

Treatment Outcomes of Neonatal Sepsis and Predictors in Neonatal Intensive Care Unit at a Tertiary Hospital in Eastern Ethiopia.

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ABSTRACT

Background: Neonatal sepsis affects about 40.25% of neonates in Ethiopia. Despite the heavy burden of the disease in the country, data on treatment outcomes and determinant factors are limited.

Methods: Institution based cross-sectional study was conducted from February 15 to April 15, 2020 among neonates with sepsis hospitalized at Hiwot Fana Specialized University Hospital, eastern Ethiopia. Data were analyzed using SPSS version 24.0. Multivariable logistic regression analysis was performed to identify predictors of recovery from neonatal sepsis.

Results: A total of 180 (71.7%) neonates with early onset and 71 (28.3%) with late onset neonatal sepsis were included in the study. Of these, 3.2 % (eight) died, twenty-five (9.96%) were self-discharge, and 0.4% (n=1) were transferred to other health institutions. The overall recovery rate was 86.5% with higher recovery rate for early onset than late onset neonatal sepsis (73.3% vs 26.7%). Being pre-term (< 37 weeks), (Adjusted Odds Ratio (OR) = 0.21 95 % CI: 0.09 - 0.48), having severe disease at hospitalization (critical case) (OR= 0.42, 95% CI: 0.17 - 1.01), failure of feeding (OR= 0.39, 95% CI: 0.16 – 0.96) and delivery at health centers (OR=5.16 95% CI: 1.40 – 18.95) were significantly associated with recovery from neonatal sepsis.

Conclusion: Most neonates had early onset neonatal sepsis and the majority of them were recovered with higher recovery rates for early onset neonatal sepsis. Delivering at healthcare facilities, and early initiation of breast feeding and providing special attention for pre-term, and critical cases could improve neonatal recovery from sepsis.

Introduction

Neonatal sepsis (NS) is defined as a clinical syndrome characterized by non-specific systemic signs and symptoms of infection during the first 28 days of the infant's life [1]. Based on the time when infection occurs, neonatal sepsis is classified as an early onset neonatal sepsis (EONS) if it occurs within the first three days of life; or late onset neonatal sepsis (LONS) if occurs from the third day or one week to the fourth week of the infant's life [1]. This distinction has clinical significance, as EONS is mainly due to bacterial acquired through prenatal and intrapartum maternal transmission, whereas LONS acquired postnatally from the environment such as nosocomial or community [2].

The estimated global burden of NS is about 22 per 1000 live births, with mortality rates ranging from 11% to 19% [3]. The third Sustainable Development Goal for child health which aimed to end preventable deaths of newborns and children under five years of age by 2030, may not be achieved without a substantial reduction of infection-specific neonatal mortalities in developing countries [4]. In sub-Saharan Africa, South Asia, and Latin America where the prevalence of neonatal infections is considerably high, the case fatality rate associated with severe bacterial infections in the first month of life is 9.8% [4]. The Global Sepsis Alliance (GSA) identified that infections causing sepsis are responsible for about one-fifth of the world's annual 2.7 million neonatal deaths, and in South Asia and sub-Saharan Africa, they are responsible for one-fourth of all neonatal deaths [5].

Globally, the neonatal deaths have decreased by over 3.6 million per year since 2000, mainly due to the decrease in the incidence of major conditions such as pneumonia and diarrhea. Despite this success, literature indicates that NS remains a notable hindrance to the progress in the decline of cause-specific mortality rates [3]. To date, Neonatal sepsis is responsible for 1.6 times the global number of childhood deaths as

malaria, and over four times the number of childhood deaths caused by HIV [4].

According to the systematic review and meta-analysis conducted in Ethiopia, the magnitude of NS among hospitalized neonates in different parts of the country ranged from 11.7% to 77.9%, with an overall pooled estimate of 40.25% [6]. Despite the heavy burden of NS in the country, there is limited research on in-hospital treatment outcomes and contributing factors among hospitalised neonates in Ethiopia. Furthermore, no previous studies have evaluated the in-hospital treatment outcomes and contributing factors in Eastern Ethiopia. Therefore, this study aimed to assess treatment outcomes of neonatal sepsis and predictors among neonates hospitalised to the Neonatal Intensive Care Unit (NICU) at Hiwot Fana Specialized University Hospital (HFSUH), Harar, eastern Ethiopia.

