

## Procalcitonin, C. Reactive Protein And Complete Blood Count As Diagnostic Markers For Neonatal Sepsis- Original Research

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### Abstract

**Background:** Sepsis remains the leading cause of neonatal mortality. While blood culture has long been considered the gold standard for diagnosis, the lengthy assay time of at least 24-48 hours necessitates the need for more reliable, rapid, sensitive, and specific biomarkers to enable early detection of neonatal sepsis.

**Aim:** this case-control study was conducted to evaluate three potential diagnostic markers for neonatal sepsis: serum procalcitonin, C-reactive protein, and complete blood count.

**Methodology:** A total of 100 neonates were included in the study A 50 neonates with proven sepsis confirmed by culture and gram stain serving as cases and 50 healthy neonates serving as controls. Blood samples were collected from all participants after ethical consent was obtained. Procalcitonin, C-reactive protein, and complete blood count were measured using the Finecare TM FIA (fluorescence immunoassay) System and Mindary 3000 hematology analyzer, respectively, and the results were compared to blood culture results. Data were analyzed using SPSS version 21.

**Results:** The study findings revealed that procalcitonin was significantly elevated in cases compared to controls, with a p-value of 0.000. Procalcitonin demonstrated a sensitivity of 100%, specificity of 100%, positive predictive value of 100%, negative predictive value of 100%, and accuracy of 100%, making it an accurate and excellent biomarker, area under the curve (AUC: 1.0). In contrast, while C-reactive protein was also significantly elevated in cases compared to controls, with a p-value of 0.000, it demonstrated a sensitivity of 84.44%, specificity of 75.18%, positive predictive value of 45.05%, negative predictive value of 95.95%, and accuracy of 79.28%, making it an accurate but inferior biomarker (AUC: 0.909).

Of note, all complete blood count parameter parameters were found to be inaccurate for early diagnosis of neonatal sepsis, except for RDW-cv, which demonstrated good accuracy (AUC: 0.7), and platelet count, which demonstrated excellent and highly accurate results (AUC: 0.948). The most common isolated organism in cases was *E.coli*, accounting for 27% of total cases.

**Conclusion:** Based on the study results, procalcitonin emerges as the fastest, most sensitive, and most specific biomarker for early diagnosis of neonatal sepsis.

**Recommendation:** Its superior performance compared to C-reactive protein and CBC parameters underscores the need to incorporate procalcitonin into routine neonatal sepsis diagnostic algorithms.

**Keywords:** C-reactive Protein, Complete Blood Count, Neonatal Sepsis, Procalcitonin.

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## **I. Introduction:**

Sepsis is a serious and potentially life-threatening condition that arises from a dysregulated response to infection, leading to organ dysfunction(1). This condition poses a significant global burden in terms of morbidity and mortality, especially among neonates, who account for 30-50% of total neonatal deaths in developing countries (2)- Despite advances in medical technology and diagnostic capabilities, sepsis remains a challenging condition to manage due to its nonspecific signs and symptoms, potential for false positive blood culture results, and concerns regarding antibiotic resistance (3)- Early detection and prompt management are crucial in reducing the number of children started on antibiotics, shortening hospital stays, and lessening treatment costs (3). Various diagnostic tests are available for neonatal sepsis, including blood culture tests, which are considered the gold standard. However, it has several limitations, including a lengthy turnaround time, potential for false positives due to contamination, and negative results in one in five subjects (4). Other commonly used diagnostic tools include total leukocyte count, absolute neutrophil count, immature neutrophil to total neutrophil ratio, and platelet count. While these tests have shown some association with neonatal sepsis, their diagnostic capabilities can be limited by other infections and conditions, making them less reliable (5)(6). On the other hand, biomarkers such as C-reactive protein and procalcitonin have shown promise in providing fast and reliable scoring systems for neonatal sepsis in its earliest stages (7). C-reactive protein is an acute-phase protein that serves as an early marker of inflammation or infection, while procalcitonin, produced by monocytes and hepatocytes, is specific to bacterial infections (8). Procalcitonin, in particular, has a wide diagnostic window and correlates with bacterial and fungal infections, making it a promising diagnostic tool for neonatal sepsis (9)(10).

