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Role of Fibroscan in Metabolic Syndrome

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Abstract

Background and objectives : Metabolic syndrome patients have a high chance of developing nonalcoholic fatty liver disease. The purpose of this study is to determine liver stiffness in patients of metabolic syndrome with the help of fibroscan.

Methods: It is a cross-sectional descriptive study of liver function (morphological and physiological changes) with the help of fibroscan in patients of metabolic syndrome, conducted on 47 patients. After a detailed history, patients of age ≥20 years and fulfilling criteria of metabolic syndrome according to the New International Diabetes Federation (IDF) were included in the study. Morning fasting venous blood samples were collected and assessed for the haematological and biochemical profile. All patients were subjected to ultrasonography of abdomen and fibroscan.

Results: In 47 patients 31 (66%) had FMSS (Fibroscan Median Stiffness Score) equal or less than 7 kPa, while 16 (34 %) had FMSS more than 7 kPa.Age of patients in which FMSS more than 7kPawas 66.69±12.6 years significantly older than FMSS equal to or less than 7 kPa was 58.39 ± 11.22 years (p value=0.026). Waist circumference and hip circumference were not different in both groups but the waist/hip ratio was significantly higher in the group which FMSS more than 7kPa, 1.07± 0.76 vs 1 in the group which FMSS equal to or less than 7kP (p value =0.002).

Interpretation &Conclusion: Metabolic syndrome patients have high prevalence of NAFLD and advanced fibrosis. Higher age is associated with high FMSS (Fibroscan Median Stiffness Score). High waist-hip ratio instead of waist circumference was significantly correlated with high FMSS.

Keywords: Metabolic syndrome; New International Diabetes Federation (IDF); Nonalcoholic fatty liver disease

Introduction

Metabolic syndrome is also called syndrome X or insulin resistance syndrome or dysmetabolic syndrome, obesity dyslipidemia syndrome [(1)] Obesity particularly abdominal obesity leads the development of insulin resistance. Insulin resistance leads to impaired glucose and fatty acid utilization, eventually to the development of diabetes mellitus and dyslipidemia.

Criteria For Metabolic Syndrome

According to the definition by the new IDF panel, the diagnostic criteria for the metabolic syndrome[(2)] include central obesity: waist circumference ≥ 90 cm (male), ≥ 80 cm (female) for South Asians with any two of the following four factors-

Dyslipidemia: TG ≥ 1.7 mmol/L (150 mg/dl), dyslipidemia: HDL-C < 40 mg/dL (male), < 50 mg/dL (female), blood pressure ≥ 130/85 mmHg

(or treated for hypertension), fasting plasma glucose ≥ 5.6 mmol/L (100 mg/dl) or previously diagnosed Type 2 diabetes.

Metabolic syndrome patients have a high chance of developing, the major hepatic disorder is nonalcoholic fatty liver disease (NAFLD). NAFLD is the common cause of chronic liver disease.;Presently, it is anticipated that the global prevalence of NAFLD is approximately 25%,to 30% observed[3].

NAFLD is characterized by triglyceride accumulation and a variable degree of hepatic injury, inflammation, and repair. In the presence of significant hepatocellular injury and inflammation, the picture is defined 'nonalcoholic steatohepatitis' (NASH), which has the potential to progress to advanced fibrosis and cirrhosis**.** So NAFLD further increases the risk of end stage liver disease and hepatocellular carcinoma (HCC). The presence of the metabolic syndrome increased the probability of histologically confirmed NASH by 40% in NASH clinical research network data[4]. In the National health and nutrition examination survey database ,metabolic syndrome is independently associated with increased overall mortality among NAFLD patients[5].

Indians have a high prevalence of insulin resistance with metabolic syndrome, which has been contributed to NAFLD, about one third of urban Indians have NAFLD.[6-8]

Fibroscan is a non-invasive device that assesses the 'hardness' (or stiffness) of the liver via the technique of transient elastography. (T.E.)It works on the principle of shear wave velocity. Shear wave velocity is determined by measuring the time the vibration wave (shear wave) takes to travel to a particular depth inside the liver.[9]Fibroscan is principally used to estimate the degree of liver scarring present (ie. stage of liver disease). This is very useful in the assessment of patients with chronic liver disease, including chronic hepatitis C, chronic hepatitis B, chronic alcohol abuse, and fatty liver. The concept is that as more fibrosis and scarring occur, the higher the liver stiffness reading will be. This reading may be used to estimate the existing degree of liver damage, monitor disease progression or regression via serial measurements, guide prognosis and further management, including treatment.

