Assessment of Nutritional Status of Patients with Hepatitis C in Mahalla Hepatology Teaching Hospital

Sahar O. Al Shafei. Samar M.Rezk, Samira H.Badr.
Nutrition & Food Science Dept., Faculty of Home Economics, Menoufia
Univ., Egypt

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Abstract

Malnutrition is prevalent among patients with chronic liver disease. Therefore, the aim of this work is to assess the nutritional status of patients with Hepatitis C virus and based therapy of sofosbuvir. Patients were compared with the different methods which used for nutritional assessment namely the anthropometric measures and the Subjective Global Assessment (SGA). Patients and Methods: This study was conducted in Mahalla Hepatology Teaching Hospital in order to assess the nutritional status of 68 chronic hepatitis C patients receiving triple antiviral regimen that consisted of (Sofosbuvir (Sovaldi) + Daklinza + Ribavirin) that were administered orally for 3 months and dual antiviral regimen that consisted of Sofosbuvir (Sovaldi) + Daklinza) that are administerd orally for 3 months with 40 chronic hepatitis C patients per group. Thorough history taking, physical examination and detailed nutritional assessment were performed including a 24- hour dietary recall. Evaluation of nutritional status was done using different anthropometric measures and the Subjective Global Assessment (SGA). Nutritional assessment based on Comparison of dual therapy with triple therapy laboratory findings of those patients that reflect their nutritional status as hemoglobin, liver enzymes (AST, ALT), total bilirubin, ultra sound, WBCs count and platelets count before treatment and after

treatment. Results: The study revealed that 73.5% of patients have good nutritional status with SGA score A, 25.0 % of patients have mild to moderate nutritional status with SGA score B, while 1.5% of patients have poor nutritional status with SGA score C. laboratory findings of those patients as follows: Triple antiviral therapy had a more evident impact in their laboratory investigations as decrease in the levels of hemoglobin, white blood cells count, platelets count, Liver enzymes (AST and ALT) and increase in level of total bilirubin than dual antiviral therapy.
Key words: Nutrition, Assessment, SGA, Liver diseases, *Sovaldi*.

Introduction

Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide **(Lavanchy, 2011)**. The long-term impact of HCV infection is highly variable, ranging from minimal histological changes to extensive fibrosis and cirrhosis with or without hepatocellular carcinoma (HCC), but most of infected persons are unaware of their infection. The implementation of extended criteria for screening for HCV is a subject of major debate among different stakeholders. Clinical care for patients with HCV-related liver disease has advanced considerably during the last two decades **(Arase *et al*., 2013)**.

Treatment of CHC infection has dramatically improved with the approval of DAA, which is more effective, easier to take and have fewer side effects than older treatments. Several new DAA against the HCV are approved and marketed. In late 2013, the United State FDA approved Sofosbuvir (Sovaldi, Gilead Sciences) as a DAA. Sovaldi is a noval nucleotide analog inhibitor that blocks a specific protein needed by the HCV to replicate **(Gaetano, 2014).**

Sofosbuvir, the first approved new Interferon-free drugs, are active against all genotypes of HCV (pangenotipic) with a genetic high barrier, low interaction with other drugs, treatment with oral use (one tablet of 400 mg/day) and shorter duration ranging from 12-24 weeks **(Focaccia, *et al .,* 2016).**

In fact, Sovaldi is to be used as a component of a combination antiviral treatment regimen for chronic HCV infection. In October 2014, Sovaldi started to be used in Egypt as a component of the new treatment regimen for HCV **(WHO, 2017)**

The functional integrity of the liver is essential for the supply and inter-organ trafficking of essential nutrients (proteins, fat and carbohydrates) and the liver plays a crucial role in their metabolism. Many factors disrupt this metabolic balance in the cirrhotic liver (**Bémeur and Butterworth, 2015).**

Such factors include an increase protein catabolism, decreased hepatic and skeletal muscle glycogen synthesis and increased lipolysis **(Campillo*et al*., 2003).**

Malnutrition is common in end-stage liver disease (cirrhosis) and is often associated with a poor prognosis. Malnutrition occurs in all forms of cirrhosis as shown by studies of nutritional status in cirrhosis of differing etiology and of varying degrees of liver insufficiency. The prevalence of malnutrition in cirrhosis ranges from 65 to 100% depending upon the methods used for nutritional assessment and the severity of liver disease **(Alberino*et al*., 2001).**