However, while there is limited information about hematological parameters as a diagnostic tool for neonatal sepsis, particularly in developing countries, biomarkers such as procalcitonin hold the potential to improve neonatal outcomes by enabling early detection and prompt management. Therefore, further research is warranted to evaluate and compare diagnostic tools and biomarkers for neonatal sepsis and determine the most sensitive and specific approach for early detection and management. By doing so, we can improve the standard of neonatal care, reduce the use of antibiotics, and prevent the development of antibiotic resistance, ultimately leading to better neonatal outcomes worldwide.

## **II. Methodology:**

After ethical approval by the research committee at faculty of medical laboratory sciences- university of El Imam El mahdi. Analytical case control design was selected to test the research hypothesis. The study conducted at Ed-dueim Teaching Hospital located in the White Nile state of Sudan from January 2023 to October 2023. The hospital serves a population of approximately 400,000 individuals from Ed-dueim town and nearby villages, and the pediatric division comprises 45 beds, including 6 incubators. The division is composed of six units with each unit consisting of a consultant, specialist, residents, general practitioners, and five medical school graduated doctors (known as house officers).

The study included all neonate patients (male and female) delivered within the hospital with sepsis (confirmed by culture and gram stain) as cases, and clinically healthy neonates as controls. Neonates with severe trauma, surgery, burn, renal disease, autoimmune disease, incomplete records, and those whose parents refused were excluded. A convenient non-probability sampling method was employed, including fifty neonates with sepsis (confirmed by culture and gram stain) as cases and fifty healthy neonates as controls. The sample size was calculated using the OpenEpi sample size calculator, yielding a minimum required sample size of 40 based on a 5% variation, 95% confidence interval design effect equals 2, and an expected frequency (response distribution) of 50%.

The questionnaire used in the study was composed of dependent variables, including symptoms, signs, procalcitonin, C-reactive protein, complete blood count, and blood culture, and independent variables, including age (days) and gender. Prior to participation, the guardians of each participant were informed about the importance and objectives of the research, voluntary participation, and the right to withdraw at any time. They were also informed that the remaining sample would not be used for other purposes and would be disposed of by incineration immediately after the research was completed. To ensure confidentiality, all data was collected and analyzed solely by the researchers, and no identifying information was collected to ensure anonymity. Each participant's guardians signed a written ethical consent form during the interview before the specimen was taken.

Data was collected by a team of medical doctors using a hard semi-structured questionnaire from records and patients taking care of them (appendix 3), translated into the local language, and filled out by the researchers. This study's rigorous methodology and ethical considerations ensure the reliability and validity of the findings, which can be used to inform clinical practice and improve neonatal healthcare outcomes.

A 5 mL of venous blood samples collected aseptically. A 2.5 ml dispensed into a brain heart infusion for the blood culture test. The rest of 2.5 mL of the blood dispensed into Ethylene Diamine Tetra Acetic acid

(EDTA) anticoagulant, which is used immediately for CBC using Mindary BS3000 and then separated by centrifugation at 3000 RPM for five minutes, plasma was used for assaying procalcitonin, C-reactive protein levels using Finecare TM FIA System. All quality control measures were adopted. Data analyzed using IBM SPSS, version 21, Numerical data expressed as mean and standard deviation, qualitative data expressed as frequency and percentage. Chi-square test was used to examine the relation between variables. P-value < 0.05 was considered significant for all tests. The Receiver operating characteristics (ROC) graph and ROC AUC (Area under the curve) analysis is used to detect the accuracy and efficiency of parameters. ROC AUC has a value and each value gives information about test quality. A 0.9 – 1.0 means that the test is excellent, 0.8 – 0.9 very good, 0.7 – 0.8 good, 0.6 – 0.7 satisfactory and 0.5 – 0.6 to unsatisfactory. The best classification has a largest area under the curve. It calculated using SPSS ROC test. Sensitivity and specificity calculated by medical calculator.

