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Original Research Article

Survival Outcome, Risk Factor and Side Effects Observed in Neonatal Sepsis Patients Treated at Tertiary Care Hospital

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Abstract:

Introduction: Neonatal sepsis is a clinical syndrome of a dysregulated host response to bloodstream infection in the first 28 days of life. It is categorized into early-onset sepsis (EOS) and late-onset sepsis (LOS) based on timing and mode of transmission. Neonatal sepsis contributes significantly to morbidity and mortality, particularly in low- and middle-income countries. Identification of risk factors, survival outcomes, and drug-related adverse events is crucial for improving management.

Methods: This observational, prospective study was conducted in the Neonatal Intensive Care Unit of the pediatrics department of a tertiary care teaching hospital in Gujarat over 12 months. A total of 120 neonates diagnosed with neonatal sepsis were included. Data regarding clinical characteristics, maternal and neonatal factors, antimicrobial therapy, laboratory investigations, and outcomes were collected using case record forms. Statistical analysis was performed using Microsoft Excel and Jamovi software, with results expressed in percentages and hazard ratios.

Results: Among 120 neonates, 69 (57.5%) were male and 51 (42.5%) were female. EOS was more frequent (76.6%) than LOS (23.3%). Majority of neonates were <7 days of age (83.3%), preterm (68.3%), and had low or very low birth weight (38.3% and 34.1%, respectively). Most neonates were delivered via normal vaginal delivery (65%) and were outborn (74.2%). Survival was 70% (84/120), while 30% (36/120) did not survive. Significant factors associated with mortality included preterm gestation [HR=2.32, P=0.014], outborn status [HR=3.66, P=0.017], delivery via LSCS [HR=2.21, P=0.018], resuscitation at birth [HR=0.48, P=0.028], maternal age >30 years [HR=2.13, P=0.044], and lack of ANC follow-up [HR=2.32, P=0.019]. Ampicillin + sulbactam (70.83%) was the most commonly prescribed antimicrobial, followed by Piperacillin + Tazobactam (55%) and Amikacin (53.33%). Three adverse drug reactions were reported, all minor and preventable.

Conclusion: Neonatal sepsis in this tertiary care NICU had a survival rate of 70%. Preterm birth, outborn delivery, LSCS, resuscitation, maternal age >30 years, and lack of ANC follow-up were significant determinants of poor outcome. Timely diagnosis, appropriate antimicrobial therapy, and careful monitoring of risk factors are essential to reduce neonatal mortality and optimize management of neonatal sepsis.

Keywords: neonatal sepsis, antimicrobial therapy, n-SOFA score, survival outcome, adverse drug reaction.

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Introduction

Neonatal sepsis is a clinical syndrome of a dysregulated host response to bloodstream infection in the first 28 days of life [1]. The clinical signs and symptoms of neonatal sepsis include, hypothermia or fever, respiratory problems such as apnea and cyanosis, difficulty in feeding, abdominal distension, diarrhea, vomiting, oliguria, lethargy and irritability [2]. Neonatal sepsis is divided into early-onset and late-onset sepsis, based on the timing of infection and presumed mode of transmission. Early-onset sepsis (EONS) within the first 72 hours is caused by the maternal intrapartum transmission of invasive organisms. Late- onset sepsis (LONS) occurs after 72 hours of birth and is attributed to pathogens acquired postnatal [3]. Risk factors for early onset of sepsis includes premature rupture of membrane (PROM), fever, chorioamnionitis, repeated vaginal examination, meconium-stained amniotic fluid, dietary intake of contaminated foods, cervical cerclage, place of birth, prematurity, low birth weight, complicated or instrument-assisted delivery, and low appearance pulse grimace activity respiration (APGAR) scores. Late onset of sepsis acquiring nosocomial infections and invasive procedures during hospital admission. [4] Neonatal sepsis can cause significant morbidity including delayed enteral feeding, prolonged duration of mechanical ventilation and hospital stay,

long-term disability and even cause death of the neonates [4,5]. Globally, about 50 percent decline has been observed in newborn deaths during 1990 to 2019. Majority of deaths of under-5 mortality occurred within the first four weeks of life and around one-third neonates die on the same day of birth (6). Neonatal sepsis is responsible for approximately 8% of neonates' deaths and is a predominant cause of neonatal mortality and long-term morbidity, especially in low- and middle-income countries. [7] Neonatal sepsis has found to be the second major cause of neonatal deaths in India followed by Asphyxia. [6]

The survival outcomes of neonatal sepsis vary in different hospitals with different setups. Early diagnosis and treatment are required to save the life of future generation. This requires identification of common risk factors for neonatal sepsis. Pharmacological therapies for Neonatal sepsis have improved the survival and quality of life of neonates. This study aims to investigate the survival outcomes and side effects associated with drug therapy of neonatal sepsis at a tertiary care hospital. By examining the clinical characteristics, treatment modalities, and understanding the factors associated with neonatal mortality in these patients and the occurrence of side effects, this study aims to provide insights into the management of neonatal sepsis and identify potential areas for improvement.

