A STUDY TO ASSESS OCCURRENCE OF NON ALCOHOLIC FATTY LIVER DISEASE AND LIVER FIBROSIS IN TYPE 2 DIABETES MELLITUS PATIENTS AND THE ASSOCIATED FACTORS

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Abstract
Background: This study aimed to evaluate the burden of NAFLD and severe fibrosis among DM population.
Methods: It was a hospital based observational and cross-sectional study. Upgraded department of General Medicine, SMS MedicalCollege and Attached Hospitals, (Jaipur).
Results: Out of 100 patients 48 patients did not have NAFLD while 52 patients had NAFLD. Thus proportion of NAFLD in diabetic patients was quite high (52%). Out of 52 NAFLD patients 27 patients (51.9%) had mild liver fibrosis, 14 patients (26.9%) had significant fibrosis and 11 patients (21.2%) had severe liver fibrosis. Thus proportion of NAFLD patients with significant and severe fibrosis was quite high (26.9% and 21.2% respectively).
Conclusion: From the study it can be concluded that the prevalence of NAFLD in adult patients with type 2 diabetes mellitus in department of medicine at S. M. S. Hospital, Jaipur is 52% and moderate and severe fibrosis is found in 26.9% and 21.2% patients respectively among them. BMI and the waist circumference are the factors in our study that have shown association with the incidence of NAFLD in type 2 DM patients.
Keywords: DM, NAFLD, BMI.

Introduction:
Paralleling the increasing prevalence of obesity, diabetes mellitus, and the metabolic syndrome in the general population, NAFLD has become the most common cause of chronic liver disease worldwide.1 NAFLD indicates the presence of fatty infiltration of the liver, defined as fat exceeding 5-10% of weight and frequently taken as >5-10% macrosteatotic hepatocytes.2 With India being the “Diabetes capital of the world”, nonalcoholic fatty liver disease (NAFLD) is becoming one of the most common causes of liver dysfunction in the country also.3 It covers a wide spectrum, ranging from simple steatosis, which is generally non-progressive, to nonalcoholic steatohepatitis (NASH), that can progress to cirrhosis, liver failure, and hepatocellular carcinoma.4 Ultimately about 10%-29% of NAFLD patients will eventually develop risk of cirrhosis in 10 years; while 4%-27% of them will lead to hepatocellular carcinoma.5 NASH is the active form of NAFLD, characterized by histological lobular inflammation and hepatocyte ballooning and is associated with faster fibrosis progression.

Data about the severity of fibrosis stage in diabetic population is scarce and Lack of data may lead to the lack of awareness among medical workers on the urgency of NAFLD triage in DM population. Therefore, this study aimed to evaluate the burden of NAFLD and severe fibrosis among DM population.

MATERIALS AND METHOD

- **Study Design:** It was a hospital based observational and cross-sectional study.
- **Study Location:** Upgraded department of General Medicine, SMS Medical College and Attached Hospitals, (Jaipur).
- **Study Duration:** July 2018 to September 2019
- **Sample Size:** 100

Sample size calculated 100 cases as per reference article having prevalence of NAFLD 45.2% and severe liver fibrosis 25% among them in T2DM patients with 80% power and 0.05 alpha error and 10% absolute error.

INCLUSION CRITERIA:
1. Pt. above 18 years of age
2. Type 2 DM diagnosed using the ADA 2018 criteria
   - Symptoms of diabetes plus random blood glucose concentration ≥200mg/dl or
   - Fasting plasma glucose (FBS) ≥ 126 mg/dl or
   - Glycated Hb (HbA1c) ≥ 6.5% or
   - 2h-plasma glucose ≥200mg/dl during an oral glucose
tolerance test

**EXCLUSION CRITERIA:**

1. Type 1 diabetics
2. Alcoholic liver disease
3. Patients positive for acute and chronic viral hepatitis
4. Any previous history of liver disease
5. Any previous use of hepatotoxic drugs
6. Autoimmune liver diseases
7. Hereditary liver diseases like Wilson disease, hemochromatosis etc.
8. Glycogen storage diseases
9. Pregnancy
10. Not given written consent

**METHODOLOGY**

Patients were made to understand in their local language and informed consent was obtained before collecting data and subjecting to investigations after applying inclusion and exclusion criteria. Patients who had given their informed consent went through history taking and physical examination to collect data of age, sex, duration of DM, other comorbidities, treatment history, height, weight, waist circumference etc.