### III. Results

This study aimed to investigate the diagnostic value of various biomarkers, including procalcitonin (PCT) and C-reactive protein (CRP), in neonatal sepsis. A case-control analytic study was conducted, including 50 neonates diagnosed with sepsis and 50 neonates as a control group. The majority of the neonates were term (83%), and 52% of them were two days old, with a predominance of male neonates (53%).

The study found that PCT and CRP had a statistically significant increase in cases compared to the control group, with a p value of 0.000 (Table 1). The area under the curve (AUC) for PCT against the gold standard (blood culture) was an excellent and highly accurate biomarker for sepsis, with an AUC of 1.0 (Table 2 and Figure 1). Similarly, the ROC curve of CRP showed that it has a large AUC, indicating its excellent diagnostic value as a biomarker.

The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of PCT were all 100%, while the sensitivity of CRP was 84.44%, specificity was 75.18%, PPV was 45.05%, NPV was 95.95%, and accuracy was 79.28% (Table 3). These findings highlight the high diagnostic accuracy of PCT and CRP in neonatal sepsis.

Regarding other biomarkers, lymphocyte, granulocyte, hemoglobin (Hb), red blood cells (RBCs), and mean platelet volume (MPV) were normal and statistically significant. In contrast, red cell distribution width coefficient of variation (RDW-cv) was significantly increased, and platelets were significantly decreased in cases compared to the control group, with a p value less than 0.05 (Table 4). The AUC for total white blood cells (TWBCs), differential count, Hb, RBCs, and indices against the gold standard (blood culture) was good only for RDW-cv, with an AUC of 0.78, and unsatisfactory for the others (AUC less than 0.5), as shown in Table 4. The AUC for platelets and platelet indices against the gold standard (blood culture) was excellent for PLT (AUC 0.948), satisfactory for plateletcrit (0.64), and unsatisfactory for MPV and platelet distribution width (PDW) (AUC less than 0.5) (Table 4).

Furthermore, the study found that gram-negative bacilli were the major isolated organisms among cases, with *E. coli* being the most common (27%), followed by group B streptococci (GBS) (4%), *Staphylococcus aureus* (3%), *Pseudomonas* (2%), and *Klebsiella pneumoniae* (2%) (Table 5).

**Table 1:** Mean and standard deviation for procalcitonin and CRP

Tests	Cases	Control	p.value	Normal range
	Mean $\pm$ SD	Mean $\pm$ SD		
Procalcitonin (ng/ml)	7.2 $\pm$ 9.7	0.3 $\pm$ 0.12	0.000*	0 – 0.5 ng/ml
CRP (mg/l)	208 $\pm$ 87.6	7.4 $\pm$ 3.3	0.000*	Up to 10mg/l

CRP: C-reactive protein

**Table 2:** Area Under the Curve for procalcitonin against the gold standard (blood culture)

*Area (AUC)	Std. Error <sup>a</sup>	Asymptotic Sig. <sup>b</sup>
1.000	.000	.000

AUC: area under the curve

**Table 3:** Sensitivity, specificity and accuracy of procalcitonin and C-reactive protein

Statistic	procalcitonin	C-reactive protein
Sensitivity	100.00%	84.44%
Specificity	100.00%	78.18%
Disease prevalence	17.50%	17.50%
Positive Predictive Value	100.00%	45.08%
Negative Predictive Value	100.00%	95.95%
Accuracy	100.00%	79.28%

