## RESEARCH ARTICLE

## TO STUDY HEMATOLOGICAL PROFILE IN COVID-19 PATIENTS IN RELATION WITH PROGNOSIS AND   OUTCOME:- A CROSS SECTIONAL OBSERVATIONAL STUDY

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*Manuscript Info*

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*Abstract*

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**Background:** SARS-CoV-2 infection are quite diverse, ranging from asymptomatic disease to pneumonia and potentially fatal consequences. The use of routine blood investigation parameters as a marker of disease severity will results in improved clinical awareness to identify the target patients at higher risk. This study aimed to evaluate haematological profile in COVID-19 patients in relation with outcome test in Covid 19 positive patients.

**Objective:** To study hematological profile in COVID-19 patients in relation with prognosis and  outcome.

**Material & Methods:** The present hospital based cross sectional observational study carried among total sample size of 384 patients aged 12 years and above who have SARS-CoV-2 infection confirmed by reverse transcriptase–polymerase- chain-reaction assay and/or Rapid Antigen test and admitted in medicine ward at tertiary care centre during Jan 2021 to Dec 2022. The study was conducted after obtaining clearance from the Ethical Committee of the institute. Patients with haematological malignancies and hemoglobinopathies like thalassemia and sickle cell disease were excluded. Data of each patient was collected in special proforma which includes clinical manifestations and laboratory values.

**Results:** The mean age of the study population was $42.50 \pm 10.94$ years with male predominance. (63.28%). Among 384 patients, 102 (26.56%) patients were having anaemia. Low MCV in 48.17%, while N/L ratio was >3.53 in 165 (42.96%) patients. It has been seen that there was statistically significant relation between the mean values of Surviours and non-surviours with respect to RDW, TLC, NLR and Platelets.

**Conclusion:** The present study concludes that laboratory parameters like  RDW,MPV, Platelet count, Total leucocyte count ,Neutrophils count ,Lymphocytes count, N/L ratio can be considered as early prognostic markers of COVID 19  disease.

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## Introduction:-

Coronavirusesformalargefamilyof RNA viruses.Thesurfaceof theviralparticlesis covered with many spikes and the viral particles as a whole resemble a corona, which isthe origin of the name "corona virus". Six sub types were found; of these, four are lesspathogenic and generally cause mild symptoms after infection; two sub types can causesevereinfections.Thenewcoronavirusisanewtypeofcoronavirus which asnotpreviously been found in humans. It is now considered a seventh sub type, but its geneshave more than 85% homology with a SARS-like virus in bats.[4]

An outbreak of 2019 coronavirus disease (COVID-19) infection began in December 2019 in Wuhan, the capital of China's central Hubei province.[2,4] The World Health Organization has declared a worldwide health emergency on January 30, 2020.[5]

The signs and symptoms of SARS-CoV-2 infection are quite diverse, ranging from asymptomatic disease to pneumonia and potentially fatal consequences like acute respiratory distress syndrome, multisystem organ failure, and death.[6-8] Serious problems are more likely to occur in older people and those who already have respiratory or cardiovascular conditions.[9,10] Early symptoms of the virus infection show common cold symptoms such as fever and swelling of the throat and can develop various conditions, including respiratory, enteric, neurological, and hepatic diseases including acute respiratory distress syndrome (ARDS), acute cardiac injury, or secondary infection.[6] In patients' group with underlying medical conditions and elderly patients, the severe respiratory disease may develop causing death.[6] COVID-19 lacks specificity in both clinical manifestations and laboratory tests. The main clinical manifestations of the disease are fever, fatigue and dry cough and, in severe cases, multi-organ failure. [6,7] Your atypical symptoms can include myalgia and diarrhea. Laboratory tests have shown that the total number of white blood cells in the initial peripheral blood is normal or decreased and the lymphocyte count progressively decreased; C-reactive protein and serum sedimentation rates increased in most patients. [8-10]

The use of routine blood investigation parameters as a marker of disease severity will results in improved clinical awareness to identify the target patients at higher risk. Early diagnosis is vital when considering the short time of onset of acute respiratory distress syndrome after admission to hospital and the high mortality rates in the COVID-19 patients.[11]

A series of recently published articles have reported the epidemiological and clinical characteristics of patients with COVID-19 disease, but data regarding the laboratory characteristics of infected individuals are limited. [12,13] This study aimed to evaluate haematological profile in COVID-19 patients in relation with outcome test in Covid 19 positive patients.