Material & Method:

This was an observational, prospective study conducted in the Neonatal Intensive Care Unit (NICU) of the Department of Pediatrics at a tertiary care teaching hospital in Gujarat. The study duration was 12 months.

The study protocol, case record forms, and informed consent documents were submitted to and approved by the Institutional Ethics Committee (IEC Approval No. PDUMCR/IEC/48/2023, Date: 06/04/2023). Written informed consent was obtained from the parents or guardians of all participants prior to enrolment. Permission to conduct the study was obtained from the Head of the Department of Pediatrics. Neonates of either gender admitted to the NICU and diagnosed with neonatal sepsis were included. Neonates discharged against medical advice (DAMA) or referred to a higher center were excluded.

A total of 120 neonates meeting the inclusion criteria were enrolled in the study. The investigator visited the NICU daily to collect data using a structured case record form. Information recorded included neonatal demographics, clinical features, maternal factors, laboratory investigations, details of antimicrobial therapy (drug, dose, and duration), and outcomes.

Enrolled neonates were monitored throughout their hospital stay. Clinical progress, laboratory investigations, culture results, and antimicrobial response were recorded weekly. Data were entered into Microsoft Excel 2019 and analyzed using Jamovi software version 2.3.28. Continuous variables were summarized as median and interquartile ranges, while categorical variables were expressed as frequencies and percentages. Survival outcomes and factors associated with mortality were assessed using Cox regression analysis.

Result

This prospective, observational study was carried out to evaluate the drug utilization pattern in neonatal sepsis in Neonatal Intensive Care Unit (NICU) of pediatrics department of a tertiary care teaching hospital Gujarat. The study was conducted over a period of 12 months in 120 admitted patients at NICU.

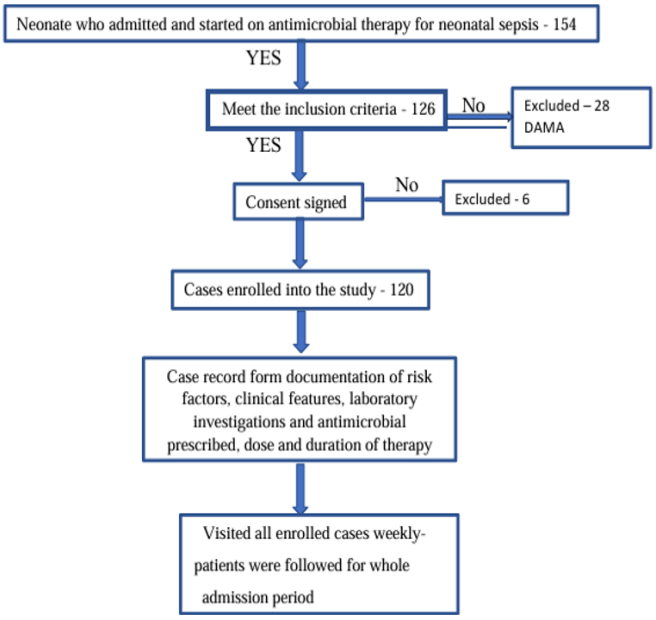

Chart 1:

Table 1: Neonatal Factors (n = 120)

Variable	Category	n (%)	Category	n (%)
Gender	Male	69 (57.5)	Female	51 (42.5)
Type of Sepsis	EOS	92 (76.6)	LOS	28 (23.3)
Age of Neonate	<7 days	100 (83.3)	>7 days	20 (16.6)
Birth Weight	NBW (>2500 gm)	20 (16.6)	LBW (<2500 gm)	46 (38.3)
	VLBW (<1500 gm)	41 (34.1)	ELBW (<1000 gm)	13 (10.8)
Gestational Age	Preterm (<37 weeks)	82 (68.3)	Term (37–42 weeks)	38 (31.7)
Place of Delivery	Inborn	31 (25.8)	Government Hospital	43 (35.8)
	Private Hospital	22 (18.3)	Health Care Hospital	19 (15.8)
	Home	5 (4.2)	—	—
Mode of Delivery	NVD	78 (65.0)	LSCS	42 (35.0)
Breastfeeding Started	Yes	27 (22.5)	No	93 (77.5)
Resuscitation Given	Yes	39 (32.5)	No	81 (67.5)
Immunization	Yes	97 (80.8)	No	23 (19.2)
CRP	Positive	58 (48.3)	Negative	62 (51.7)
C/S Report	Positive	23 (19.1)	Negative	32 (26.6)
	Not Done	65 (54.2)	—	—
WBC Count	4000–10000	40 (33.3)	10000–20000	73 (60.8)
	>20000	7 (5.8)	—	—

Table 2: Maternal Factors (n = 120)

Variable	Category	n (%)	Category	n (%)
Age of Mother	19–29 years	98 (81.6)	30–34 years	12 (10.0)
	>35 years	10 (8.4)	—	—
Residence	Urban	57 (47.5)	Rural	63 (52.5)
Number of Pregnancy	Primi	48 (40.0)	Multi	72 (60.0)
ANC Follow-up	Yes	91 (75.8)	No	29 (24.2)
Twin Pregnancy	Yes	14 (11.7)	No	106 (88.3)

A total of 120 neonates diagnosed with sepsis were enrolled. Males accounted for 69 (57.5%) cases and females for 51 (42.5%).

