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The Impact of Ramadan Fasting on Fatty Liver Disease Severity: A Retrospective Case Control Study from Israel

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is emerging as an important public health condition. The effect of Ramadan fasting on several metabolic conditions has been previously assessed.

Objectives: To assess the impact of Ramadan fasting on non-alcoholic steatohepatitis (NASH) severity scores.

Methods: A retrospective, case control study was conducted in Nazareth Hospital between 2017 and 2019. We included NAFLD patients who had been diagnosed by abdominal ultrasonography. The study population was divided in two matched groups: NASH subjects who fasted all of Ramadan and NAFLD/NASH subjects who did not fast (control). Metabolic/NASH severity scores, homeostatic model assessment of β -cell function and insulin resistance (HOMA-IR), NAFLD Fibrosis Score (NFS), BARD scores, and fibrosis-4 (FIB4) scores were assessed in both groups before and after the Ramadan month.

Results: The study included 155 NASH subjects, 74 who fasted and 81 who did not. Among the fasting group, body mass index decreased from 36.7 ± 7.1 to 34.5 ± 6.8 after fasting (P < 0.003), NFS declined from 0.45 ± 0.25 to 0.23 ± 0.21 (P < 0.005), BARD scores declined from 2.3 ± 0.98 to 1.6 ± 1.01 (P < 0.005), and FIB4 scores declined from 1.93 ± 0.76 to 1.34 ± 0.871 (P < 0.005). C-reactive protein decreased from 14.2 ± 7.1 to 7.18 ± 6.45 (P < 0.005). Moreover, HOMA-IR improved from 2.92 ± 1.22 to 2.15 ± 1.13 (P < 0.005).

Conclusions: Ramadan fasting improved on inflammatory markers, insulin sensitivity, and noninvasive measures for NASH severity assessment.

IMAJ 2021; 23: 94-98

KEY WORDS: fatty liver, liver enzymes, metabolic syndrome, Ramadan fasting

Non-alcoholic fatty liver disease (NAFLD) is emerging as an important public health abnormality [1,2]. NAFLD spectrum ranges from simple hepatic steatosis to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, and hepatocellular carcinoma (HCC). NAFLD is recognized as a common origin of incidental elevated liver enzymes in hepatology practice [3].

The prevalence of NASH in Europe and the United States has increased in the recent years reaching 14–20% of the population; this increase in the prevalence is directly related to the obesity epidemic seen in these populations [4]. Treatment of NASH continues to be challenging for physicians as there is no approved effective pharmacotherapy for this disorder and lifestyle modification remains the mainstay of therapy for these patients [5]. Weight loss and nutritional and caloric restrictions play crucial role in the management of NAFLD/NASH patients [6,7].

Islam is one of the three Abrahamic monotheistic religions, together with Judaism and Christianity. Moslems constitute the second largest religious group universally, accounting for approximately a quarter of the entire global population. Fasting during the month of Ramadan, the ninth month of the Islamic calendar, is one of the five pillars of the religion's principles. Religious adherents abstain from eating, drinking, and smoking, as well as from sexual intercourse, from sunrise until sunset. Smoking is forbidden during the fasting periods of Ramadan. Studies have shown a significant reduction in smoking in public places that might be related to mortality and morbidity.

During the month of Ramadan, Muslims consume only two major meals, one shortly before dawn and the other immediately after sunset The Ramadan fasting is one type of fasting strategy. Others include periodic fasting for weight loss, caloric restriction, energy restriction or energy balance, dietary restriction, or food manipulation. However, it should be noted that the Ramadan fasting represents a unique form of fasting in that it consists of alternate abstinence and time-restricted feasting (re-feeding) periods.

Many studies have focused on the effect of Ramadan fasting on metabolic changes and health outcomes in different groups of Muslim populations. Studies reported that total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), and blood glucose levels have improved after Ramadan among athletes [8-11]. Focused studies have assessed the impact of Ramadan fasting on different aspects of human metabolism and health such as the immune system, hormones secretion, and gestation [12-14].