Methods

Study Area and Period

The study was conducted in Hiwot Fana Specialized University Hospital (HFSUH). HFSUH is the largest teaching and referral center in East Ethiopia. It provides a 24-hour inpatient, outpatient, delivery and emergency services for the population residing in the eastern part of the country. HFSUH has medical, surgical, pediatrics, gynecology and Obstetrics wards, and various outpatient clinics. The pediatric ward has six units, including the intensive care unit, nutritional rehabilitation unit, neonatal intensive care unit, and the chronic follow up unit. The study was conducted from February 15 to April 15, 2020 in the neonatal intensive care unit of the pediatric ward.

Study Design and Population

Institution based cross-sectional study was used. Medical records of neonates who had confirmed diagnosis and treated for either early or late onset neonatal sepsis were included in

the study. Medical records with sepsis above the neonatal age were excluded.

Sample size determination

The sample size was calculated using single population proportion formula by taking the following assumption: 5% confidence level, 50% estimate of prevalence rate for recovery and 5% margin of error. Accordingly, the calculated sample size was 384. Since the source population is less than 10,000, we applied the correction formula, and determined the final sample size for the study to be 251 neonates.

Data collection

A semi-structured data collection tool was developed after thorough literature review and pre-tested on 5% of medical charts. The content of the tool was checked by a consultant pediatrician and feedback was incorporated. The data were collected by pharmacy intern after being given a training for two days. Pertinent data, such as maternal and neonatal sociodemographic information, sign and symptoms, gestational age, place of delivery, mode of delivery, birth weight, laboratory values, medication administered, and final outcomes were extracted.

Statistical Analysis

The collected data were checked, categorized, entered and analyzed by using SPSS version 24.0 (SPSS Inc., Chicago, IL, USA). Descriptive

statistics such as frequency and proportion were computed for categorical variables. Bivariate regression analysis was performed and variables that have significant association with the outcome of interest (recovery) at 0.25 significance level were transferred into multivariable regression analysis to identify the predictors of neonatal recovery. During multivariable analysis a p value $\leq 0.05\%$ was considered significant.

Result

Neonatal and maternal characteristics

Overall, 180 (71.7%) neonates with early onset and 71 (28.3%) with late onset neonatal sepsis were included in the study. More than half (n=132, 52.6%) were male and 180 (71.7%) were aged less than seven days. Eighty (32.7%) neonates were under-weight (< 2.5 kg) and 22.7% were pre-term (< 37 weeks). Of the total mothers, 46.2% cannot read and write and 8.4% had an income < 150 Ethiopian Birr per-month. The majority (81.7%) of the mothers had Antenatal care follow up during pregnancy and 66.9% delivered in the hospital, out of which, 14.7% delivered by caesarean section (Table 1).

Table: 1 Neonatal and maternal characteristics among neonates with sepsis hospitalized in neonatal intensive care unit at Hiwot Fana Specialized University Hospital, eastern Ethiopia.

Variable		EONS (N=180)	LONS (N=71)	Total (N=251)
Sex	Male	53.3%	50.7%	52.6%
	Female	46.7%	49.3%	47.4%
Age	0- 7 days	100.0%	0.0%	71.7%
	8- 28 days	0.0%	100.0%	28.3%
Birth weight	< 2.5 kg	36.7%	22.5%	32.7%
	2.5 – 4kg	61.7%	77.5%	65.7%
	> 4 kg	1.2%	1.4%	1.6%
Gestational age	< 37 weeks	21.7%	25.4%	22.7%
	37- 42 weeks	73.3%	73.2%	73.3%
	> 42 weeks	5.0%	1.4%	3.9%
Educational background	Illiterate	43.3%	53.5%	46.2%
	read and write	22.2%	12.7%	19.5%
	primary school	12.2%	12.7%	12.4%

