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Liver Cirrhosis: Impact Of Nutritional Regimen On Patients Outcome

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Abstract : *Death rate of liver cirrhosis is 41.6% in Egypt. It is important to assess the nutritional status of this group of patients and design nutritional regimen because these patients suffer from protein calorie malnutrition.*
The aim *of this study was assessment of the impact of a designed nutritional regimen on patients with liver cirrhosis.*
Patient and Methods*: 60 adult patients with liver cirrhosis as a study group and 20 patients as a control group, the study were conducted at Tropical Medicine and Gastroenterology Department at Asyut University hospital.* ***Tools*** *utilized for data collection were :****(I)*** *patient assessment sheet* ***(II)*** *nutritional assessment sheet, and* ***(III)*** *Construction of nutritional regimen.*
Results: *The most common malnutrition risk factors were dry mouth, taste alteration, food intolerance, multiple medications and the presence of ascites. Number of patients who didn't suffer from malnutrition increased post implication of the nutritional regimen one and three months later.*
Conclusions*: the application of the nutritional regimen for patients with liver cirrhosis showed an improvement in patient's nutritional status.*
Recommendations: *Nutritional support and regimen, advice and guidelines by dietitian should be undertaken for all cirrhotic patients to prevent occurrence of complications of malnutrition and improve clinical outcome.*
Keywords *- Designed nutritional regimen, Liver cirrhosis, Patient outcome.*

I. Introduction

Liver cirrhosis is a chronic hepatic disease characterized by diffuse destruction and fibrotic regeneration of hepatic cells. As necrotic tissue yields to fibrosis, this disease alters liver structure and normal vasculature, impairs blood and lymph flow, and ultimately causes hepatic insufficiency [1,2]. The incidence of cirrhosis is increasing in the developed world, mainly because of the life style factors which lead to its development [3].

According to the World Health Organization , there is about 3% of the world's population is infected with Hepatitis C virus (HCV) and that there are more than 170 million chronic carriers who are at risk of developing liver cirrhosis and/or liver cancer. More than 240 million people have chronic (long-term) liver infections. More than 780 000 people die every year due to the acute or chronic consequences of hepatitis B. [4,5].

Available studies indicated that liver cirrhosis developed in 4 % to 24% of persons after 20 years of infection with HCV. These estimates of cirrhosis risk are influenced strongly by the population studied and cohort recruitment methods [6]. Hepatitis C virus (HCV) is recognized as a major threat to global public health, especially in Egypt which has possibly the highest HCV prevalence in the world; 10% - 20% of the general populations are infected. HCV is the leading cause of liver cirrhosis, hepatocellular carcinoma (HCC) and chronic liver disease in this country [7].

Frequent finding in patients with liver cirrhosis is protein-calorie malnutrition (PCM), leading to severe consequences to the general state and clinical evaluation of the patient. It had been demonstrated that PCM is an independent risk factor for death among patients with chronic hepatic disease, contributing to the emergence of more severe complications in cirrhotic patients, such as ascites, hepatic encephalopathy and infections. Multiple factors which are common to the underlying disease directly contribute to malnutrition, among them; anorexia, nausea, deficient food intake and absorption and catabolic state [8].

In addition, the many dietary restrictions used to control symptoms and specific complications, such as ascites and hepatic encephalopathy, aggravate the nutritional status, predisposing the patients to infections and worsening of the functional hepatic status [9].

In spite of the well-known impact on morbidity and mortality, malnutrition in cirrhotic patients is still under diagnosed and untreated in clinical practice. Most of the traditional parameters for nutritional assessment are not reliable markers of malnutrition in this population. Body weight, BMI, weight loss, and body cell mass estimated by bio impedance analysis, are affected by fluid retention. The concentration of plasma proteins (albumin and pre albumin) reflects liver impairment more than nutritional deficits [10].

Nutritional support for preventing and treating of malnutrition in liver cirrhosis should include: assessment of nutritional status, dietetic counselling for: adequate and balanced diet, frequent meals and late-evening snack, alcohol withdrawal, oral nutritional supplements (complete formulas), artificial nutrition (enteral nutrition as first choice), and vitamin and mineral supplementation as thiamine, folate, calcium, vitamin D3, vitamin A, vitamin E, zinc and magnesium according to specific needs)[10].

The nurse has a major role in caring for patients with liver cirrhosis through assessment the patient for subjective complaints such as malaise, fatigue, pruritus (itching), nausea, anorexia, and abdominal pain. Objective data, such as baseline weight, vomiting, pale stools, amber- or dark-colour (tea-coloured) urine, and jaundice, are recorded. The patient's vital signs are taken, and a low-grade fever or any abnormal bruising or bleeding is reported immediately. Assessment the patient for knowledge of disease process and how to prevent spread of the disease is necessary [11].

Screening all patients with chronic liver disease for nutritional abnormalities can identify those at risk of developing preventable complications. The initiation of nutritional therapy has the potential to reduce the risk of such complications, and to improve the overall mortality rate. [12].

The aims of the study:

To assess the impact of a designed nutritional regimen on patients with liver cirrhosis.

Hypothesis:

To fulfil the aim of the study the following research hypothesis was formulated:-

The patient nutritional status will be better after the application of designed nutritional regimen.

Significance of the Study

According to the World Health Organization (WHO), there is about 3% of the world's population is infected with Hepatitis C virus (HCV) and there were more than 170 million chronic carriers who are at risk of developing liver cirrhosis and/or liver cancer[4]. Death rate of liver cirrhosis is 41.6% in Egypt [1], there was an increase in incidence and prevalence of liver cirrhosis. It was important to assess the nutritional status of this group of patients and design nutritional regimen because these patients suffer from protein calorie malnutrition which was contributing to sever complications such as ascites, hepatic encephalopathy and infections and it causes significant health- related quality of life (QOL) impairment and morbidity. These patients were in need for special nutritional regimen to minimize their complications and positive progression. 1840 patients with liver cirrhosis were reported in Tropical Medicine and Gastroenterology department at Assiut University Hospital through 2014.

