DISSERTATION SUBMITTED FOR THE MASTER'S DEGREE IN MEDICAL PHYSIOLOGY

Inspiring Excellence

TITLE

"CORRELATION OF LIVER FUNCTION TESTS WITH HEMATOLOGICAL PARAMETERS IN PREGNANT WOMEN"

SUBMITTED BY

ANIL KUMAR

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Dissertation submitted to

Integral Institute of Medical Sciences and Research

In partial fulfilment of the requirements for the award of degree of

Master of Science in Medical Physiology

By

ANIL KUMAR

Enrolment No.2000102491

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DECLERATION BY CANDIDATE

I hereby declare that this dissertation entitles **"CORRELATION OF LIVER FUNCTION TESTS WITH HEMATOLOGICAL PARAMETERS IN PREGNANT WOMEN IN LUCKNOW"** is a Bonafide & genuine research work carried out by me under the guidance of Dr. Khallel ahmed manik, HOD & Professor, Department of Physiology and Co-supervision Dr. Meenakshi Srivastava Professor, Department of Obs & Gynae.

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This is to certify that the dissertation entitled **"CORRELATION OF LIVER FUNCTION TESTS WITH   HEMATOLOGICAL PARAMETERS IN PREGNANT WOMEN IN LUCKNOW"** is a bonafide & genuine research work carried out by ANIL KUMAR under the guidance of Dr. Khallel ahmed manik, HOD & Professor, Department of Physiology and Co-supervision Dr. Meenakshi Srivastava Professor, Department of Obs & Gynae.
 in partial fulfillment of requirement for the degree of Master of Science in Medical Physiology. The research methods and procedures described have been done by the candidate and result observed by the Guides periodically.

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CERTIFICATE BY THE GUIDE AND CO-GUIDE

This is to certify that ANIL KUMAR student of M.Sc. MEDICAL PHYSIOLOGY; Integral University has completed his dissertation entitled **"CORRELATION OF LIVER FUNCTION TESTS WITH HEMATOLOGICAL PARAMETERS IN PREGNANT WOMEN"** successfully. He has completed this work from the department of Physiology, Integral Institute of Medical Sciences and Research, Integral University under the guidance of Dr. Meenakshi Srivastava. The dissertation was a compulsory part of his M.Sc. degree. I wish him good luck and bright future.

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ANIL KUMAR

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List of Abbreviations

ALT	:	Alanine amino transferase
AST	:	Aspartate amino transferase
BP	:	Blood pressure
BMI	:	Body Mass Index
CKD	:	Chronic Kidney Disease
CVS	:	Cardiovascular System
EPO	:	Erythropoietin
HELLP	:	Hemolysis elevated liver enzymes and low platelets
Hb	:	Haemoglobin
MCV	:	Mean Corpuscular Volume
SBP	:	Systolic Blood Pressure

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INTRODUCTION

The liver is a vital organ that serves 500 various purposes in the human body. It plays a significant function in the metabolism and detoxification of several substances in addition to being the location of the formation of bilirubin, albumin, and clotting factors. Progesterone and other pregnancy hormones, such as oestrogen, affect the liver's metabolic and synthesis processes. Additionally affected the hepatobiliary secretion of bile and compounds dissolved in it, such as bilirubin, bile salts, and medications. Plasma volume rises by 40–50% from the non- gravid state during pregnancy, with the maximum Plasma values occurring in the second and third trimesters.[1]

After the heart, the liver is the most crucial organ in the human body. It performs numerous vital tasks like metabolism and the production of albumin and blood clotting factorss. The importance of liver disease as a serious health issue has been growing throughout time. Bilirubin, total protein (TP), alkaline phosphate (ALP), globulin (GLB), albumin (ALB), alanine transaminase (ALT), aspartate transaminase (AST), and lactate dehydrogenase are examples of liver function markers.[2]

The body of the pregnant woman alters to assist the development and growth of the foetus. The levels of blood oestrogen and progesterone rise gradually throughout pregnancy and peak in the third trimester. These sex hormones have an impact on the hepatic excretory, synthetic, and metabolic processes.[3]

LFTs are often requested blood tests that assess liver function, liver disease, and biliary system function, including the function of the gallbladder and intra- and extrahepatic bile ducts. LFTs also assess physiology in areas other than the hepatobiliary system; for example, they

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offer information on disorders including coagulation, hemolysis, nutrition, bone turnover, and others.[4]

Hepatic enzymes, synthetic function tests, and bilirubin are the particular tests covered in LFTs. Four hepatic enzymes are often of interest: gamma glutamyl transferase (GGT), alkaline phosphatase (ALP), aspartate aminotransferase (AST), and alanine aminotransferase (ALT) . Aminotransferases or transaminases collectively refer to AST and ALT. Serum albumin and the International Normalized Ratio are two tests for the synthetic function of the liver, whichmeasures how efficiently it can produce new substances, particularly proteins [4]

Pre-eclampsia is characterised by pregnancy-induced hypertension with other complications, making the determination of liver enzymes like aspartate transferase (AST), alanine transferase (ALT), alkaline phosphatise (ALP), and other parameters like bilirubin, uric acid, important in the diagnosis and medical management of the condition (oedema, proteinuria, convulsion). Pregnant women are more likely to develop eclampsia in the third or second trimester of pregnancy.[5]

During a healthy pregnancy, including total bile acids concentration, serum alanine transaminase (ALT), aspartate transaminase (AST), gamma-glutamyl transpeptidase (GGT), and bilirubin, stay within the normal range.[6]

LDH levels reflect both hemolytic cell damage and hepatic dysfunction, bilirubin levels reflect both hemolysis and hepatic dysfunction, and AST levels reflect both tissue damage and hepatic dysfunction. [7]

The current study looks at haemoglobin concentration (HB), white blood cell count (WBC), red blood cell count (RBC), and platelet count in normal pregnant women. [8]

In pregnancy, the red blood cell indices alter. The average mean corpuscular volume (MCV) in an iron-replete woman increases, reaching its peak at 30-35 weeks of pregnancy.

