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Research Article

Functional Dyspepsia Prevalence Among Egyptian Chronic Hepatitis C Patients Using Rome lV Questionnaire.

Omar Abdelazim[1], Alshymaa A Hassnine[1], Fatma M M Kamel[2], Nehal Abbas[3], Zienab M. Saad[1], Haitham A Mahmoud[1], Safaa M Abdelhalim[1].

[1] *Department of Gastroenterology Hepatology and Tropical Medicine, Faculty of Medicine, Minia University, Minia, Egypt.*
[2] *Department of Internal Medicine, Faculty of Medicine, Minia University, Minia, Egypt.*
[3] *Derartment of clinical pathology, faculty of medicine, Minia university, Minia, Egypt.*

Abstract

Background: The prevalence of Functional dyspepsia (FD) in chronic HCV (Hepatitis C virus) patients, as defined by the Rome IV criteria, is unknown despite the frequent association between gastrointestinal symptoms and HCV.
Aim: We aimed to evaluate prevalence of functional dyspepsia according to Rome IV criteria in chronic HCV patients and investigate the risk factors for FD in those patients.
Methods: Our study involved 962 individuals (556 chronic HCV patients and 406 healthy controls). All individuals were subjected to a complete medical history, clinical examination, basic investigations, and Rome IV diagnostic questionnaire. HCV patients were diagnosed by HCV RNA PCR (polymerase chain reaction) and underwent shear wave elastography for non-invasive estimation of fibrosis. Upper gastrointestinal tract (GIT) endoscopy was done for patients only.
Results: FD was significantly higher in chronic HCV patients than normal controls (78.8% vs 54.7%, respectively) (p = 0.001). The postprandial distention syndrome (PDS) subtype was the predominant type in both groups, accounting for 65.1% in the HCV group and 62.6% in the control group. No statistically significant differences were found between HCV patients with FD and those without in ALT levels (p = 0.396), fibrosis score (p = 0.157), or viral load as measured by HCV RNA PCR (p = 0.325). A multivariate regression analysis revealed a significant association between male gender and FD (OR: 2.289, p = 0.047).
Conclusion: FD is associated with chronic hepatitis C with a relatively high prevalence with a predominant PDS subtype. Male HCV patients are more likely to have FD.

Keywords: Functional dyspepsia, ROME IV, Hepatitis C virus

INTRODUCTION

Hepatitis C virus (HCV) infection is a significant health burden that affects a large number of individuals globally with an estimated 1 million new cases annually. (1) Chronic HCV is a systemic condition that manifests both hepatic and extrahepatic. The well-known clinical consequences of hepatic manifestation include cirrhosis and hepatocellular carcinoma, which can result in liver transplantation or liver-related death. (2) HCV is associated with numerous extra-hepatic manifestations, such as endocrine, metabolic, renal, neuropsychiatric, cardiovascular, and arthritic-like pain. (3) Several studies discovered links between HCV and clusters of gastrointestinal, somatic, and neuropsychiatric symptoms. (4–7) One of the most common symptoms in patients with chronic HCV is dyspepsia. (8)

In clinical practice, dyspepsia is one of the most common gastrointestinal disorders. It is a group of symptoms pertaining to the gastroduodenal region. (9) According to recent studies, up to 85% of patients with dyspeptic symptoms had normal upper endoscopy results. Most people who have dyspepsia that a standard clinical assessment cannot explain are ultimately diagnosed with functional dyspepsia (10) Although the exact pathogenesis of FD is not well known, visceral hypersensitivity, abnormal sensorimotor function, reduced stomach adaptation, and altered central processing are features of this gut-brain interaction disorder. (8)

According to the Rome IV criteria, FD is defined by the

***Corresponding Author:** **Alshymaa A. Hassnine MD**, Department of gastroenterology, and tropical Medicine, Minia University, Minia, Egypt.
Tel: 00201092004294 **Email:** Alshiamaa.Ahmed@mu.edu.eg.
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Rome Foundation, the expert group in charge of classifying all functional gastrointestinal disorders, as bothersome postprandial fullness, early satiety, epigastric pain, or epigastric burning, despite the absence of structural disease, including at upper GI endoscopy, which would account for the symptoms. Based on the primary symptoms and potential causes of the illness, the disorder is divided into three subtypes: postprandial distress (PDS), epigastric pain syndrome (EPS), and mixed EPS-PDS. (8)