II. Patients And Methods

Research design:

Quasi-experimental research design was utilized in this study.

Study variables:

The independent variable in this study is a designed nutritional regimen for liver cirrhosis while the dependent variables are: patients with liver cirrhosis as well as the interactions of diet components and drugs.

I. Technical design:

Setting:

The study was conducted in the Tropical Medicine and Gastroenterology department at Assiut University Hospital.

Subjects:

Sixty adult patients diagnosed with liver cirrhosis as a study group with whom the nutritional regimen was applied and the effect was evaluated in addition twenty patients with liver cirrhosis considered as control group (for laboratory investigations and anthropometric measurements only). Start with 105 patients; 4 patients died and 21 patients missed during follow up stages so they were excluded from the study and nutritional assessment.

*Study group was selected according to the following criteria:

Inclusive Criteria:

- Patients with liver cirrhosis (Child class A and B only), patient's age from 18 years to 65 years, and ability to complete the participation in the research regardless educational level.

Exclusive Criteria:

- Patient with Child class(C) liver cirrhosis, patient with hepatic coma, renal failure, diabetes mellitus, and cancer.
- Control group was selected from patients who had liver cirrhosis and have the same inclusion and exclusion criteria of the study group.

Tools:

Tool I: patient assessment sheet:

It was developed by the researcher after reviewing of literature; it was consisted of two parts:

Part (1): Personal and Medical Data Sheet:

Socio-demographic variables of study sample (80 patients) patient's age, sex, level of education, occupation, marital status, residence, aetiology, ascites, oesophageal varices, jaundice, essential medication data, …...etc.). This includes 27 questions.

NB. The interview questionnaire sheet was administered by the researchers to the patients for answering all its components then collected prior the implementation of the regimen, after one month then after three months

Part (2): Child Pugh score:

Modified Child Pugh scale (Child et al., 1964 was developed by Pugh in1973 [13]. To rank severity of liver disease based on signs and the findings.

Table (1): Child Pugh score

Clinical variable	1 point	2 point	3 point
Bilirubin	<2 mg/dl (34 UM/l)	2-3 mg/dl (34-50 UM/l)	>3 mg/dl (50 UM/l)
Albumin	>3.5 g/dl	3.5-2.8	<2.8
PT prolongation (INR)	< 4seconds (<1.7)	(4 -6) seconds (1.7-2.3)	>6 seconds (>2.3)
Ascites	Absent	Mild-Moderate	Severe/Refractory
Encephalopathy	Absent	Mild (I-II)	Severe (III-IV)

Child-Pugh Bottom interpretation Score:

- Class A = 5-6 points
- Class B = 7-9 points
- Class C = 10-15 points

Tool II: Nutritional assessment sheet:

This sheet is to cover data related to patient nutritional status and includes four parts:

Part (1): Risk factors affecting nutritional status, this part aimed to identify the risk factors which effect on nutritional status and contained 17 questions such as (dry mouth, taste alteration, vomiting, diarrhoea, constipation, failure to thrive: combination of three or five symptoms, including: weakness, slow walking speed, low physical activity and unintentional weight loss, Exhaustion. …etc.).

Part (2): Anthropometric measurements:

A) Patient weight in kg.
B) Patient height in cm.
C) BMI = (Weight in kg/height in m^2).
   Standards classify a BMI for adult at less than 18.5 as underweight, a BMI between 25 and 29 as overweight and a BMI greater than 30 as obese. A healthy BMI for adults is considered between 18.5 and 24.9.
D) Triceps skin fold thickness (TSF): [14]. By using digital caliper.

Fig (1), shows the balance device that used in measuring triceps skin fold thickness of the patients.

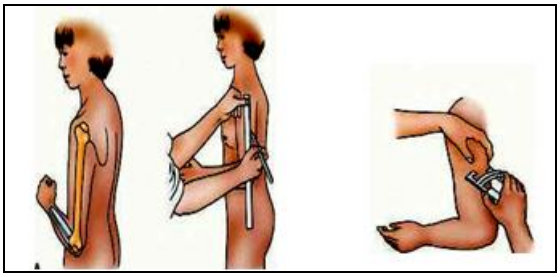

Fig (2), shows the steps of measuring triceps skin fold thickness of the patients.

E) Measure mid-arm circumference (MAC) normal values are 18.5-25.5 cm for adults [15]. Using measuring tape.

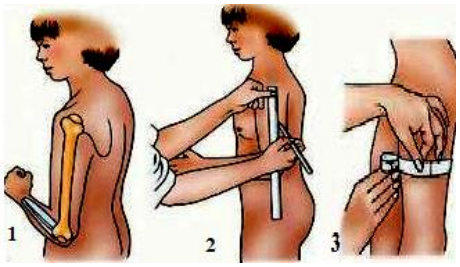

Fig (3), shows the steps of measuring mid-arm circumference of the patients.

Calculate mid-arm muscle circumference (MAMC) = MAC- (0.314(TST)) [15].
D) Calf circumference using measuring tape.
This part aimed to assess patient anthropometric measurements before, after one month and after three months of the implementation of the regimen.

