (8)

Risk factors of neonatal sepsis result from interaction of maternal-fetal colonization, transplacental immunity and cellular and physical defense mechanisms of neonate. Most of the previous studies were done on inborn neonatal sepsis as against the neonates who have outborn been previously admitted at different health facility or might have been delivered at home and sometimes older at admission and more susceptible to community acquired infections. Data on such .With neonates are scanty this background, this study aimed to evaluate predictors of mortality in outborns with neonatal sepsis. (9)

Materials and methods

This study is prospective observational study, which was done on 50 out born neonates who admitted to neonatal intensive care unit of Benha University Hospitals and Serselyan general hospital of both sexes after obtaining an informed consent from the children's *caregiver with maternal and neonatal risk factors of sepsis*

The study was carried out from april2021 to October 2021.

We recruited all referred out born neonates with one or more clinical features of sepsis admitted either through outpatient or emergency department after informed valid consent from parents. The data were collected following admission either from the mother or care giver using the proforma specially designed for the study. The data include Full history taking:

Prenatal history of mother (Fever, rash, dysuria, abdominal pain suggesting renal disease, chorioamnionitis, history of Premature Rupture Of Membrane and history of any hospital admission), perinatal (Mode of delivery, gestational age, any history of obstructed labor or birth trauma).

Natal history: Mode of delivery, place of delivery and Apgar score if documented

Postnatal, and present history of (Apnea, convulsion, temperature instability, tachycardia, tachypnea, need for positive pressure ventilation or increased ventilator support or fraction of inspired oxygen, feeding intolerance).

Examination:

A. Full clinical examination of the neonates:

- 1. General examination: General look, vital signs (Respiratory rate, heart temperature and blood rate, pressure), anthropometric measures (Weight, height, head circumference abdominal and girth), head examination. neck examination, upper limb examination, lower limb examination, back examination and genitalia examination.
- 2. Systemic examination including cardiac, chest, abdominal and neurological examination
- 3. Clinical signs and symptoms of sepsis such as sick looking, apnea, increased respiratory rate >60/min, chest retraction, grunting, central cyanosis, refusal to feed, increased prefeed aspirate, abdominal distension, increased abdominal girth 2 lethargy, by cm, seizures. hypothermia (axillary temperature <36 C), fever (axillary temperature >37.5 C), bradycardia (Heart rate <100/min) and tachycardia (Heart rate >160/min) (10).

All outborn neonates undergo the following investigations

Blood culture

With all aseptic precautions, 1-ml sample of blood was collected in a blood culture

bottle containing 5-10 ml of culture media before starting antibiotic administration. All blood cultures were performed on blood agar and MacConkey's agar, they and were observed for 7 days before reported as negative

Sepsis screen

 Including Complete blood count (CBC), C-reactive protein and Absolute neutrophil count. Cerebrospinal fluid (CSF) examination, renal function test, urine culture, chest X ray, abdomen X ray, abdominal ultra sound and
 Isolation of the infective agent from either blood, cerebrospinal fluid (CSF) or urine cultures

b. Probable sepsis:

- Positive cultures were not obtained.
- Presence of clinical signs suggestive of sepsis.
- Two positive screening parameters (10).

All outborn neonates were observed for clinical events and managed according to our standard protocol and followed up to discharge or death.

Research Ethics Committee: Ms.5.8.2020

Statistical analysis

The clinical data were recorded on a report form. These data were tabulated and analysed using the computer program SPSS (Statistical package for social science) version 26 to obtain:

$$x^{2} = \frac{\sum (observed - expected)^{2}}{Expected}$$

 $Expected = rac{col.total\ x\ rowtotal}{Grand\ total}$

3- Logistic regression:- to find multivariate relationships between variables.

A *P* value <0.05 was considered statistically significant (*) while >0.05statistically insignificant P value <0.01was considered highly significant (**) in all analyses. ECHO were performed in indicated neonates. **Septic neonates were grouped into two categories according to sepsis diagnosis:**

a. Definite sepsis:

- Presence of clinical signs and symptoms of sepsis.

Descriptive data

Descriptive statistics were calculated for the data in the form of:

- 1. Mean and standard deviation $(\pm SD)$ for quantitative data.
- 2. Frequency and distribution for qualitative data.
- 3. Analytical statistics

In the statistical comparison between the different groups, the significance of difference was tested using one of the following tests

- 1- Student's *t*-test:- Used to compare mean of two groups of quantitative data.
 - Inter-group comparison of categorical data was performed by using chi square test (X^2 -value) and fisher exact test (FET).