A wide variety of dyspepsia frequencies were reported in several previous studies that used the Rome I to IV criteria. The progression of ROME criteria from I to IV and the diverse FD manifestations account for the substantial variations in dyspepsia prevalence among populations. (11) The Rome III criteria for gastrointestinal disorders were developed in 2006 and were replaced by the Rome IV criteria in 2016. The goal of Rome IV approach was redesigned to replace diagnostic tools. (12) For FD, the Rome IV criteria provide increased specificity. (13) Limited data addressing the potential link between FD and HCV infection, using the definition of the Rome IV criteria. Therefore, we studied the prevalence of FD using the Rome IV questionnaire and evaluated the potential risk factors for FD in Egyptian chronic hepatitis C patients.

PATIENT & METHODS

Between January 2024 and September 2024, 406 healthy controls and 644 patients with chronic HCV participated in this cross-sectional, observational study. The study was conducted in compliance with the Helsinki Declaration and authorized by the Faculty of Medicine's institutional review board at Minya University in Egypt. All participants gave their informed consent.

Inclusion criteria

1. All patients > 18 years willing to participate in the study
2. Chronic HCV patients were selected randomly from the outpatient clinic of the Tropical Medicine Department, Minia University Hospital
3. Control group selected randomly from healthy volunteer (medical staff, medical students and nurses). Their age- and sex-matched to the patients.

Exclusion criteria

1. Presence of disorders or clinical situation that could avoid patients from answering the questionnaires
2. Patients not agreeable to upper GI endoscopy
3. Patients with recognized gastric disease
4. Patients with alarm feature (red flags); Loss of Weight, Chronic Vomiting, Odynophagia, Dysphagia, History of gastrointestinal bleeding or History of upper GIT malignancy
5. Patients with other chronic systemic disorders [e.g., heart failure, Gall bladder disease, etc]

Everyone, including the controls and patients, was exposed to

1. At enrolment, a thorough history and examination were taken, and body mass index (BMI) was estimated. Body weight (measured in kilograms) divided by squared height (measured in meters) yielded the BMI.
2. Basic tests such as complete blood count (CBC), random blood glucose, liver and renal function tests, HCV RNA PCR, and abdominal ultrasonography for patients only. The liver stiffness of HCV patients was evaluated by Shear Wave Elastography (SWE).
3. ROME IV questionnaire: The ROME IV questionnaire, which was suitably translated into Arabic to accommodate people who did not speak English, was used to interview all eligible participants. To guarantee accurate comprehension and efficient communication, the interviews were held in the participants' native tongue. The Rome committee validated the Rome IV diagnostic questionnaire for FD.

The Rome Foundation website (http://www.romecriteria.org/questionnaires/) provided the FD module.

Subtypes of functional dyspepsia include the following

a. The syndrome of postprandial distress

For the previous three months, at least one of the following must be present at least three days per week:

1. Bothersome Postprandial fullness (i.e., severe enough to affect habitual activities)
2. Severe early satiety makes it difficult to finish a regular-sized meal.
3. Lack of evidence of metabolic, systemic, or organic conditions that could explain the symptoms with standard investigations (including upper endoscopy)

b. The syndrome of epigastric pain

The following criteria must be achieved at least one day per week over the previous three months:

1. Bothersome epigastric pain (severe enough to interfere with regular activities) OR
2. Bothersome epigastric burning (severe enough to interfere with regular activities)
3. Routine investigations (including upper endoscopy) revealed no signs of organic, systemic, or metabolic disorders that could account for the symptoms.
4. The development of symptoms at least six months before the diagnosis

Statistical analysis

All analyses were done using SPSS version 20. Quantitative data were obtainable *via* mean, and standard deviation while

qualitative records were presented *via* frequency distribution. The Chi-square test was used to compare among proportions or Fisher exact test "if >20 of cells had predictable count less than 5". An Independent sample t-test was used to compare two means.

Logistic regression analysis was used to predict the outcome of dissimilar independent variables on the target (dependent variable). The probability of less than 0.05 was used as a cut-off point for significant tests.

