

Association Of Prothrombin Time, INR, Glycaemic Control, And Blood Cell Indices With Ultrasonographic Grades Of Fatty Liver Disease: A Prospective Observational Study In Eastern U.P.

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Abstract

Background: Fatty liver disease is increasingly associated with metabolic, haematological, and coagulation abnormalities.

Objective: To evaluate the association of Prothrombin Time (PT), International Normalized Ratio (INR), glycaemic indices (HbA1c), and haematological parameters with ultrasonographic grades of fatty liver disease.

Methods: This prospective observational study included 103 patients. Demographic data, haematological indices, coagulation profile, and glycaemic parameters were analyzed and correlated with fatty liver grading.

Results: Majority of patients were aged 51–66 years (35%) and males (65%). Grade 1 fatty liver was most common (71.8%). PT and INR showed variation across grades, with INR markedly elevated in Grade 3. Platelet count and TLC showed substantial variation, especially in advanced disease. HbA1c showed mild elevation across all grades.

Conclusion: Coagulation abnormalities, haematological indices, and glycaemic status demonstrate significant variation with fatty liver severity and may serve as useful clinical markers.

Keywords: Fatty liver, PT, INR, HbA1c, platelet count, TLC, Ultrasonography

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I. Introduction

Fatty liver disease, particularly non-alcoholic fatty liver disease (NAFLD), is a growing global health concern linked with metabolic syndrome, insulin resistance, and systemic inflammation [1]. Ultrasonography remains a widely used modality for grading fatty liver due to its accessibility and cost-effectiveness [2].

Liver dysfunction can alter coagulation pathways, leading to abnormalities in PT and INR [3]. Additionally, chronic inflammation and metabolic dysregulation influence haematological parameters such as haemoglobin, total leukocyte count (TLC), and platelet count [4].

Glycaemic control, assessed via HbA1c, is closely associated with hepatic steatosis and disease progression [5]. However, integrated evaluation of coagulation, haematological, and glycaemic parameters in relation to fatty liver grading remains underexplored.

II. Materials And Methods

Study Design and Setting

This study was designed as a hospital-based analytical, prospective, observational, and descriptive study conducted in the Departments of Gastroenterology, Biochemistry, and Radio diagnosis & Imaging at Sir Sunderlal Hospital, Institute of Medical Sciences, Banaras Hindu University (BHU), Varanasi.

Study Duration

The study was carried out over 02 years, during which patients meeting the eligibility criteria were consecutively enrolled.

Study Population and Sample Size

In the present analysis, 103 patients were evaluated from Eastern Uttar Pradesh. Patients of all Ultrasonography grades of fatty liver (Grade 1, Grade 2, and Grade 3) were included.

Fatty liver disease was diagnosed:

- ❖ Clinically, based on history and examination
- ❖ Radiologically, using Ultrasonography (USG) of the liver
- ❖ Biochemically, supported by lipid profile and liver function tests (LFTs)

Both alcoholic and non-alcoholic cases were initially considered, but only eligible patients fulfilling inclusion criteria were enrolled.

Inclusion Criteria

- ❖ Patients of either sex, aged 20–80 years
- ❖ Non-alcoholic patients
- ❖ Patients with Ultrasonography confirmation of fatty liver
- ❖ Patients with supportive lipid profile findings
- ❖ Patients with liver function test (LFT) confirmation

Exclusion Criteria

- ❖ Patients with conditions affecting lipid metabolism or liver status, including:
 - History of liver failure
 - History of liver cirrhosis
- ❖ Alcoholic patients

Data Collection

After obtaining informed consent, the following data were collected:

Demographic Data

- ❖ Age
- ❖ Sex

Laboratory Parameters

- ❖ Coagulation Profile:
 - Prothrombin Time (PT)
 - International Normalized Ratio (INR)
- ❖ Haematological Parameters:
 - Haemoglobin (Hb)
 - Total Leukocyte Count (TLC)
 - Differential Leukocyte Count (DLC)
 - Platelet Count
 - Mean Corpuscular Volume (MCV)
- ❖ Glycaemic Parameters:
 - Random Blood Sugar (RBS)
 - Glycated Haemoglobin (HbA1c)

Radiological Assessment

- ❖ Ultrasonography (USG) was used to grade fatty liver into:
 - Grade 1 (Mild)
 - Grade 2 (Moderate)

➤ Grade 3 (Severe)

Ethical Considerations

The study was conducted following approval from the Institutional Ethics Committee. An informed written consent was obtained from all participants.