Part (3): Biochemical measurements:

Biochemical assessments reflect both the tissue level of a given nutrient and any abnormality of metabolism in the utilization of nutrients. These determinations are made from studies of serum complete blood count; (haemoglobin, white blood cells, mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), mean corpuscular haemoglobin concentration (MCHC), platelet count, and total lymphocyte count), serum albumin, prothrombine time & concentration and bilirubin.

Part (4): Mini- Nutritional Assessment (MNA) (malnutrition indictors score) [16].

The aim of this part is a rapid and reliable tool for evaluating the nutritional status. It is composed of 18 items.

Malnutrition indicator Score.

- Malnourished (MNA<17),
- At risk of malnutrition (17 < MNA < 24), and
- Well nourished (MNA > 24).

Tool III: Construction of nutritional regimen:

The content of it was developed by the researchers after passing through an extensive and relevant literature review and according to the patient's needs. This regimen aimed to enhance the patient knowledge about nutrition in liver cirrhosis disease and contained the following:

1. Calories: should be given a high - calorie meals so that the patient gets at least 2000 - 2500 calories/day.

2. Proteins: provide ample amounts of protein to help in the regeneration of liver cells. To compensate for the albumin loss the patient was given about 2 g / kg of body weight per day, while refraining from any protein if the patient is in a coma liver.
3. Fat: The patient is given 1 g / kg of body weight of the patient in the event of a fatty liver, taking into account the provision of sufficient quantities of proteins at the same time.
4. Carbohydrates: provide ample amounts according to patient's desire.
5. Mineral: reduce the intake of sodium and provide compensatory amounts of potassium and iron.
6. Vitamins: should contain vitamin (D, A, K, C and B12).
7. Blocked list.
8. List of allowances.

III. Operational Design:

This study was conducted through:

- Tools development.
- Content validity was done by expertise (nutritional staff), (medical staff) & (nursing staff) from the medical-surgical nursing field. Modifications were made accordingly, and then the tools were designed in their final format and tested for reliability using internal consistency for all of the tools which was measured using Cronbach test. The tools proved to be reliable (0.73.0.71 and 0.81, respectively).
- An official permission was obtained from the head of the Tropical Medicine and Gastroenterology department at Assiut University Hospital to conduct the study.

Ethical consideration

- An informed consent was obtained from patients to participate in the study and the nature and purpose of the study were explained to them.
- The researchers initially introduced themselves to all optional subjects and they were assured that the collected data would be absolutely confidential.
- They were informed that participation is voluntary and that they could withdraw at any time of the study.
- Confidentiality of the patient's data was ascertained. Confidentiality and anonymity were assured.
- Patient's names were coded for data entry so that their names could not be identified. Then, through this patient's interview.

Pilot study

- **A** pilot study was conducted on 10% of sample (8 patients) in a selected setting to evaluate the applicability & clarity of the tools. According to this pilot study, the required modifications were made. Those patients who were involved in the pilot study were included in the study.
- Baseline data was obtained from the study and control group patients to fill in Tools: I and II (pre-test) At initial interview the researcher introduce herself to initiate line of communication, explain the nature & purpose of the designed nutritional regimen and fill out the patient assessment sheet (tool I) which contains; Personal and Medical Data Sheet and Child Pugh score.
- Tool II: Nutritional assessment sheet contains; risk factors affecting nutritional status, anthropometric measurements, Biochemical measurements and Mini- Nutritional Assessment (MNA) (malnutrition indictors scores).
- Application of the nutritional regimen was explained by researchers for the patient (tool III) first prepared the training places, teaching aids and media (pictures, handouts and booklet). This was followed by arranging for the teaching schedule based on the contents of booklet, number of patients involved, time availability.

Teaching sessions:

- Patients (study group) were divided into small groups; each group contains maximum 2 patients. Each patient chose the optimal time for receiving the teaching sessions whenever they have ready to learn.
- The nutritional support, prescribed for study patients, aimed to elaborate the impact of implementing the nutritional regimen on patients with liver cirrhosis. A booklet was given to patients or one of the family members about allowed and prohibited food. The nutrition support was presented to all patients included in the study group in 2 sessions weekly, was taken a duration of 40 minutes and given to each patient individually and the title was covered as following:
- Each session usually started by a summary of what had been taught during the previous session and the objectives of the new session. After each session there was 10 minutes for discussion and gave feedback. Reinforcement of teaching was performed according to patient's needs to ensure their understanding. Each

patient in the study group obtains a copy of the teaching booklet. The researcher used pictures for illustration, diagram, and video to educate the patient.

The first session:
Contains three parts:
Part I: Information about anatomy of liver
Part II: Information about liver cirrhosis.
Part III: Good nutrition and pattern of healthy nutritional food, blocked and allowances list, and healthy nutrition for liver cirrhosis.

The second session:
Contains one part: Special Nutritional managements in cases of diarrhea, abdominal distention, muscles cramps, oesophageal varices, ascites, and examples of menu day.

- Control group exposed to routine diet.
- Data were collected through the period for a year.
- After one and three months of the nutritional regimen application (tool II). The patients (study group) had been evaluated by the researchers through filling the tool (I and II) post-test.
- Post-test was performed to assess the patient (control group) using (tools I and II) without application of the nutritional regimen one month and three months later of the pre-test.

Statistical design:
Data entry was done using compatible personal computer by the researcher. All data was entered into statistical packages for the social sciences (SPSS) version 17.0 (Chicago, Illinois, USA) software for analysis and Excel for figures. The content of each tool was analysed, categorized and then coded by the researcher. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables. Pearson's correlation analysis was used for assessment of the inter-relationships among quantitative variables. Using chi square to determine significance for non-paretic's variables. Statistical significance difference was considered when statistical significance was considered at p-value < 0.05.