Interpretation Of Result

Fibro Scan results range from 2.5 kPa to 75 kPa. Between 90–95% of healthy people without liver disease will have a liver scarring measurement <7.0 kPa (median is 5.3 kPa). Liver biopsy as the 'gold standard' for assessing liver scarring, has indicated the optimal cut-off for the detection of cirrhosis is around 14 kPa. A patient with chronic hepatitis C and a liver stiffness >14 kPa has approximately a 90% probability of having cirrhosis, while patients with liver stiffness >7 kPa have around an 85% probability of at least significant fibrosis.[10,11] The interpretation of the readings may vary to some degree depending on the liver disease etiology. Therefore, interpretation of the results is best performed in conjunction with other clinical and/or biochemical parameters, and ideally by someone experienced in managing chronic liver disease. A 5-point scale is used in grading the degree of liver fibrosis: F0= no fibrosis, F1= minimal fibrosis, F2= fibrosis has occurred and spread inside the areas of the liver including blood vessels, F3= fibrosis is spreading and connecting to other liver areas that contain fibrosis, F4= cirrhosis or advance liver fibrosis

Material & Methods

Design

It was a cross sectional descriptive study of liver function (morphological and physiological changes) with the help of fibroscan in patients of metabolic syndrome. The study was approved by the institutional ethics committee (F1/Acad/MC/JU/17/1496 dated-23/1/2017)

Source Of Data

Patient visiting OPD or admitted at Dr. S.N. medical college's affiliated hospitals, Jodhpur, Rajasthan.

Sample Size: 47 cases

Duration of study: 12 months (December 2016 to December 2017)

Inclusion criteria include age of ≥20 years and all patients fulfilling criteria of metabolic syndrome according to new IDF panel, the diagnostic criteria for the metabolic syndromeinclude central obesity: waist circumference ≥ 90 cm (male), ≥ 80 cm (female) for South Asians with any two of the following four factors-dyslipidemia: TG ≥ 1.7 mmol/L (150 mg/dl), dyslipidemia: HDL-C < 40 mg/dL (male), < 50 mg/dL (female), blood

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pressure ≥ 130/85 mmHg (or treated for hypertension), fasting plasma glucose ≥ 5.6 mmol/L (100 mg/dl) or on medication for diabetes.

Patients who areconsuming significant alcohol intake[12], patients with positive viral markers (egHBsAg, HCV), clinical possibility of other types of liver disease in the patients, (confirmed by appropriate investigations), pregnancy or breast feeding were excluded.

Methodology:-

Patients of metabolic syndrome as per New International Diabetes Federation (IDF) criteria will be included in study. An informed consent will be taken from all participants. They will be requested to undergo a medical interviews, physical examinations, and laboratory investigations. A record questionnaire of waist circumference, waist- hip ratio, and body mass index were recorded to all selected patients Morning fasting venous blood samples were collected and assessed for the haematological and biochemical profile. All patients were subjected to ultrasonography of abdomen and fibroscan.

Statistics Analysis –

IBM SPSS Statistics 27 was used for statistical analyses. Shapiro–Wilk test was used to assess the normality of quantitative variables. Chi-Square and Fisher exact tests were used for categorical variables. Student's t-test for independent samples and Mann–Whitney U test were used to compare variables with and without normal distribution, respectively in two groups. Data are presented as n (%), mean ± SD or median (quartile [q] 25–q75). P value of <0.05 was considered statistically significant.

Results-

The present study included 47 patients who fulfilled inclusion criteria and attended the outpatient department, at Mahatma Gandhi Hospital, attached to Dr. S.N. Medical College, Jodhpur. The data obtained from these cases formed the basis of our study.