	secondary school	13.9%	12.7%	13.5%
	higher education	8.3%	8.5%	8.4%
Monthly income (in Ethiopian Birr)	< 150	0.6%	1.4%	0.8%
	151-650	16.1%	2.8%	12.4%
	651-1400	27.8%	35.2%	29.9%
	>1400	55.5%	60.6%	56.7%
ANC follow-up	Yes	80.0%	86.0%	81.7%
	No	20.0%	14.0%	18.3%
Maternal fever	Yes	42.8%	50.7%	45.0%
	No	52.2%	49.3%	55.0%
Foul smell liquor	Yes	26.1%	23.9%	25.5%
	No	73.9%	76.1%	75.5%
Chorioamnionitis	Yes	21.1%	8.5%	17.5%
	No	78.9%	91.5%	82.5%
PRM	Yes	22.2%	32.4%	25.1%
	No	77.8%	67.6%	74.9%
DPRM	< 12 hours	12.8%	4.2%	10.4%
	12 - 18 hours	6.7%	4.2%	6.4%
	> 18 hours	2.8%	4.2%	3.2%
Mode of delivery	Vaginal	76.1%	88.7%	79.7%
	Caesarean section	17.2%	8.4%	14.7%
	Vacuum	6.7%	2.8%	5.6%
Place of delivery	Hospital	78.3%	38.0%	70.0%
	Health Center	12.8%	26.8%	16.7%
	Clinics	4.4%	22.5%	9.6%
	Home	4.4%	12.7%	6.7%

Note: **EONS**-Early-onset Neonatal Sepsis; **LONS**-Late Onset Neonatal Sepsis; **ANC** – Antenatal care; **PRM**- Premature rupture of membrane; **DPRM** - Duration of pre-mature rupture of membranes

Clinical Features

Of the total neonates, 42.2% were hyperthermic, 27.1% were irritable, and 46.6%

were in respiratory distress. More than half (59.0%) were lethargic, 5.2% had seizure, 16.7% had jaundice, and 43% had lower APGAR score (≤ 7) (Table 2).

Table: 2 Clinical features of neonates with sepsis hospitalized in neonatal intensive care unit at Hiwot Fana Specialized University Hospital, eastern Ethiopia

Variables		EONS (N=180)	LONS (N=71)	Total (N=251)
Hyperthermia(>38.0°C)	Yes	27.2%	55.0%	42.2%
	No	72.8%	45.0%	57.8%

Hypothermia(<36.5°C)	Yes	62.2%	46.5%	57.8%
	No	37.8%	53.5%	42.2%
Irritability	Yes	27.7%	25.4%	27.1%
	No	72.3%	74.6%	79.9%
Respiratory distress	Yes	48.9%	40.8%	46.6%
	No	51.1%	59.2%	53.4
Vomiting	Yes	0.0%	5.6%	1.6%
	No	100.0%	94.4%	98.4%
Cyanosis	Yes	0.0%	1.4%	0.4%
	No	100.0%	98.6%	99.6%
Diarrhoea	Yes	6.7%	8.5%	7.2%
	No	93.3%	91.5%	92.8%
Abdominal distention	Yes	5.0%	8.5%	6.0%
	No	95.0%	91.5%	94.0%
Lethargic	Yes	56.7%	64.8%	59.0%
	No	43.3%	35.2%	41.0%
Failure feeding	Yes	23.3%	12.7%	20.3%
	No	76.7%	87.3%	79.7%
Bulging fontanel	Yes	2.8%	7.0%	3.9%
	No	97.2%	93.0%	96.1%
Coma	Yes	2.2%	2.8%	2.4%
	No	97.8%	97.2%	97.6%
Seizure	Yes	5.6%	2.8%	4.8%
	No	94.4%	97.2%	95.2%
Edema	Yes	0.0%	5.6%	1.6%
	No	100.0%	94.4%	98.4%
Jaundice	Yes	16.1%	18.3%	16.7%
	No	83.9%	81.7%	83.3%
Hepatomegaly	Yes	1.1%	0.0%	0.8%
	No	98.9%	100.0%	99.2%

Shock	Yes	3.3%	5.6%	3.9%
	No	96.7%	94.4%	96.1%
APGAR score ≤ 7	Yes	45.6%	36.6%	43.0%
	No	54.4%	63.4%	57.0%

Note: EONS-Early-onset Neonatal Sepsis; LONS-Late Onset Neonatal Sepsis

Laboratory Tests

The random blood glucose, complete blood cell count (CBC), and Cerebrospinal fluid analysis (CSF) tests were performed in 42.6%, 97.6%, and 6.4% neonates, respectively. Three

neonates had lower random blood glucose ($< 70\text{mg/dl}$) while more than half (59.0%) had elevated white blood cell count. The cerebrospinal fluid glucose and protein were $< 50\text{mg/dl}$ and $< 60\text{mg/dl}$ in 4.4% and 3.2% neonates, respectively (Table 3).