RESULTS

Our study involved 962 participants, including 406 healthy controls and 556 chronic HCV patients. Of the 556 chronic HCV patients enrolled in the study, 492 met the criteria for functional dyspepsia and underwent upper endoscopy. There were approximately 438 patients with FD with no upper endoscopy abnormalities, 17 patients with gastroesophageal reflux disease, 6 with peptic ulcers, 15 with gastro-esophagitis, and 16 with esophageal varices. The patients with HCV were older, with a mean age of 48.9 years compared to 42.2 years in the control group (p = 0.001). However, gender distribution did not significantly differ between the two groups (p = 0.600). Rural versus urban residents also showed no significant association (p = 0.243). Conversely, BMI and smoking status differed between the groups. HCV Patients had a higher mean BMI (29.86 vs. 29, p = 0.001) and were more likely to smoke (61.2% vs. 45.1%, p = 0.001). **(Table 1)**

Table 1. Socio-demographic and clinical criteria of HCV patients and normal control.

Variable	HCV patients (n=556)	Normal Control (n=406)	P value
Age			
Mean ± SD	48.9 ± 9.6	42.2 ± 11.7	0.001*
Median (Q1-Q3)	49 (41- 57)	43 (33.75- 52)	
Sex			
Male	340 (61.2%)	241 (59.4%)	0.600
Female	216 (38.8%)	165 (40.6%)	
Residence			
Rural	250 (45%)	198 (48.8%)	0.243
Urban	306 (55%)	208 (51.2%)	
BMI			
Mean ± SD	29.86 ± 3.77	29 ± 3.47	0.001*
Median (Q1-Q3)	30 (27.25- 32)	30 (27 – 31)	
Smoking			
Yes	340 (61.2%)	183 (45.1%)	0.001*
No	216 (38.8%)	223 (54.9%)	

BMI: body mass index

- Mann-Whitney U test used to compare non parametric quantitative data between two groups

- Chi-square test was used to compare qualitative data between two groups

**: Significant difference (p value ≤ 0.05)*

- Q (Quartile)

HCV patients showed a statistically significant higher prevalence of FD (78.8%) compared to controls (54.7%) (p = 0.001). **(Table2) (Figure 1)**.

Table 2. Prevalence of functional dyspepsia among HCV patients and normal control

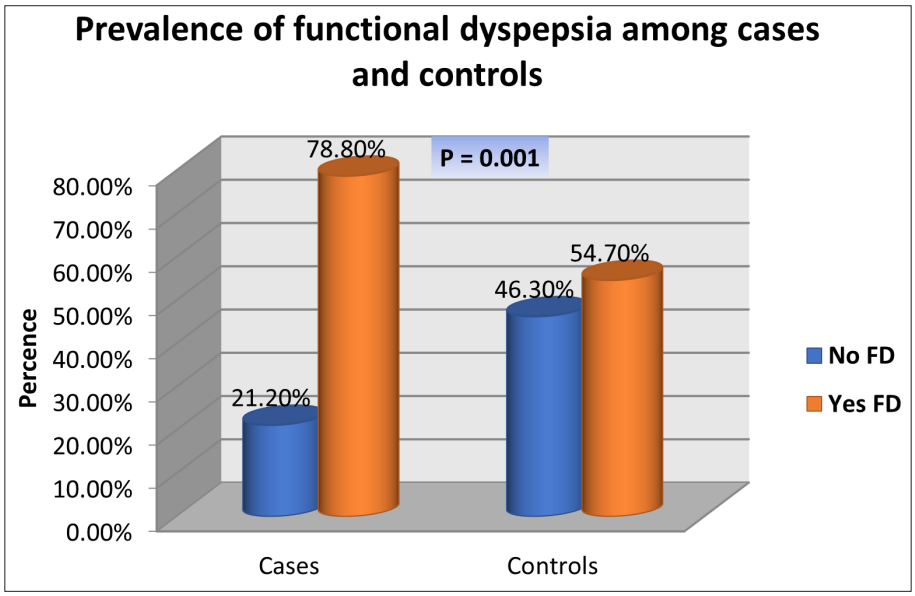
FD	HCV Patients (n=556)	Normal Control (n=406)	P value
FD			
Yes	438 (78.8%)	222 (54.7%)	0.001*
No	118 (21.2%)	184 (45.3%)	