Early-onset sepsis (EOS) was more prevalent, affecting 92 neonates (76.6%), while late-onset sepsis (LOS) occurred in 28 neonates (23.3%).

Most neonates (83.3%) were aged less than 7 days at admission. Regarding birth weight, 46 (38.3%) neonates were low birth weight (LBW, <2500 g), 41 (34.1%) very low birth weight (VLBW, <1500 g), 13 (10.8%) extremely low birth weight (ELBW, <1000 g), and 20 (16.6%) were normal birth weight. Preterm neonates (<37 weeks) comprised

68.3%, while term neonates comprised of 31.7%. The majority of deliveries were normal vaginal (65%), and most neonates were outborn (74.2%) (Table 1).

Most mothers were aged 19–29 years (81.6%), followed by 30–34 years (10%) and >35 years (8.4%). Urban and rural residences were 47.5% and 52.5%, respectively.

Multigravida mothers accounted for 60%, with primigravida comprising 40%. Antenatal care (ANC) follow-up was completed by 75.8% of mothers, and 11.6% of pregnancies were twin gestations (Table 2).

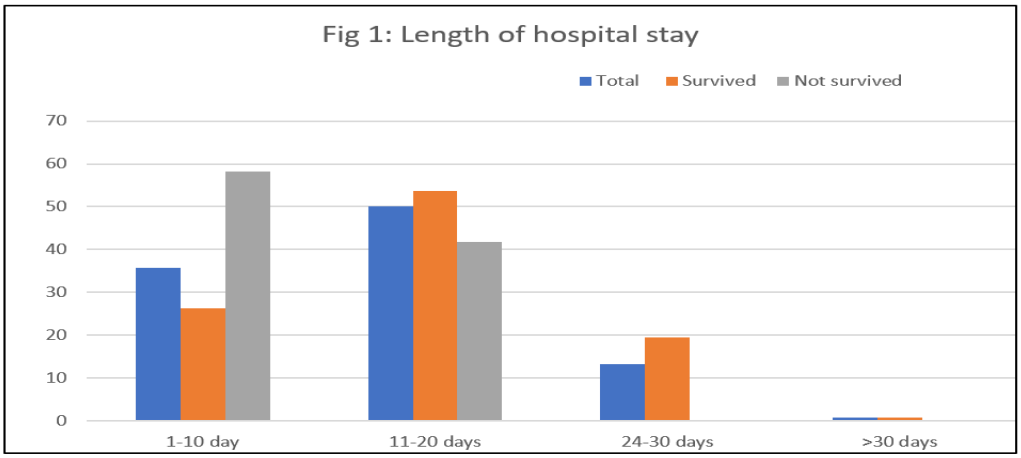

Figure 1: Distribution of hospital stay and survival outcomes among neonates with sepsis

	Total	Survived	Not survived
1-10 days	43 (35.8)	22 (26.2)	21 (58.3)
11-20 days	60 (50)	45 (53.6)	15 (41.7)
24-30 days	16 (13.3)	16 (19.4)	0
>30 days	1(0.8)	1 (0.8)	0

The duration of hospital stay varied from 1 day to over 30 days.

Fifty percent of neonates stayed 11–20 days, 35.8% stayed 1–10 days, 13.3% stayed 21–30 days, and 0.8% stayed longer than 30 days. Survival differed across categories: 26.2% of neonates survived in the 1–10 days group, 53.6% survived in the 11–20 days group, and all neonates survived in the 21–30 days and >30 days groups.

Mortality was highest in neonates with 1–10 days of hospitalization, where 58.3% of non-survivors died (Table 3, Fig. 1).

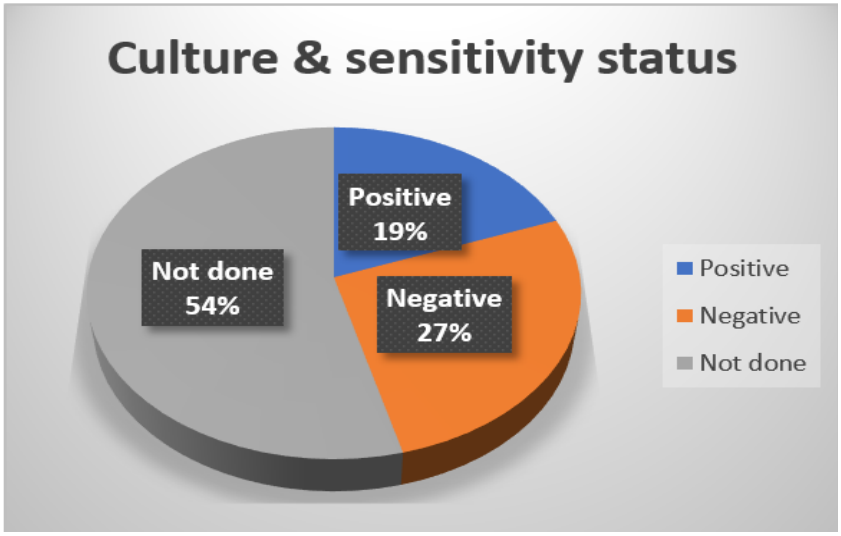

Figure 2: Culture and sensitivity results in neonates with sepsis.