The increased MCV (owing to a higher proportion of immature RBCs that are larger in size) is properly explained by increased RBC production to satisfy the needs of pregnancy.[9]

Due to the foetus' ongoing development during pregnancy, there are several physiological and haematological changes. Pregnancy-induced systemic vasodilation and increased vascular capacitance cause hormonal changes. [10]

Anemia, the most prevalent haematological condition encountered in pregnancy, is characterised by a reduction in haemoglobin or red cell mass. Anemia during pregnancy can cause both the mother and the foetus to suffer from morbidity and mortality. Anaemia during pregnancy is one of the main causes of low birth weight newborns, which results in recurrent infections in the early stages of infancy. Anaemia in pregnancy is a haemoglobin concentration of less than 11.0 g/dl. W.H.O. recommendations define mild anaemia as having a haemoglobin (Hb) level between 10.0 and 10.9 g/dL, moderate anaemia as 7.0 to 9.9 g/dl, and severe anaemia as less than 7 g/dl.[11]

Expanded Plasma volume, physiologic anaemia, mild neutrophilia in some people prothrombotic condition are the main hematologic changes that occur during pregnancy. Physiologic anaemia, neutrophilia, moderate thrombocytopenia, elevated coagulants factors, and decreased fibrinolysis are the most important haematological changes. To accommodate the expanding and maturing fetoplacental unit, nearly every organ system undergoes numerous physiological changes throughout a normal pregnancy.[12]

Pregnancy is the state in which an ovum that has been fertilised by a spermatozoon attaches to the maternal uterus, followed by the growth and development of the foetus. Pregnancy is regarded as to last roughly 40 weeks (280 days) following the final menstrual period or 38 weeks (266 days). The process of fertilisation to create a zygote and ends in abortion, miscarriage or delivery. The World Health Organization defines anaemia in pregnancy as a condition in which the packed cell volume (PCV) is less than 0.33% or the total circulating haemoglobin content is less than 11g/dl.[13]

Complete blood count (CBC) parameters can have different values depending on a variety of analytical, pathological, and physiological factors, including age, sex, height, environment, race, nutritional status, ethnic origin, lifestyle, use of tobacco, alcohol, or medications, or even pregnancy. Physiologic anaemia, which results from separate and uneven fluctuations inplasmatic volume (+ 40%) and corpuscular volume (+15%), is one of the most significant haematological changes for pregnant women.[14]

Plasma volume begins to expand in the first trimester of a healthy pregnancy, increases at the fastest rate in the second trimester, and peaks late in the third trimester.

When compared to non-pregnant conditions, plasma volume increases by more than 1L during pregnancy. Plasma volume increase in the third trimester is 13.3% lower in pregnancies complicated by pregnancy-induced hypertension, preeclampsia, or foetal growth restriction than in normal pregnancy.[15]

REVIEW OF LITRATURE

Pregnancy causes profound changes in the physiological functions of the pregnant woman's body. Indeed, there is a significant increase in metabolic needs during pregnancy, as well as changes in hormonal balance. These phenomena are sufficient to justify haematological disorders. The purpose of this study was to estimate the reference values of CBC parameters.

According to the WHO, anaemia affects 30.2% of reproductive-age women and 41.8% of pregnant women worldwide. The WHO defines anaemia in pregnant women as having a haemoglobin level of less than 11 g/dL and an HCT level of less than 33% at any time during the pregnancy. Other authors in previous studies conducted in industrialised countries suggested an HCT rate of less than 30% for practical clinical use. The mean values of the erythrocytes index MCV, MCH and MCHC showed a significant difference ($p < 0.05$) between pregnant women.

During normal pregnancy, changes occur and can be observed in haematological indices such as red blood cell (RBC) count, haemoglobin (HB) concentration "physiologic anaemia", platelet (PLT) count, and white blood cell (WBC) count.[14]

During pregnancy, plasma volume increases by 50%. Red cell mass increases as well, but at a slower rate than plasma volume. As a result, a decrease in haemoglobin (HGB) concentration leads to dilution anaemia during pregnancy. During pregnancy, there were no changes in mean carpuscular haemoglobin (MCH) or mean carpuscular haemoglobin concentration (MCHC).

During pregnancy, the total platelet count gradually decreased. During pregnancy, the white blood cell count increased. In non pregnant female normal WBC count is somewhere between 5 and 10 (5,000–10,000cells/mm3),[16]

The WBC count, neutrophils, monocytes, lymphocytes, and basophils did not change throughout the pregnancy. In the third trimester, eosinophils were lower than in the second and first trimesters.

RBC, Hb, and Hct levels were lower in the second and third trimesters compared to the first. The values remained constant from the second to the third trimester of pregnancy. MCV increased in the second and third trimesters when compared to first trimester values.

When compared to the second and first trimesters, the platelet count decreased while mean platelet volume (MPV) and platelet distribution width (PDW) increased in the third trimester.[15]

Hemoglobin (Hb), Red blood cell (RBC) count, Hematocrit (PCV - packed cell volume), Mean Corpuscular volume (MCV), Mean Corpuscular haemoglobin (MCH), Mean corpuscular haemoglobin concentration (MCHC), Total Leucocyte count (TLC), Differential Leucocyte count (DLC), Platelet count, and Peripheral smear were the haematological parameters studied. The following parameters were calculated.

When red cell parameters from pregnant and non-pregnant women were compared, it was discovered that the differences in mean haemoglobin concentration, RBC count, PCV, MCV, and MCHC were statistically significant. We justify this disparity by pointing out that pregnant women need micronutrients and proximate food components for their growing foetus, as well as for the growth of various body parts, body fluids, and so on.

