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Clinical Register of Neonatal Sepsis in Beni-Suef University Hospital

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Abstract:

Background: Neonatal sepsis can fall under the early (days 0-3) or late (days 4-9) onset groups (day of life 4 or later).

Objectives: We aimed to study clinical and laboratory data of neonatal sepsis in Beni-Suef University Hospital. Also, to detect the risk factors for neonatal sepsis and prognosis. Moreover, comparing sepsis group with controls.

Methods: This prospective case control study was conducted on 79 patients in Neonatal Intensive Care Unit of Beni-Suef University Hospital from April 2022 to December 2022 after approval by the institutional ethical committee. Patients were followed up for signs of sepsis and were divided in two groups; group A (sepsis group) and group B (control group).

Results: Among the cases of group A there were 26 (47.3%) female and 29 (52.7%) males, the mean gestational age of group A was 36.84 (±2.7 SD) with range (28-40) weeks, among the studied cases there were 14 (25.4%) with positive consanguinity, there were 10 (18.2%) with UTI, 7 (12.7%) with chorioamnionitis, 19 (34.5%) with fever .According to mode of delivery there were 42 (76.4%) CS and 13 (23.6%) NVD, there were 18 (32.7%) with PROM and 13 (23.6%) with complicated delivery. there was statistically significant difference between the studied groups as regard clinical and laboratory data.

Conclusion: we concluded that there were many risk factors for neonatal sepsis, including gestational age, admission duration, chorioamnionitis, and PROM, with significant differences in clinical and laboratory data, and associated with poor prognosis and increased mortality.

Keywords: Neonatal sepsis, Risk factors, Clinical data, Laboratory data

1. Introduction

Neonatal sepsis may be categorized as early-onset or late-onset. Of newborns with early-onset sepsis, 85% present within 24 hours, 5% present at 24-48 hours, and a smaller percentage present within 48-72 hours. Onset is most rapid in premature neonates. Early-onset sepsis is associated with acquisition of microorganisms from the mother. Transplacental infection or an ascending infection from the cervix may be caused by organisms that colonize the mother's genitourinary (GU) tract; the neonate acquires the microorganisms as it passes through the colonized birth canal at delivery **(1)**. Late-onset sepsis (LOS) is sepsis occurring after 72 hours in NICU infants and 7 days of life in term infants, has been variably defined as occurring up to the age of <90 or 120 days, and may be caused by vertically or horizontally acquired pathogens **(2)**. All neonates suspected of having sepsis should have a blood sample sent for cultures. Blood culture is the gold standard to diagnose sepsis, but it take to much time to have an accurate result **(3)**.

Treatment for a newborn with sepsis may be necessary to combat the illness's severe systemic effects. Until the infant's health stabilizes, cardiopulmonary support and intravenous (IV) nourishment may be necessary during the acute stage of the illness. It is crucial to monitor your vital signs, including your blood pressure, hematocrit, platelet count, and coagulation profile. Transfusion of blood products, such as packed red blood cells (PRBCs), platelets, and fresh frozen plasma (FFP), is frequently necessary **(4)**.

The infant may require transfer to a level III or IV perinatal center, especially if he or she requires cardiopulmonary support, parenteral nutrition, or prolonged IV access. The multidisciplinary services available at larger centers may be necessary if the neonate's condition is acutely compromised **(5)**. Granulocyte transfusion, IV immune globulin (IVIg) infusion, exchange transfusion, plasmapheresis, and the use of recombinant cytokines are among the other treatments being researched for newborn sepsis. However, no significant clinical trials have demonstrated the value of these treatments **(6)**.

This study aimed to study clinical and laboratory data of neonatal sepsis in Beni-Suef University Hospital. Also, to detect the risk factors for neonatal sepsis and prognosis. Moreover, comparing sepsis group with controls.

Patients and methods

This prospective case control study was conducted in Neonatal Intensive Care Unit of Beni-Suef University Hospital from April 2022 to December 2022 after approval by the institutional ethical committee. Patients were followed up for signs of sepsis and were divided in two groups; group A (sepsis group) and group B (control group). We compared copeptin level between the two groups. Study was designed to not influence the treatment of the participating patients. Sample size was of 79 neonate, 55 neonate diagnosed with sepsis and the other 24 healthy neonate as control.