## Objectives:-
1. To study the hematological parameters in covid 19 patients.
2. To study the relation between hematological profile and outcome of disease in patients affected with COVID-19.

## Materials And Methodology:-

The present hospital based cross sectional observational study carried among patients who have SARS-CoV-2 infection confirmed by reverse transcriptase–polymerase- chain-reaction assay and/or Rapid Antigen test and admitted in medicine ward at tertiary care centre during Jan 2021 to Dec 2022. The study was conducted after obtaining clearance from the Ethical Committee of the institute. A total sample size of 384 patients aged 12 years and above admitted were selected. The patients fulfilling the inclusion criteria were included in study.

**Inclusion Criteria:**
All the patients who have age >12 years and SARS-CoV-2 infectionconfirmed by reverse-transcriptase–polymerase-chain-reaction assayand/or Rapid Antigen test.

**Exclusion Criteria:**
1. Patients with haematological malignancies and hemoglobinopathies like thalassemia and sickle cell disease.
2. Patients with coagulation disorder.
3. Patients with history of IHD or CVE and receiving antiplatelet medication.
4. Patients with chronic kidney disease.

5. Patients with COPD
6. Alcoholic liver cirrhosis patients.
7. Patients with pulmonary embolism and deep vein thrombosis.
8. Patients with other viral infections like hepatitis and HIV .
9. COVID-19 RT-PCR tested negative patients but showing COVID-19 symptoms.

Detailed history regarding onset, duration and progression of symptoms was taken. History of comorbidities like Diabetes, hypertension, thyroid disorders etc was taken and was noted in case record form. Findings of general examination was entered in case record form special attention will be given to temperature, heart rate, systolic blood pressure, oxygen saturation, and respiratory rate, need of oxygen support. All routine investigations was done including CBC, liver function tests, LDH, D -dimer, CRP. Data of each patient was collected in special proforma which includes clinical manifestations and laboratory values. Data was summarized in percentages and proportions. Chi-square test and Fisher Exact test had been used whenever the data is presented in terms frequency, and student t-test has been used to test significance when the results are presented as mean ± standard deviation (SD). P value <0.05 was considered statistically significant.

## Results:-
**Table 1:-** Distribution according to demographic variables:

| Variables | | No. of Patients (n=384) | Percentage |
|---|---|---|---|
| Age group (years) | >12-20 | 16 | 4.16 |
| | 21-30 | 51 | 13.54 |
| | 31-40 | 62 | 16.67 |
| | 41-50 | 79 | 20.57 |
| | 51-60 | 66 | 17.44 |
| | 61-70 | 74 | 19.53 |
| | 71-80 | 20 | 5.23 |
| | >80 | 11 | 2.86 |
| Gender | Male | 243 | 63.28 |
| | Female | 141 | 36.72 |

The table no. 1 describes demographic profile of the patients. Most of the patients in the present study were in age group 41-50 years of age. (20.57%) The mean age of the study population was 42.50 ±10.94 years with male predominance. (63.28%)

**Table 2:-** Distribution according to hematological variables:

| Variables | | No. of Patients (n=384) | Percentage |
|---|---|---|---|
| Anemia | Present | 102 | 26.56 |
| | Absent | 282 | 73.44 |
| RBC count | Decreased | 128 | 33.33 |
| | Normal | 229 | 59.64 |
| | Increased | 27 | 07.03 |
| Hematocrit | Decreased | 103 | 26.82 |
| | Normal | 257 | 66.93 |
| | Increased | 24 | 06.25 |
| MCV | Reduced (<80 fL) | 185 | 48.17 |
| | Normal (80-100 fL) | 164 | 42.70 |
| | Increased (>100fL) | 35 | 9.13 |
| MCH | <27pg/dl | 111 | 28.90 |
| | Normal (27-31pg/dl) | 243 | 63.28 |
| | >31pg/dl | 30 | 7.82 |
| MCHC | <32g/dl | 117 | 30.46 |
| | Normal 32-36(g/dl) | 267 | 69.54 |
| | >36g / dl | 0 | 0 |
| TLC count | <4000 | 34 | 08.85 |