Poor nutritional status contributes to fatigue, anemia, and infection, all of which impair successful HCV treatment, as well nourished patients are more likely to tolerate treatment, require less disruption of treatment, or dose reductions, and, consequently, have a more successful outcome, than those who are nutritionally depleted **(Paterson et al., 2014)**. Therefore, Nutritional assessment of all patients with HCV related liver disease especially who are treated with combination therapy is an essential to identify their nutritional needs and problems for optimizing their nutritional status to achieve better treatment response and disease outcome **(Bhatia *et al .*, 2014).**

Subjects And Methods
Subjects:

The study was conducted in Mahalla Hepatology Teaching hospital – Gharbia Gavarnorate, Egypt. The study was included (68) patients with

hepatitis C and treated with Sofosbuvir (Sovaldi).Inclusion criteria chronic HCV infected patients aged 18-60 years old who fulfilled the following criteria for treatment with triple (Sofosbuvir + Daklinza + Ribavirin) and dual therapy sofosbuvir + daklinza) for 3 months, both males and females, not hospitalized and receiving regular diet. Exclusion criteria patient out of Egyptian ministry of health hepatitis C treatment protocol, Ministry of Health, Egypt. The sample patients were randomly selected for each group after being involved in the protocolled treatment, 28 patients with hepatitis C- treated with sofosbuvir (Sovaldi) ,Daklinza and rRebavirin that were administered orally for 3 month, and 40 patients with hepatitis C- treated with dual therapy that consisted of Sofosbuvir (Sovaldi) and daklinza that were administered orally for 3 months at the study setting.

Methods :

Each patient was interviewed 2 times, once before the treatment then 3 months after completion of the treatment. Data was collected from patients using a predesigned structured questionnaire:

1- Socio-demographic data: including: Sex, Marital status: which included four categories; single, Married, divorced and widowed, occupation which included office employee, unemployed, level of education which included: not educated, educated, residence which included urban and rural residence.

2-Anthropometric assessment: including 1-Weight:weight was measured in kg using beam balance (Beurer BG42) scale by bioelectric impedance technique with minimum clothing without shoes, reading we taken to the nearest 0.5 kg (**Tai, *et al.,* 2010**). 2-Body mass index: body mass index (BMI) was calculated according to the following equation, weight in (kg) / height in metre^2 (kg/m^2). The participant was considered underweight when BMI <18.5kg/m^2, normal weight when BMI was 18.5-24.9kg/m^2, overweight when BMI >25-29.9kg/m^2 , obese class 1 when BMI was 30-34.9kg/m^2, obese class 2 when BMI was 35- 39.9kg/m^2 and morbid obese when BMI was $\geq$ 40kg/m^2 (**Smith, 2016**).3-Body composition:body fat percentage, body water percentage and body muscle percentage were documented before treatment and after treatment using bioelectric impedance analysis InBody 170 (**Bering, *et al*., 2018**) (**Kyle, *et al.,* 2004**).

3-Dietary assessment: 24 hours recall method: obtaining accurate amounts of foods and beverages consumed by patients in the three days preceding data collection, and the data from the 3 days dietary recall were used to arrive at estimates of daily nutrient intake from standard recipes (in 24 hours) **(Martin, 2005).**

4-Biochemical assessment: Records were reviewed to investigate the changes in AST, ALT, total bilirubin, ultra sound, WBCs count, platelets count and hemoglobin before treatment and after treatment **(Taneja, *et al*., 2018).**

5 –Nutritional status: will be performed for each patient and scored by using SGA. Subjective Global Assessment (SGA) is a simple evaluation tool that allows physicians to incorporate clinical findings and subjective patient history into nutritional assessment. Based on history taking and physical examination, and after meticulous collection of all these data the nutritional status of the patients was rated as follows: Normal (well-nourished-A), mild (malnourished-B) and Moderate (malnourished-C). The SGA has been shown to be a valid and useful clinical nutritional assessment tool for patients of various medical conditions weather suffering from liver diseases or not **(Fontes, *et al.,* 2014)**.

6-Statistical analysis of data:

Results were expressed as the arithmetic mean ± standard deviation (SD). Data for multiple variable comparisons were analyzed by one-way analysis of variance (ANOVA statistical measure). For the comparison of significance between groups, Duncan's test was used as a post hoc test according to the statistical package program (SPSS version 17.0) **(Armitage, and Berry, 1987)**

RESULTS AND DISCUSSION

Table (1) showed the socio-demographic data of the 68 adult patients were divided into 44 (64.7%) females and 24 (35.3 %) males. These results were not in agreement with **Nelson et al., (2015) t**hey reported that HCV was significantly higher in males compared to females. These findings might be because most the Egyptian females are housewives and they are not involved in health insurance sector. As regards to the marital status, there

were 11 (16.2%) widowed, 53 (77.9%) married, 2 (2.9%) divorced and 2 (2.9%) single.