Data related to socio-demographic characteristics of cirrhotic liver patients of the studied sample were initially collected as a base line data, and then the nutritional assessment form was completed, each patient was interviewed individually. Data were analysed using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables. Correlation Coefficient (r) analysis was used for assessment of the inter-relationships among quantitative variables. Using chi square to determine significance form non significance variables. Statistical significance difference was considered when statistical significance was considered at p-value < 0.05.

Limitation of the study:
1. Participants suffered from transportation and financial problems.
2. During preparation of a teaching booklet, the level of literacy in the patient population was considered. A lack of reading skills limited the ability of patients to access and use critical information.
3. Missed patients during the period of the study for that the research takes a long period of data collection.
4. Limitation of this study is that the investigation findings are limited in generalizability because the sample was selected from one geographical area in Arab Republic of Egypt (Tropical Medicine and Gastroenterology department at Asyut University Hospital).
5. There is no standard of nutritional regimen special for cirrhotic patient.
6. The researchers start the study with 115 patients. 20 patients died and 15 were missed during follow up stage so they excluded from the study.

IV. Results

The current study was carried out to assess the impact of a designed nutritional regimen on patients with liver cirrhosis.

Table 1: **Socio-demographic characteristics of both study group (n=60) and control group (n=20):**

	Study group (n=60)		**Control group (n=20)**	
	No.	**%**	**No.**	**%**
Age groups Mean ± SD	56.0±8.1		55.1±6.4	
18 -30 years	1	1.7	0	0.0
31-40 years	2	3.3	2	10.0
41-50 years	9	15.0	1	5.0

	Study group (n=60)		Control group (n=20)	
	No.	%	No.	%
51-65 years	48	80.0	17	85.0
Gender				
Male	26	43.3	9	45.0
Female	34	56.7	11	55.0
Marital Status				
Single	3	5.0	0	0.0
Married	50	83.3	18	90.0
Widow	7	11.7	2	10.0
Level of education				
Illiterate	41	68.3	15	75.0
Read and write	0	0.0	1	5.0
Basic education	3	5.0	1	5.0
Secondary/ deplume	12	20.0	2	10.0
University	4	6.7	1	5.0
Occupational status				
House wife	33	55.0	11	55.0
Worker	8	13.3	1	5.0
Farmer	2	3.3	4	20.0
Unemployed	0	0.0	1	5.0
Retired	8	13.3	1	5.0
Employer	9	15.0	2	10.0
Residence				
Urban	9	15	4	20.0
Rural	51	85	16	80.0
Etiology of liver cirrhosis				
HCV	37	61.7	13	65.0
Unknown causes	1	1.7	1	5.0
Bilharzia	1	1.7	3	15.0
HBV	10	16.7	1	5.0
HCV & Bilharzia	6	10.0	1	5.0
HCV & others	5	8.3	1	5.0

Table (1): shows that ; the majority of both study and control group were female, married , illiterate , house wife, from rural areas , HCV was the main cause of cirrhosis, and their age ranged from 51 to 65 years old.

Table (2): Clinical presentations of both study and control group:

	Study group (n=60)						P. value	Control group (n=20)						P. value
	Before		1 month		3 months			Before		1 month		3 months		
	No.	%	No.	%	No.	%		No.	%	No.	%	No.	%	
Bleeding tendency														
Yes	33	55.0	16	26.7	12	20.0	<0.001**	12	60.0	11	55.0	13	65.0	0.812^{Ns}
No	27	45.0	44	73.3	48	80.0		8	40.0	9	45.0	7	35.0	
If yes the site														
Nose	12	20.0	8	13.3	7	11.7	0.575^{Ns}	6	30.0	6	30.0	7	35.0	0.414^{Ns}
Gums	15	25.0	7	11.7	4	6.7		5	25.0	4	20.0	3	15.0	
Rectum	1	1.7	0	0.0	0	0.0		0	0.0	0	0.0	1	5.0	
Nose & gums	5	8.3	1	1.7	1	1.7		1	5.0	1	5.0	2	10.0	
Ascites														
Yes	34	56.7	29	48.3	27	45.0	0.420^{Ns}	13	65.0	14	70.0	13	65.0	0.928^{Ns}
No	26	43.3	31	51.7	33	55.0		7	35.0	6	30.0	7	35.0	
Splenomegaly														
Yes	24	40.0	24	40.0	25	41.7	0.933^{Ns}	4	20.0	5	25.0	7	35.0	0.551^{Ns}
No	36	60.0	36	60.0	35	58.3		16	80.0	15	75.0	13	65.0	
Jaundice														
Yes	35	58.3	37	61.7	30	50.0	0.414^{Ns}	17	85.0	17	85.0	16	80.0	0.887^{Ns}
No	25	41.7	23	38.3	30	50.0		3	15.0	3	15.0	4	20.0	
Severity of liver cirrhosis														
Class A	10	16.7	15	25.0	28	46.7	<0.001**	5	25.0	3	15.0	2	10.0	0.085^{Ns}
Class B	50	83.3	45	75.0	30	50.0		15	75.0	16	80.0	15	75.0	
Class C	0	0.0	0	0.0	2	3.3		0	0.0	1	5.0	3	15.0	

* =Significant difference **= highly significance Ns= Non significant difference

Table (2): shows that there were statistical significant differences found in study group as regard presence of bleeding tendency and severity of liver cirrhosis which are improved after application of diet regimen. In control group there was no statistical significant difference in clinical presentation. After one month one patient (5%) became Child class C from the control group, while after 3 months 2 patients (3.3%) from study group and 3 patients (15%) from the control group became Child class C.