**Table 4:** Mean and standard deviation for complete blood count

Complete Blood count parameters	Cases	Control	p.value	Normal range	Area (AUC)	Std. Error <sup>a</sup>	Asymptotic Sig. <sup>b</sup>
	Mean ± SD	Mean ± SD					
<b>TWBCs</b>	11.6 ± 6.6	9.9 ± 3.0	0.121	4 – 11	0.497	.064	.966
<b>Lymph</b>	38.0 ± 16	28.4 ± 17.6	0.007*	20 – 55	0.648	.055	.013
<b>Mid</b>	9.8 ± 8.0	9.9 ± 3.9	0.929	3.0 – 15.0	0.359	.058	.018
<b>Gran</b>	52.0 ± 17.4	61.5 ± 17.8	0.009*	50 – 70	0.403	.057	.105
<b>Hb</b>	14.9 ± 3.2	16.9 ± 2.0	0.011*	11 – 16	0.350	.062	.012
<b>RBCs</b>	4.38 ± 0.85	4.7 ± 0.68	0.029*	3.50 – 5.50	0.399	.063	.092
<b>HCT</b>	44.0 ± 9.6	46.1 ± 5.4	0.174	35.0 – 54.0	0.411	.062	.138
<b>MCV</b>	99.7 ± 10.7	96.8 ± 9.0	0.154	80 – 100	0.577	.061	.195
<b>MCH</b>	33.9 ± 3.8	34.4 ± 3.1	0.458	27.0 – 34.0	0.412	.061	.141
<b>MCHC</b>	34.0 ± 2.7	35.0 ± 2.0	0.052	32.0 – 36.0	0.387	.060	.058
<b>RDW-cv</b>	16.4 ± 1.5	15.6 ± 1.2	0.003*	11.0 – 16.0	0.721	.062	.000
<b>RDW-sd</b>	59.5 ± 9.3	60.1 ± 7.1	0.713	35.0 – 56.0	0.514	.064	.820
<b>Platelet</b>	124.5 ± 11.4	269.4 ± 9.2	0.000*	150 - 450	0.948	.028	.000
<b>MPV</b>	10.5 ± 3.1	8.0 ± 1.02	0.001*	6.5 – 12.0	0.180	.043	.000
<b>PDW</b>	17.0 ± 2.1	14.6 ± 2.12	0.44	9.0 – 18.0	0.157	.043	.000
<b>PCT</b>	0.31 ± 0.3	0.34 ± 0.44	0.692	0.150 – 0.350	0.647	.066	.014

WBCs: White blood cell, Lymph: lymphocyte, Mid: eosinophil: Gran: granulocyte

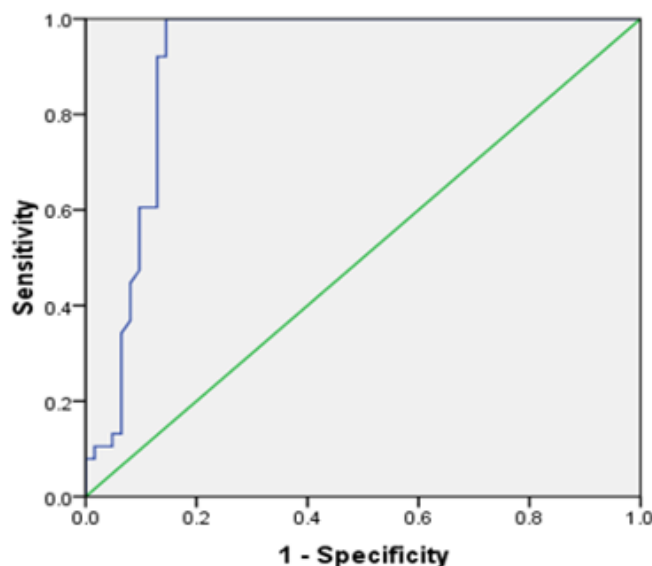
RBCs: Red blood cells, Hb: Hemoglobin, HCT: haematocrit, MCV: mean cell volume, MCH: Mean cell hemoglobin, MCHC: mean cell hemoglobin concentration, RDW-Cv: red cell distribution width – coefficient of variation, RDW –sd: Red cell distribution width – standard deviation. MPV: mean platelet volume, PDW: platelet distribution width, PCT; Plateletcrit.