Baseline Data-

Baseline characteristics of metabolic syndrome patients were shown in table 1(a, b). Out of 47 patients, 19 (40%) were male, and 28 patients (60%) were female. The mean age of study participants was 61.21 ±12.25 years. The mean BMI of study group was 28.76± 6.46 kg/m.^{2} The mean waist circumference and hip circumference were 104.27±10.8 cm, 100± 9 cm respectively. The mean waist/hip ratio was 1.04±0.09. The mean systolic blood pressure was 141.66 ±16.76 mm Hg, mean diastolic blood pressure was 87.77 ±7.7 mm Hg. The mean Fasting Blood Sugar was 171.81±63.34 mg/dl. The mean serum cholesterol was 183±49.38 mg/dl. The mean serum LDL cholesterol was 115.36±46.64 mg/dl. Serum albumin of study participants was 4(3-4) gm/dl. Total bilirubin of the study group was 1(0.97-1) mg/dl; direct and indirect serum bilirubin of the study group was 1(0.97-1) mg/dl , 0.30(0-0.5) mg/dl respectively. Mean Fibroscan Median Stiffness Score (FMSS) was 8.5 ± 6.8 kPa.

As New International Diabetes Federation (IDF) criteria in addition to waist circumference, out of 4, there is minimum 2 criteria are necessary for diagnosing metabolic syndrome. Table 2 showed that all (100%) fulfilled New International Diabetes Federation (IDF) criteria for plasma glucose. Out of 53 patients, 44 (93.16%) fulfilled IDF criteria for blood pressure, 23 (48.9%) fulfilled IDF criteria for serum triglycerides, and 41 (87.2%) fulfilled IDF criteria of metabolic syndrome for high-density lipoprotein.

Metabolic Syndrome Patients And Fibroscan Median Stiffness Score (FMSS)-

Metabolic syndrome patients were further divided into two groups based on Fibroscan Median Stiffness Score (FMSS), as FMSS equal to or less than 7 kPa is normal, more than 7 is elevated. Out of 47 patients, 31 (66%) had FMSS equal to or less than 7 kPa while 16 patients (34%) had FMSS more than 7 kPa (Table 3).

Comparison of variables in patients of metabolic syndrome with fibroscan median stiffness value-

Comparison of variables in patients of metabolic syndrome with fibroscan median stiffness value equal to or less than 7kPa and more than 7 kPa was shown in Table 4 (a,b). Age of patients in which FMSS more than 7kPawas 66.69±12.6 years significantly older than FMSS equal to or less than 7 kPa was 58.39 ± 11.22 years (p value=0.026). Waist circumference and hip circumference was not different in both groups (p value >0.05) but waist/hip

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ratio was significantly higher in group which FMSS more than 7kPa, 1.07± 0.76 vs 1 in group which FMSS equal to less than 7kPa (p value =0.002). Total cholesterol, VLDL, and triglyceride were not different in both groups (p value >0.05) but LDL cholesterol was significantly lower in group which FMSS more than 7kPa, 95.38±40.71 mg/dl vs 125.68±46.7 mg/dl in group which FMSS equal to or less than 7kPa (p value=0.033).

Serum albuminwas significantly lower in the group which FMSS more than 7kPa, 3.1(2.9-3.75) gm/dl while 4 (3-4) gm/dl in the group which FMSS equal to or less than 7kPa(p value=0.00). Total bilirubin was 1(1-1) mg/dl in the group which FMSS equal to or less than 7kPa not different from 0.91 mg/dl (0.6-1.38) in group which FMSS more than 7kPa (p value = 0.117) but direct and indirect bilirubin significantly higher in the group which FMSS more than 7 kPa than in group which FMSS equal to or less than 7kPa (p value < 0.05). SGOT, SGPT, PT/INR, haemoglobin, and platelet was not different in both groups (p value >0.05)

FMSS and U.S.G. finding

Out of 47 cases 13 (27.6%) had U.S.G showed normal in which 9 (69.2%) cases had FMSS score was equal to or less than 7 and 6(30.8%) cases had FMSS score was greater than 7. Out of 47 cases 22 (46.8%) had U.S.G. showed hepatomegaly with grade I fatty liver in whom 16 (72.7%) cases had FMSS score was equal to or less than 7 and 6(27.3%) cases had FMSS score was greater than 7.