Anemia is one of the country's major public health issues, and anaemia during pregnancy contributes to significant morbidity and mortality in a developing country like India, particularly in rural areas. Anaemia was found in half of the Antenatal cases in our study as well. Severe anaemia affects 2.66% of anaemic antenatal mothers. Mild and moderate antenatal cases account for 46.67% and 50.67% of all cases, respectively.[11]

Serum albumin levels were found to be lower in both the first and second trimesters. Das et al. observed a similar trend in albumin levels. From the first to the third trimester, maternal plasma volume increases by up to 50%.[1]

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Pregnant women go through some physiological changes in order to support foetal growth and development. Both progesterone and estradiol levels rise gradually during pregnancy. Sex hormones influenced hepatic metabolic, synthesis, and excretory functions. serum liver function tests are critical in the management of liver diseases in adults.

According to this study, there was no significant difference in serum AST between pregnant and non-pregnant women, but there was a significant difference in ALT in pregnant versus non-pregnant women. The effects of pregnancy on serum ALT and AST activity levels are debatable.

Except for alkaline phosphatase, most serum liver function test values remain below the normal upper limits established in non-pregnant women during normal pregnancy. When liver disease is clinically suspected in a pregnant woman, any increase in serum ALT and AST activity levels, as well as serum bilirubin, should be considered pathologic and warrant further evaluation. Furthermore, for all subscales and total mean scores, the majority of the studied sample has a low level of health literacy.[17]

We must distinguish between two types of liver disease in pregnant women with suspected liver disease: non-pregnancy-related liver diseases and the few diseases that are directly related to pregnancy. Non-pregnancy-related liver diseases can occur at any time, whereas pregnancy-related liver disorders have trimester-specific symptoms.

Hypermesis-gravidarum (HG) is defined as nausea and vomiting that causes dehydration, ketosis, and weight loss of more than 5% of body weight. Clinical manifestations include dehydration and increased renal values, electrolyte abnormalities, metabolic alkalosis, and erythrocytosis. Approximately half of all pregnant women have abnormal liver test results. Serum aminotransferase elevations typically reach 200 U/L and are the most common abnormal liver test result. Other biochemical abnormalities include

elevated serum amylase and lipase levels. [6]

Liver diseases during pregnancy are difficult for both the foetus and the mother. Younger pregnant women are more likely to have abnormal LFT. Most studies report that the cause of abnormal LFT is a pregnancy-specific disorder, with a prevalence ranging from 60% to 80% . In viral hepatitis and ALFP, the mean ALT, AST, and ALP levels were higher.[2]

In this study, Bilirubin concentrations were significantly lower in second and third trimester pregnant women than in first trimester pregnant women. Several studies have found a decrease in serum total bilirubin concentrations during pregnancy. Because albumin is the protein that transports bilirubin, hemodilution could be at least partially responsible for the decrease in bilirubin concentration.

During labour, there was an increase in AST and ALT levels, which could be attributed to uterine muscle contraction. During pregnancy, AST and ALT activity remain normal.

Serum total protein concentration did not change significantly, but serum albumin level was significantly lower and serum globulin concentration was significantly higher in all three trimesters compared to nonpregnant women. The concentration of albumin in late pregnancy was significantly lower than in early pregnancy. When compared to nonpregnant and first trimester pregnant women, the serum albumin/globulin ratio was significantly lower in the second and third trimesters. The decrease in albumin to globulin ratio seen in certain hepatic diseases is caused by a decrease in albumin concentration combined with a normal slight increase in serum globulin. [3]

AIM AND OBJECTIVES

AIM

To determine correlation of liver function test with hematological parameter in pregnant women Lucknow.

OBJECTIVES

1. To estimate Hematological parameter (HB, RBC, WBC, Platelets count) in pregnant women.

2. To estimate Liver function test (SGOT, SGPT, Bilirubin) in pregnant women.

3. To look for correlation of hematological parameter and Liver function test in pregnant women

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MATERIALS AND METHOD

TYPE OF STUDY – Cross-sectional Study.

PLACE OF STUDY - The study was performed in the Department of Obs and Gynae. At Integral Institute Medical Science & Research, Lucknow (U.P.).

Duration of Study- 6 months. (January2022 to July 2022)

INCLUSION CRIETERIA-

1. Pregnant females between18 to 45 years of age.

2. Patients who have signed the written informed consent

EXCLUSION CRIETERIA-

1. Pregnant females with a known history of blood disorder pregnancy for example- bleeding disorder, clotting disorder, aplastic anemia etc.
2. Pregnant women with known liver diseases prepregnancy for example- Chronic liver diseases, cholelithiasis, liver cirrhosis.
3. Pregnant female who do not give consent.
4. Patients on tobacco consumption , drug addicts and alcoholic subject.

Ethical Clearance- Has been obtained from institutional ethics committee (IEC/IIMS&R/2022/27).

COLLECTION OF DATA

1. Data of pregnant females between 18 - 45 years of age presenting themselves in the
    antenatal clinic of IIMSR was collected after signing of the informed consent form.

2. 3ml of blood was collected using all aseptic precaution in the clotting vials for estimation
    of Bilirubin, SGOT and SGPT level by using Erba Chem-5 plus.

3. 3 ml of blood was collected using all aseptic precaution in the EDTA vials for estimation
    of Haemoglobin, WBC, RBC and Platelets count by using Erba Mannheim.

SAMPLE SIZE-

The sample size is calculated using the formula:

$$N = \frac{Z_{\alpha/2} P(1 - P)}{d^2}$$

N = Desired sample size

Z1−α/2 = Critical value and a standard value for the corresponding level of confidence. (At 95%

CI or 5% level of significance (type-I error) it is 1.96)

p = Prevalence 65.5% (Pathania A, et.al ;2019)

d = Margin of error or precision 5%

Non -response = 10% (Daniel WW;1999)

The study will include 146 cases diagnosed.

RESULTS AND OBSERVATION

Participants characteristics:-

Distribution of participants by the age:-

Distribution according to the age was found 30% from 18-24 years, 51.3% from 25-34

years and 18.7% from 35 and below seen in table 1.

The gravidity among study population:-

The participants were found 28% had primigravida and 72% had multigravida table 1.