**Table 5:** Frequency of blood culture in study population

Blood culture		Case control		Total
		Case	control	
Gram positive cocci		9	0	9
		18.0%	.0%	9.0%
Gram negative bacilli		29	0	29
		58.0%	.0%	29.0%
No growth		12	50	62
		24.0%	100.0%	62.0%
Total		50	50	100
		100.0%	100.0%	100.0%

**Figure 1:** Area Under the Curve for CRP against the gold standard (blood culture)

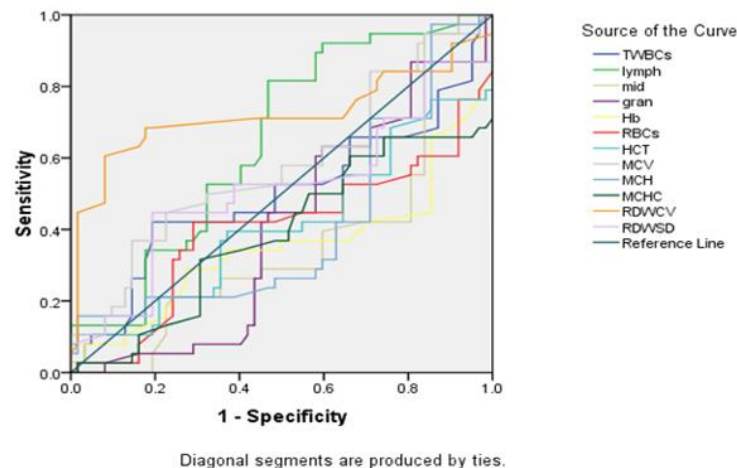
#### ROC Curve



Diagonal segments are produced by ties.

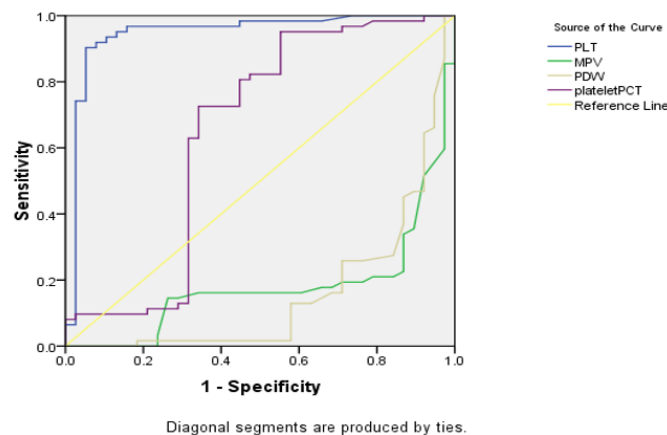
ROC: Receiver Operating Characteristic curve  
CRP: C. reactive protein

**Figure 2:** Roc curve of WBCs, differential, Hb, RBCs and indices  
**ROC Curve**



**ROC: Receiver Operating Characteristic curve**

**Figure 3:** Roc curve of platelet and platelet indices  
**ROC Curve**



**ROC: Receiver Operating Characteristic curve**

#### IV. Discussion

Neonatal sepsis is one of the most common causes of neonatal morbidity and mortality especially in developing countries.

Early diagnosis of neonatal sepsis and intervention are essential to avoid serious complications. This study aimed to evaluate serum procalcitonin, C.reactive protein and complete blood count as diagnostic marker for neonatal sepsis. The study show that out of the total population (100), the cases (50 neonates) classified as: 16 neonate admitted at the first day of life while 34 neonate admitted at the second day, so all these cases are refer to have an EOS. The control, 32 neonates at day one while 18 neonates at day two. A 27 (27%) of cases were female, while 23 (23%) were male. In control 30 (30%) were male and 20 (20%) were female.