Results

The present study was carried out on outborn neonates with risk factors of sepsis from april2021 to October 2021.In a total of 50 outborn neonates with sepsis, the incidence of early onset sepsis was 58% while that of late onset sepsis was 42%.The culture positive sepsis was 31(62%).The percentage of male outborn neonates was 70% while females was 30%.Thirty seven (74%) outborn neonates were delivered by caesarian section while thirteen (26%) were delivered by normal vaginal delivery. Sixteen (32%)out born neonates with low socioeconomic level from rural areas **Table 1.**

The mean gestational age (weeks)was 33.68+_3.30while the mean birth weight (gm)2299.4+_639.05.The mean duration of hospital stay was 17.3+_8.14.The mean distance during transport to hospital was 15.5+_6.34.Thirty seven(74%).

Clinical and laboratory features

As regard neonatal history. There was highly statistically also significant increase in died group regarding presence of convulsions (p value0.003) and distance during transport to hospital (p and value0.001) highly statistically significant increase in died group regarding use of mechanical ventilation and statistically significant decrease in died group regarding duration of hospital stay. There was statistically significant decrease in died group regarding gestational statistically age and significant increase in died group regarding cyanosis

As regards maternal history, mothers were suffering from anemia was thirty seven (74%) followed by twenty four (48%) were suffering from hypertension during pregnancy. Twenty (40%) mothers were suffering from premature rupture of membranes and seventeen (34%) were suffering from urinary tract infection **Table 2**.

As regard neonatal examination There highly statistically was significant decrease in died group regarding mottling and absent or poor suckling (p value 0.001) and highly statistically significant decrease in died group regarding APGAR score at 0 and 10 minutes and 5 minutes statistically significant There was increase in died group regarding hypothermia (p value0.009) Table 3.

Other important laboratory features increase CRP level in died group than survived group (p=0.009) and decrease Hb level in died group than survived group(p=0.011). There is also decrease albumin level in died group than survived group (p=0.041). In 21 outborn neonates who had suspected meningitis CSF examination was done abnormal cellularity was found in 11 neonates. Microorganisms were isolated in 31 neonates 19 in EOS and 12 in LOS, ECOLI was the commonest 22% followed by klebsiela18%then Pseudomonas16% Table 4.

Out of 50 outborn neonates with clinical sepsis21 neonates died giving a mortality rate of 42%. On multivariate logistic regression long distance during transport to hospital and Hypothermia were the major risk factors of mortality in outborn neonatal sepsis. (**Table 5**)

	The studied group (50)			
	No	%		
Gender	15	30.0		
Female	35	70.0		
Male				
Mode of delivery	13	26.0		
Normal vaginal delivery	37	74.0		
Caesarean section				
Socioeconomic level	10	20.0		
High	16	32.0		
LOW	24	48.0		
Middle				
Onset of sepsis	29	58.0		
Early onset	21	42.0		
Late onset				
GA (weeks) Mean \pm SD	33.68±3.30			
BW (gm) Mean ±SD	2299.4 ±639	9.05		
Duration of hosp stay (d)Mean ±SD	17.3 ± 8.14			
Distance during transport to Hospital (Km)	15.5±6.34 (5-30)			
Mean ±SD (range)				
Place of delivery				
Hospital	45	90.0		
Home	5	10.0		
B trauma	2	4.0		

 $\label{eq:table1} Table \ 1: Distribution \ of \ the \ studied \ group \ according \ to \ neonatal \ history.$

Table 2: Comparison between the studied groups according to-neonatal history-

	Mortality			Statistical test	P value	
	No		Yes			
	No	%	No	%		
GA (weeks) Mean ±SD	34.55±	3.39	32.48	±2.84	St t=2.29	0.027*
BW (gm) Mean ±SD	2485.95±391.19 21		2164.3	31±748.58	St t=1.80	0.08
Convulsions	3	10.3	10	47.6	X2= 8.80	0.003**
Cyanosis	8	27.6	13	61.9	X2= 5.89	0.02*
Apnea	3	10.3	1	4.8	FET= 0.04	0.85
ICH	3	10.3	0	0.0	FET= 0.84	0.36
Use of MV	3	14.3	19	65.5	X2=12.97	< 0.001**
Previous incubator	20	69.0	14	66.7	X2 = 0.03	0.86
admission						
Duration of hosp stay	20.79±8.18		12.48 ± 5.13		St t= 4.11	<0.001**
(d)						
Distance during	10.62 ± 3.61		19.03 ± 5.49		St t= 6.12	<0.001**
transport to Hospital						
(Km) Mean ±SD						
(range)						
Place of delivery	26	89.7	19	90.5	FET = 0.0	1.0
Hospital	3	10.3	2	9.5		
Home						
B trauma	0	0.0	2	9.5	FET= 0.931	0.33