FD: functional dyspepsia

-Chi-square test was used to compare qualitative data between three groups

**: Significant difference (p value ≤ 0.05)*

Figure 1. Prevalence of functional dyspepsia among HCV patients and normal control



The distribution of FD subtypes between HCV patients and controls is not significantly different (p = 0.788), with Epigastric Pain Syndrome (EPS) and Postprandial Distress Syndrome (PDS) being the most common subtypes. In both groups, PDS was the predominant subtype, affecting over 60% of individuals, while EPS accounted for around 20%. The overlap between these subtypes was seen in about 14% of individuals. **(Table 3) (Figure 2)**

Table 3. Prevalence of functional dyspepsia subtypes among HCV patients and normal control

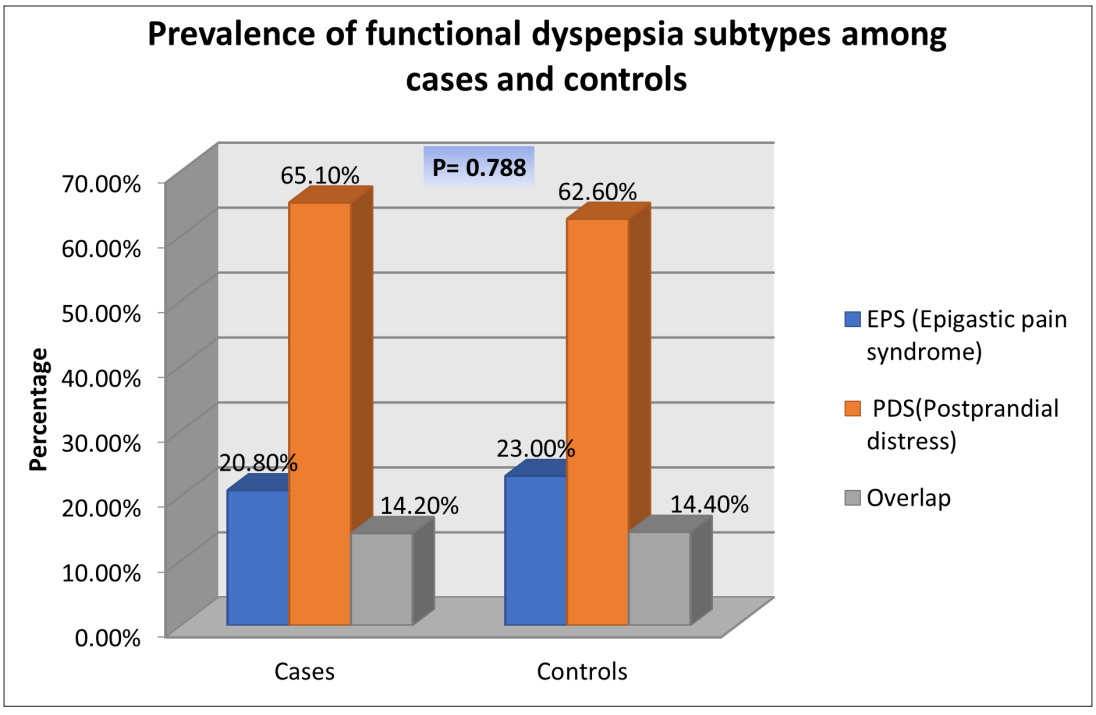
FD	HCV patients (n=438)	Normal Control (n=222)	P value
FD			
EPS (Epigastric pain syndrome)	91 (20.8%)	51 (23%)	0.788
PDS (Postprandial distress)	285 (65.1%)	139 (62.6%)	
Overlap	62 (14.2%)	32 (14.4%)	

FD: functional dyspepsia

- Chi-square test was used to compare qualitative data between three groups

**: Significant difference (p value ≤ 0.05)*

Figure 2. Prevalence of functional dyspepsia subtypes among HCV patients and normal control



Regarding the biochemical and pathological factors in HCV patients with and without FD; No statistically significant differences were found between those with FD and those without in terms of ALT levels (p = 0.396), fibrosis score (p = 0.157), or viral load as measured by HCV RNA PCR (p = 0.325). **(Table 4)**

Table 4. Biochemical, serological and pathological characteristics of HCV patients with functional dyspepsia