In the present study serum procalcitonin (PCT) level was significantly increase in case, when compared to control group (p.value 0.000), PCT increase because macrophages and monocyte derived cells of liver increase procalcitonin secretion during the process of sepsis.(6) PCT is not detectable in healthy individual since protein not released into the blood in absence of inflammation(7). This study agree with a study conducted by Mino Adib, et al, 2012 which found that procalcitonin in suspected sepsis was higher than control group (8). another study conducted by Nyamnyi Konyak et al 2021 reported that procalcitonin level in culture positive was elevated as compared to their negative counterparts. P.value (0.001) (11) . A study done by Arowosegebe AO, et al, 2016 reported that Two of the 12 neonates in the control group had procalcitonin higher than 0.5 ng/ml which disagree to present study (4). This may be due to physiological increase of procalcitonin or a condition rather than bacteria, many author reported that PCT slightly increase with viral infection, trauma and burn. Procalcitonin evaluation in this study demonstrated sensitivity of 100 %, specificity

of 100 %, PPV of 100.625% ,NPV of 100 % and accuracy 100% , these finding support by another study conducted by Claudio Chiesa, et al, which studied the reliability of the PCT, they observed that the sensitivity of 92.6% , specificity of 97.5% , PPV of 94.3% and NPV of 96.5% .(9) Another study also support the present study finding conducted by Yildiz, et al who studied 97 term neonates admitted to hospital with the diagnosis of suspected sepsis. They found the specificity of 94.3%, sensitivity of 92.1%, PPV of 94% and NPV 92% .(10) Omar A.K, et al. 2018 reported that PCT sensitivity in the early diagnosis of neonatal sepsis was found to be 83-100% while the specificity was 70-100%. This study disagree to study done by Adediwura Arowosegbe, et al.,2016 who found that sensitivity of 75.7% , specificity of 45.7% , PPV of 50 % and NPV of 69 %.(4) ROC AUC of procalcitonin is an excellent biomarker (1.0 - p.value 0.000) when compared to gold standard blood culture, this result supported by another study conducted by Omar A. K. Al-azaawi et al 2018 who calculate ROC AUC for procalcitonin and reported that PCT showed an excellent biomarker AUC (91.7%,  $p < 0.001$ ). (1) A Nigerian study conducted by Adediwura Arowosegbe et al 2016 calculated ROC AUC of procalcitonin and found that ROC AUC was satisfactory (AUC: 0.686) which disagree to this study. (4) This variations is due elevation of PCT in two of 12 control which affect their sensitivity and specificity.

This study show that C.reactive protein (CRP) was significantly increase in cases when compared to control group, p.value 0.000, the elevation because CRP rise much more significantly during acute inflammation than the other acute phase reactants.(9) This result agree with another study done by Mohamed Abdul Fattah et al 2019 reported that CRP was higher in suspected sepsis groups when compared to control group (P.value 0.002).(12)

Out of cases (50 neonates suspected to have sepsis), 38 of them are positive and have elevation in CRP, 12 are negative blood culture and they also have elevation in CRP, in control group there were 7 neonates have negative blood culture and elevation of CRP. it may be due to other conditions like, maternal fever during labour, prolonged rupture in membrane, respiratory distress syndrome, fatal hypoxia and stressful delivery or fatal distress.

In this study CRP evaluation demonstrated sensitivity of 84.44%, specificity of 75.18 % , PPV of 45.05% ,NPV of 95.95 % and accuracy 79.28%, these findings agree to a study published by Mohamed Abdul Fattah, et al., 2019 reported that CRP sensitivity ranged between 70% to 93% and specificity ranged between 41% to 98% (12), but these study also disagree to study conducted by omer, et al., 2017 reported that. validity of CRP (sensitivity, specificity, positive predictive value, and negative predictive value) in NS (EONS & LONS) remained 35.52%, 58.0%, 85.0%, and 11.83%, respectively (13). Diversity in different results concluded from multiple studies suggest that some physiological changes observed in the first few days of life and the effect of prenatal and postnatal antibiotic administration will affect the CRP level. The ROC AUC for CRP in study was excellent (0.909) which indicate high accuracy of CRP as biomarker, this result confirm with a study conducted by Mohamed Abdul Fattah et al 2019 who calculate ROC AUC and reported it was excellent (0.979) (12).