	Mortality				Statistical test	P value
	No		Yes			
	No	%	No	%		
APGAR 0 Mean ±SD	5.57±1	.40	4.52±1	.33	St t= 2.71	0.009**
APGAR 5 Mean ±SD	7.33±0	.97	6.41±1	.35	St t= 2.66	0.011*
APGAR 10 Mean	9.1±0.6	53	8.28±1	.25	St t=2.76	0.008**
$\pm SD$						
AdmisionTemperature						
Hypothermia	1۲	41.4	1^	85.7	FET= 9.36	0.009**
Normal	1	3.4	1	4.8		
Hyperthermia	1٦	55.2	۲	9.5		
Mottling	23	79.3	2	9.5	X2=23.73	< 0.001**
Moro reflex						
Absent (weak)	13	44.8	15	71.4	X2= 3.5	0.06
Present	16	55.2	6	28.6		
Suckling						
Present	3	10.3	12	57.1	X2=12.7	<0.001**
Absent or poor	26	89.7	9	42.9		
Prolonged capillary	13	44.8	10	47.6	X2 = 0.04	0.85
refill time						

Table 3 Comparison between the studied groups according to-neonatal examination

Table 4: Comparison between the studied groups according to---laboratory investigations ,CSF and blood culture

	Mortality				Statistical	P value
					test	
	No		Yes			
CRP (mg/L)	51.83±24.13		80.55±43.75		St t=2.72	0.009**
Hb (g/dl)	11.11±1.61		9.93±1.52		St t= 2.64	0.011*
Htc %	37.32±3.05		34.38±5.54		St t=2.20	0.032*
WBCs (10 ³ /mm ³)	13.66±1.86		14.01±2.39		St t=0.56	0.58
Plts $(10^3/\text{mm}^3)$	245.67±104.42		205.28±94.77		St t=1.43	0.16
Neutrophil %	62.52±6.98		65.9±7.71		St t=1.62	0.112
Lymph %	18.22±4.12		18.4±3.31		St t=0.16	0.87
Urea (mg/dl)	81.03±21.25		77.95±26.72		St t=0.45	0.65
Creat (mg/dl)	0.73±0.23		0.75±0.22		St t=0.26	0.80
Blood sugar	87.38±8.43		82.45±16.37		St t=1.39	0.17
SGOT (U/I)	23.93±8.11		23.86±7.21		St t=0.03	0.97
SGPT (U/I)	17.28 ± 4.42		18.62±6.27		St t=0.89	0.38
Ca (m mol/L)	9.0±0.97		8.45 ± 1.06		St t=1.90	0.063
Na (m mol/L)	129.48±3.11		128.62±2.77		St t=1.01	0.318
K (m mol/L)	4.43±0.60		4.67±0.46		St t=1.50	0.14
Albumin (g/dl)	2.78±0.51		2.47±0.51		St t=2.10	0.041*
	No	%	No	%		
Blood culture	29	100	21	100	-	-
Culture						
Coagulase negative	1	3.4	0	0.0	FET= 4.35	0.523
staph	8	27.6	3	14.3		
E COLI	2	6.9	0	0.0		
Gram positive strept	5	17.3	4	19.0		
Klebsiela	3	10.3	5	23.8		
Pseudomonas	10	34.5	9	42.9		
No growth						
CSF (late onset)						
Normal	6	46.2	4	50.0	FET= 0.08	0.78
Abnormal	7	53.8	4 50.0			

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-	Exp (b)	P value		95% CI
Duration of hospital	0.966	0.771	0.766	1.218
stay(DAY)				
Age of mother	1.213	0.270	0.860	1.711
Distance during transport to	0.558	0.041*	0.318	0.977
H(km)				
GA(Week)	1.424	0.246	0.784	2.588
Temprature at admission	11.174	0.009**	1.826	68.368
D'1 C / C / 1'/				

Table5 : Risk factors for mortality in the studied groups (multivariate logistic regression).