Maternal follow up during pregnancy in the participants:-

In the study population showed that, 115 (76.7%) had maternal follow upbut 35 (23.3%)

received table 1.

| Participant characters		Number	Percent
Age	**18-24**	43	30%
	25-34	75	51.3%
	>35	28	18.7%
Gravidity	**Primigravida**	42	28%
	Multigravida	104	72%
Maternal follow up	**Yes**	111	76.7%
	No	35	23.3%
Religions	**Muslim**	115	82.5%
	Hindu	31	17.5%
	Total	146	100%

Table (1): Participant characteristic.

The educational level in the study population:-

Distribution according to education showed that, 37% were illiterate, 31% had primary education, 19% hadsecondary education and 13% found to have high education figure 1.

Education level	Numbers	Percentage
Illiterate	54	37%
Primary	46	31%
Secondary	27	19%
High	19	13%
Total	146	100%

Table (2): The educational level in the study population .
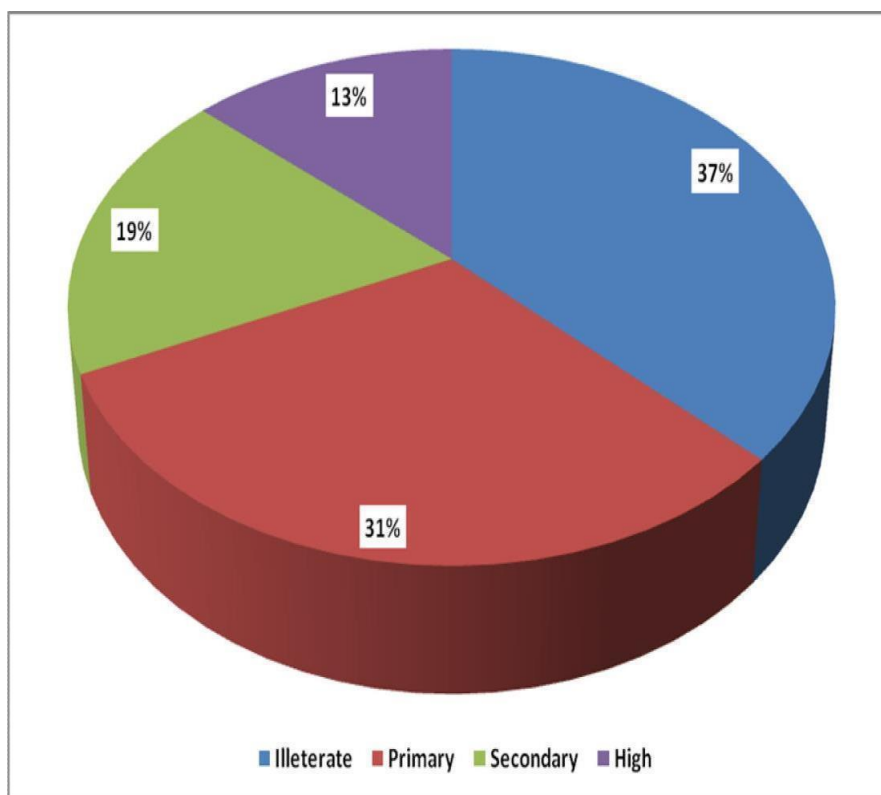
Figure (1): The education level in the study population.

Distribution of the study group according to socioeconomic status showed that, 63.3% were of low socioeconomic status, 35.3% were of moderate status and 1.3% was of high status.

Socioeconomic Status	Numbers	Percentage
Low	92	63.3%
Moderate	52	35.3%
High	2	1.3%
Total	146	100%

Table (3): The socioeconomic status among the participants.
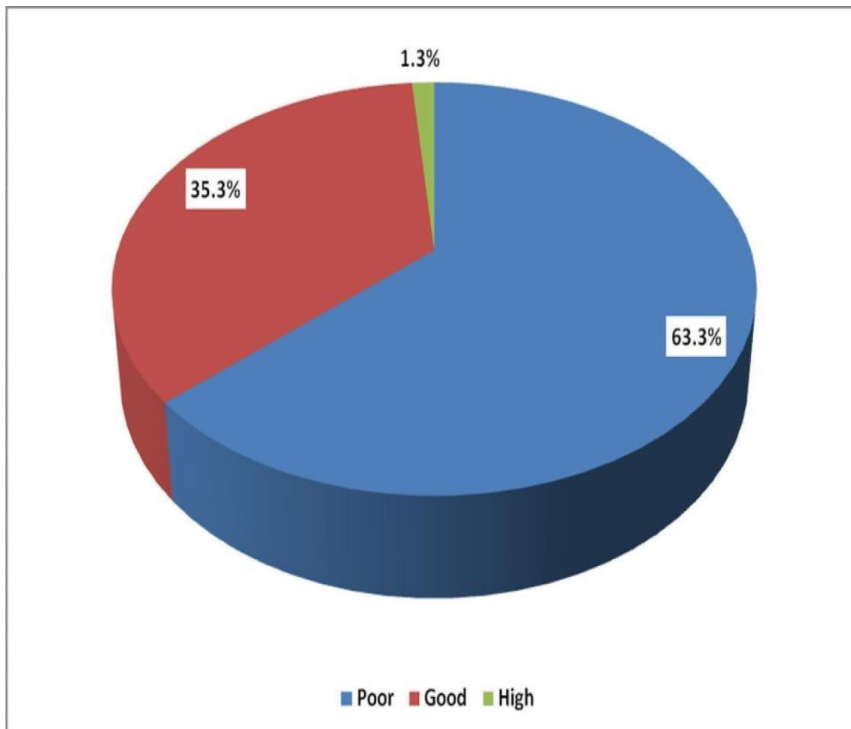
Figure (2) The socioeconomic status of the participants.

The effect of the gestational age on Hb, TWBC, RBCs count and platelets count:-

11.37±1.3g/dl, 10.95±1.5g/dl and 10.64±1.9g/dl is the hemoglobin concentration found in the first, second and third trimester respectively.