Table (3): Risk factors for malnutrition in both study and control groups:

Risk factors	Study group (n=60)				Control group (n=20)				P. value
	yes		No		yes		No		
	N o.	%	No.	%	No.	%	No.	%	0.412 Ns
Dry mouth	51	85.0	9	15	15	75.0	5	25.0	0.197 Ns
Taste alteration	40	66.7	20	33.3	10	50.0	10	50.0	0.737 Ns
Vomiting	17	28.3	43	71.7	7	35.0	13	65.0	0.710 Ns
Diarrhea	6	10.0	54	90.0	3	15.0	17	85.0	0.167 Ns
Constipation	25	41.7	35	58.3	4	20.0	16	80.0	0.625 Ns
Poor fitting or no dentures / poor dental health	20	33.3	40	66.7	6	30.0	14	70.0	0.270 Ns
Food allergies or intolerance	7	11.7	53	88.3	0	0.0	20	100	0.485 Ns
Transportation problems	17	28.3	43	71.7	3	15.0	17	85.0	0.830 Ns
Inability to prepare meals	25	41.7	35	58.3	8	40.0	12	60.0	0.827 Ns
Loneliness and /or depression	25	41.7	35	58.3	9	45.0	11	55.0	0.587 Ns
Failure to thrive	35	58.3	25	41.7	14	70.0	6	30.0	0.336 Ns
History of OTC drugs	13	21.7	47	78.3	2	10.0	18	90.0	0.655 Ns
Acute or chronic pain	26	43.3	34	56.7	7	35.0	13	65.0	0.763 Ns
History of surgery/trauma	32	53.3	28	46.7	12	60.0	8	40.0	0.246 Ns
Multiple medications	31	51.7	29	48.3	6	30.0	14	70.0	0.747 Ns
Low income	20	33.3	40	66.7	8	40.0	12	60.0	0.531 Ns
Smoking	15	25.0	45	75.0	3	15.0	17	85.0	0.412 Ns

Ns= Non significant difference

Table (3): clarifies that there were no statistical difference between study and control group regarding all risk factors of malnutrition among cirrhotic patients.

Table (4): Mean and Standard deviation for anthropometric measurements between the study group (N= 60) and Control group (N=20) (n=20) pre, one month and three months after application of nutritional regimen:

Anthropometric measurements		Study group(n=60)			P. value	Control group(n=20)			P. value
		Before	1 month	3 month		Before	1 month	3 month	
BMI	M	26.5±3.9	26.3±4.5	26.5±4.6	0.974	26.7±5	26±5.3	26.6±5.4	0.913
	F	27±4.8	27.2±4.6	27.5±4.8	0.912	27.2±4	27.2±3.7	26.3±3.2	0.930
Triceps skin fold thickness Male	M	1.1±0.6	1.2±0.5	1.2±0.6	0.909	1.1±0.3	1.1±0.3	1.1±0.4	0.799
	F	1.3±0.6	1.3±0.6	1.4±0.5	0.902	1.3±0.7	1.3±0.6	1.3±0.7	0.815
Mid arm circumference	M	27.8±3.5	27.3±3.6	28.3±4.1	0.980	27.3±3.9	27.9±3.8	26.7±3.7	1
	F	26.8±3.7	26.9±3.6	27.1±3.6	0.974	26±3.1	26.9±2.8	25.3±2.9	0.936
Calf circumference	M	33.9±3.2	33.9±3.4	34.2±3.8	0.297	33.9±3.7	33.9±3.6	33.4±3.8	0.856
	F	33.3±4	33.7±4	33.9±3.9	0.999	33.1±4.2	32.9±4	31.8±4.5	0.740

Table (4): clarifies that there was no statistical deference in anthropometric measures between study and control group in all stages of the study.

Table (5): mean and Follow up laboratory tests among the study (n=60) and control groups (n =20):

	Study group (n=60)			P. value	Control group (n=20)			P. value
	Before	1 month	3 months		Before	1 month	3 months	
	Mean ± SD				Mean ± SD			
Serum albumin	2.82±0.41	3.21±0.61	3.4±0.71	0.042*	2.74±.27	2.84±0.29	2.83±0.56	0.409 Ns
Hemoglobin	10.41±2.02	11.97±2.03	13.5±1.7	0.032*	9.32±1.93	9.3±1.92	9.2±3.6	0.227 Ns
Hematocrite	33.5±8.7	34.9±8.1	36.9±9.4	0.039*	29±7.6	28.9±9.5	31.7±8.7	0.062 Ns
White blood cells	5.9±2.7	7.4±13.7	8.2±14.5	0.539	6.1±4.4	6.5±4.2	5.7±2.3	0.786 Ns
Prothrombine time	15.8±4.6	14.4±5.1	13.4±3.2	0.012*	19.3±7.2	18.8±7.6	15.5±6	0.178 Ns
INR	1.6±1.8	1.4±0.4	1.3±0.3	0.035*	1.6±0.6	1.5±0.6	1.5±0.6	0.658 Ns
Platelet count	121.4±74	128.5±59.8	132.4±58.7	0.234 Ns	112.3±64.4	126.4±66.6	121.5±73	0.405 Ns
Serum Bilirubin	20.6±68.6	17.9±68.6	17.7±68.6	0.967 Ns	3.5±6.4	3.2±7.7	1.8±1	0.594 Ns

* =Significant difference **= highly significance Ns= Non significant difference

Table (5): Shows that there was statistical significant difference in study group as regard the improvement in albumen, hemoglobin, Hematocrite, prothrombine time and INR after one and three months, while in the control group there was no statistical significant difference after one and three months.