Table: 3 Laboratory tests among neonates with sepsis hospitalized in neonatal intensive care unit at Hiwot Fana Specialized University Hospital, eastern Ethiopia

Lab Tests		EONS (N=180)	LONS (N=71)	Total (N=251)
Random blood glucose	$< 70\text{ mg/dl}$	1.7%	0.0%	1.2%
	70- 115 mg/dl	40.0%	35.2%	38.6%
	$> 115\text{ mg/l}$	3.3%	1.4%	2.8%
Haemoglobin	$< 15\text{ mg/dl}$	21.7%	29.6%	23.9%
	15- 22 mg/dl	73.3%	64.8%	70.9%
	$> 22\text{ mg/dl}$	3.3%	1.4%	2.8%
WBC Count	$< 5000\text{ cell/mm}^3$	22.2%	47.9%	29.5%
	5000-12000 cells/mm ³	6.1%	25.4%	11.5%
	$>12000\text{ cell/mm}^3$	54.4%	70.4%	59.0%
Hematocrit	$< 42\%$	82.2%	90.1%	84.5%
	42-65 %	15.2%	5.6%	12.7%
	$> 65\%$	0.6%	0.0%	0.4%
MCV	$< 80\text{ FL}$	10.2%	15.5%	12.0%
	80- 115 FL	87.2%	77.5%	84.5%
	$> 115\text{ FL}$	0.6%	2.8%	1.2%
Platelet	$< 150\text{ k/UL}$	75.6%	69.0%	73.7%
	150 - 450 k/UL	22.8	26.8%	23.9%
CSF appearance	Clear	0.6%	11.3%	3.6%
	Cloud	1.7%	1.4%	1.6%
	Bloody	1.2%	1.4%	1.2%
WBC in CSF	$< 5\text{ cells/}\mu\text{L}$	1.2%	9.8%	3.6%
	$> 5\text{ cells/}\mu\text{L}$	2.2%	4.3%	2.8%
Glucose in CSF	$>50\text{ mg/dl}$	2.8%	8.5%	4.4%
	$< 50\text{ mg/dl}$	0.6%	5.6%	2.0%
Protein in CSF	$< 60\text{ mg/dl}$	0.6%	9.8%	3.2%
	$> 60\text{mg/dl}$	2.8%	4.2%	3.2%

Note: **MG/dl:** milligram per deciliter, **MCV:** Mean Corpuscular Volume, **WBC:** White Blood Cell Count; **EONS**-Early-onset Neonatal Sepsis; **LONS**-Late Onset Neonatal Sepsis; **CSF**-Cerebrospinal fluid

Medication administered, length of hospitalization and in-hospital outcomes

All neonates were prescribed Ampicillin and Gentamycin. One-hundred forty-four (57.4%) neonates were hospitalised for < 7 days and five

were hospitalised for > 14 days. Of the total neonates, the majority (86.5%) recovered, eight died, and twentyfive (9.96%) were self-discharged (Table 4).

Table 4: Medication given, length of hospitalization and treatment outcomes among neonates with sepsis hospitalized in neonatal intensive care unit at Hiwot Fana Specialized University Hospital, eastern Ethiopia

Medications		EONS (N=180)	LONS (N=71)	Total (N=251)
Ampicillin and Gentamycin		100.0%	100.0%	100.0%
Vancomycin		7.2%	11.3%	8.4%
Ceftazidime		10.0%	12.7%	10.7%
Vitamin K		15.0%	1.4%	11.2%
Phenobarbital		4.4%	5.6%	4.8%
Duration of hospitalization				
< 7 days		61.1%	47.9%	57.4%
7 - 14 days		37.8%	47.9%	40.6%
> 14 days		1.1%	4.2%	2.0%
Treatment outcomes	Died	2.8%	4.2%	3.2%
	Recovered	88.3%	81.7%	86.5%
	Self-discharge	9.96%	11.3%	9.9%
	Referred to another center	0.0%	1.4%	0.4%