Complete blood count (CBC) was the first test used to diagnose neonatal sepsis, hematological indices still being the most extensively used in practice, currently in association with new markers for infection. The recent result show TWBCs count was increase in cases , it have statistically insignificant when compared to control group , p.value 0.121.leukocytosis can be a reaction to various infectious, inflammatory and physiological process, the body produce more infection fighting cells.(14) This finding agree to Mohamed Abdul Fattah, et al., 2019 found that the mean of TLC in suspected sepsis was statistically insignificant (p.value 0.88), Lymphocyte and neutrophil were not affected (normal) in cases, they have statistically significant, (P.value less than 0.05) when compared to control group.

Monocyte, eosinophil and basophil were counted together as mid according to instrument used to do CBC (Mindary), they were normal (not affected) in cases and statistically insignificant, p.value 0.929 when compared to control group.

The ROC AUC were calculated to WBCs and differential, unsatisfactory (0.4) for TLC, satisfactory (0.64) for lymphocyte, unsatisfactory (0.35) for Mid and unsatisfactory (0.4) for neutrophil, TWBCs supported by Christoph P. Hornik, et al., 2012 who calculated ROC AUC for TLC and reported that it was 0.66. Hb, RBCs were not affected in cases and statistically significant when compared to control group p.value less than (0.05). RDW-cv was statistically significant increase in cases when compared to control group (p.value 0.003). Melak Aynalem et al 2022 found that hemoglobin (Hgb) was not affected and statistically significant p.value less than 0.5 which agree to our finding. Ilham, et al.,2021 reported that an average RDW was higher in 103 (92.7%) of suspected sepsis. Martin et al showed that the mean of the normal range of RDW-cv was significantly increase p-value  $< 0.001$ .which agree to our finding.(15) HCT,MCV,MCH,MCHC and RDW-sd were not statistically significant when compared to control group. P.value (more than 0.05).

ROC AUC was calculated for Hb, RBCs, HCT,MCV,MCH,MCHC,RDW-cv and RDW-sd it is good only for RDW-cv (AUC 0.78) and un satisfactory for the others (AUC less than 0.5). In conducted study platelet was significantly decrease in case when compared to control group, p.value 0.000. Low platelet count because it

bound to endothelium, resulting in sequestration and destruction.(16) This result agree with study conducted by Venkata Sri Laxmi, et al., 2022 who found that PLT was significantly decrease , p.value 0.002.

MPV was not affected in cases, it was statistically significant when compared to control group p.value 0.003, this finding agree also to Venkata, et al, conducted that it was normal in cases and statistically significant when compared to control group p.value 0.04 . PDW was not affected and statistically insignificant p. value 0.44, this finding disagree to Ventaka, et al., which found that it was significant p.value 0.003.(16) ROC AUC was calculated for PLT and PLT indices, for PLT it was excellent (AUC 0.948 ), satisfactory for Plateletcrit (0.64) and unsatisfactory for MPV and PDW (AUC less than 0.5). these finding agree to a study conducted by Santosh Kumar et al 2022, Samira Z. Sayed, et al., 2020, they calculate ROC AUC for PLT and it was very good (AUC 0.80 ),(AUC 0.83) respectively. In the observed study, out of 50 case 38 (76%) were positive blood culture(17)(18). 9 (18%) were gram positive cocci, 29 (58%) were gram negative bacilli, and 12 (24%) no growth. According to published literature gram positive and gram negative results varying in their frequencies, the present study finding agree to Shah, et al. 2012 which reported that the percentage of gram negative isolates from sepsis cases were 92.8% organisms were gram negative bacilli and disagree to Marchant, et al.,2013 who found that gram-positive organisms accounted for the majority of neonatal sepsis cases (up to 70%) while sepsis due to gram negative organisms accounted for (15 to 20%)(19)(20). the variations in frequencies, may be due to variation in mode of transmission and environmental factors also maternal health factors. In the current study the most common isolated organism in cases was E.coli (27%) then group B streptococci (GBS) (4%) then staph aureus (3%), then pseudomonas (2%) and k.pneumoniae (2%), these findings supported by A Nigerian study conducted by Kirsty sands, et al., 2023 who reported that A study including Middle East countries listed E. coli in the top three bacterial causes for EOS for both the HICs and middle-income countries with aggregated data into the study(21). Another report agree this finding published that, The aetiology of EOS reported in a 2019 systematic review with K. pneumoniae, S. aureus and E.coli most dominant, followed by CoNS.(18) Which may also supported the finding of the current study that E.coli is one of the most dominant cause of EOS, and this finding may be due to contamination or from mother genital tract to newborn during childbirth.(19)