- ❖ Consent forms were provided in both Hindi and English to ensure clear understanding.
- ❖ In cases where participants were unable to consent, consent was obtained from legally acceptable relatives.

Statistical Analysis

Data were entered and analyzed using appropriate statistical software (SPSS-24).

- ❖ Descriptive statistics were used to summarize demographic and clinical variables.
- ❖ Mean values of laboratory parameters were compared across different grades of fatty liver.
- ❖ Results were presented in the form of tables and charts.

III. Results

1. Demographic Characteristics: A total of 103 patients were included in the study.

Age Distribution

AGE GROUP	Frequency	Percent	Valid Percent	Cumulative Percent
Age 20-35 yrs	21	20.4	20.4	20.4
Age 36-50 yrs	32	31.1	31.1	51.5
Age 51-66 yrs	36	35.0	35.0	86.4
Age Above 66 yrs	14	13.6	13.6	100.0
Total	103	100.0	100.0	

The majority of patients belonged to the 51–66 years age group (35.0%), followed by:

- ❖ 36–50 years: 31.1%
- ❖ 20–35 years: 20.4%
- ❖ Above 66 years: 13.6%

This indicates a higher prevalence of fatty liver disease in the middle-aged and elderly population.

Sex Distribution

Sex	Frequency	Percent	Valid Percent	Cumulative Percent
Male	67	65.0	65.0	65.0
Female	36	35.0	35.0	100.0
Total	103	100.0	100.0	

- ❖ Males: 67 (65.0%)
- ❖ Females: 36 (35.0%)

A clear male predominance was observed.

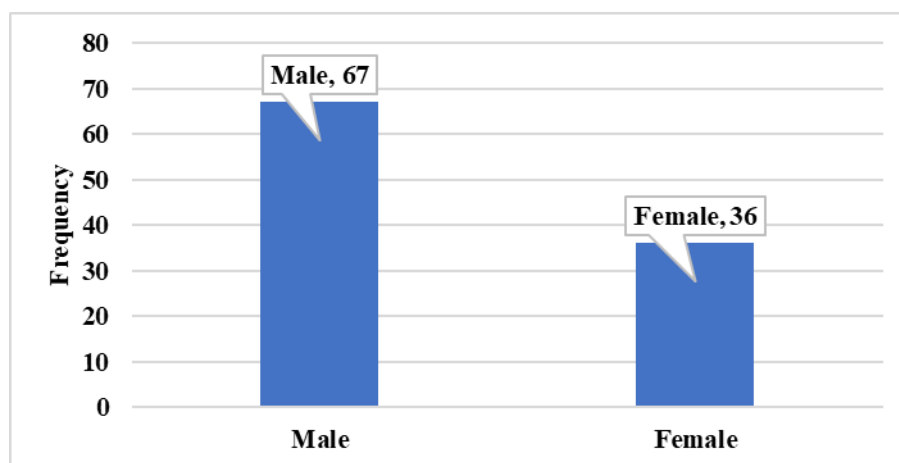


Fig: Bar diagram of Sex Distribution

The bar chart illustrates the sex-wise distribution of the study population. Out of a total of 103 patients, 67 (65%) were males and 36 (35%) were females, demonstrating a clear male predominance. This suggests that fatty liver disease was more commonly observed in males in the present study cohort.