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The effect of Ramadan fasting on several gastrointestinal conditions has been reported in studies that address the impact the custom has on cardiovascular risk factors (i.e., body mass index [BMI] and lipid profile), athlete performance, diabetes, and transplantation. The aim of the current study was to assess the impact of caloric restrictions during Ramadan fasting on severity index of NASH patients [12-19].

PATIENTS AND METHODS

A retrospective, case-control study was conducted at the Nazareth Hospital between 2017 and 2019. The study population was divided into two groups. The first group represented NASH subjects who decided to fast all the Ramadan month, and the second group, control group, NAFLD/NASH subjects who decided not to fast.

The current study was approved by the hospital ethics committee and was conducted according to the Helsinki guidelines. The data were coded to keep anonymity of the patients. Informed consent was waived because of the non-interventional study design.

All medical records of eligible patients from our liver clinic were reviewed. The following parameters were collected: demographic data (age, gender, body mass index), background diseases (diabetes mellitus, ischemic heart disease, congestive heart failure, chronic renal failure, smoking), laboratory tests (alanine aminotransferase [ALT], aspartate transaminase [AST], alkaline phosphatase [ALP], gamma-glutamyl transferase [GGT], total bilirubin, amylase, and C-reactive protein [CRP]). Insulin resistance markers as well as NASH noninvasive severity scores were determined before and after Ramadan fasting.

The NAFLD was diagnosed by abdominal ultrasonography based on the presence of fatty liver (hepatic parenchymal brightness, visualization of portal and hepatic borders, liver-to-kidney contrast, deep beam attenuation, and bright vessel walls).

Patients with other hepatic pathology or autoimmune phenotypes (e.g., alcoholic liver disease, drug-induced liver injury, autoimmune hepatitis, viral hepatitis, cholestatic liver disease; and metabolic/genetic liver disease) were excluded using specific clinical, laboratory, radiological and/or histological criteria/tests (serology of viral hepatitis A, B, and C; autoimmune markers including ANA, anti-LKM, anti-smooth mussels protein electrophoresis, and immune electrophoresis; metabolic markers such as serum ceruloplasmin; 24-hour urine collection for copper, ferritin, iron, transferrin saturation, TSH; and hemoglobin A1c [HbA1c] and alpha-1 antitrypsin). Patients who had a history of alcohol consumption of more > 30 grams per day for at least 5 years were also excluded.

The homeostatic model assessment of β -cell function and insulin resistance (HOMA-IR) in serum was calculated using fasting insulin (FINS) and fasting blood glucose (FBG) with the following formula: HOMA-IR=FINS/(22.5×10–FBG). HOMA-IR

in normal adult is generally < 2.7. A higher HOMA-IR indicates that a patient possesses a metabolic disorder.

The following three blood tests were used to assess the NASH severity, according to fibrosis stage and necr-oinflammatory activity:

- NAFLD fibrosis score (NFS) = (-1.675 +0.037 × age (year) + 0.094 × BMI (kg/m2) + 1.13 ×IFG/diabetes (yes = 1, no = 0) + 0.99 × AST/ALT ratio 0.013 × platelet count (× 109/L) 0.66 × albumin [g/dl])
- BARD score (BMI \geq 28 = 1; AST/ALT ratio \geq 0.8 = 2; diabetes = 1; score \geq 2, odds ratio for advanced fibrosis = 17)
- Fibrosis-4 (FIB4) score = age (year) × AST [U/L]/(platelets [109/L] × (ALT [U/L])

The severity of NASH was assessed using non-invasive markers including HOMA-IR, NFS, BARDA score, and FIB4 score.