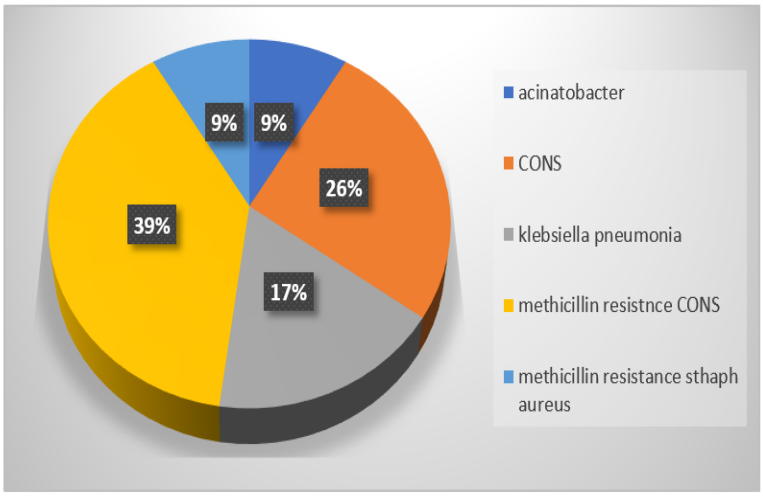

Figure 3: Distribution of organisms isolated from positive cultures.

Culture and sensitivity testing was performed in 46% of neonates. Among these, 19% were positive, 27% result were negative.

The most frequently isolated organisms were methicillin-resistant coagulase-negative staphylococci (MRCONS, 39%), coagulase-negative staphylococci (CONS, 26%), Klebsiella pneumoniae (17%), Acinetobacter species (9%), and methicillin-resistant Staphylococcus aureus (MRSA, 9%) (Figs. 2 and 3).

Table 3: Dose of antimicrobial used:

Drugs	Dose (mg/kg)	No. of prescriptions
Ampicillin + sulbactam	50	85 (70.83%)
Amikacin	15	64 (53.33%)
Gentamycin	7.5	49 (40.83%)
Piperacillin + Tazobactam	100	66 (55%)
Cefotaxime	50	13 (10.83%)
Levofloxacin	10	27 (22.5%)
Meropenem	40	47 (39.16%)
Metronidazole	10	44 (36.66%)
Vancomycin	15	23 (19.16%)
Linezolid	10	14 (11.66%)
Colistin	25000 IU	3 (2.5%)

Table 4: Total dose per day, Median and IQR of individual antimicrobial drugs:

Sr. No.	Antimicrobial	Total Dose used/ Day (mg/day)	Median of total dose (mg)	1st Quar-tile Q1	3rd Quar-tile Q3	IQR of median total dose
1	Cefotaxime	35-130	100	70	105	35
2	Amikacin	7.5-50	25	19.5	30.25	10.75
3	Metronidazole	5-110	17	13	21.25	8.75
4	Meropenem	20-136	63	44	82	38
5	Linezolid	7-27	16	12.75	20.75	8
6	Gentamicin	5-22.5	11	8.75	16	7.25
7	Piperacillin + Tazobactam	20-340	155	120	200	80
8	Vancomycin	14-42	30	21	38	17
9	Levofloxacin	5-35	17	13.5	23	9.5
10	Ampicillin + Sulbactam	25-175	75	60	100	40
11	Colistin	35000-125000	75000	65000	87500	22500

Eleven different antimicrobials were prescribed during the study period. Ampicillin + Sulbactam was the most commonly used (70.83%), followed by Piperacillin + Tazobactam (55%) and Amikacin (53.33%). Gentamycin (40.83%), Meropenem (39.16%), and Metronidazole (36.66%) were also frequently administered. Less commonly prescribed agents included Cefotaxime (10.83%),

Linezolid (11.66%), and Colistin (2.5%) (Table 4). The median daily doses and interquartile ranges for individual antimicrobials are presented in Table 5. Cox regression analysis revealed several factors significantly associated with mortality. Preterm neonates had a twofold increased risk of death compared to term neonates [HR=2.32, P=0.014]. Outborn neonates were three times more likely to die than inborn neonates [HR=3.66, P=0.017], and those delivered via caesarean section had a higher mortality risk than vaginally delivered neonates [HR=2.21, P=0.018]. Additional significant predictors included resuscitation at birth [HR=0.48, P=0.028], maternal age >30 years [HR=2.13, P=0.044], and lack of ANC follow-up [HR=2.32, P=0.019]. Other variables, including sepsis type, age ≥7 days, birth weight, breastfeeding initiation, immunization status, CRP positivity, WBC count, residence, parity, and twin pregnancy, were not significantly associated with mortality (Table 6)