Inclusion criteria: Any neonate admitted at nicu presented with clinical sign of neonatal sepsis, and confirmed by positive blood culture were included in this study.

Exclusion criteria: Patient over age 30 days old, Refusal of the parents to sign the detailed written consent, Patient with hypoxic insult as hypoxic ischemic encephalopathy and Patient with multiple congenital anomalies.

Methods

All patiens were subjected to the following:

Full history taking included maternal risk factors (prolonged rupture of membranes, fever, urinary tract infection, chorioamnionitis, and meconium stained amniotic fluid). Clinical signs of infection included poor feeding, lethargy, respiratory problems (such as tachypnea, apnea, grunting, cyanosis, and retraction),

temperature instability (such as hyperthermia and hypothermia), gastrointestinal problems (as vomiting, abdominal distension, diarrhea, and abnormal gastric residual), and central nervous system symptoms (such as convulsion, hypotonia, and irritability), Complete blood count, C- reactive protein, blood culture and antibiotics susceptibility and other cultures if needed as CSF culture or urine culture.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level. The used tests were Chi-square test and Student t-test.

Results

Table (1): Descriptive data of the studied groups;

	Group A *Sepsis Cases* (n = 55)		**Group B *Control* (n = 24)**	
Gender	No.	%	No.	%
Female	26	47.3	8	33.3
Male	29	52.7	16	66.7
Gestational age				
Range.	28 – 40		36 – 39	
Mean ± SD.	36.84 ± 2.7		37.04 ± 0.8	
Consanguinity	No.	%	No.	%
Negative	41	74.5	20	83.3
Positive	14	25.5	4	16.7
Maternal infection during pregnancy				
UTI	10	18.2	0	0.0
Chorioamnionitis	7	12.7	0	0.0
Fever	19	34.5	0	0.0
Mode of delivery				
CS	42	76.4	20	83.3
NVD	13	23.6	4	16.7
PROM	18	32.7	1	4.2
Complicated delivery	13	23.6	1	4.2

SD: Standard deviation χ^2: Chi square test t: student t-test p: p value for comparing between studied groups *: Statistically significant at $p \leq 0.05$

Among the cases of group A there were26 female and 29 male cases, with a mean gestational age of 36.84 weeks. The cases had positive consanguinity, UTI, chorioamnionitis, fever, and mode of

delivery. In group B, there were 8 females and 16 males, with a mean gestational age of 37.04 weeks. Positive consanguinity was present in 16.7% of cases. (Table 1)

Table (2): Distribution of group A according to birth weight

	Group A *Sepsis group* (n = 55)
Birth weight(Kg)	
Range.	1 – 3.2
Mean ± SD.	2.54 ± 0.47

The mean birth weight of group A was 2.54 (±0.47 SD) kg. (Table 2)

Table (3): Distribution of group A according to Vital signs

	Group A (n = 55)	
Heart rate (beat/min.)		
Range.	90 – 175	
Mean ± SD.	144.78 ± 15.05	
Respiratory rate (rate/min)		
Range.	36 – 66	
Mean ± SD.	49.6 ± 7.82	
Temperature rate (36.3-36.9° Celsius)	No.	%
Normal	48	87.3
Decreased	4	7.3
Increased	3	5.5
Systolic BP(mm Hg)		
Range.	40 – 90	
Mean ± SD.	68.91 ± 12.39	
Diastolic BP(mm Hg)		
Range.	20 – 70	
Mean ± SD.	40.91 ± 11.39	

The mean heart rate of group A was 144.78 (±15.05 SD), the mean respiratory rate was 49.6 (±7.82 SD), among the studied cases there were 48 (87.3%) with normal temperature, 4 (7.3%) with

decreased temperature and 3 (5.5%) with increased temperature, the mean systolic BP was 68.91 (±12.39 SD) and the mean diastolic BP was 40.91 (±11.39 SD). (Table 3)

Table (4): Distribution of group A according to reflexes

	Group A (n = 55)	
Moro reflex	No.	%
Poor	18	32.7
Weak	6	10.9
Fair	17	30.9
Good	14	25.5
Sucking reflex		
Poor	13	23.6
Weak	25	45.5
Fair	11	20.0
Good	6	10.9