STATISTICAL ANALYSIS

Before commencing any statistical processing and analysis, data were visually inspected and checked for outliers. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 24 (SPSS, IBM Corp, Armonk, NY, USA). Categorial variables were tested using the chi-square test or Fisher's exact test, as appropriate. Continuous variables were examined using Student's t test if normally distributed and Mann–Whitney test if not. To identify variables associated with the severity of NASH, univariate analysis was performed. Variables that were significantly associated (P<0.05)

RESULTS

Overall, 155 NASH subjects were included, 74 patients who fasted during Ramadan and 81 who did not. Regarding the baseline characteristics of the study participants, there was no significant difference in anthropometrics and biochemical variables between the groups. Baseline characteristics of the study groups are presented in [Table 1].

Among the fasting group, the mean age was 51.8 ± 20.9 years, 39 (52.7%) were men. BMI decrease from 36.7 ± 7.1 at baseline to 34.5 ± 6.8 after fasting (P < 0.005), CRP decreased from 14.2 ± 7.1 to 7.18 ± 6.45 (P < 0.005), AST declined from 44.2 ± 12.80 to 34.23 ± 9.434 (P < 0.005), ALT decline from 51.43 ± 9.36 to 39.23 ± 8.24 (P < 0.005), and GGT decline from 52.3 ± 13.8 to 43.25 ± 11.42 (P < 0.005) [Table 2].

NFS declined from 0.45 ± 0.25 to 0.23 ± 0.21 (P < 0.005), BARD scores declined from 2.3 ± 0.98 to 1.6 ± 1.01 (P < 0.005), and FIB4 scores declined from 1.93 ± 0.76 to 1.34 ± 0.871 (P < 0.005). Moreover, levels of fasting insulin decreased from 24.71 ± 5.21 IU/ml to 20.32 ± 3.26 (P < 0.005), HbA1c (%) 5.89 ± 0.63 to 5.28 ± 0.76 (P < 0.005), and HOMA-IR improved from 2.92 ± 1.22 to 2.15 ± 1.13 (P < 0.005).

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Table 1. Demographics, clinical and laboratory baseline characteristics of the study groups

Parameters	Group A (fasting patients)	Group B (non-fasting patients)	P value
Number of patients	74	81	
Age (years) (mean ± standard deviation)	51.8 ± 20.9	52.6 ±19.3	NS
Gender, n (%) Male Female	39 (52.7) 35 (47.3)	42 (51.8) 39 (48.2)	NS NS
Body mass index	36.7±7.1	34.3 ± 6.3	NS
Ischemic heart disease, n (%)	12 (16.2)	14 (17.2)	NS
Congestive heart failure, n (%)	3 (4.05)	4 (4.93)	NS
Chronic renal failure, n (%)	1 (1.35)	0	NS
Metabolic syndrome, n (%)	60 (81.08)	67 (82.71)	NS
Smoking, n (%)	13 (17.56)	16 (19.75)	NS
ALT (Unit/L)	51.43 ± 9.36	53.16 ± 11.76	NS
AST (Unit/L)	44.2 ± 12.80	43.8 ± 10.56	NS
GGT (Unit/L)	52.3 ± 13.8	53.7 ± 15.2	NS
Fasting insulin (IU/ml)	24.71 ± 5.21	23.34 ± 6.41	NS
HbA1c (%)	5.89 ± 0.63	5.76 ± 0.76	NS
HOMA-IR	2.92 ± 1.22	2.87 ± 1.14	NS
CRP (mg %)	14.2±7.1	15.2±4.3	NS
NFS	0.45 ± 0.25	0.42 ± 0.36	NS
BARD score	2.30 ± 0.98	2.31 ± 0.81	NS
FIB4 score	1.93 ± 0.76	1.91 ± 0.65	NS

ALT = alanine aminotransferase, AST = aspartate transaminase, CRP = C-reactive protein, FIB4 = fibrosis-4, GGT = gamma-glutamyl transferase, HbA1c = hemoglobin A1c, HOMA-IR = homeostatic model assessment of β -cell function and insulin resistance, NFS = non-alcoholic fatty liver disease fibrosis score