Table 5: Analysis of factors affected with mortality:

Variable	Category	Treatment outcome		Hazard ratio	p-value
		Survived 84(%)	Not survived 36(%)		
Type of sepsis	EOS	67 (79.7)	25 (69.4)	1	0.244
	LOS	17 (20.2)	11 (30.6)	1.53(0.75-3.15)	
Age of neonate	< 7 days	71 (84.5)	29 (80.5)	1	0.570
	>7 days	13 (15.5)	7 (19.5)	0.76(0.29-1.96)	
Birth weight	>2500	14 (16)	6 (16.6)	1	0.600
	<2500	70 (84)	30 (83.4)	1.27(0.52-3.07)	
Gestational age	Preterm	63 (75)	19 (52.7)	2.32(1.19-4.55)	0.014*
	Term	21 (25)	17 (47.3)	1	
Place of delivery	Inborn	27 (32.1)	4 (11.1)	1	0.017*
	Out born	57 (67.9)	32 (88.9)	3.66(1.26-10.59)	
Mode of delivery	NVD	59 (70.2)	19 (52.7)	1	0.018*
	LSCS	25 (29.8)	17 (47.3)	2.21(1.14-4.27)	
Breast feeding started	Yes	15 (17.8)	8 (22.3)	1	0.052
	No	69 (82.2)	24 (66.7)	0.50(0.25-1.01)	
Resuscitation given	Yes	21 (25)	18 (50)	0.48(0.25-0.92)	0.028*
	No	63 (75)	18 (50)	1	
Immunization given	Yes	73 (87)	24 (66.7)	1	0072
	No	11 (13)	12 (33.3)	1.89(0.94-3.78)	
CRP	Positive	33 (39.2)	25 (69.4)	0.50(0.24-1.02)	0.057
	Negative	51 (60.8)	11 (30.6)	1	
WBC count	<10000/cells	26 (31)	14 (38.8)	1	0.517
	>10000/cells	58 (69)	23 (61.2)	0.80(0.4.-1.58)	
Age of mother	<30 years	73 (87)	26 (72.2)	1	0.044*
	>30 years	11 (13)	10 (27.8)	2.13(1.02-4.46)	
Residence	Urban	39 (46.4)	18 (50)	1	0.653
	Rural	45 (53.6)	18 (50)	1.17(0.59-2.30)	
No. of pregnancy	Primi	32 (38.1)	16 (44.4)	1	0.806
	Multi	52 (61.9)	20 (55.6)	0.92(0.48-1.78)	
ANC f/u	Yes	67 (79.7)	24 (66.7)	1	0.019*
	No	17 (20.3)	12 (33.3)	2.32(1.15-4.72)	
Twin pregnancy	Yes	7 (8)	7 (19.4)	0.68(0.29-1.56)	0.359
	No	77 (92)	29 (80.6)	1	

***p<0.05 suggest significant correlation**

The neonatal Sequential Organ Failure Assessment (nSOFA) score was used to evaluate organ dysfunction and predict outcomes in neonates with sepsis.

Scores were assessed at the time of admission and at discharge or completion of treatment. Among the total patients, 53% of neonates showed improvement in their nSOFA scores at discharge compared to admission, indicating recovery of organ function. In 16% of neonates, nSOFA scores remained within the normal range throughout hospitalization, reflecting stable clinical status. Conversely, 30% of neonates demonstrated deterioration in nSOFA scores during their hospital stay, which correlated with increased mortality in this subgroup.

In our study, the majority of neonates with sepsis survived with clinical improvement (70%), while 30% of neonates did not survive.

Table 6: Reported suspected ADR:

No.	Reaction	Suspected drug	Causality	Severity	Preventability
1	Hyperbilirubinemia	Gentamycin	Probable	Minor	Preventable
2	Increase s. creatinine	Amikacin	Probable	Minor	Preventable
3	Increase s. creatinine	Gentamycin Ampicillin+ sulbactam	Possible	Minor	Preventable

Discussion

Our study was conducted in NICU in a tertiary care teaching hospital of Gujarat. In this study total of 120 admitted neonates of both sexes with diagnosis of Neonatal Sepsis were included. In present study, males are affected more with 57.5%, similar to study by Tewabe T. et al in North West Ethiopia where males were affected 64% with neonatal sepsis(4), but in contrast to study by Wale A. et al in South West Ethiopia where female preponderance was found with 52% [3]. Incidence of Early Onset Neonatal sepsis (EOS) cases were more at 76.6% than Late Onset (LOS) type of neonatal sepsis (23.3%), which is similar finding in a study carried out by Tewabe T. et al [4] with 75.1% while in study by Wale A. et al LOS were more with 76.3 % cases [3].