2. Age and Sex Distribution

AGE GROUP	SEX	
	Male	Female
	Count	Count
Age 20-35 yrs	11	10
Age 36-50 yrs	25	7
Age 51-66 yrs	26	10
Age Above 66 yrs	5	9

- ❖ In the 20–35 years group, males (11) and females (10) were nearly equal.
 - ❖ In the 36–50 years group, males (25) significantly outnumbered females (7).
 - ❖ In the 51–66 years group, males (26) predominated over females (10).
 - ❖ In patients >66 years, females (9) were relatively more than males (5).
- Overall, male predominance was seen in middle age, whereas female proportion increased in older age groups.

3. Distribution of Fatty Liver Grades

FATTY LIVER GRADE			Total
Fatty Liver Grade 1	Fatty Liver Grade 2	Fatty Liver Grade 3	
17	4	0	21
19	8	5	32
26	8	2	36
12	1	1	14
74	21	8	103

- ❖ Grade 1: 74 patients (71.8%)
 - ❖ Grade 2: 21 patients (20.4%)
 - ❖ Grade 3: 8 patients (7.8%)
- Grade 1 fatty liver was the most common, while severe disease (Grade 3) was least frequent.

4. Age Group vs Fatty Liver Grade

AGE GROUP VS FATTY LIVER GRADE				
Cross tabulation				
AGE GROUP	FATTY LIVER GRADE			Total
	Fatty Liver Grade 1	Fatty Liver Grade 2	Fatty Liver Grade 3	
Age 20-35 yrs	17	4	0	21
Age 36-50 yrs	19	8	5	32
Age 51-66 yrs	26	8	2	36
Age Above 66 yrs	12	1	1	14
Total	74	21	8	103

- ❖ 20–35 years: Predominantly Grade 1 (17/21); no Grade 3 cases
 - ❖ 36–50 years: Higher proportion of advanced grades (Grade 2: 8; Grade 3: 5)
 - ❖ 51–66 years: Majority Grade 1 (26), with fewer Grade 2 (8) and Grade 3 (2)
 - ❖ >66 years: Predominantly Grade 1 (12), minimal higher grades
- Higher grades (Grade 2 and 3) were more frequent in the 36–50 years age group.

5. Age-wise Laboratory Parameters

Parameters	AGE GROUP			
	Age 20-35 yrs	Age 36-50 yrs	Age 51-66 yrs	Age Above 66 yrs
	Mean	Mean	Mean	Mean
PT	17	22	20	18
INR	1	3	2	1
Hb	11	9	9	10
Platelet	189	216	155	232
TLC	1446	1158	879	1927
DLC	68.1	73.8	68.5	71.1
MCV	117	89	84	82
Random	167.0	164.3	172.9	164.2
HbA1C	6	5	6	7

Coagulation Profile

- ❖ PT: Highest in 36–50 years (22 sec)
- ❖ INR: Highest in 36–50 years (3), lower in other groups

Haematological Parameters

- ❖ Hb: Lower in middle-aged groups (9 g/dL) compared to younger (11 g/dL) and elderly (10 g/dL)
- ❖ Platelet Count: Highest in >66 years (232), lowest in 51–66 years (155)
- ❖ TLC: Highest in >66 years (1927), lowest in 51–66 years (879)
- ❖ DLC: Relatively stable (~68–73%)
- ❖ MCV: Declined with age (117 in younger group to 82 in elderly)

Glycaemic Parameters

- ❖ Random Blood Sugar: Highest in 51–66 years (172.9 mg/dL)
- ❖ HbA1c: Highest in >66 years (7%), moderate in others (5–6%)

6. Fatty Liver Grade-wise Laboratory Parameters

Parameters	FATTY LIVER GRADE			p-value
	Fatty Liver Grade 1	Fatty Liver Grade 2	Fatty Liver Grade 3	
	Mean	Mean	Mean	
PT	19	21	19	0.393
INR	2	2	5	0.005
Hb	10	9	9	0.506
Platelet	163	167	518	0.731
TLC	766	345	7765	0.071
DLC	70.2	71.1	70.6	0.231
MCV	95	84	84	0.884
Random	172.5	145.3	185.5	0.011
HbA1C	6	5	6	0.026