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|  | 4000 to 11000 | 266 | 69.27 |
|---|---|---|---|
|  | >11000 | 84 | 21.88 |
| N/L ratio | <0.78 | 91 | 23.70 |
|  | 0.78 to 3.53 | 128 | 33.34 |
|  | >3.53 | 165 | 42.96 |
| Platelet count | <1.5 lakh | 245 | 63.80 |
|  | 1.5 to 4.5 lakh | 139 | 36.20 |
| RDW levels | <11.5% | 23 | 5.98 |
|  | 11.5 to 14.5% | 190 | 49.48 |
|  | >14.5% | 171 | 44.54 |
| Eosinophils | <50 | 112 | 29.16 |
|  | Normal 50-500 | 239 | 62.23 |
|  | >500 | 33 | 8.61 |
| Lymphocytes | <1500 | 168 | 43.75 |
|  | Normal 1500-5000 | 143 | 37.24 |
|  | >5000 | 73 | 19.01 |
| Neutrophils | <2500 | 53 | 13.80 |
|  | Normal 2500-8200 | 214 | 55.73 |
|  | >8200 | 117 | 30.47 |

The table no. 2 describes haematological profile of the patients. It was observed that among 384 patients, Maximum number of patients had normal RBC Count, Hematocrit, MCH, MCHC , RDW, TLC count , Eosinophils,Neutrophils. 102 (26.56%) patients were having anaemia. Low MCV in 48.17%, while N/L ratio was >3.53 in 165 (42.96%) patients with COVID-19. 63.80 % patients had low platelet count and 43.75% had low lymphocytes.

**Table 3:-** Comparison of parameters with severity:

| Investigations | Mild (Mean ±SD) | Moderate (Mean ±SD) | Severe (Mean ±SD) | P value |
|---|---|---|---|---|
| Haemoglobin | 13.01 ±2.11 | 11.78 ±2.17 | 10.68 ±2.23 | 0.09 (NS) |
| RBC COUNT | 4.69 ±1.72 | 4.42 ±2.18 | 4.10 ±2.11 | 0.31 (NS) |
| MCH | 33.83 ±3.85 | 30.88 ±4.03 | 27.71 ±3.09 | 0.45 (NS) |
| MCHC | 36.63 ±4.75 | 33.51 ±4.28 | 30.11 ±2.45 | 0.16 (NS) |
| MPV | 7.03 ±1.81 | 8.87 ±1.96 | 9.20 ±1.68 | 0.22 (NS) |
| Haematocrit | 31.42 ±10.08 | 34.28 ±9.33 | 39.47 ±8.51 | 0.31 (NS) |
| RDW | 11.95 ±2.30 | 12.82 ±2.21 | 13.84 ±2.14 | <0.01 (S) |
| MCV | 79.78 ±12.87 | 80.78 ±12.60 | 88.23 ±11.22 | 0.28 (NS) |
| Neutrophils | 3.76 ±2.29 | 4.37 ±2.93 | 5.18 ±2.19 | 0.19 (NS) |
| Lymphocytes | 2.70 ±.0.87 | 1.61 ±.0.83 | 1.10 ±.0.22 | <0.01 (S) |
| Eosinophils | 351.27 ±102.8 | 303.18 ±98.81 | 280.22 ±91.7 | 0.11 (NS) |
| Total Leucocyte Counts | 8.25 ±7.04 | 14.31 ±9.11 | 19.08 ±6.78 | <0.01 (S)* |
| N/L ratio | 3.44 ±2.74 | 10.72 ±3.78 | 14.18 ±2.81 | <0.01 (S)* |
| Platelets | 295.27 ±90.17 | 199.07 ±104.1 | 130.36 ±111.4 | <0.01 (S)* |

The above table shows that when parameters used in study are compared in severity of COVID-19disease ,the calculated p values of RDW (p value <0.01), TLC (p value <0.001), Lymphocytes ( p value 0.01), NLR( p value 0.01 ),Platelets ( p value 0.03), were less than 0.05 which shows there is statistical significance between RDW, TLC, Lymphocytes, NLR, Platelet with severity of COVID-19disease .