Risk factors of mortality

Discussion

Neonatal period is the most vulnerable time for child survival. Globally, approximately 7000 newborns die every day. In 2016, around 2.6 million during deaths occurred neonatal period. India contributes 24% of the global newborn deaths and has a neonatal mortality rate of 25.4/1000 live births with interstate and ruralurban variations. Infections (36%), prematurity (28%) and birth asphyxia (23%) are the major causes of neonatal deaths in developing countries, whereas prematurity and malformations are mainly responsible for neonatal mortality in developed countries (11).

The Global Burden of Disease (GBD) Study 2016/2017 estimated 1.3 (95% CI 0.8 to 2.3) million annual incident cases of neonatal sepsis worldwide, resulting in 203 000 (95% CI 178 700 to 267 100) sepsis-attributable deaths (**12**). The present study showed that, our mortality rate in outborn neonatal sepsis was (42%).

High mortality (72%) was reported by (13) and (**14**) (44.2%),

Whereas lower mortality rates in outborn neonatal sepsis were reported by (15) (11.7%) and (16) (16%).Most

of the studies were performed on outborn neonates.

These differences in mortality may be due to socioeconomic, geographical and racial factors and health facilities.

Our study revealed a male predominance (70%) among out born neonates than female (30%). As regard mortality from neonatal sepsis, a study correlated this to X-linked immuneregulatory genes. This is similar to the finding reported by another study (**17**). While, another study revealed that female gender had poor outcome in neonatal sepsis (**18**).

As regards blood culture, the percentage of negative culture is 38%, E coli is 22%, Klebsiella is18%, Pseudomonas is 16% and the culture-positive rate was (62%).

A group of researchers reported that, the culture-positive rate (5.93%) in their study was very low (**19**). This might be due to the fact that most of the neonates had received antibiotics before referral at primary or secondary healthcare level. Gram-negative sepsis remains an important cause of neonatal sepsis in developing countries.

In our study, the mortality rate in EOS was 61.9%, and it was higher than in

LOS (38.1%). This is similar to findings in a previous study (**20**).

In this study, there was statistically significant decrease in died group compared to survived group regarding gestational age $(32.48\pm2.84 \text{ vs.} 34.55\pm3.39 \text{ respectively})$ (P= 0.027).

Another study reported that, prematurity (<37 weeks) was associated with a higher mortality (54%) (21). This is in concordance with other studies done at different centers (22).

This might be explained by the fact that premature infants are at increased risk for developing complications of septicemia because of deficiencies in humoral and cellular immunity

On logistic regression analysis, the predictive factors for mortality were temperature at admission then distance during transport to hospital.

Outborn neonates and those with moderate hypothermia at admission were identified as subjects at high risk of mortality. This is noteworthy since half of admissions were outborn, which mirrors the geographical distribution of population in Ethiopia, where over 80% of people resides in the rural part of the country (**23**).

Thermal care and appropriate feeding play an important role in these thus neonates. prevention and treatment of hypothermia (i.e. kangaroo mother care) and the promotion of early and exclusive breastfeeding are warranted (24).

In the current study there is highly statistically significant increase in died group regarding distance during transport to hospital and highly statistically significant decrease in died group regarding duration of hospital stay.

There are many possible reasons that outborn neonatal mortality was higher than inborn including ineffective stabilization procedures before or during transport as well as delays in use of assisted ventilation, exogeneous surfactant, and transport. In addition, transport itself is a stressor that can adversely affect newborns. Transport quality itself can also affect the disease severity and affect the morbidity and mortality complicating condition. Better training in the care of mothers newborns at delivery, and and improved staffing and equipment at community hospitals may improve outcomes of outborn newborns (25).

There was highly statistically significant difference in died group regarding CRP level, while there was no statistically significant difference in mortality regarding CSF examination, Neutrophils, Blood sugar and serum calcium level.

Another study reported that, it was seen that the mortality rate was higher when neonates had thrombocytopenia, positive CRP, CSF cellularity and abnormal radiological findings. They could not demonstrate a significant correlation with anaemia, neutropenia, serum calcium and blood sugar with increased mortality (**19**).

On logistic regression analysis, the predictive factors for mortality were temperature at admission then distance during transport to hospital.

Conclusion

• Our mortality rate in outborn neonatal sepsis was (42%).

- The predictive factors in our study for neonatal sepsis mortality were temperature at admission then distance during transport to hospital.
- Convulsions, cyanosis, hypothermia and absent or poor suckling were significantly higher among died than survived group.

Recommendations

- It is important to pay attention to neonatal sepsis with the identified predictors to reduce sepsis-related mortality.
- Safe transport of neonates in ambulance with skilled workforce.
- Further studies are needed on larger scales.

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