Table (6): Malnutrition indicator score among study and control groups before, after one month, and after three months of application of the nutritional regimen:

Malnutrition Indicator	Baseline				P. value	After 1 month				P. value	After 3 month				P. value
	Cases (n=60)		Control (n=20)			Cases (n=60)		Control (n=20)			Cases (n=60)		Control (n=20)		
	No.	%	No.	%		No.	%	No.	%		No.	%	No.	%	
Malnourished	40	66.7	12	60.0		31	51.7	12	60.0		20	33.3	14	70.0	
At risk of malnutrition	10	16.7	5	25.0	0.141	12	20.0	7	35.0	0.041*	16	26.7	6	30.0	0.000**
Normal nutritional status	10	16.7	3	15.0		17	28.3	1	5.0		24	40.0	0	0.0	

* =Significant difference **= highly significance ^{Ns}= Non significant difference

Table (6): this table shows significant improvement in nutritional status in study group after one and three months after application of the nutritional regimen in comparison to control group.

Table (7): Malnutrition indicator score among the study (n=60) and control groups (n=20) according to Child Pugh Classes (A and B) before nutritional regimen application:

Malnutrition Indicator		Severity of liver disease (Child Pugh Classes)									p. value
		Class A				P. value	Class B				
		Study (n=10)		Control (n=5)			Study (n=50)		Control (n=15)		P. value	
		No.	%	No.	%		No.	%	No.	%		
Baseline	Malnourished	5	50	3	60		35	70	9	60		•0.131
	At risk of malnutrition	3	30	1	20	0.180	7	14	4	26.7	0.120	••0.675
	Normal nutritional status	2	20	1	20		8	16	2	13.3		
After 1 month	Malnourished	3	30	3	60		28	56	9	60		•0.042*
	At risk of malnutrition	2	20	1	20	0.060	10	20	6	40	0.101	••0.086
	Normal nutritional status	5	50	1	20		12	24	0	0		
After 3 months	malnourished	1	10	4	80		19	38	10	66.7		•0.034*
	At risk of malnutrition	2	20	1	20	0.004*	14	28	5	33.3	0.017 *	••0.627
	Normal nutritional status	7	70	0	0		17	34	0	0		
p. value		➢0.001**		➢0.408			➢0.002**		➢0.144			
p. value		➢➢0.001**		➢➢0.214			➢➢0.001**		➢➢0.170			

* =Significant difference **= highly significance ^{Ns}= Non significant difference
•P – value of study group for Child class (A and B)
•• P – value of control group for Child class (A and B)
➢ P – Value of baseline and after 1 month
➢➢ P – Value of baseline and after 3 month

Table (7): Shows highly significant difference in malnutrition indicator after one and three months in both child classes A and B in the study group while in the control group there is no any significance. Also the table shows that there was a statistical significance difference between Child class A and B in study group only where the improvement in malnutrition indicator after one and three months is better in child class A.

Table (8): Correlation between risk factors and malnutrition indicators scores in all patients (n=80):

	Malnutrition Indicator						P. value
	Malnourished (n=52)		At risk of malnutrition (n=15)		Normal nutritional status (n=13)		
Risk factors	No.	%	No.	%	No.	%	
Dry mouth	49	94.2	13	86.7	4	30.8	0.001**
Taste alteration	36	69.2	10	66.7	4	30.8	0.034*
Vomiting	14	26.9	6	40.0	4	30.8	0.847
Diarrhea	6	11.5	1	6.7	2	15.4	0.538
Constipation	21	40.4	4	26.7	4	30.8	0.271
Poor fitting or no dentures / poor dental health	19	36.5	4	26.7	3	23.1	0.526
Food allergies or intolerance	6	11.5	1	6.7	0	0.0	0.037*
Transportation problems	15	28.8	3	20.0	2	15.4	0.244
Inability to prepare meals	24	46.2	6	40.0	3	23.1	0.173
Loneliness /depression	24	46.2	6	40.0	4	30.8	0.424
Failure to thrive	33	63.5	10	66.7	6	46.1	0.293
History of OTC drugs	9	17.3	3	20.0	3	23.1	0.212
Acute or chronic pain	22	42.3	7	46.7	4	30.8	0.238
History of surgery / trauma	29	55.8	11	73.3	4	30.8	0.408
Multiple medications	29	55.8	6	40.0	2	15.4	0.048*
Low income	19	36.5	5	33.3	4	30.8	0.335

* =Significant difference **= highly significance ^{Ns}= Non significant difference

Table (8) this table clarifies that, dry mouth, taste alteration, food allergies or intolerance, and multiple medications are the main risk factors for malnutrition in our study.

Table (9): Correlation between malnutrition indicator score and medical data of all studied patients (n=80):

	Malnutrition Indicator score						P. value
	Malnourished (n=52)		At risk of malnutrition(n=15)		Normal nutrition(n=13)		
	No.	%	No.	%	No.	%	
Severity of liver disease Child class A	8	15.4	4	26.7	3	23.1	0.312
Child class B	44	84.6	11	73.3	10	76.9	
Bleeding tendency							
Yes	32	61.5	7	46.7	5	38.5	0.083
No	20	38.5	8	53.3	8	61.5	
Ascites							
Yes	41	78.8	4	26.7	2	15.4	0.015*
No	11	21.2	11	73.3	11	84.6	
Splenomegaly							
Yes	18	34.6	6	40.0	4	30.8	0.591
No	34	65.4	9	60.0	9	69.2	
Jaundice							
Yes	38		9	60.0	5	38.5	0.069
No	14	73.1	6	40.0	8	61.5	
		26.9					

* =Significant difference **= highly significance ^{Ns}= Non significant difference

Table (9): shows that the presence of ascites was correlated with the presence of malnutrition.