In group A according to Moro reflex , there were 18 cases with poor reflexes (32.7%), 6 with weak reflexes (10.9%), 17 with fair reflexes (30.9%), and 14 with good reflexes (25.5%), and according to Sucking reflex, there were 13 with poor reflexes (23.6%), 25 with weak reflexes (45.5%), and 11 with fair reflexes (20%). (Table 4)

Table (5): Distribution of group A according to Systems examination;

	Group A (n = 55)	
Cardiac examination	No.	%
Bradycardia	6	10.9
Tachycardia	8	14.5
Prolonged CRT	29	52.7
Respiratory examination		
Apnea	6	10.9
RD	50	90.9
Abdominal examination		
Poor feeding	28	50.9
Vomiting	27	49.1
Distention	21	38.2
Jaundice	15	27.3
Petechial	18	32.7
Bleeding	24	43.6
Neurological examination		
Irritability	5	9.1
Lethargy	21	38.2
Seizures	5	9.1

A according to cardiac examination there were 6 (10.9%) with bradycardia, 8 (14.5%) with tachycardia and 29 (52.7%) with prolonged capillary refilling time (CRT)and according to respiratory examination there were 6 (10.9%) with apnea and 50 (90.9%) with respiratory distress, according to abdominal examination there were 28 (50.9%) with poor feeding, 27 (49.1%) with vomiting, 21 (38.2%) with distention, 15 (27.3%) with jaundice, 18 (32.7%) with petechial and 24 (43.6%) with bleeding and according to neurological examination there were 5 (9.1%) with irritability, 21 (38.2%) with lethargy and 5 (9.1%) with seizures. (Table 5)

Table (6): Comparison between studied cases according to CBC

	Group A (n = 55)	**Group B (n = 24)**	**Test of Sig.**	**p**
TLC (X10#3 /mm^3)				
Range.	2 – 40	9.9 – 26.8	t= 2.898	0.005*
Mean ± SD.	11.33 ± 7.8	16.26 ± 4.37		
I:T ratio				
Range.	0.02 – 0.81	0.15 – 0.24	t= 2.095	0.039*
Mean ± SD.	0.26 ± 0.17	0.19 ± 0.03		
Hb(g/dl)				
Range.	8.2 – 19.8	11.5 – 18	t= 1.801	0.076
Mean ± SD.	13.48 ± 2.68	14.56 ± 1.81		
PLTs(X 10^3/micoL)				
Range.	16 – 663	120 – 542	t= 3.401	0.001*
Mean ± SD.	180.87 ± 129.03	285.71 ± 118.62		

SD: **Standard deviation t: student t-test** p: p value for comparing between studied groups *: Statistically significant at $p \leq 0.05$

There was statistically significant difference between the studied groups as regard TLC, I:T ratio and PLTs P<0.05. (Table 6)

Table (7): Distribution of group A according to CRP and culture

	Group A (n = 55)
CRP	
Range	8 – 171
Mean value	53.47 ± 37.89

Blood culture	No.	%
Accinetobacter	2	3.6
E.coli	1	1.8
Enterobacter	2	3.6
G. -Ve bacilli	2	3.6
Klebsiella	9	16.4
Pseudomonas	2	3.6
S.aureus	7	12.7
no growth	30	54.5
Septum culture		
Accinetobacter	1	1.8
Candida	1	1.8
E.coli	2	3.6
G. -Ve bacilli	5	9.1
G. +Ve cocci	1	1.8
Klebsiella	10	18.2
MRSA	2	3.6
Pseudomonas	1	1.8
no growth	32	58.2
Urine culture		
Candida	1	1.8
Pseudomonas	2	3.6
no growth	4	7.3

This table shows that the mean CRP of group A was 53.47 (±37.89 SD), among the cases of group A according to blood culture there were 2 (3.6%) with Accinetobacter, 1 (1.8%) with E.coli, 2 (3.6%) with Enterobacter, 2 (3.6%) with gram negative bacilli, 9 (16.4%) with klebsiella, 2 (3.6%) with pseudomonas, 7 (12.7%) with S.aureus and 30 (54.5%) with no growth, according to septum culture there were 1 (1.8%) with Accinetobacter 1 (1.8%) with candida, 2 (3.6%) with E.coli, 5 (9.1%) with gram negative bacilli, 1 (1.8%) with gram positive bacilli, 10 (18.2%) with klebsiella, 2 (3.6%) with MRSA, 1 (1.8%) with pseudomonas and 32 (58.2%) with no growth and according to urine culture there were 1 (1.8%) with candida, 2 (3.6%) with pseudomonas and 4 (7.3%) with no growth.