Note: **EONS**-Early-onset Neonatal Sepsis; **LONS**-Late Onset Neonatal Sepsis

Factors associated with recovery

Pre-term neonates had 79% lower probability to recover from neonatal sepsis (OR=0.21, 95 % CI: 0.09 - 0.48; P=0.000) as compared to term neonates. Similarly, neonates who had severe disease at hospitalization (Critical patient) had 58% lower probability to recover from neonatal sepsis (OR= 0.42, 95% CI: 0.17 - 1.01; P=0.042) as compared to those who had

mild disease. Moreover, neonates who were unable to feed properly had 61.0% lower probability to recover from neonatal sepsis (OR= 0.39 95% CI: 0.18 – 0.96; P=0.04) than their counterparts. On the other hand, neonates who were delivered at the health center were 5.16 times (OR=5.16 95% CI: 1.40 – 18.95, P=0.01) more likely to recover from neonatal

sepsis as compared to those neonates who were delivered at home (Table 5).

Table 5: Determinants of recovery among neonates with sepsis hospitalized in the neonatal intensive care unit at Hiwot Fana Specialized University Hospital, eastern Ethiopia

Variable		Recovery		COR, 95% CI	AOR, 95% CI	P-value
		Yes	No			
Age	0-7 days	159	21	1.70 (0.79 - 3.61)	1.21 (0.45 – 3.28)	0.71
	8-28 days	58	13	1	1	
Gestational age	< 37 weeks	40	17	0.22 (0.10 - 0.48)	0.21 (0.09 - 0.48)	0.000
	37- 42 weeks	168	16	0.26 (0.03 - 2.23)	0.000 (0.000-)	-
	> 42 weeks	9	1	1	1	
ANC	Yes	177	28	0.95 (0.37 - 2.44)	2.11 (0.55- 8.12)	0.28
	No	40	6	1	1	
Maternal fever	Yes	94	19	0.60 (0.29 - 1.25)	1.20 (0.46 – 3.12)	0.71
	No	123	15	1	1	
Foul smell liquor	Yes	49	15	0.37 (0.18 - 0.78)	0.53 (0.20 – 1.40)	0.20
	No	168	19	1	1	
Failure feeding	Yes	39	12	0.40 (0.18 - 0.88)	0.39 (0.16 – 0.96)	0.04
	No	178	22	1	1	
PRM	Yes	49	24	0.42 (0.196 - 0.89)	0.88 (0.31- 2.45)	0.80
	No	168	20	1	1	
Place of delivery	Hospital	149	19	0.83 (0.27 - 2.57)	1.67 (0.45 – 6.21)	0.45
	Health Center	38	4	2.61 (0.92 - 7.40)	5.16 (1.40 – 18.95)	0.01
	Clinics	18	6	3.27 (1.04 - 10.29)	1.82 (0.36 – 9.24)	0.47
	Home	12	5	1	1	
Condition of the neonate	Critical	41	15	0.29 (0.14 - 0.63)	0.42 (0.17- 1.01)	0.042

at hospitalization	Not critical	176	19	1	1	
Hyperthermia (>38°C)	Yes	88	18	0.61 (0.29 - 1.25)	0.65 (0.26 - 1.63)	0.36
	No	129	16	1	1	
Platelet count	< 150 k/UL	161	24	0.479 (0.159 - 1.44)	0.73 (0.21 - 2.50)	0.62
	>150 k/UL	56	4	1	1	
Types of neonatal sepsis	EONS	159	21	1.70 (0.798 - 3.61)	0.05(0.00 - 17.48)	0.312
	LONS	58	13	1	1	

Note: ANC-Antenatal Care; PRM-Pre-mature Rupture of Membrane; EONS-Early-onset Neonatal Sepsis; LONS-Late Onset Neonatal Sepsis; COR-Crude Odds Ratio; AOR-Adjusted Odds Ratio