5.762± 1.7× 109 cell/l 6.958± 2.2×109 cell/l and 7.150± 2.9×109 cell/l   is the TWBCs which has increased in the first, second and third trimester respectively.

 4.00±0.5×1012 cell/l, 3.76±0.4×1012 cell/l and 3.87±0.6×1012 cell/l is the RBCs count in the first, second and third trimester respectively.

  285.200±91.5×109 cell/l, 276.940± 78.0×109 cell/l and 243.400±64.7×109cell/l is the Platelets count which is decreasing in the first, second and third trimester respectively.

Parameters	First trimester Mean± SD	Second trimester Mean± SD	Third trimester Mean± SD
HB (g/dL)	11.37 ± 1.3 (8.6 – 13.6)	10.95± 1.5 (8.2 -14.7)	10.64± 1.9 (1.9 – 13.4)
TWBCs×10^{9}Cell/L	5.762 ± 1.7 (2.8 – 11.1)	6.958 ± 2.2 (2.6 – 13.5)	7.150 ±2.9 (3.2 – 15.4)
RBCs×10^{12}(Cell/L)	4.00 ± 0.5 (3.05 – 5.46)	3.76 ± 0.4 (3.06 – 4.72)	3.87 ± 0.6 (0.97 – 4.58)
PLT ×10^{9}Cell/L	285.200 ± 91.5 (113 – 634)	276.940 ± 78.0 (138 – 466)	243.400 ± 64.7 (115 – 381)

*Mean within the same row with different superscripts was significantly differentatP≤ 0.05.

Table (4): The effect of the gestational age on Hb, RBCs,WBC and Platelets count.
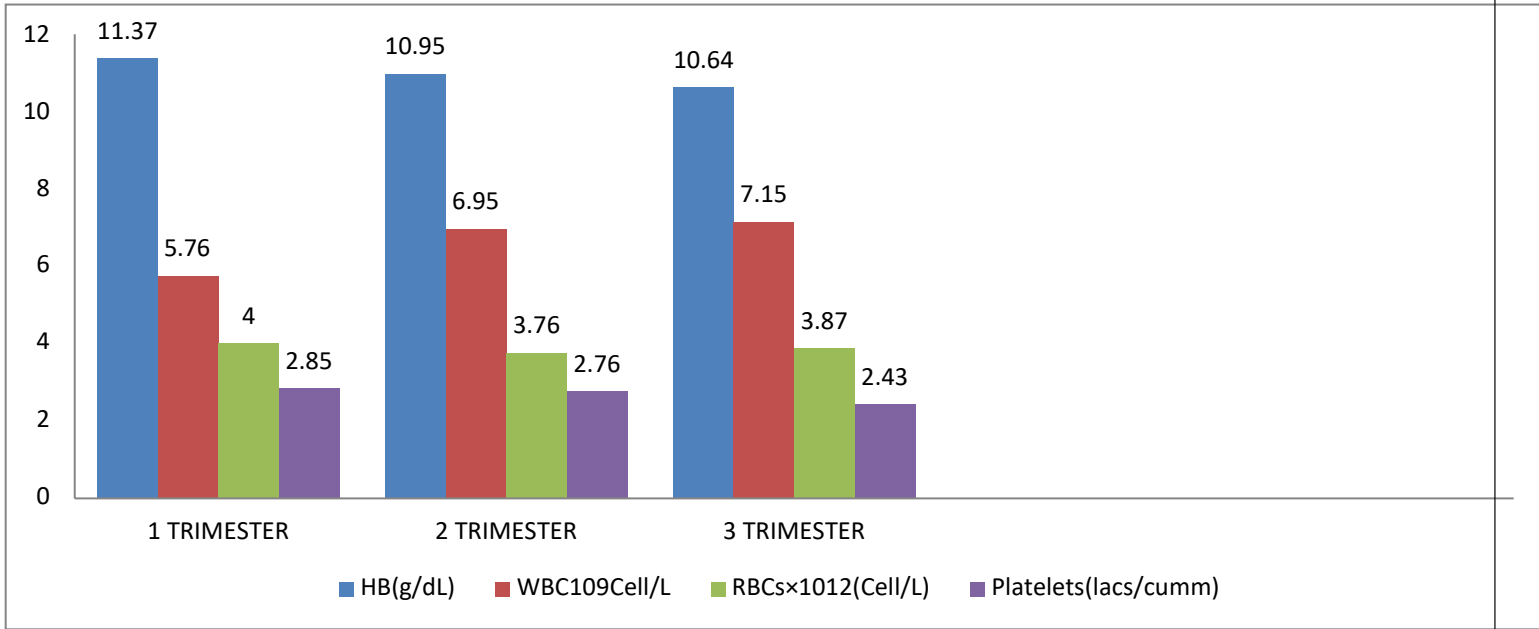
Figure (3): Distribution of the gestational age on Hb, RBCs,WBC and Platelets count.

Distribution of the participants according to HB level and severity of anemia:-

Distribution of participants according to hemoglobin level showed that, 71(48.7%) had normal hemoglobin level (>11g/dL), 65(44.7%) had mild anemia 9(10.9g/dL), 9(6%) had moderate anemia (7.1– 8.9g/dL) and only one patient (0.7%) was suffering from severe anemic (<7g/dL) figure.