**Table 4:-** Comparison of parameters according to outcome**:**

| Investigations | Survivor (Mean ±SD) | Non-survivor (Mean ±SD) | P value |
|---|---|---|---|
| Haemoglobin | 12.69 ±1.84 | 10.80 ±2.44 | 0.14 (NS) |
| RBC COUNT | 4.56 ±.2.38 | 4.18 ±1.84 | 0.21 (NS) |
| MCH | 30.12 ±.3.29 | 28.22 ±2.71 | 0.09 (NS) |
| MCHC | 34.29 ±.2.18 | 31.13 ±1.28 | 0.07 (NS) |

| MPV | 7.12 ±.1.18 | 8.11 ±1.73 | 0.031(S) |
|---|---|---|---|
| Haematocrit | 34.11 ±6.19 | 38.56 ±8.12 | 0.21 (NS)* |
| RDW | 11.06 ±1.34 | 12.82 ±2.23 | <0.001 (S)* |
| MCV | 78.1 ±12.91 | 86.19 ±10.18 | 0.07 (NS)* |
| NEUTROPHILS | 3.13 ±.1.09 | 5.21 ±1.98 | 0.03 (S) |
| LYMPHOCYTES | 1.67 ±.0.34 | 1.12 ±.0.18 | 0.01 (S) |
| EOSINOPHILS | 332.11 ±.89.72 | 289.71 ±90.82 | 0.06 (NS) |
| Total Leucocyte Counts | 13.39 ±7.50 | 18.79 ±5.57 | <0.001 (S)* |
| N/L ratio | 9.35 ±3.28 | 12.69 ±3.89 | 0.01 (S)* |
| Platelets | 260.6 ±121.4 | 130.36 ±111.4 | 0.03 (S) |

(*$P<0.05$ statistically significant by unpaired t test)

The above table shows that when parameters used in study are compared in surviours and non-survivors of COVID-19disease ,the calculated p values of RDW (p value <0.001), TLC (p value <0.001), Neutrophils ( p value0.03), Lymphocytes ( p value 0.01), NLR( p value 0.01 ) , MPV (p value 0.031) ,Platelets ( p value 0.03),  were less than 0.05 which shows there is statistical significance between RDW, TLC, Neutophils, Lymphocytes, Eosinophils, NLR ,Platelet with outcome of COVID-19disease .

## Discussion:-

The world has been facing an unprecedented coronavirus (Covid-19) outbreak that started in China and rapidly spread internationally since December 2019. In particular, to develop patient treatment algorithms, it is crucial to determine the factors that affect the mortality and clinical conditions of patients

The present hospital record based cross sectional study was conducted at tertiary care hospital to study to assess the relation of hematological parameters with outcome in patients infected with COVID-19. Total 384 subjects were enrolled in this study with inclusion and exclusion criteria. In the study, subjects in maximum number of patients are in 41 to 50 years of age group i.e 20.57%. The mean age of the study population was 42.50 ±10.94 years. Similar findings were observed in study Archana Bhatt et al [14] observed mean age of patients was 44.82 years and 30% were below 30 years of age. Study conducted by the Charvi Patel et al [15] observed that the maximum number of patients belonged to the age group of 51-60 years and the mean age was 46.13 (±15.71) years. There are 243 males i.e 63.28% and 141 females 36.72%. Male preponderance in present study was similar to other Indian studies, though it was lower than western studies.

In the present study, about 26.56 % of the patients had anaemia amongst which 19.34% are males and 39 % are females. Aytenew Atnaf et al [16] in a study on hematological profile observed the prevalence of anemia as 6.3%. Patel et al. [15] from India reported decreased hemoglobin in 36% of cases while Chen et al.[17] from China reported a reduction in hemoglobin in 51% of cases which was almost similar to the present study. The increased prevalence of anemia among COVID-19 patients are associated with SARS-CoV-2 infection which may lead to hemolytic anemia directly through cytopathic injury of red cells or indirectly through formation of auto-antibodies. Mean hematocrit in survivors was 34.11 ±6.19 and nonsurviours is 38.56 ±8.12.The purpose of red blood cells is to transfer oxygen from the lungs to body tissues, a blood sample's hematocrit [the red blood cell volume percentage] can become a point of reference of its capability of delivering oxygen. Hematocrit levels that are too high or too lowcan indicate a blood disorder, dehydration, or other medical conditions. Normal values differ in males and females about 40-50% and 35-46% respectively.