Neonates with age on admission <7 days are more with 83.3% cases. Neonates with low birth weight (<2500 kg) were more associated with neonatal sepsis with 38.3% followed by very low birth weight (<1500 kg) with 34.1% in this study, this observation corroborates with studies of Tewabe T. et al [4] and Wale A. et al [3], because LBW is one of the predisposing factor of neonatal sepsis [9] but in study of Fekadu A. et al, percentage of normal birth weight babies were higher (92.5%) [8] Preterm babies were more affected with neonatal sepsis (68.3%) compared to term neonates. These finding is may be due to low immunity in preterm babies. This finding differs from studies conducted by Wale A. et al and Tewabe T. et al where term neonates are affected more. [4,3] Neonatal sepsis cases are more seen with those delivered outside the study site hospital, more with government hospital-35.8% compared to inborn where incidence of neonatal sepsis is 25.8%. In this study, home delivery cases associated with neonatal sepsis are 4.16% which corroborates with study done by Tewabe T. et al where incidence was 4.9% [4]. Normal vaginal deliveries are more associated with Neonatal Sepsis in compare to Caesarean section (CS) deliveries. It might be due to Microbes ascending from rectoperineum through birth canal secretion and amniotic fluid [10]. Based on the studies from India [11,12], following risk factors seem to be associated with increased risk of EON, prematurity, foul smelling liquor, rupture of membranes > 24 hours, Single unclean or > 3 sterile vaginal examination(s) during labor, Prolonged labor (duration of 1st and 2nd stage of labor ≥ 24 hr) and perinatal asphyxia (Apgar score < 4 at 1 minute). Similar result is found in study of Wale A. et al, Tewabe T. et al and Fekadu A. et al [3,4,8]. Breast feeding was not started in 77.5% neonates within one hour of delivery. Resuscitation was required in 32.5% neonates after delivery, while in study done by Tewabe et al 54% neonates required resuscitation [4]. From 120 cases of Neonatal sepsis, 80.8% neonates were immunized, though 19.1% neonates were non-immunized, which may lead them to future health problems. Strict immunization is recommended.

In this study majority of mothers of neonates (81.6%) belonged to age group of 19-29 years followed by 30-34 years and >35 years. This order of age group findings is similar to the study done by Wale A. et al [3] and Tewabe T. et al [4]. 52.5% mothers belonged to rural area which is similar to study of Tewabe T, where 59.1% mothers were from rural area but in contrary to study by Wale A. et al where 55.5% mothers from urban residence. Neonatal sepsis was associated more with multigravida mother (60%) compared to primigravida (40%). This is similar to study of Tewabe T. et al but in Wale A. et al neonatal sepsis was associated more with primigravida mothers. 11.6% mothers of neonatal sepsis had twin pregnancy. ANC visits and follow up during pregnancy were done in 75.8% mothers in contrast to study done by Wale A.et al where it was present in 35.5% mothers only.

Blood culture is the gold standard for diagnosis of sepsis and should be performed in all cases of suspected sepsis prior to starting of antibiotics. In this study culture and sensitivity report were done in 46% patients. Out of them 19% patients showed positive culture reports. Blood sample collection after initiation of empirical therapy may have resulted in less organisms being isolated. It is similar to finding of Tewabe T. et al with 17.3% culture positive [4]. In study of Wale A et al. there are 56% culture have isolated organism, though they have also included CSF culture, besides blood culture. In this study, among the positive culture report most common isolated organism was methicillin resistance CONS 39%, followed by CONS 26%, Klebsiella pneumonia 17% and Acinetobacter and methicillin resistance staph aureus both are 9%. This finding is different from Wale A. et al study, in which Group B Streptococcus was most commonly isolated organism followed by E.coli [3]. In this study in CRP was positive in 48.3% cases. In 60.8% cases WBC count were in the range of 4000-20000. In 5.8% cases WBC count were >20000, while in study done by Wale A. et al it was 11.3%.

In this study length of hospital stay of neonates with neonatal sepsis varied from 1-10 days to even >30 days. Half of the total neonates (50%) stayed in hospital for 11-20 days followed by length of hospital stay of 1-10 days (35.8%). 13.3% neonates stayed in hospital for 24-30 days. This result is different from study done by Fekadu A. et al where majority of neonates (61%) stayed in hospital for <5 days [8]. From the total survived neonates majority stayed in hospital for 11-20 days (53.6%) and majority neonates who did not survived, who stayed in hospital for 1-10 days (58.3%).