Table 2. Laboratory and metabolic parameters among fasting groups

	Before fasting	After fasting	<i>P</i> value
CRP	14.2 ± 7.1	7.18 ± 6.45	< 0.005
AST	51.43 ± 9.36	39.23 ± 8.24	< 0.005
ALT	44.2 ± 12.80	34.23 ± 9.434	< 0.005
HOMA-IR	2.92 ± 1.22	2.15 ± 1.13	< 0.05
NFS	0.45 ± 0.25	0.23 ± 0.21	< 0.05
ВМІ	36.7 ± 7.1	34.5 ± 6.8	< 0.005
BARD	2.3 ± 0.98	1.6 ± 1.01	< 0.005

ALT = alanine aminotransferase, AST = aspartate transaminase, BMI = body mass index, CRP = C-reactive protein, HOMA-IR = homeostatic model assessment of β -cell function and insulin resistance, NFS = non-alcoholic fatty liver disease fibrosis score

Among the non-fasting group, the mean age was 52.6 ± 19.3 years, 42 (51.8) were men. BMI was stable from 34.3 ± 6.3 to 34.9 ± 7.2 (P=0.92), CRP decreased from 15.2 ± 4.3 to 14.67 ± 4.36 (P=0.91), AST changed from 43.8 ± 10.56 to 42.98 ± 9.65 (P=0.355), ALT declined from 53.16 ± 11.76 to 51.45 ± 10.22 (P=0.865), and GGT from 53.7 ± 15.2 to 51.98 ± 13.2 (P=0.892).

NFS was stable from 0.42 ± 0.36 to 0.41 ± 0.41 (P = 0.915), BARD scores declined from 2.31 ± 0.81 to 2.26 ± 1.06 (P = 0.823) and FIB4 scores declined from 1.91 ± 0.65 to 1.89 ± 0.768 (P = 0.912).

Levels of fasting insulin decreased from 23.34 \pm 6.41 IU/ml to 23.32 \pm 3.26 (P < 0.95), HbA1c (%) 5.76 \pm 0.76; to 5.72 \pm 0.86 (P < 0.93), and HOMA-IR from 2.87 \pm 1.14 to 2.85 \pm 1.19 (P < 0.92).

DISCUSSION

Changes in diet and exercise are the mainstay preventative approaches for NAFLD. However, the majority of obese patients

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are unable to accomplish or sustain intentional weight reduction by diet and exercise alone [14]. Medical therapies (e.g., drugs) have had limited benefit [16]. In contrast, bariatric surgery has been shown to improve hepatic steatosis, fibrosis, and necro-inflammatory activity in the morbidly obese patients with NASH [18,19] but the mechanisms have not yet been fully worked out. Numerous complementary and alternative remedies have been tested and have shown some promise in ameliorating NAFLD, but none have been proven to have significant efficacy [20,21] and some have been shown to cause drug-induced liver injury.

It has been suggested that time-restricted food intake might be a successful intervention to prevent and manage obesity, metabolic syndrome, and its complications due to neurohormonal adaptions [22-24]. Altering feeding time, whether it is a primary intervention or adjunctive to dietary caloric content, may have a net benefit, especially to those most afflicted. Several recent rodent studies have shown that dysregulation of the circadian secretion of melatonin increases the risk for diabetes and sequelae [25], and supplemental melatonin administration resulted in a modest improvement in the parameters of human metabolic syndrome.

We found that NAFLD improved significantly after intermittent fasting during Ramadan. The improvement was observed by decreases of the liver function tests, BMI, noninvasive severity markers of fatty liver disease as well as improved insulin sensitivity markers among the fasting group, but not among the non-fasting group. To the best of our knowledge, few reports describe this association between the fasting during Ramadan and improvement in the severity of fatty liver disease.

Due to the increasing prevalence of obesity worldwide and the resultant increasing prevalence of NAFLD (approximately 30% of the general population) the rate of obesity, metabolic syndrome, and fatty liver disease is increasing. There is currently no specific treatment targeting fatty liver disease, making the life style changes and diet the corner stone in managing fatty liver disease.