	Number	Percentage
Normal	71	48.7%
Mild	65	44.7%
Moderate	9	6.0%
Severe	1	0.7%
Total	146	100%

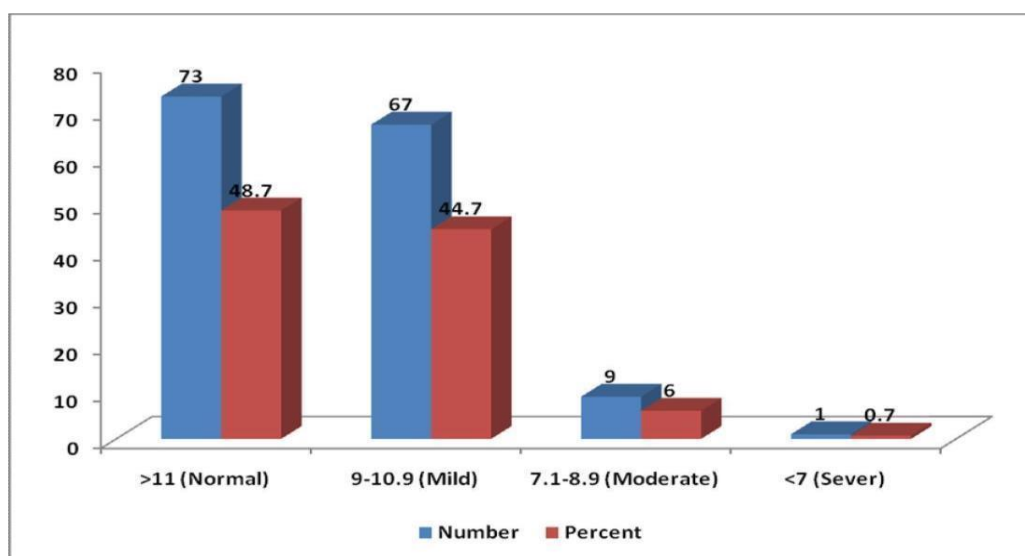**Table no. (5): Grades of anemia.**

Figure (4) Distribution of the participants according to HB level and severity ofanemia.

Abnormal level of liver enzymes only in 20 percent to 30 percent of patients of pregnancies with pre-eclampsia and eclampsia. In the current study, abnormal level of liver enzymes, i.e. SGPT(AST), SGPT(ALT), Due to changes in membrane permeability, vasoconstriction, and liver injury, abnormal liver enzymes may develop. In our study, among 146 patients, SGOT (AST) increased in 20%, SGPT (ALT) increasedin 21%, bilirubin increased in any 42%.

S.No.	Parameters	Range
1	SGOT(AST)	Upto 40 units/l
2	SGPT(ALT)	Upto 40 units/l
4	Bilirubin	Upto 1.0 mg/dl

Table no. (6): The normal (reference range) level of biochemical parameters:

.

There were 146 patients. After analysis the above data, we identified that in our study using

Pearson correlation coefficient test.

r- value of Bilirubin is -0.11for HB, it shows stastically negative correlation.

r- value of Bilirubin is +0.08 for RBC, it shows stastically positive correlation.

r- value of Bilirubin is -0.25 for WBC, it shows stastically negative correlation.

 r- value of Bilirubin is -0.09 for Platelets, it shows stastically negative correlation.

Hematology parameter	Liver enzyme	r- value	P- value
HB	Bilirubin Level	-0.11	0.18
RBC	Bilirubin Level	+0.08	0.33
WBC	Bilirubin Level	-0.25	0.00
Platelets	Bilirubin Level	-0.09	0.27

Table (7): Correlation between Bilirubin and Hb, RBC,WBC,Platelets

There were 146 patients. After analysis the above data, we identified that in our study using

Pearson correlation coefficient test.

r- value of SGOT is -0.05 for HB, it shows stastically negative correlation.

r- value of SGOT is +0.02 for RBC, it shows stastically positive correlation.

r- value of SGOT is -0.00 for WBC, it shows stastically negative correlation.

r- value of SGOT is -0.06 for Platelets, it shows stastically negative correlation.

Hematology parameter	Liver enzyme	r- value	P- value
HB	SGOT Level	-0.05	0.54
RBC	SGOT Level	+0.02	0.81
WBC	SGOT Level	-0.00	1.00
Platelets	SGOT Level	-0.06	0.47

Table (8): Correlation between SGOT and Hb, RBC,WBC,Platelets

There were 146 patients. After analysis the above data, we identified that in our study using

Pearson correlation coefficient test.

r- value of SGPT is -0.01for HB, it shows stastically negative correlation.

r- value of SGPT is +0.02 for RBC, it shows stastically positive correlation.

r- value of SGPT is +0.12 for WBC, it shows stastically positive correlation.

r- value of SGPT is +0.06 for Platelets, it shows stastically positive correlation.

Hematology parameter	Liver enzyme	r- value	P- value
HB	SGPT Level	-0.01	0.90
RBC	SGPT Level	+0.02	0.81
WBC	SGPT Level	+0.12	0.14
Platelets	SGPT Level	+0.06	0.47

Table (9): Correlation between SGPT and Hb, RBC,WBC,Platelets

Discussion

There were 146 patients. After analysis the data, we identified that in our study using

Pearson correlation coefficient test, r- value of Bilirubin is -0.11for HB, it shows stastically negative correlation, r- value of Bilirubin is +0.08 for RBC, it shows statistically positive correlation, r- value of Bilirubin is -0.25 for WBC, it shows stastically negative correlation, r- value of Bilirubin is -0.09 for Platelets, it shows stastically negative correlation. Furthermore similar finding were also reported by Khalil et al.(2017)

The prevalence of anaemia among pregnant women was very clear in different forms at ages less than 40 years and during the first trimester of pregnancy, Hypertension was commonly associated with pregnancy aside from few other complications due to poor dietary habits and lack of nutritional education, many strategies will be very helpful to prevent and control this problem by providing health facilities and dealing with socioeconomic status.[18]

According to a recent study, pregnant women are more prone to anaemia, particularly in the third trimester. Nutrition is extremely important during pregnancy. As a result, it is strongly advised to educate the female about a healthy and balanced diet during pregnancy, including iron-containing foods (meat and spinach), proper treatment, and the negative effect of black tea on iron absorption reported by Taj N et al. (2019).[19]

This study concluded that pregnancy had no effect on RBCs, Hb, platelets, WBC levels in women, and that there were no significant differences among Sudanese pregnant women.