Variable	Total (n=556)	No FD (n=118)	FD (n=438)	P value
ALT				
Normal	59 (10.6%)	10 (8.5%)	49 (11.2%)	0.396
Elevated	497 (89.4%)	108 (91.5%)	389 (88.8%)	
Fibrosis score				
F0-F1	124 (22.3%)	32 (27.1%)	92 (21%)	0.157
F2-F3	432 (77.7%)	86 (72.9%)	346 (79%)	
HCV RNA(PCR)				
Mean ± SD	509802 ± 738157	527716 ± 595741	504931 ± 772886	0.325
Median (Q1-Q3)	353245 (75327 – 713746)	423375 (75353 – 741372)	345674 (75320 – 676106)	

ALT alanine transaminase, , PCR Polymerase chain reaction, FD functional dyspepsia
- Mann-Whitney U test used to compare non parametric quantitative data between two groups
- Chi-square test was used to compare qualitative data between two groups
**: Significant difference (p value ≤ 0.05)*
- Q (Quartile)

Multivariate analysis revealed that male sex was significantly associated with a higher risk of FD in HCV patients (OR: 2.289, p = 0.047). No other variables, including age, smoking, BMI, elevated ALT, fibrosis, or viral load, were significantly related to FD in this population. This suggests that male gender may be an independent risk factor for FD among HCV patients, while liver disease severity or viral load may not play a direct role in the development of this disorder. Further research is needed to clarify the underlying mechanisms behind this gender-specific association. **(Table 5)**

Table 5. Multivariate regression analysis of factors associated with FD in HCV patients (n=556)

Variable	Univariate Regression		Multivariate Regression	
	OR (CI 95%)	P value	OR (CI 95%)	P value
Age > 40	0.771 (0.457 – 1.03)	0.331	0.783 (0.460 – 1.33)	0.368
Sex male	1.502 (0.996 – 2.265)	0.052	2.289 (1.011 – 5.18)	0.047*
Smoking	1.259 (0.834 – 1.09)	0.273	0.597 (0.261 – 1.36)	0.221
BMI >25	0.627 (0.327 – 1.202)	0.160	0.589 (0.301 – 1.153)	0.122
Elevated ALT	0.735 (0.360 – 1.499)	0.397	0.790 (0.381 – 1.638)	0.527
Fibrosis	1.39 (0.878 – 2.231)	0.158	1.456 (0.901 – 2.35)	0.125
PCR	1 (1 – 1)	0.766	1 (1 – 1)	0.759

BMI body mass index, ALT alanine transaminase, FD functional dyspepsia, PCR Polymerase chain reaction; CI confidence interval
**: Significant difference (p value ≤ 0.05)*

DISCUSSION

Functional dyspepsia (FD) is a widespread functional gastrointestinal disorder that reduces quality of life. (14) Research showed that the global prevalence of FD ranges from 4.8 to 30 %. (14, 15)

Chronic hepatitis C patients typically experience a variety of gastrointestinal symptoms. In clinical practice, patients with HCV who do not have organic lesions often have abdominal pain or discomfort. In many patients, the functional cause of abdominal symptoms is suggested. (16) Functional dyspepsia and chronic hepatitis C have not been thoroughly studied in relation to one another. Because of this knowledge gap, we are interested in investigating the potential association between functional dyspepsia and chronic hepatitis C.

In our study the patients with HCV were notably older, with a mean age of 48.9 years compared to 42.2 years in the control group (p = 0.001). BMI and smoking status differed markedly between the groups. HCV Patients had a higher mean BMI (29.86 vs. 29, p = 0.001) and were more likely to smoke (61.2% vs. 45.1%, p = 0.001). This finding matches another study by Mohamed

et al who found that there was a significant difference in the demographics between the control groups and the HCV group concerning smoking and BMI. (17)

In our study, the prevalence of FD among HCV patients (78.8%) was significantly higher compared to controls (54.7%) (p = 0.001). This finding agreed with Hassanin et al who found that the percentage of FD according to Rome IV criteria was significantly higher in patients with chronic HCV than in normal controls (51.3% vs. 43.2%, respectively). (18) Also, a study by Mohamed et al, using Rome III criteria, found that the prevalence of FD was significantly higher in HCV patients than in healthy controls (65.9 % vs 28.7 %, respectively). (17)

The marked difference in FD prevalence suggests that chronic HCV infection may be associated with a higher risk of developing functional gastrointestinal disorders. This could be due to various factors, including the inflammatory state induced by chronic infection, altered gut motility, or psychosocial stress related to chronic illness.