Table (8): Comparison between studied cases according to follow up

	Group A (n = 55)	
Follow-up	No.	%
Improved	33	60.0

Died	22	40.0

According to follow up, 60% of studied cases improved while 40% died.

Discussion

Our data showed that among the cases of group A there were 26 (47.3%) female and 29 (52.7%) males, among the studied cases there were 14 (25.4%) with positive consanguinity, there were 10 (18.2%) with UTI, 7 (12.7%) with chorioamnionitis, 19 (34.5%) with fever, according to mode of delivery there were 42 (76.4%) CS and 13 (23.6%) NVD, there were 18 (32.7%) with PROM and 13 (23.6%) with complicated delivery. Among the cases of group B there were 8 (33.3%) female and 16 (66.7%) males, among the studied cases there were 4 (16.7%) with consanguinity, according to mode of delivery there were 20 (83.3%) CS and 4 (16.7%) NVD, there were 1 (4.2%) with PROM and 1 (4.2%) with complicated delivery. In the study of **Alemu et al., (7)** More than two thirds (70.7%) of cases and 79.9% controls were delivered by spontaneous vaginal delivery. The proportion of mothers who had history of urinary tract infections (UTI) during the index pregnancy were 19.5% in cases and 2.4% in controls.

In a study of 242 infants with septicemia conducted between March 1996 & June 1997 at Hubli, Karnataka, 43.39% infants had 'very early onset' sepsis (VOS), 40.08%, had 'early onset' sepsis (EOS), and 16.53% 'late onset' sepsis (LOS). Early-onset sepsis is considered up to ≤6 days of life **(8).** Sepsis was found in 514 (4.3%) neonates, and appeared as early-onset in 387 and as late-onset in 127 neonates. Sepsis, defined as the microbial isolation of any biological sample, was found in 87 neonates (16.9%); 9 were from early-onset and 78 from late-onset sepsis **(9).** Currently in the literature, there is no consensus on temporality and type of sepsis; for example, early-onset sepsis can be defined by a period ranging from birth to 48 h or until 6 days of life; this discrepancy affects the interpretation of the rates reported and renders comparison difficult among the different studies. Our findings showed that the mean birth weight of group A was 2.54 (±0.47 SD) with range (1-3.2) kg.,and the mean gestational age of group A was 36.84 (±2.7 SD) with range (28-40) weeks, while the mean gestational age of group B was 37.04 (±0.8 SD) with range (36-39) weeks.

In this thesis, we found the mean heart rate of group A was 144.78 beat/min (±15.05 SD) with range (90-175), the mean respiratory rate was 49.6/min (±7.82 SD) with range (36-66), among the studied cases there were 48 (87.3%) with normal temperature, 4 (7.3%) with decreased temperature and 3 (5.5%) with increased temperature, the mean systolic BP was 68.91mmHg (±12.39 SD) with range (40-90) and the mean diastolic BP was 40.91mmHg (±11.39 SD) with range (20-70). Also, among the cases of group A according to cardiac examination there were 6 (10.9%) with bradycardia, 8 (14.5%) with tachycardia and 29 (52.7%) with prolonged capillary refilling time (CRT) and according to respiratory examination there were 6 (10.9%) with apnea and 50 (90.9%) with respiratory distress, according to abdominal examination there were 28 (50.9%) with poor feeding, 27 (49.1%) with vomiting, 21 (38.2%) with distention, 15 (27.3%) with jaundice, 18 (32.7%) with petechial and 24 (43.6%) with bleeding and according to neurological examination there were 5 (9.1%) with irritability, 21 (38.2%) with lethargy and 5 (9.1%) with seizures. A total of 122 term neonates were included in the study of **Aguilar et al., (10)** as 78 were diagnosed with EOS and 44 were healthy controls. Tachycardia or apnea with bradycardia were the most common clinical signs of the onset of EOS in neonates in the EOS