WBC count showed statistically significant differences reported by Mohamed Ao et al.[20]

The different parameters of the CBC test were also tested during the pregnancy's three trimesters. According to the findings of this study, the rate of HB was significantly lower in pregnant women.

In this study during th trimesters the reference value range for total serum bilirubin was significantly higher Reported by Othman AIB et al.[17]

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We identified that in our study using Pearson correlation coefficient test, r- value of SGOT is -0.05 for HB, it shows stastically negative correlation, r- value of SGOT is +0.02 for RBC, it shows stastically positive correlation, r- value of SGOT is -0.00 for WBC, it shows stastically negative correlation, r- value of SGOT is -0.06 for Platelets, it shows stastically negative correlation.

In our finding a progressive decline in Hb concentration was found from the first to the third trimester. In this study decrease in RBCs count between the first and second trimester, and an insignificant increase in the third trimester when compared with the other two trimesters.

In this study it was found an increase in the TWBCs count with a significant variation between the first trimester when compared with the second and third trimesters.

In this study a gradual decrease in PLT count was observed.

The total white blood cell (WBC) count decreased, but not statistically significantly by Babker AM et al.[12] There was no significant difference in the reference range in serum AST. Reported by Othman AIB et al.[17]

Normal laboratory values associated with hepatic function are altered due to physiologic changes that occur in every organ system during pregnancy. The serum ALT level, in particular, was reduced during the third and second trimesters, whereas the AST level showed only a minor variation between trimesters when compared to the first trimester pregnant women reported by Prakash S et al.[21]

There were 146 patients. After analysis the data, we identified that in our study usingPearson correlation coefficient test. r- value of SGPT is -0.01for HB, it shows stastically negative correlation. r- value of SGPT is +0.02 for RBC, it shows stastically positive correlation. r- value of SGPT is +0.12 for WBC, it shows stastically positive correlation. r- value of SGPT is +0.06 for Platelets, it shows stastically

positive correlation.

In this study, the mean haemoglobin concentration for pregnant women was 9.9±0.6g/dl. which was significantly higher.

In the first, second, and third trimesters, there is a statistically significant difference in haemoglobin concentration.

The total white cell count in pregnant women in the second and third trimesters was significantly higher. However, there was no statistically significant difference in total white cell count between pregnant women in their first trimester.

Platelet counts were significantly higher in female controls than in pregnant women. Platelet counts in pregnant women in the third trimester were lower in the study than in the second and first trimesters.[13]

Serum ALT activity increased significantly during the third trimester (8.63±4.26 IU/L) compared to the first trimester (12.86±6.27 IU/L).[17]

Conclusion

The present study had concluded that the in the current study, the determination of liver function tests, including liver enzymes, bilirubin in preeclampsia and eclampsia, was shown to be crucial criteria in the treatment of pregnancy and lowered risk of foetal morbidity and death in area in Lucknow region of India.

Age, gravidity, maternal follow-up (ANC) booking, education, and socioeconomic status were not related to the anaemic condition.

Serum bilirubin and the liver enzymes ALT and AST were shown to be elevated in preeclampsia patients.

During pregnancy, haematological markers Hb, RBCs, PLT exhibited alterations, with the majority of changes occurring as the trimester stages continue and an increase in TWBcs. When evaluated in accordance with gestational age.

SUMMARY

The liver is a vital organ that serves 500 various purposes in the human body. It plays a significant function in the metabolism and detoxification of several substances in addition to being the location of the formation of bilirubin, albumin, and clotting factors. Progesterone and other pregnancy hormones, such as oestrogen, affect the liver's metabolic and synthesis processes. Additionally affected the hepatobiliary secretion of bile and compounds dissolved in it, such as bilirubin, bile salts, and medications. Plasma volume rises by 40–50% from the non- gravid state during pregnancy, with the maximum Plasma values occurring in the second and third trimesters.[1]

Hemoglobin (Hb), Red blood cell (RBC) count, Hematocrit (PCV - packed cell volume), Mean Corpuscular volume (MCV), Mean Corpuscular haemoglobin (MCH), Mean corpuscular haemoglobin concentration (MCHC), Total Leucocyte count (TLC), Differential Leucocyte count (DLC), Platelet count, and Peripheral smear were the haematological parameters studied. The following parameters were calculated.

Abnormal level of liver enzymes only in 20 percent to 30 percent of patients of pregnancies with pre-eclampsia and eclampsia. In the current study, abnormal level of liver enzymes, i.e. SGPT(AST), SGPT(ALT), Due to changes in membrane permeability, vasoconstriction, and liver injury, abnormal liver enzymes may develop. In our study, among 146 patients, SGOT (AST) increased in 20%, SGPT (ALT) increasedin 21%, bilirubin increased in any 42%.

Limitations

- This was a single centred, hospital based, longitudinal study with small sample size (n=146). As a result, we cannot generalise our findings as there was no specific type of association found in our study.

- Demographical distribution also influences the Haemoglobin level.

- There were many confounding factors which could be excluded by considering large sample size from different regions so that specific association between Hematology with Liver enzyme can be detected among elderly population.

  .

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ANNEXURE

CONSENT FORM

I………………………age……. W/o,D/o…………………Address…………………………

……………………………………………………. agree to participate in the research work

Topic "ASSOCIATION OF LIVER FUNCTION TESTS WITH   HEMATOLOGICAL PARAMETERS IN PREGNANT WOMEN IN LUCKNOW"

 I have known the details of the research work very well and I give my consent for the same.

Date:

Signature/thumb impression of the patients: Name of research scholar

Signature/thumb impression of the witness: Signature of research scholar:

INFORMATION SHEET (FOR CASES)

I, Anil Kumar of Medical Physiology is a research scholar in IIMS&R.I

am associated with your treating doctor panel.

You are a newly diagnosed case of liver function test and hematological parameter.

For this study, I will take few drops of your blood sample for the estimation of haemoglobin level.

The blood will be used for estimation of haemoglobin level and not for any other purpose.

I will also measure your blood pressure with Sphygmomanometer.

You will be neither charged for any of the above test nor be paid.