**STATISTICAL ANALYSIS**

Data entry was done using MS Excel 2013. IBM SPSS Version 22.0 was used for statistical analysis. Descriptive statistics was used for clinical, demographic and lab data. Chi square test and Fisher exact test were used for finding statistically significant difference in proportions. P value < 0.05 was considered to be statistically significant.

**RESULTS**

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<td><strong>Subject’s characteristics</strong></td>
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<td>Sex</td>
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<td>Duration of Diabetes (yr)</td>
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Out of 100 patients 10 patients were of <40 years of age and 90 patients were ≥40 years of age. So most of the patients (90%) were of age above 40 years. Mean age of patients was 54.6±11.03 years. Out of 100 patients 51 patients were male and 49 patients were female. So male to female ratio was relatively balanced in this study. Out of 100 patients 28 patients were of <5 years of duration of diabetes and 72 patients were of >5 years of duration of diabetes. Mean duration of diabetes was 8.2±5.83 years. So most of the patients (72%) were of ≥5 years of duration of diabetes. Out of 100 patients 24 patients had HbA1c level of <7% and 76 patients had HbA1c level of ≥7%. Mean HbA1c was 9.12±2.68. So most of the patients (76%) had HbA1c of ≥7%. Out of 100 patients 46 patients had normal BMI and 54 patients had high BMI. Mean BMI of study subjects was 25.4±3.76. Hence ratio of patients with normal and high BMI was relatively balanced in this study. Above table depicts that out of 100 patients 48 patients did not have NAFLD while 52 patients had NAFLD. Thus proportion of NAFLD in diabetic patients was quite high (52%).

Above table depicts that out of 52 NAFLD patients 27 patients (51.9%) had mild liver fibrosis, 14 patients (26.9%) had significant fibrosis and 11 patients (21.2%) had severe liver fibrosis. Thus proportion of NAFLD patients with significant and severe fibrosis was quite high (26.9% and 21.2% respectively).

**DISCUSSION**

In present study we recruited 100 patients with T2 diabetes mellitus. Most of the patients (90%) were of more than 40 years of age with mean age of 54.62 years. Male to female ratio was relatively balanced with 51 male and 49 female patients. 72% patients were suffering from diabetes for more than 5 years and 76% patients had HbA1c level of more than 7%. 54 patients were in high BMI category and 76% patients were found obese. Lipid profile was abnormal in most of the patients so most patients were under metabolic syndrome criteria. Only few patients had abnormal liver function tests in form of SGOT, SGPT and serum albumin levels and only 14% patients had abnormal platelet count. So patients characteristics in our study were largely comparable to the study done by Prasetya IB et al.

In our study 52 patients, who were having NAFLD underwent transient elastography to assess degree of liver fibrosis. Out of 52 patients 27 patients (51.9%) had mild fibrosis, 14 patients (26.9%) had moderate or significant fibrosis and 11 (21.2%) patients had severe fibrosis. These results are consistent with the results of Prasetya IB et al study in which they found that 25% of patients of diabetes with NAFLD had severe fibrosis. In contrast our results are higher than result of a study conducted in Sudan showing that severe fibrosis only found in 14.3% of the diabetes mellitus population with NAFLD. However, study to examine the degree of fibrosis in patients with NAFLD is still considered rare. The available studies are mostly conducted in general population; therefore, result of our study is one of few data that assess the degree of fibrosis performed in Type 2 DM patients. However in our study we have not found any factor associated with degree of fibrosis in diabetes mellitus patients with NAFLD.

So in view of the high prevalence of NAFLD and severe liver fibrosis among T2DM patients early screening by non invasive methods such as fibroscan is warranted in this population so their grave complications could be prevented or managed on time. It is need of the hour to create awareness about this less known complication of diabetes along with other complications. Further patients should be counselled about risk factors such as high BMI and...
increased waist circumference those are associated with high incidence of NAFLD so that patients can change their habits and lifestyle accordingly and lead a better life ahead.

CONCLUSION
From the study it can be concluded that the prevalence of NAFLD in adult patients with type 2 diabetes mellitus in department of medicine at S. M. S. Hospital, Jaipur is 52% and moderate and severe fibrosis is found in 26.9% and 21.2% patients respectively among them. BMI and the waist circumference are the factors in our study that have shown association with the incidence of NAFLD in type 2 DM patients.

REFERENCES