Regarding the education status of the patients, there were 50 (73.5%) not educated while the rest of them were educated. These findings were in agreement with **Waked *et al*., (2017);** in their study about HCV burden of infection in Egypt where the results from a nationwide survey revealed that lack of education was also strongly associated with HCV infection. It is conceivable that lack of knowledge about HCV transmission routes among the least educated participants puts them at risk of infection.

Forty-seven patients (69.1%) were Unemployed while, only 21 (30.9) of them were Employee**.** These results were in agreement with **El Rouby et al., (2017)** they reported that 53.4% of the study participants were housewives, whereas 39% had stopped working because of their inability to work as a result of liver disease.

Almost all of our patients (66) (97.1%) came from rural areas while, only 2 (2.9%) patients came from urban areas. This results agreement with **El Rouby et al., (2017),** it might be because more poverty and decrease level of education were found more in rural an compared to urban also this finding is in agreement with **mohamoud et al., (2013)** in their systematic review about the epidemiology of hepatitis C virus in Egypt which revealed that prevalence of chronic HCV infection is higher in people from rural areas than those from urban areas.

Table (1): Socio-demographic data of the studied groups:

Chronic hepatitis C patients		N=68
Sex	Male	(24) 35.3%
	Female	(44) 64.7%
Marital status	Widow	(11)16.2%
	Married	(53) 77.9%
	Divorced	(2) 2.9%
	Single	(2) 2.9%
Education	Not educated	(50) 73.5%

	Educated	(18) 26.5%
Occupation	Employee	(21) 30.9%
	Unemployed	(47) 69.1%
Residency	Urban	(2) 2.9%
	Rural	(66) 97.1%

Results in **Table (2)** showed the anthropometric measurements of the two studied groups, the distribution of weight of the two studied groups of chronic hepatitis C patients receiving the triple and dual treatment regimens during treatment period where there was a significant weight loss in the Triple group more than the dual group.

In the dual treatment group, the weight decreased from 87.99 ± 18.78 Kg Pre treatment to 86.08±17.55 Kg Post treatment, and in the triple treatment group the weight decreased from 89.66 ± 20.38Kg Pre treatment to 86.86 ± 20.12 Kg Post treatment.

In this study, among Triple group, there was a significant weight loss between the pre and post treatment and this may be due to adaptation of the studied patients to the effects of treatment and these results are similar to outpatient department of Pakistan Medical and Research Centre **(Sajjad et al., 2012)** that reported that 67.7% of the studied chronic hepatitis C patients experienced weight loss by the completion of therapy. The reason for that might be the small number of the studied patients in the present study in comparison to that study (260 patients) also, the shorter duration of the triple therapy (3 months) in comparison to that study (6 months of treatment). Dual group had a slight weight loss between pre and post treatment and this may be due to adaptation of the patients to the effects of treatment, and illustrated BMI decrease from 34.0 ± 7.14 to 33.05 ± 6.Kg/m^{2}in the dual treatment regimen, while in the triple treatment regimen, BMI decreased from 35.17 ± 7.82 to 33.84 ± 7.42 Kg/m^2. There was a significant decrease in BMI between the pre and post treatment among the Triple group which is consistent with the results obtained by **El Rouby et al., (2017)** , this might be because of the side effects from treatment which included fatigue, loss of appetite, abdominal pain, and nausea that were

reported more commonly and frequently during the first month from starting the treatment protocol than after that , these side effects might interfere with the dietary intake leading to weight loss and subsequently and shows the distribution of waist/hip ratio of the two studied groups of chronic hepatitis C patients receiving the triple and dual treatment regimens during Pre and post treatment periods where there was more evident decrease in waist/hip ratio between the two periods among Dual group than triple group regimens. In the dual treatment group, waist/hip ratio decreased from 0.9736±0.060 Pretreatment to 0.9371±0.06Post treatment, and in the triple treatment group, it decreased from 0.985±0.067Pre treatment to 0.936±0.060 Post treatment. There was a slight decrease between pre and post treatment in both groups which was inconsistent with the results reported from a Japanese study **(Takahashi et al., 2015)**

Table(2): Anthropometric assessment of the two studied groups of chronic hepatitis C patients receiving the triple and dual treatment regimens.