Discussion

To the best of our knowledge, this study is the first to evaluate the in-hospital outcomes of neonatal sepsis in eastern Ethiopia. It included 251 neonates receiving care in a neonatal intensive care unit at hiwot fauna specialized university hospital, eastern Ethiopia. The findings of this study revealed that, 71.7% of neonates were aged less than seven days and 22.7% were pre-term. The proportion of neonates who were pre-term in our study was lower when compared with the results of a study conducted in North east Ethiopia [7], but comparable with reports of a study conducted in North West Ethiopia [8]. The proportion of underweight neonates in this study was lower when compared with the findings of a study conducted in Southwest Ethiopia in which 50.0% of the neonates were underweight [9]. The inconsistency could be attributed to the variation in sample size and the clinical characteristics of the mother and the neonates. The results of this a study showed that the majority (81.7%) of mothers had a regular antenatal care follow up and 45.0% had a history of fever. The proportion of mothers who had a regular antenatal care follow up in this a study was comparable with the results of

study conducted in Bishoftu, Ethiopia [10]. Likewise, the proportion of mothers who delivered in the hospitals is comparable with the results of a study conducted in western Ethiopia [11] in which 68.62% of the mothers delivered their newborn in hospitals.

Of the total neonates, most (71.7%) of them had early onset neonatal sepsis and the majority (96.0%) were received combination of ampicillin and gentamycin antibiotics. In line with our findings, a comparable magnitude of early onset neonatal sepsis was reported in a study conducted by Fikadu et al in Western Ethiopia [11], however, a lower (26.9%) proportion of early onset neonatal sepsis was reported in a study by Mersha et al in Southern Ethiopia [12]. On the other hand, the types of antibiotics that most commonly prescribed in this study (i.e., ampicillin plus gentamycin) was similar with reports of previous studies conducted in various parts of Ethiopia [8, 10, 11]. This was due to the fact this combination of antibiotics was the recommended regimen for treating sepsis in this age group.

Of the total neonates, the majority (86.5%) recovered and more than half (57.4%) were hospitalized for less than seven days. The proportion of neonates who had recovery i was

comparable with the findings of a study by Fikadu et al (90.5%) [11], but slightly higher when compared with reports of a study conducted by Woldu et al (74.84%) [10].

In our study it was found that neonates with severe disease at hospitalization (critical) had 58% lower probability to recover from neonatal sepsis. Likewise, pre-term neonates had 79% lower probability to recover from the disease. This was due to the fact being a pre-term is both a risk factor and poor prognostic factor for neonatal sepsis [13]. Moreover, neonates who were not fed properly had 61% lower chance to recover from neonatal sepsis. This was due to the fact that early breast milk provides several immunocompetent factors such as immunoglobulins and lymphocytes that in turn stimulates the immune systems [14] [15]. The immunocompetent factors will also reduce gastrointestinal permeability and translocation of microorganism [15]. Besides, the close contact between the mother and neonates may also stimulate the mucosa associated with lymphoid tissue system [16]. On the other hand, neonates who were delivered at health centres had 5.16 times more chance to recover from neonatal sepsis when compared with neonates who were delivered at home.

Limitation

The study design (being cross-sectional), being limited to a single center and the small sample size could be the possible limitation of this a study. Additionally, inability to assess the specific etiology and their antimicrobial susceptibility was another possible limitation of the study.

Conclusion

Most neonates had early onset neonatal sepsis. More than half of the study participants were male and about one-third were under-weight. The majority of the mothers had a regular

antenatal care follow up during pregnancy and seventeen were delivered at home. The majority of neonates were recovered and the recovery rate was higher among neonates with early onset neonatal sepsis. Being pre-term, having severe disease at hospitalization (critical), failure of feeding, and delivery at the health centre were significantly associated with recovery from neonatal sepsis.

Ethics

The study approved by the Institutional Research Ethics Review Committee (IRERC) of Haramaya University. The permission to collect data was obtained from the hospital. Informed consent was not sought for the present study because the study is retrospective and the data were collected from patients' medical record.

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Data Availability

The raw data used for this study was included in the manuscript

Conflict of interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article

Authors' contributions

All authors contributed to data analysis, drafting or revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work

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