The present study also found that Group B streptococci (GBS) is the most common gram positive bacteria , and this finding supported by another study done by Velaphi, et al (South Africa), in 2019 published data to the contrary revealing GBS to be the most frequently reported cause of EOS.(20)

Our study is the first of its kind in Sudan and the region, providing valuable insights into the diagnosis and management of neonatal sepsis. The study aimed to evaluate the diagnostic accuracy of serum procalcitonin, C. Reactive protein, and complete blood count in comparison to blood culture. The study was conducted in an important endemic area with a scarcity of data, and the results are applicable to similar centers with low facilities. The matching group nature of the study design provided more reliable results than other types of observational studies. Nonetheless, the study has several limitations that could affect the generalizability of the findings.

The small sample size and the mismatching between cases and control groups, which could be attributed to the short duration of the study, are among the limitations. Another limitation is the retrospective nature of the study design, which could lead to recall bias. Additionally, the study failed to detect the causative pathway of the bacteria that caused the sepsis, whether it was hospital-acquired or from the mother.

## **V. Conclusion:**

The study found that procalcitonin is the fastest, most sensitive and specific diagnostic marker for neonatal sepsis. While C-reactive protein is sensitive, it is less specific than procalcitonin in early diagnosis of neonatal sepsis. All complete blood count parameters are inaccurate for early diagnosis of neonatal sepsis except for RDW-cv, which has good accuracy.

The study recommends more studies with larger sample sizes, testing the source of the infection, and containing follow-up on its nature. A further effort should be made to raise awareness among obstetricians and pediatricians about neonatal sepsis and its seriousness through presentations, workshops, and conferences to encourage earlier detection of neonatal sepsis, strong treatment guidelines, and strict follow-up.

## **Declarations:**

### **Ethical approval and Consent to participate:**

Before commencing the study, ethical clearance was obtained from the Research and Ethics Committee, ( No E.T.H.2.4), ON 10/1/2023 Ministry of Health, White Nile state, Sudan. We confirm that all methods were carried out according to relevant research ethics guidelines and regulations. Before filling out the questionnaire, all the neonates Guardians provided informed consent. Participants were assured of the confidentiality of any obtained information. The responses were kept confidential and data from this research was managed only by research team.

**Availability of data and materials:**

The data set used and/or analyzed during the study are available from the corresponding author on reasonable request

**Conflict of interest:**

The authors declared no competing interest.

**Funding:**

The study was self-funded

**Author contribution:**

M.O.A: Conceptualization, Data Curation, Methodology, Investigation, Writing initial draft.

A.I.E, Supervision, Data curation, Data analysis, Methodology, Validation, Writing initial draft, Revision of Final Draft.

A.I.I,H.H.E: Data curation, Methodology, Validation, Writing initial draft, Revision of Final Draft.

A.I.M: Data curation, methodology, revision final draft

M.M.F: Methodology, Validation, Writing initial draft, Revision of Final Draft.

A.A.M: Methodology, Validation

W.M.S: Revision of Final Draft

A.E.M: Methodology, Validation, Revision of Final Draft

K.H: Methodology, Validation, Revision of Final Draft

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