LIMITATIONS

Our study has several limitations. The major drawback is the cross-sectional study design which, due to its very nature, does not enable the deduction of causal inferences with regard to the relationship between fasting and NASH in terms of development, severity and pathophysiology. In addition, sample size of the study group was small.

CONCLUSIONS

Intermittent fasting showed significant improvement on inflammatory markers, insulin sensitivity as well as in noninvasive measures for NASH severity assessment. Future prospective and laboratory studies are needed to confirm the positive effect of intermittent fasting among NASH subjects.

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In three words I can sum up everything I've learned about life: it goes on.

Robert Frost (1874-1963), American poet

Capsule

Cryoablation or drug therapy for initial treatment of atrial fibrillation

Guidelines recommend a trial of one or more antiarrhythmic drugs before catheter ablation is considered in patients with atrial fibrillation. However, first-line ablation may be more effective in maintaining sinus rhythm. Andrade et al. randomly assigned 303 patients with symptomatic, paroxysmal, untreated atrial fibrillation to undergo catheter ablation with a cryothermy balloon or to receive antiarrhythmic drug therapy for initial rhythm control. All the patients received an implantable cardiac monitoring device to detect atrial tachyarrhythmia. The follow-up period was 12 months. At 1 year, a recurrence of atrial tachyarrhythmia had occurred in 66 of 154 patients (42.9%) assigned to undergo ablation and in 101 of 149 patients (67.8%) assigned to receive antiarrhythmic drugs (hazard ratio 0.48, 95% confidence interval [95%CI] 0.35-0.66, P < 0.001). Symptomatic atrial tachyarrhythmia had

recurred in 11.0% of the patients who underwent ablation and in 26.2% of those who received antiarrhythmic drugs (hazard ratio 0.39I 95%CI 0.22–0.68). The median percentage of time in atrial fibrillation was 0% (interquartile range 0–0.08) with ablation and 0.13% (interquartile range 0–1.60) with antiarrhythmic drugs. Serious adverse events occurred in five patients (3.2%) who underwent ablation and in six patients (4.0%) who received antiarrhythmic drugs. The authors concluded that among patients receiving initial treatment for symptomatic, paroxysmal atrial fibrillation, there was a significantly lower rate of atrial fibrillation recurrence with catheter cryoballoon ablation than with antiarrhythmic drug therapy, as assessed by continuous cardiac rhythm monitoring.

N Engl J Med 2021; 384: 305 Eitan Israeli

Capsule

Autoimmune and chronic inflammatory disease patients with COVID-19

There are limited data on the impact of coronavirus disease-2019 (COVID-19) on hospitalized patients with autoimmune and chronic inflammatory disease (AICID) compared with patients who do not have AICID. Ungaro and colleagues performed a multi-center retrospective cohort study with patients presenting to five hospitals in a large academic health system with polymerase chain reactionconfirmed COVID-19 infection. They evaluated the impact of having an AICID and class of immunosuppressive medication being used to treat patients with AICID (biologics, nonbiologicimmunosuppressives, or systemic corticosteroids) on the risk of developing severe COVID-19 defined as requiring mechanical ventilation (MV) and/or death. A total of 6792 patients with confirmed COVID-19 were included in the study, with 159 (2.3%) having at least one AICID. On multivariable analysis, AICIDs were not significantly associated with severe COVID-19 (adjusted odds ratio [aOR] 1.3, 95% confidence interval [95%CI]: 0.9–1.8). Among patients with AICID, use of biologics or non-biologic immunosuppressives did not increase the risk of severe COVID-19. In contrast, systemic corticosteroid use was significantly associated with an increased risk of severe COVID-19 (aOR 6.8, 95%CI: 2.5–18.4). The authors concluded that patients with AICID are not at increased risk of severe COVID-19 with the exception of those taking corticosteroids. These data suggest that patients with AICID should continue on biologic and non-biologic immunosuppression but limit steroids during the COVID-19 pandemic.

ACR Open Rheumatol https://onlinelibrary.wiley.com/doi/10.1002/ acr2.11221 Eitan Israeli