Paramilitary	Dual(n = 40) Mean ± SD	Triple (n = 28) Mean ± SD
Weight (Kg) Pre treatment Post treatment	87.99 ±18.78 86.08±17.55	89.66 ± 20.38[*] 86.86 ± 20.12[#]
BMI (Kg/m^2) Pre treatment Post treatment	34.0 ± 7.14 33.05 ± 6.56	35.17 ± 7.82[*] 33.84 ± 7.42[#]
Waist /hip ratio Pre treatment Post treatment	0.9736±0.060 0.9371±0.064	0.985±0.067* 0.936±0.060[#]

N=Number
SD=Standard Deviation
The results are expressed as the M ± SD.
(*) Significant, p≤0.05; triple group before treatment as compared with dual group before treatment.

(#) Significant, p≤0.05; triple group after treatment as compared with dual group after treatment.

Regarding the hemoglobin level of the two studied groups of chronic hepatitis C patients receiving the triple and dual treatment regimens, data given in **Table (3)** shows hemoglobin decreased from 12.26 ± 1.53(g\dl) to 11.83 ±1.58 (g\dl) in the Dual treatment regimen, while in the Triple treatment regimen, hemoglobin decreased from 12.97±1.537 to 10.5 ±1.05 (g\dl).

There was significant difference between the measured hemoglobin level before and after treatment in Triple group, these agreements with a study in Shebein EL-Kom Teaching Hospital, Hepatology Department as a part of the Egyption Ministry of Health project for the treatment of hepatitis C virus (**Lashin et al., 2013)** where decrease in hemoglobin in 28.8% of the Triple group. the Platelet count ×1000mm³ decrease from 217.55 ± 87.85(cells\mcL) to 197.00 ±71.46 (cells/mcL) in the Dual treatment regimen, while in the Triple treatment regimen, the Platelet count ×1000mm³ decreased from 210.62 ±64.63to 171.10 ± 67.59 (cells/mcL).

As regards the Platelet count in the two studied groups before and after treatment, there was a significant decrease in both groups before and after the treatment and these results matching with **(EASL, 2016).**

A another finding of the present study that, among Triple and Dual groups, there was significant decrease in mean total bilirubin after treatment than before it, which was inconsistent with the results obtained from a study **Alzubaide et al., (2015).**

Table (3) Biochemical assessment of the two studied groups of chronic hepatitis C patients receiving the triple and dual treatment regimens:

Triple (n = 28) Mean ± SD	Dual (n = 40) Mean ± SD	Paramilitary
12.97 ± 1.537* 10.5 ±1.05#	12.26 ± 1.53 11.83 ±1.58	Hemoglobin (g\dl) Pre treatment Post treatment
210.62 ±64.63* 171.10 ± 67.59#	217.55 ± 87.85 197.00 ±71.46	Platelets ×1000mm³(cells\mcL) Pre treatment Post treatment

1.09 ± 0.415* 0.9693 ± 0.495[#]	0.914 ±.467 0.729 ±.278	Total bilirubin(mg\dl) Pre treatment Post treatment
44.07±12.65* 34.78± 10.08[#]	45±15.48 44.35± 28.63	ALT(U\L) Pre treatment Post treatment
42.71± 12.4* 32.5± 11.0[#]	46.6± 18.47 36.12± 12.87	AST(U\L) Pre treatment Post treatment

N=Number

SD=Standard Deviation

The results are expressed as the M ± SD.

(*) Significant, p<0.05; triple group before treatment as compared with dual group before treatment.

 (#) Significant, p<0.05; triple group after treatment as compared with dual group after treatment.

Regarding liver enzymes (ALT and AST), Triple group had a significant decrease in the ALT and AST levels post and pre treatment which agreed with the results of **Alzubaide et al., (2015)** in their study .While among Dual group, there was also a significant decrease in the AST and ALT levels but with a lower value pre and post treatment in comparison to triple group.

Daily dietary intake of the studied groups of chronic hepatitis C patients:

A significant decrease in all daily macronutrients intake was observed between pre and post treatment visits, also there was more evident decrease in the fat and protein than carbohydrates intake due to the nutritionists' advice to the patients to decrease adding fat in cooking also due to patients' belief that red meat had a harmful effect on them and that is another probable reason why losing some body muscle was present **(Fontes, *et al.,* 2014)**.
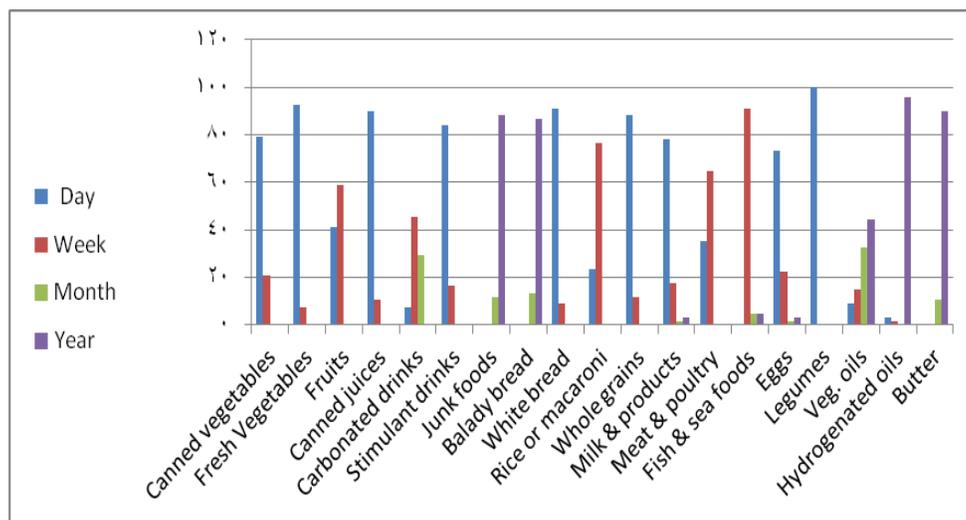
Figure (1) Daily dietary intake (%) of the studied groups of chronic hepatitis C patients:

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تقييم الحالة الغذائية لمرضى الالتهاب الكبدي سي بمستشفى كبد المحلة التعليمي

سحر عثمان الشافعي ، سمر محمود رزق ، سميرة حامد بدر الدين

الملخص العربى

ينتشر سوء التغذية بين مرضى أمراض الكبد المزمنة. لذلك ، فإن الهدف من هذا العمل هو تقييم الحالة التغذوية للمرضى الذين يعانون من فيروس التهاب الكبد الوبائي C والعلاج القائم على sofosbuvir. المرضى موضع الدراسة ومقارنة الطرق المختلفة المستخدمة في التقييم الغذائي وهي مقاييس الجسم البشري والتقييم العالمي الذاتي (SGA). المرضى : أجريت هذه الدراسة في مستشفى المحلة الكبدي التعليمي من أجل تقييم الحالة التغذوية لـ (68) مريض من الاناث والذكور. واشتملت الدراسة على مجموعتين الاولى تكونت من 28 مريضا بالتهاب الكبد الوبائي المزمن C الذين يتلقون نظامًا مضادًا للفيروسات ثلاثي يتكون من (Sofosbuvir (Sovaldi) + Daklinza + Ribavirin) التي أجريت لمرضي المجموعه الاولى و المجموعه الاخرى اشتملت علي 40 مريضا بالتهاب الكبدي الفيروسي C وخضعت لنظام مضاد للفيروسات يتكون من Daklinza + Sofosbuvir (Sovaldi)) التي تؤخذ عن طريق الفم لمدة 3 أشهر لكل مجموعة. تم إجراء أخذ التاريخ الشامل والفحص البدني والتقييم الغذائي المفصل بما في ذلك المؤشر الغذائي على مدار 24 ساعة. تم تقييم الحالة التغذوية باستخدام مقاييس أنثروبومترية مختلفة والتقييم العالمي الذاتي (SGA). تقييم غذائي يعتمد على مقارنة العلاج الثنائي مع النتائج المختبرية للعلاج الثلاثي لهؤلاء المرضى الذين يعكسون حالتهم التغذوية مثل الهيموغلوبين ، وأنزيمات الكبد (AST، ALT) ، والبيليروبين الكلي ، والصوت الفائق ، وعدد كرات الدم البيضاء ، وعدد الصفائح الدموية قبل العلاج وبعد العلاج. النتائج: كشفت الدراسة أن 73.5 ٪ من المرضى لديهم حالة غذائية جيدة مع درجة SGA ، و 25 ٪ من المرضى لديهم حالة غذائية خفيفة إلى معتدلة مع درجة SGA B ، في حين أن 1.5 ٪ من المرضى يعانون من حالة غذائية سيئة مع نتائج SGA المختبر C. من هؤلاء المرضى على النحو التالي: كان للعلاج المضاد للفيروسات الثلاثي تأثير أكثر وضوحا في التحاليل المخبرية حيث انخفض في مستويات الهيموغلوبين ، وعدد خلايا الدم البيضاء ، وعدد الصفائح الدموية ، وأنزيمات الكبد (AST و ALT) وزيادة في مستوى البيليروبين الكلي مقارنة بالمزدوجات العلاج المضاد للفيروسات.

الكلمات الدالة: التغذية ، التقييم ، SGA ، أمراض الكبد ، سوفالدي .