Your identity will be kept confidential and information and result of your blood test will not be revealed to any other except you if you, so desire.

The result of this test may or may not be helpful for your treatment but may improve the knowledge and understanding of disease and the knowledge may be helpful in future.

After having the all above information would you like to participate in our study?   YES   NO

INTEGRAL INSTITUTE OF MEDICAL SCIENCE & RESEARCH,

INTEGRAL UNIVESITY, LUCKNOW

II CASE REPORT PERFORMA

Registration No/Date: OPD [   ]   IPD [   ]

Name (in capital):

Father Name/Husband's Name: [   ]

Mother Name: [   ]

Date of Birth:

Age:

Sex: Male [   ]   Female [   ]

Marital status:

Permanent Address:

Current Address:

Mobile no: [   ]

Category: GEN   OBC   SC   ST

Nationality

Mather Tongue:

Social/Economical Status: Annual income (approx.)

Educational level: Uneducated / Metric /Graduate / Postgraduate / Ph.D.

Vegetarian / Non-Vegetarian:

Physical Activity: Sedentary / Moderate / Active

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सूचना पत्र

1. मै अनिल कुमार आईआईएमएसआर लखनऊ में शोध विद्यार्थी हूँ

 2. इस परीक्षण के लिए ना ही शुल्क लिया अथवा दिया जायेगा .

3. इस दौरान आपके द्वारा दी गयी सारी जानकारी परीक्षण गोपनीय रखा जायेगा।

4. आप अगर चाहेंगे तो उसका परिणाम आपको बताया जायेगा।

5. आप इस अध्धन में अपनी स्वेच्छा से शामिल अथवा इंकार कर सकते हैं ।

6. इससे आपके इलाज पर कोई दुष्प्रभाव नहीं पड़ेगा ।

7. इस समस्त तत्व को समझते हुए क्या अध्धन में योगदान देने की सहमति प्रदान करते हैं   हां / नहीं ।

स्वीकृति / सहमति पत्र

मै ……………………………………………………उम्र ……………………पुत्र / पुत्री / पत्नी ……………………………
निवासी…………….

…………………………………………………………………………………………………

मुझे अध्ययन शीर्षक "गर्भवती महिलाओं में हेमेटोलॉजिकल पैरामीटर के साथ लिवर फंक्शन टेस्ट का सहसंबंध" अतः मै सूचित करता / करती हूँ एवं लिखित सहमति देता / देती हूँ , कि मेरे रक्त/पेशाब का नमूना केवल ऊपर कहे गये अध्ययन के लिय एकत्रित किया जाए ।

रोगी के हस्ताक्षर / अँगूठे के निशान   शोध छात्र के हस्ताक्षर

गवाह के हस्ताक्षर / अंगूठे के निशान

III   <u>DEMOGRAPHICS</u>

1. **Age:**   **years**

2. **Sex:**   **Male**   ☐   **Female**   ☐

3. **Religion:**

4. **Height:**   **Cm**

5. **Weight:**   **Kg**

6. **Body Mass Index (BMI):**   **kg/m^2**

7. **Waist Hip Ratio:**

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I.INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRIETRIA

1. Subject with anemia and hypertension. ☐ ☐

2. Age group between 65-95 years. ☐ ☐

EXCLUSION CRITERIA

1. Healthy subjects. ☐ ☐

2. Any serious medical condition other than anemia and hypertension. ☐ ☐ ☐

3. Drug addicts and alcoholic subjects. ☐ ☐

Subject is eligible for the study, if all **INCLUSION** criteria are **YES** and all **EXCLUSION** criteria are **NO**

INVESTIGATOR'STATEMENT

I have verified the data entered in the case report form and have determined that it is complete, accurate and compatible with the source documents.

_____   _____

Investigator's name   Investigator's signature   Date

II.   **WORKING PROFORMA**

1. Registration No.:   **Date**   **OPD** ☐   **IPD** ☐

2. Contact No:

3. Name: ☐   ☐   ☐   **Age**   **Sex**: a) Male   b) Female

4. Father 's Name:

5. Place of Residence: a) Urban   b) Rural

6. Address:

7. Marital status: a) Unmarried   b) Married c) Divorced   d) Widow

8. Education:

9. Occupation:

10. Diet: a) Vegetarian   b) Non-Vegetarian

11. Height:

12. Weight:

III.   <u>Family history</u>

1. Mother   ### 2. Father

a) Mother suffers from Thyroid Disorders: b) Father suffers from Thyroid Disorders.

Yes,   No   Unknown   **Yes,   No   Unknown**

3. No. of siblings: ☐

   How many of them suffering from Hypertension? ☐

IV.   **MEDICAL HISTORY**

1. Duration of Hypertension: ☐

	Yes	**No**
2. Hypertension complications:	☐	☐
3. Smoker/tobacco consumer:	☐	☐
4. Alcohol consumer:	☐	☐
5. Treatment:	☐	☐

 If yes, specify:

‒ Duration of treatment:

3. Patient complications; -	**Low**	**Fair**	**High**
	☐	☐	☐

INSTITUTIONAL ETHICS COMMITTEE (IEC)

IIMS&R INTEGRAL UNIVERSITY, LUCKNOW

IEC/IIMS&R/2022/27

CERTIFICATE

This is to certify that research work entitled **"Correlation of liver function tests with Hematological parameters in pregnant women"** submitted by **Anil Kumar, Dr.(Prof.)Khaleel Ahmad Manik, Dr.Meenakshi Srivasatava** for ethical approval before the Institutional Ethics Committee IIMS&R.

The above mentioned research work has been approved by Institutional Ethics Committee, IIMS&R with consensus in the meeting held on **19 May 2022**.

Dr.Deepak Chopra
(Jt.Member Secretary)
IRC/IEC
IIMS &R

Dr.Q.S.Ahmed
(Member Secretary)
IRC/IEC
IIMS &R

TO WHOM SO EVER CONCERNED

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INTRODUCTION

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