11 different antimicrobials were used as per our setup while the study conducted in same setup by Parmar R C et al observed 17 different antimicrobials were used [13]. In this study 70.83% neonates were prescribed Ampicillin + sulbactam combination for treatment of neonatal sepsis, while the study conducted by Wale A. et al and Tewabe T. et al 78.2% and 90.2% patient were prescribed combination of Ampicillin with Gentamycin respectively [3,4]. Most of neonates (49.16%) were prescribed 3-5 antimicrobial agents (AMA), while in study of Parmar R C et al majority of neonates (32.85%) received 3-5 AMA & in study of Das M et al. majority of neonates (43%) received at least 3 AMA (13,14). In our study, 36.66% neonates received at least 2 AMA and 14.16% received 6-8 AMA. The reason for change of drug regimen were clinical deterioration or different isolated organism from blood culture than the suspected organism. Piperacillin + Tazobactam is the second most common prescribed antibiotic combination (55% cases) in our study followed by Amikacin (53.33%) and Gentamycin (40.83%). Empirical therapy in LOS, combination of Ampicillin or Cloxacillin with Gentamicin or Amikacin may be instituted [15]. Amikacin or gentamicin was the preferred for empirical antibiotic therapy both EON and LON. Meropenem was most commonly prescribed antimicrobial in LON as empirical treatment, though, Meropenem is reserved drug for empirical therapy [16]. In this study 39.16% cases of neonatal sepsis were treated with Meropenem. 36.66% cases were treated with Metronidazole and 22.5% & 19.16% cases were treated with Levofloxacin and Vancomycin respectively. In 10.83% cases, 3rd generation Cephalosporin (Cefotaxime) were used, it may be due to their lack of dose related toxicity but Cephalosporines are generally avoided for empiric regimen [16]. Linezolid and Colistin are the last resort of drugs and were used in 11.6% and 2.5% cases of neonatal sepsis. The actual choice varies across the institutions depending on susceptibility profile of prevalent sepsis pathogens. Thus, being unit- specific, a single empirical regimen cannot be universal, so as empirical therapy, antimicrobials vary with different time and places, which is justifiable [9]. Life-threatening organ dysfunction is quantified using the Sequential Organ Failure Assessment (SOFA) score, which categorizes the degree of organ dysfunction and helps predict the risk of death or the need for intensive care unit (ICU) admission. However, unlike in adult and pediatric ICUs, the neonatal ICU (NICU) often lacks widespread recognition of sepsis as distinct from general infection, as well as the integration of organ dysfunction assessments. In neonatology, sepsis is typically defined based on the isolation of bacterial pathogens from blood cultures and the duration of antimicrobial treatment, rather than on a standardized scoring system like SOFA [17]. The nSOFA utilizes categorical scores (total scorerange0–15) to objectively describe dynamic changes in: (1) the need for mechanical ventilation and oxygen requirement (score range 0–8), (2) the need for inotropic support including the use of corticosteroid support (for presumed adrenal insufficiency or catecholamine-resistant shock) (score range0–4), and (3) the presence and degree of thrombocytopenia (score range 0–3) (5).

In this study nSOFA score was taken at the time of admission of patient and at the time of completion of treatment or discharge. In 53.3% patient of neonatal sepsis patient nSOFA score improved at the time of discharge compared to score taken at the time of admission and in 16.6% patients nSOFA score remain within normal range at the start and at the end of treatment suggesting good clinical outcome in these patients. In 30 % patients score deteriorate at the end of treatment compared to starting of treatment which suggesting, mortality in these patients.

In this study 70% neonates (84 cases) survived and had clinical improvement while 30% neonates (36 cases) did not survive. In study done by Wale A. et al 67.8% neonates survived with good clinical outcome. In this study cox regression analysis was done to see of factors associated with mortality significantly in neonates. It was observed that gestational age of neonate, place of delivery, mode of delivery, resuscitation given at the time of birth, age of mother and ANC follow up by mothers were significantly associated with mortality in neonates. These findings are different from study done by Wale A. et al where other factors like very low birth weight, age of neonates, maternal history of infection and maternal education were significantly associated with mortality in neonates [3].

In this study, preterm neonates [P = 0.014, HR = 2.32, 95% CI: (1.19, 4.55)] were at increased the risk of death by two times compared to term neonates. Those neonates with place of delivery outside our hospital setup like in health centre [P = 0.017, HR = 3.66, 95% CI: (1.26, 10.59)] were three times more likely to suffer an early death or decreased survival compared to those neonates born inside hospital setup. Neonates delivered via caesarean section [P = 0.018, HR = 2.21, 95% CI:

(1.14, 4.27)] were two times more likely to die compared to those who delivered by normal vaginal delivery. Neonatal sepsis patients who received resuscitation after birth [(P = 0.028, HR = 0.48, 95% CI: (0.25, 0.92)] were associated with higher mortality than those who did not receive it. Those neonates born from mother aged >30 years [P = 0.044, HR = 2.13, 95% CI: (1.02, 4.46)] were two times more likely associated with mortality compared to those born from mother age <30 years. Neonates of mothers who did not attended ANC follow up during pregnancy [P = 0.019, HR = 2.32, 95% CI: (1.15, 4.72) succumbed earlier by two times compared to those whose mothers attending ANC visits.