In the present study, amongst the study 69.27 % of patients had normal level of TLC count whereas 21.88% of patients had high levels of TLC count.8.85% of patients had low TLC count. Chen N et al [17] study done in Wuhan, China, indicated 24% leukocytosis **and** 9% leukopenia. N Chandran et al [18] studied hematological parameters among COVID 19 patients observed 14 cases (21.5%) had leukopenia, and eight cases (12.3%) had leukocytosis. Patel et al.[15] from India, leukopenia was seen in 4% of cases while leukocytosis was seen in 20% of cases. In the present study, maximum patients amongst study population had high N/L ratio i.e about 42.96%. N Chandran et al[18] studied hematological parameters among COVID 19 patients observed out of 65 cases, 28 patients (43%) had high NLR values with four cases (6.1%) having markedly raised NLR of more than 10.

In the present study, 36.20% of patients had thrombocytopenia and 63.80% of patients had normal platelet levels.

Patel et al.[15] from India reported thrombocytopenia in 16% of cases while thrombocytosis was seen in 8% of cases, unlike the present study. Zhou et al.[19] from China reported thrombocytopenia in 7% of cases almost similar to the present study. The possible mechanism of thrombocytopenia in COVID-19 infected patients might be related to direct effect of the virus on the bone marrow cells or platelets by reducing platelet synthesis, creating dysfunctional marrow microenvironment; liver damage by the virus leading to decreased thrombopoietin production; pulmonary endothelial damage followed by platelet aggregation in the lungs, subsequent formation of microthrombi, and platelet consumption; and finally, the destruction of platelets by cross reacting antibodies. A study had shown that thrombocytopenia increased the risk of COVID-19 severity over five folds. [15,19]

In the present study, comparison of severity of COVID-19disease with hematological parameters showed the calculated p values of RDW (p value <0.01), TLC (p value <0.001), Lymphocytes ( p value 0.01), NLR( p value 0.01 ),Platelets ( p value 0.03),  were less than 0.05 which shows there is statistical significance between RDW, TLC, Lymphocytes, NLR, Platelet with severity of COVID-19disease .

A study conducted by Manish Jha et al [20] and Chong Chen et al [15]  showed that there is significant correlation between anemia and covid 19 severity. In Khushbhun Nahar Lyla et al[21] study done on Red cell profile in patients with mild, moderate, severe COVID19 study found significant correlation with MCH, MCHC, MCV levels with severity. In Zahra-- Rostami -Far et al[22] study conducted on complete blood count as an indicator of severity, found significant correlation with Neutrophil, eosinophils, lymphocytes and NLR  levels with severity.

In the present study, it has been seen that there is statistically significant difference between the mean values of Surviours and non-surviours RDW, TLC, NLR and Platelet. Chang Cheng Shi et al [23] in a meta-analysis on mortality in patients with coronavirus disease 2019 observed the values of the following laboratory parameters were significantly higher in the deceased patients than in survivors: white blood cells (WBCs), neutrophils (NEUs).  The lymphocyte (LYM), monocyte (MON), platelet (PLT), counts were significantly lower in the non-survivors than in the survivors. In study conducted retrospectively by Maha Anani[24] survivors exhibited lower hemoglobin (Hb) and hematocrit (HCT), while showed higher Red Cell Distribution Width (RDW), neutrophil lymphocyte ratio (NLR), and lymphocytes. Logistic regression analysis showed high NLR were associated with more deaths. The present study was based on laboratory data. Further studies incorporating the clinical, radiological, and laboratory data will provide better insight into the relationship between the various hematological parameters and the clinical severity of COVID-19 infection.

Subtle hematological changes might appear early in the course of COVID-19 infection; progressive disease associates with significant hematological changes that may lead the management plan and predict patient outcome.

## Conclusion:-
The present study concludes that laboratory parameters like  RDW, MPV, Platelet count, Total leucocyte count ,Neutrophils count ,Lymphocytes count, N/L ratio can be considered as early prognostic markers of COVID 19 disease and have great  significance with severity of disease.The most of patients had hematological abnormalities like lymphopenia, raised N/L ratio,raised MPV ,thrombocytopenia. Thus, hematological profile will ultimately be of great help in early management of critical illness.

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