In our study, there was no significant difference regarding subtypes of FD in HCV patients and healthy controls. Postprandial distress syndrome (PDS) was the predominant subtype in both groups. In HCV patients, PDS affects 65.1 % of patients, while epigastric pain syndrome (EPS) accounts for 20.8 %. Mohamed et al.'s study revealed similar findings, indicating that in both groups, the PDS subtype predominated over the EPS. (16) This is also in keeping with the findings of Hassanin et al., who found that among HCV patients, postprandial distress syndrome (PDS) predominated over epigastric pain syndrome (EPS). (18)

Our findings are consistent with those of Ahmed et al., who found that patients with chronic HCV had a considerably greater prevalence of FD than the controls (67.8% vs. 32.4%, respectively). The EPS subtype was less common than the PDS subtype. (19)

Postprandial symptoms in patients with chronic HCV may be due to the increase in portal blood flow and volume changes following a meal. This may cause increased congestion and lead to stretch of Glisson's capsule, (20) which in turn may trigger vagal stimulation and postprandial fullness, nausea, and pain. Further studies on the neuromuscular function of the stomach and gastric emptying are required. (21)

We found that no statistically significant difference in ALT levels, fibrosis score, or viral load among HCV patients with FD and those without. These findings suggest that functional dyspepsia is not associated with the biochemical severity of liver disease or the viral load in this population, implying that other mechanisms, possibly gut-brain interactions or psychosocial factors, may play a more central role in FD pathophysiology among HCV patients.

On the other hand, Mohamed et al. noticed that HCV patients with FD had significantly higher ALT levels and fibrosis stages than patients without (P < 0.04, P < 0.0001, respectively), but there was no significant difference in the HCV viral load between the two groups (P < 0.2). (17)

In this study, male gender may be an independent risk factor for FD among HCV patients (OR: 2.289, p = 0.047), while liver disease severity or viral load may not play a direct role in the development of this disorder. Further research is needed to clarify the underlying mechanisms behind this gender-specific association. Gender and functional dyspepsia (FD) in the general population have not been extensively studied.

On the contrary, previous research has identified fibrosis scores, positive PCR, high BMI, and higher levels of education as risk factors for the prediction of FD in individuals with chronic HCV. (17,18)

LIMITATIONS OF THE STUDY

It should be noted that our study had limitations. First, diagnosing functional problems assertively is clinically challenging, and the questionnaire was applied subjectively.

CONCLUSION

The study's findings revealed significant associations between functional dyspepsia and chronic HCV especially among male patients. Pattern of subtype distribution of FD in chronic HCV patients was similar to general population with PDS predominance. While endoscopic findings indicate less severe pathology in FD patients, the absence of significant biochemical and virological differences suggests that FD in HCV patients is likely multifactorial, potentially involving psychosocial, neurogenic, or inflammatory mechanisms rather than being directly related to the severity of HCV infection or liver disease. These insights emphasize the need for comprehensive management of FD in HCV patients, considering both physical and psychological health dimensions.

Disclosure

The authors have no conflict of interest related to this publication.

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Authors' contributions

Omar Abdelazim: Conception and design of the study, analysis, and interpretation of data, and approval of the version submitted

Alshymaa A Hassnine: Data acquisition

Fatma M M Kameln Nehal Abbas: Methodology

Zienab M. Saad: Supervision

Haitham A Mahmoud: analysis of data

Safaa M Abdelhalim: Drafting, analysis and interpretation of data

Declaration of interest: none.

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Availability of data and materials

The datasets used in this study are available from the corresponding author on reasonable request.

Abbreviations

FD: Functional dyspepsia;
HCV: Hepatitis C virus;
CBC: complete blood count;
PCR: polymerase chain reaction;
GIT: gastrointestinal tract;
PDS: postprandial distention syndrome;
EPS: epigastric pain syndrome;
BMI: body mass index;
SWE: Shear Wave Elastography;
ALT: alanine transaminase

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