group. This group had significantly higher neutrophil counts, axillary temperatures, neutrophil – lymphocyte ratio (NLRs), platelet to lymphocyte ratio PLRs and C-reactive proteins levels compared with the control group. Our data showed that among the cases of group A according to moro reflex there were 18 (32.7%) with poor reflexes, 6 (10.9%) with weak reflexes, 17 (30.9%) with fair reflexes and 14 (25.5%) with good reflexes and according to sucking reflex there were 13 (23.6%) with poor reflexes, 25 (45.5%) with weak reflexes, 11 (20%) with fair reflexes and 6 (10.9%) with good reflexes. **Rass et al., (11)** found the most common clinical finding among the infected group was weak suckling (92.3%), weak Moro reflex (77%), respiratory distress (69.2%), lethargy (69.2%), and feeding intolerance (65.9%)**.**

RAHA BK et al., (12) reported that, the most frequent clinical presentations of patients with culture-proven sepsis were poor moro reflex (92.2%)**.** We found that there was statistically significant difference between the studied groups as regard TLC, I:T ratio and PLTs. Our stud showed that the mean CRP of group A was 53.47 (±37.89 SD) with range (8-171). This finding was in agreement with **Younis et al., (13)** who found that the mean CRP level was significantly higher in patients with sepsis than controls. Also they reported that CRP has high sensitivity and specificity for establishing the diagnosis of neonatal sepsis which is comparable to that of blood culture results. Serial CRP estimation may also of great value in monitoring the degree of response to treatment in clinically infected neonates and thus may guide the clinicians to estimate duration of antibiotic therapy correctly**.** Similar to **Salim et al., (14)** who reported that neutrophil left shift (I/T ratio≥ 0.2) showed a significant correlation with early clinical signs of sepsis (P < .001), and higher incidence of LOS (P = .001). CRP level was elevated only in 30% of controls, and 76.7% of cases with a statistically significant difference (P = 0.01), there was statistically significant difference between the studied groups as regard TLC, I:T ratio and PLTs **Salim et al., (14).** In this thesis, among the cases of group A according to blood culture there were 2 (3.6%) with Accinetobacter, 1 (1.8%) with E.coli, 2 (3.6%) with Enterobacter, 2 (3.6%) with gram negative bacilli, 9 (16.4%) with klebsiella, 2 (3.6%) with pseudomonas, 7 (12.7%) with S.aureus and 30 (54.5%) with no growth, according to septum culture there were 1 (1.8%) with Accinetobacter 1 (1.8%) with candida, 2 (3.6%) with E.coli, 5 (9.1%) with gram negative bacilli, 1 (1.8%) with gram positive bacilli, 10 (18.2%) with klebsiella, 2 (3.6%) with MRSA, 1 (1.8%) with pseudomonas and 32 (58.2%) with no growth and according to urine culture there were 1 (1.8%) with candida, 2 (3.6%) with pseudomonas and 4 (7.3%) with no growth. In another study the microbiological profile was as follows: Gram-positive bacteria [mainly Coagulase-Negative Staphylococcus Group (CoNS)] were identified in 59 (67.8%) patients; Gram-negative bacteria (mainly Klebsiella spp.) were isolated in 15 (17.2%), and Candida spp. was found in 13 (14.9%) patients **(15).** Gram-negative bacilli, particularly species of Klebsiella and Escherichia coli, were responsible for 61% of infections, whereas Gram-positive isolates (especially staphylococci) and Candida strains accounted for 37 and 2%, respectively **(16).** The Gram positive and Gram negative bacteria accounted for 6 (9.4%) and 58 (90.6%) of the isolates respectively. Around two third of the culture-proven septic neonates (70.3%) presented with early onset sepsis, while 29.7% presented with late onset sepsis. Klebsiella pneumoniae was the most common pathogen both in early onset (31.25%) and late onset (6.25%) sepsis. Serratia (18.75%) was the second most common pathogen in early onset sepsis. Total mortality rate was 9.38% **(12).**

Conclusion

we concluded that there were many risk factors for neonatal sepsis, including gestational age, admission duration, chorioamnionitis, and PROM, with significant differences in clinical and laboratory data, and associated with poor prognosis and increased mortality.

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