Out of 47 cases 8 (17%) had U.S.G. showed hepatomegaly with grade II fatty liver in whom 6 (75%) cases had FMSS was equal to or less than 7 and 2(25%) cases had FMSS was greater than 7. Out of 47 cases 1 (2.12%) had U.S.G. showed hepatomegaly with grade III fatty liver, in which FMSS was greater than 7. Out of 47 cases 2(4.2%) had U.S.G. showed hepatomegaly with altered echotexture/ C.L.D in which FMSS was greater than 7.

Discussion-

Insulin resistance is the main pathogenic factor of non-alcoholic fatty liver with metabolic syndrome. Obesity, type 2 diabetes mellitus, dyslipidemia, and hypertension contribute to risk for liver disease and its progression. Multiple metabolic abnormalities are associated with the severity of the liver disease. Patients have a high risk for cardiovascular morbidity and mortality, mediated by early atherosclerosis. This evidence has precise therapeutic implications: only a behavioural approach to lifestyle correction will address all alterations characterizing the metabolic syndrome, including metabolic liver disease. [13]

In the present study out of 47 patients, 31 (66%) had FMSS equal to or less than 7 kPa while 16 patients (34%) had FMSS more than 7kPa. Mean FMSS was 8.5 ± 6.8.kPa.This is similar to a study done by Hajiani E et al[14] who found a mean FMSS of 8.32 ± 3.29 kPa in diabetic patients with nonalcoholic fatty liver disease.

Age was significantly higher in the group in which FMSS more than 7kPa than FMSS equal to or less than 7 kPa, so higher age is associated with more chances of NAFLD.

Waist circumference and hip circumference was not different in both groups FMSS equal to or less than 7 kPa and FMSS more than 7kPa but waist/hip ratio was significantly higher in group which FMSS more than 7 group which FMSS equal to or less than 7kPa, tell the importance of waist/ hip ratio in NAFLD, as high waist/hip ratio is associated with high chances of liver fibrosis.

A study done in China by Zheng et al[15]also showed waist hip ratio is closely related to the occurrence of NAFLD. Another study done in Sweden by Andreasson et al[16] waist hip ratio and other measures of body composition reflecting visceral adiposity were superior to BMI in predicting the risk for future severe liver disease in both men and women.

FMSS did not correlate with systolic, diastolic blood pressure, and plasma blood sugar.

Serum albuminwas significantly lower in group which FMSS more than 7kPathan FMSS equal to or less than 7 kPa. Total bilirubin was not different in both groups but direct and indirect bilirubin were significantly higher in group which FMSS more than 7kPa than in group which FMSS equal to or less than 7kPa. SGOT, SGPT, PT/INR, haemoglobin, and platelet were not different in both groups. So low albumin, high direct and indirect bilirubin are associated with higher fibrosis.

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Fatty liver on U.S.G does not always indicate true liver fibrosis**.**

Strength – It is the first Indian study in metabolic syndrome patients with the use of fibroscan to assess severity of liver fibrosis.

This study has a few limitations which include; the study number is small and needs a larger data set to confirm our results. Ideally, normal control population should also be included for comparison.

Interpretation &Conclusion-

Metabolic syndrome patients have high prevalence of NAFLD and advanced fibrosis. Higher age is associated with high FMSS (Fibroscan Median Stiffness Score). High waist/hip ratio instead of waist circumference was significantly correlated with high FMSS (fibroscan median stiffness score). Lower serum albumin, high direct and indirect serum bilirubin was significantly associated with high FMSS.

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Table 1a: Base line characteristics of metabolic syndrome patients

Variable	Total (47)
Age (years)	61.21±12.25
Weight (kg)	71.34±10.72
Height (cm)	156.48±8.5
BMI (kg/m^2)	28.76±6.46
Waist circumference (cm)	104.27±10.8
Hip circumference (cm)	100±9
Waist/hip ratio	1.04±0.09
Systolic Blood pressure. (mm/Hg)	141.66±16.76
Diastolic Blood pressure (mmHg)	87.7±7.7
Fasting Blood Sugar (mg/dl)	171.81±63.34
Post-prandial Blood Sugar (mg/dl)	223.3±76.4
Serum Creatinine	1.57±1.72
Serum cholesterol (mg/dl)	183±49.38
S. VLDL (mg/dl)	30.17±12.2
S. LDL (mg/dl)	115.36±46.64
Serum Triglycerides. (mg/dl)	181.87(107-186)
Serum High density lipoprotein (mg/dl)	35(33-38)`
Serum albumin (g/dl)	4(3-4)
PT	14.1±2.17
INR	1.15±1
Total bilirubin(mg/dl)	1(0.97-1)
Direct .bilirubin (mg/dl)	0.13(0-0.76)
Indirect bilirubin (mg/dl)	0.30(0-0.5)
S.G.O.T ((I.U/ml)	31(27-44)
S.G.P.T(I.U/ml)	23(19-33)
Hb (g/dl)	11.66±1.9