Coagulation Profile

- ❖ PT: Comparable across grades (19, 21, and 19 sec); not statistically significant (p = 0.393)
- ❖ INR: Markedly elevated in Grade 3 (mean = 5); statistically significant (p = 0.005)

Haematological Parameters

- ❖ Hb: Slight decline across grades (10 → 9 g/dL); not significant (p = 0.506)
- ❖ Platelet Count: Markedly higher in Grade 3 (518), but not significant (p = 0.731)
- ❖ TLC: Substantially elevated in Grade 3 (7765); near significance (p = 0.071)
- ❖ DLC: Stable across grades; not significant (p = 0.231)
- ❖ MCV: No meaningful variation; not significant (p = 0.884)

These findings suggest a trend toward increased inflammatory response in severe fatty liver, though most haematological parameters did not reach statistical significance.

Glycaemic Parameters

- ❖ Random Blood Sugar: Highest in Grade 3 (185.5 mg/dL); statistically significant (p = 0.011)
- ❖ HbA1c: Slightly higher in Grade 1 and 3 (6%) compared to Grade 2 (5%); statistically significant (p = 0.026)

IV. Discussion

The present prospective observational study evaluated the association of coagulation parameters, haematological indices, and glycaemic markers with ultrasonographic grades of fatty liver disease. The findings demonstrate important clinical correlations, particularly with INR and glycaemic parameters, highlighting their potential role in disease stratification.

Demographic Profile

In this study, fatty liver disease was more prevalent in the middle-aged population (51–66 years), with a clear male predominance (65%). Similar demographic trends have been reported in previous studies, where NAFLD is more common in middle-aged males due to higher prevalence of metabolic risk factors such as obesity and insulin resistance [6,7]. The increasing proportion of females in older age groups observed in this study may be attributed to postmenopausal metabolic changes [8].

Fatty Liver Severity and Age

Higher grades of fatty liver (Grade 2 and 3) were more frequently observed in the 36–50 years age group, suggesting that disease progression may begin earlier in metabolically active individuals. This is consistent with previous reports indicating that fatty liver severity correlates with duration and severity of metabolic dysfunction [9].

Coagulation Parameters

The most significant finding of this study was the marked elevation of INR in Grade 3 fatty liver ($p = 0.005$), while PT remained statistically non-significant. This suggests that INR may be a more sensitive marker of hepatic synthetic dysfunction. Similar findings have been described in studies showing that worsening liver disease is associated with impaired coagulation factor synthesis, reflected by elevated INR levels [10,11].

Although PT did not show statistical significance, its mild variation across grades may still indicate early subclinical hepatic dysfunction, as reported in earlier literature [12].

Haematological Parameters

Haematological parameters showed variable trends:

- ❖ TLC demonstrated a marked rise in Grade 3, approaching statistical significance ($p = 0.071$), indicating a possible inflammatory response in advanced fatty liver. Chronic low-grade inflammation is a known hallmark of NAFLD progression [13].
- ❖ Platelet count was markedly elevated in Grade 3, although not statistically significant. This may represent reactive thrombocytosis due to systemic inflammation, as suggested in previous studies [14].
- ❖ Haemoglobin levels showed a mild decline with increasing severity, though not significant, which could be related to chronic disease or nutritional deficiencies [15].
- ❖ DLC and MCV remained relatively stable, suggesting limited utility in assessing fatty liver severity.

Overall, while most haematological parameters were not statistically significant, their trends support the role of inflammation and systemic involvement in advanced disease.

Glycaemic Parameters

Glycaemic indices showed significant associations with fatty liver severity:

- ❖ Random blood sugar ($p = 0.011$) and
- ❖ HbA1c ($p = 0.026$)

These findings are consistent with established evidence linking insulin resistance and poor glycaemic control with NAFLD progression [16,17]. HbA1c, as a marker of long-term glycaemic status, has been shown to correlate with hepatic steatosis and fibrosis [18].

The persistence of elevated glycaemic parameters across all grades further reinforces the concept that fatty liver disease is a metabolic disorder with systemic implications.

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