In present study, 3 ADR were reported, from which 2 were probably and 1 was possibly related to suspected antimicrobial according to WHO causality assessment scale. All adverse drug reaction were preventable according to Naranjo ADR preventability score [18] and all were minor according to modified hartwing's severity scale. Hyperbilirubinemia was probably related to the drug Gentamycin while increase in s.creatinine is probably related to Amikacin in one patient while possibly related to Gentamycin and Ampicillin-sulbactam in other patient. Action was taken following the Adverse Drug Reaction was withdrawn of drug and changed to other antibiotics in all three cases.

Conclusion

The present study evaluated the survival outcome of neonatal sepsis patients admitted in a tertiary care NICU and showed that the favourable outcomes of neonatal sepsis was 84 (70%). The determinant factors for poor outcome were preterm babies, out born individuals, delivered via LSCS, those who received resuscitation at birth, neonates with maternal age over 30 years and mothers who did not attend ANC follow up. Timely and accurate diagnosis and management are essential, although diagnosis remains challenging due to nonspecific clinical signs and symptoms. In many developing countries, empirical treatment remains the primary approach, which may contribute to antimicrobial resistance. Therefore, essential newborn care, appropriate follow up and early detection and management of neonatal infections are important to improve neonatal outcome.

References

1. Agarawal R, Deorari A, Paul V, Sankar MJ SA. Sepsis in the Newborn. In: AIIMS Protocols in Neonatology. 3rd ed. Delhi: Nobel; 2024. p. 259-71.
2. Atif M, Zia R. et al Treatment outcomes, antibiotic use and its resistance pattern among neonatal sepsis patients attending Bahawal Victoria Hospital, Pakistan. PLOS ONE. 2021;16(1): 1-16
3. Wale A, Chelkeba L, et al Treatment Outcome and Associated Factors of Neonatal Sepsis at Mizan Tepi University Teaching Hospital, Southwest Ethiopia: A Prospective Observational Study. Pediatric Health, Medicine and Therapeutic. 2021;12: 467-479.
4. Tewabe T, Mohammad S, Tilahun Y. Clinical outcome and risk factors of neonatal sepsis among neonates in Felege Hiwot referral Hospital, Bahir Dar, Amhara Regional State, North West Ethiopia 2016: a retrospective chart review. BioMed Central. 2017;10(265): 1-7.
5. Wynn JL, Polin RA. A neonatal sequential organ failure assessment score predicts mortality to late-onset sepsis in preterm very low birth weight infants. Pediatric Research. 2019;88: 85-90.
6. Salve PS, Naikar SK, Noolvi C. Neonatal Mortality in India: A District-Level Analysis Using Health Management Information System data. Demography India. 2021;50(1): 126-133.
7. Muhammad HAH, Parekh R, Dhandibhotla S. et al. Insight Into Neonatal Sepsis: An Overview. Cureus. 2023;15(9): 1-12.
8. Fekadu G, Abera T, Tekle T. Clinical Treatment Outcomes of Neonatal Sepsis in Neonatal Intensive Care Unit of Wollega University Teaching and Referral Hospital, Nekemte Town, Western Ethiopia. Pediatrics & Therapeutics. c 2018;9(1): 1-7.
9. Eichenwald E c, Hansen RA, Martin CR, Stark AR. Cloherty and Stark's Manual of neonatal care. Vol. 8 Ed, Wolters Kluwer. 2021. 1124 p.
10. Gupta P. Neonatal Sepsis. In: Manon P, Ramji S, Lodha R (eds.) PG textbook of Pediatrics. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; c 2022. p. 632-8.
11. Takkar VP. Bhakoo ON NA. Scoring system for the prediction of early neonatal infection. Indian pediatr 1974:11:597-600.
12. Singh M, Narang A BO. Predictive perinatal score in the diagnosis of neonatal sepsis. J Trop Pediar. 1994;40(6):365–8.
13. Parmar R C, Singh A P. Antimicrobial use and Adverse Drug Reaction in Newborns with Neonatal Sepsis: A Prospective Observational Study from a Tertiary Care Teaching Hospital. Indian Journal of Neonatal Medicine and Research. 2024;12(2): 32-38.
14. Das M, Pal N, Dolui SK, Choudhury S. Pattern of antimicrobial usage in neonatal septicemia at neonatal intensive care unit of a tertiary care hospital in Kolkata. J Nat Sci Biol Med. 2019 Jul 1;10(2):178–83.
15. Agarawal R. Deorari A, Paul V, Sankar MJ SA. Sepsis in the Newbom. In: AIIMS Protocols in Neonatology. 2nd ed. Delhi: Nobel; 2019. p. 303-15.
16. Cotten CM, Taylor S, Stoll B et al. Prolonged duration of initial empirical antibiotic treat-

ment is associated with increased rates of necrotizing enterocolitis and death for extremely low birth weight infants. Pediatrics. 2009; 123(1):58–66.
17. Fleiss N, Coggins SA, Lewis AN. Evaluation of the Neonatal Sequential Organ Failure Assessment and Mortality Risk in Preterm Infants with Late-Onset Infection. JAMA Network Open. 2021;4 (2): 1-11.
18. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Robert EA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981; 30:239– 45.