V. Discussion

Based on the results of present study; the majority of the patients were females were in fifties, as regards the marital status, the majority were married. As regard the level of education, the majority were illiterate. These finding are consistent with **Sallam** [17] who reported that; more than half of the study patients were illiterate. According to the study which was carried out by **Vanderplas et al.** [18] on a number of cirrhotic liver patients, it revealed that the majority of the sample had secondary education, this result disagreed with the present study which may be due to the different nature of the study population.

Cahill et al. [19]**, Buczko** [20]**, Vanderplas et al.**[18]**, Smith** [21]**, and Dataller and Gines** [22] weren't in the same line with the current study finding which, mentioned that; liver cirrhosis is as twice as common in men than in women and agreed in prevalent among malnourished patients over age 50 years of age. In our study, females were more cooperative than male in participation.

In relation to patient's residence, The results of the present study agreed with study by **Rao et al.** [23] who reported that; in Egypt, liver cirrhosis was more common in rural than urban regions because rural regions presented a suitable environment for developing a schistosomal infection due to exposure to canal water that may be polluted by snails that harbor the schistosomal parasite. likewise, **Abd el Ghaffar** [24] added that in Egypt, liver cirrhosis with or without chronic active hepatitis constituted about 50% of all chronic liver diseases that met within Egypt and even higher percentage in rural Egypt. This means that cirrhosis is the commonest chronic liver disease in the country.

In relation to marital status, and occupation, the present study revealed that, the majority of male patients were married and work as employers and farmers. While most of the female patients were married and housewives., this result was supported by **Rao et al.** [23] and **Vanderplas et al. [**18], finding according to the study which was carried out on a number of cirrhotic liver patients in Egypt which reported that the majority of the sample were working as farmers which put them at high risk for developing schistosomal infection and the majority of the patient were married.

The current study represented that; the majority of the study patients were infected with HCV and suffered from mild to moderate ascites and this result agrees with **Sharif, et al.** [25]**,** finding who stated that twenty-five to thirty-five percent of patients with chronic hepatitis C virus progress to cirrhosis. Hepatitis C virus (HCV) is recognized as a major threat to global public health, especially in Egypt which has possibly the highest HCV prevalence in the world; 10% - 20% of the general populations are infected. HCV is the leading cause of liver cirrhosis, hepatocellular carcinoma (HCC) and chronic liver disease in this country.

Hassan et al. [26] and **Faust and Reedy** [27] added that**, over** the past decade, chronic hepatitis C (HCV) had replaced alcohol as the leading cause of cirrhosis. **Cesario**, **Choure, and Carey** [28] reported that ascites was the most common major complication of cirrhosis and is an important landmark in the natural history of chronic liver disease. If observed for 10 years, approximately 60% of patients with cirrhosis developed ascites requiring therapy.

The results of present study revealed that, the severity of liver cirrhosis was classified according to Child Pugh class more than half of them were in class B. This finding agrees with **Tai et al.** [29]**,** who reported that; all patients had advanced liver disease with 16 (44.4%) cases of Child-Pugh B and 20 (55.6%) cases of Child-Pugh C cirrhosis and this result disagrees with] **Faiyaz** et al. [30]**,** who reported that; 109 patients were selected with 72 males and 37 females patient, classified according to Child class A, B & C was (30, 38 & 41; respectively) this is because the present study were excluded patient Child class C.

The present study revealed that; the most common risk factors for malnutrition are dry mouth, taste alteration, food allergies or intolerance, multiple medications and the presence of ascites. This result partially agrees with finding of ; **Yao et al.** [31], **Plauth & Schutz** [32], **Aweseman** [33] , **Hogan & Madyag** [34], **Figueiredo, Perz and Kondo** [35]**, Carvalho & Rober** [36], and **Kondrup** [37]**,**who reported that; Multiple factors which are common to the underlying disease directly contribute to malnutrition, among them, anorexia, nausea, deficient food intake, maldigestion, malabsorption and catabolic state. In addition, the many dietary restrictions used to control symptoms and specific complications, such as ascites and hepatic encephalopathy, aggravate the nutritional status, predisposing the patients to infections and worsening of the functional hepatic status and **David** [38]**,** who added that, the liver plays a role in normal appetite regulation and liver disease may impair food intake

Likewise the results agrees with **Anne and Alan** [39]**,** who reported that; many patients with advanced liver disease had an altered sense of taste, which might be related to vitamin A and/or zinc deficiency, often experience early satiety that is related to mechanical compression from massive ascites.

Nardi et al. [10] stated that, skin fold anthropometry is considered a useful technique for assessment of body composition in patients with chronic liver disease. It is value in detecting mild or moderate signs of malnutrition, which are difficult to recognize clinically. Likewise 0f **Caregaro et al.** [40] stated that, because of limitations of other nutritional indexes, skin fold anthropometry represents-at present-the most reliable clinical measure of nutritional status in patients with chronic liver disease. Its correlation with survival could be used to improve the accuracy of the commonly used prognostic formulas.

Carvalho and Rober [36] stated that alteration of the anthropometric and biochemical parameters of the cirrhotic patients based on TSFT values, the groups already presented a 50% loss of fat reserves regardless of the etiology of the disease. However, this loss was more significant in females (46.6% presented a moderate to severe TSF loss) than in males (26.5%).

The present study revealed that, the majority of both sex in the study group of patients increased after 1and 3 months of the application of the nutritional regimen compared to basal values of Triceps Skin fold Thickness (TSFT), mid arm circumference (MAC) and calf circumference (CC). The results of the present study supported by **Riggio et al.** [42] and **Fyke** [43], who stated that, there was an increased risk of malnutrition associated with liver cirrhosis, therefore cirrhotic patients may lose their weight rapidly and become susceptible to malnourishment because they can't absorb valuable vitamins, calories, and iron.