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Table 1b: Base line characteristics of metabolic syndrome patients

Variable	Total (47)
Platelet (lakh)	2.57±1.1
Fibroscan median stiffness value	8.5 ± 6.8

Table 2: Variables of metabolic syndrome that fulfil New International Diabetes Federation (IDF) Criteria other than central obesity -

Metabolic syndrome parameter	N = 47	Percent
Fasting plasma glucose ≥ 5.6 mmol/L (100 mg/dl) or on medication for diabetes	47	100%
Blood pressure ≥ 130/85 mmHg (or treated for hypertension)	44	93.16%
Serum triglycerides (mg/dl) ≥ 1.7 mmol/L (150 mg/dl)	23	48.9%
Serum high density lipoprotein (mg/dl) < 40 mg/dL (male), < 50 mg/dL (female)	41	87.2%

Table 3: Distribution of cases according to fibroscan median stiffness score (FMSS)

FMSS (kPa)	N	Percent
≤ 7	31	66
> 7	16	34
Total	47	100.0

Table 4 a : Comparison of variables in patients of metabolic syndrome with fibroscan median stiffness value-

Variable	**Fibroscan median stiffness(kPa) ≤7 (n=31)**	**Fibroscan median stiffness (kPa) >7 (n=16)**	**P value**
Age	58.39 ± 11.22	66.69±12.6	0.026
Weight (kg)	70.87 ±9.7	72.25±12.7	0.681
Height (cm)	157.61±8.1	154.25 ±9	0.203

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BMI	27.77±6.2	30.7±6.6	0.142
Waist circumference (cm)	102.45±10.40	107.7±10.98	0.109
Hip circumference (cm)	100.16 ±7	99.69±12.28	0.888
Waist/hip ratio	1±0.0	1.07±0.76	0.002
Systolic Blood pressure. (mm/Hg)	140(130-150)	140(140-147.5)	0.821
Diastolic Blood pressure (mmHg)	90 (88-90)	90 (81.5-90)	0.447
Fasting Blood Sugar (mg/dl)	176 ± 65.5	163.69±60.13	0.534
Post-prandial Blood Sugar (mg/dl)	221.6±83	223.5±64.3	0.939
Serum Creatinine	1.48±1.63	1.96±1.8	0.361
Serum cholesterol	192.81±52.14	164±38.15	0.057
S. VLDL	31.87±11.54	26.88±13.1	0.187
S. LDL	125.68±46.7	95.38±40.71	0.033
Serum Triglycerides. (mg/dl)	162(111-217)	134(88.2-154.7)	0.119
Serum High density lipoprotein (mg/dl)	34(32-39)	35.5(34-38)	0..603
Serum Albumin	4 (3-4)	3.1(2.9-3.75)	0.000
PT	14.3±2.25	13.8±1.9	0.413
INR	1.06±0.249	1.13±0.22	0.359

Table 4 b : Comparison of variables in patients of metabolic syndrome with fibroscan median stiffness value-

Variable	**Fibroscan median stiffness(kPa) ≤7 (n=31)**	**Fibroscan median stiffness (kPa) >7 (n=16)**	**P value**
T.bilirubin(mg/dl)	1(1-1)	0.91(0.6-1.38)	0.117
D .bilirubin (mg/dl)	0.0(0.0-1)	0.44(0.24-0.74)	0.001
I .bilirubin (mg/dl)	0(0-0)	0.38(0.27-0.6)	0.000
S.G.O.T ((I.U/ml)	31(28-41)	35(23-72.25)	0.582
S.G.P.T(I.U/ml)	23(17-32)	24.5(20.2-64.5)	0.200
Hb (g/dl)	11.66±1.9	12±1.72	0.073
Platelet (lakh)	2.52±0.811	2.67±1.52	0.713

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