Demling and Desanti [44] reported that (MAC), (TSFT), (MAMC) are useful in identifying the most severely malnourished patients especially those with fluid retention as a result of disease. On the other hand **American physician family** [45] reported that mild to moderate protein calorie malnutrition was found in liver cirrhosis, adults generally lose their body weight although edema may mask weight loss, triceps skin fold thickness and mid arm muscle area are reduced below than normal range.

With reference to mean of anthropometric measurements, the study shows that, there was no statistical significant difference found between study and control group in TSFT, MAC, and CC. Male patients were higher than female patients in mid arm circumference (MAC) and calf circumference (CC), while they are lower than female patients in TSFT. this result disagree with **Carvalho and Rober** [36]**,** who reported that, fat reserves, evaluated by TSFT, were more depleted in females than in males (48.6% and 26.6%) regardless of the etiology of the cirrhosis. According to the study which was carried out by **Fusha** [46] on patients with liver cirrhosis, which revealed that the mean values for (MAC) decreased in female more than male patients with liver cirrhosis.

In the present study application of malnutrition indicator scale on the studied patients revealed that most of malnourished are Child Pugh Class (B). This was supported by **Kawabe, Hashimoto, and Yoshioka** [47], who reported that, the higher grade of the Child–Pugh classification was significantly more prevalent in the patients with moderate malnutrition than in those with mild malnutrition (P = 0.0001**)**.

The current study found that there was a significant increase in serum albumen, hemoglobin, hematocrite and decrease in Prothrombine time and INR after one and three months of application of the nutritional regimen among the study group. This finding was in line with **Gunsar et al** [48]**,** who stated that

there is significant increase in serum albumin in the first and second week among well-nourished cirrhotic patients, also this finding was in line with **Elwan** [49]**,** who mentioned that the mean value of serum albumin in the control group was decreased than the study group this decrease was attributed to the dietary restriction which was established in hospital. Also his finding agrees with **kontorinis** [50] and. **Dataller and Gines** [22] who pointed out that anemia is a common manifestation of liver cirrhosis; it may be due to gastrointestinal bleeding.

Our finding was contradicted by **Iwasa, Iwata., and Kaito** [51], who reported that there is no difference in laboratory data before and after nutritional treatment.

In our study there is increase in platelets count without significant difference in the study group while in the study done by **Matsumoto, Okumura, and Aria** [52] they showed a significant decrease in platelets count.

The study reported that the patients who did not suffer from malnutrition increased after one and three months of application of the nutritional regimen. Likewise there was statistical significance deference after 3 months. There was a significance difference between male and female patients and the majority of both having malnutrition and; while the minority of them had a risk for malnutrition. According to study which was carried out on a number of hospitalized cirrhotic patients by **Campillo et al.** [53]**,** cirrhotic patients had a high prevalence rate of malnutrition, and most of them don't satisfy their nutritional requirements, so their caloric intake were decreased which is an independent risk factor of short term mortality and according to study which was carried out by **Gunsar et al.** [48]**,** (42%) of the patients were well nourished, (40%) were mildly or moderately malnourished and (18%) were severely malnourished.

Pablo and Alday [54] pointed out that the majority of them were malnourished on admission. Malnutrition is a complication of liver cirrhosis that should be treated together with the others complications **Kondrup** [37]. **Caregaro et al.,** [40] reported that nutritional disorders are common in both alcoholic and viral cirrhosis and are related to the severity of liver disease rather than to its etiology. This predisposing the patients to infections and worsening of the functional hepatic status **Carvalho, and Rober** [36].

The study reported that there was a statistical difference between the malnutrition indicator score and Child class A and B in study group which agrees with **Nutrition Research Newsletter** [55]**,** who mentioned that there is a relationship between prevalence and characteristics of malnutrition, nutritional status, and the severity of liver disease

Abd el fatah [56] stressed that nutrition education for all patient with liver cirrhosis is important for improving nutritional status. Nevertheless, although the implementation of this present study program has led to significantly improved nutritional status, this nutritional regimen proved to have an effect on nutritional status of patients suffering from liver cirrhotic by time, after three months. To safeguard against this undesirable side effect, the nutritional regimen for patients should be continuous, not a once-per-life-event. This specific conclusion that has been reached in the present study had been very well emphasized by **ZeenEl-Abedin** [57]**,** who confirmed that counseling should be provided for all cirrhotic patients regarding nutritional support to prevent occurrence of complications such as hepatic encephalopathy, hepato-renal syndrome and improve clinical outcome.

In conclusion the present study findings support that nutritional treatment is an essential part of medical and nursing care for liver cirrhotic patients to identify who are nutritionally at risk.

VI. Conclusion And Recommendations

Conclusion:

Based on the results of the present study, it can be concluded that:

The most common risk factors for malnutrition are dry mouth, taste alteration, food allergies or intolerance, multiple medications and the presence of ascites.

Application of the nutritional regimen for patients with liver cirrhosis showed an improvement in patient's nutritional status.

The researchers found that, the majority of patients with decompensate liver cirrhosis were malnourished regardless the etiology of liver cirrhosis, however, the minority of patients were at risk for developing malnutrition the results show the numbers of patients who didn't suffer from malnutrition increased post implication of the nutritional regimen one and three months later.

Recommendation:

Nutritional support, advice and guidelines by dietitian of the nutritional regimen should be undertaken for all cirrhotic patients to prevent occurrence of complications of malnutrition and improve clinical outcome.

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