

Original Research Article

Effect of high protein intervention on royal free hospital nutrition prioritising tool scores in patients with decompensated liver cirrhosis: a randomised control trial

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ABSTRACT

Background: The Royal Free Hospital Nutrition Prioritising Tool (RFH-NPT) is an effective instrument for assessing the nutritional status of individuals suffering from cirrhosis, demonstrating high sensitivity and specificity in detecting malnutrition risk among patients with liver cirrhosis.

Methods: 110 male patients with decompensated cirrhosis were randomized, to a standard diet and a peptide supplement. The nutrition prioritizing tool, royal free hospital nutrition prioritising tool (RFH-NPT) was used to assess the effects on anthropometrics, dietary and biochemical markers. The statistically significance were analysed at $p < 0.05$.

Results: The peptide group showed significant improvement in nutrition tool scores, malnutrition and body mass index compared with controls (0.64 ± 1.20 vs. 4.76 ± 1.70 , $p < 0.00$ at 95% CI).

Conclusions: The RFH-NPT is a valuable tool for identifying cirrhosis patients at risk of malnutrition, thereby allowing patients to receive nutritional care to improve their nutritional status and overall clinical outcomes.

Keywords: High protein, Liver cirrhosis, Nutrition screening tool, Royal free hospital nutrition prioritizing tool, Randomised controlled trial, Serum albumin and ascites

INTRODUCTION

Liver damage and scarring are the outcomes of chronic liver cirrhosis. Numerous variables, including viral hepatitis, autoimmune disorders and excessive binge drinking, are causes of cirrhosis.¹ Impaired liver function can result in complications such as ascites, jaundice and hepatic encephalopathy.²

In people with decompensated chronic liver disease (DCLD), the liver's capacity to maintain nutrition is seriously compromised, in addition to many other vital functions.³ Protein-calorie malnutrition is the most

prevalent sign of inadequate nutrition in this population. Anorexia and elevated metabolic demands are linked to DCLD, both of which intensify the state of malnutrition.^{4,5} More than 60% of cirrhosis patients visiting hospitals in India are either at risk of malnutrition or already malnourished when they are admitted, making it a common issue associated with increased risk of infection and organ failure, poor quality of life and death.⁶ This warrants the application of nutritional screening tools for anthropometry, nutritional biochemical and comprehensive dietary examination to precisely determine a patient's nutritional form. This is important because malnutrition influences systemic effects and negatively

affects patient's prognosis.^{7,8} To prevent malnutrition and initiate proper nutrition for the management of cirrhosis, several screening tools are used to assess the risk of poor nutrition in cirrhosis patients.⁹ With the use of screening techniques, patients can be identified for malnutrition risk and dietary interventions such as nutritional supplements, enteral or parenteral nutrition and dietary counselling can be provided to improve their nutritional status. One of the validated screening tools, the royal free hospital nutrition prioritising tool (RFH-NPT), which is used to evaluate the nutritional status of individuals with cirrhosis, has high sensitivity and specificity for identifying malnutrition risk in liver cirrhosis patients.¹⁰ It is a simple, quick and easy-to-use tool that identifies malnutrition better than other tools, such as the subjective global assessment (SGA) and the nutritional risk screening tool (NRS).

Components of the royal free hospital nutrition prioritising tool

The instrument comprises a basic scoring mechanism that detects individuals who are susceptible to malnourishment and helps individuals judge the suitable dietary measures to improve their nutritional condition. A series of inquiries that comprised the screening components evaluated the patients' risk of malnutrition based on their hepatitis, weight, hunger, fluid retention body mass index, illness status and recent history of weight loss. Patients are classified for malnutrition risk as none (0), moderate risk (1-2) or high risk (2-7) on the basis of the sum of the values of these components.¹¹

The accuracy and reliability of the RFH-NPT in identifying malnourished patients with cirrhosis have been evaluated through multiple validation studies. According to a few studies, the RFH-NPT can detect individuals who are malnourished with a sensitivity of 97% and a specificity of 60%.¹²⁻¹⁴ The National Institute for Health and Care Excellence (NICE) and the British Association for Parenteral and Enteral Nutrition (BAPEN) have both suggested using the RFH-NPT to assess risk level and address malnutrition in patients with cirrhosis.¹⁵

It is crucial to address the issue of malnutrition, which affects more than 70% of Indian patients with cirrhosis, to improve their overall clinical outcomes. Although the SGA and MUST are used in some corporate healthcare settings to assess the risk of malnutrition, dietary interventions typically involve only counselling. Research on malnutrition in Indian patients with cirrhosis has primarily focused on the SGA and MUST.¹⁶⁻¹⁹

Some studies on high protein and BCAA intake have shown no significant correlation with liver cirrhosis, whereas others have suggested that a high-protein diet could enhance liver function and prevent fibrosis.^{20,21} We noted that there is a paucity of data on the application of a high-protein diet and the evaluation of RFH-NPT in Indian patients with decompensated liver cirrhosis. Therefore, this study aimed to determine the suitability of this

screening tool and the impact of a high-protein diet on the RFH-NPT score in patients with decompensated liver cirrhosis.

METHODS

The current study was conducted to gain a comprehensive understanding of nutritional management strategies for patients with hypoalbuminemia, with the goal of preventing decompensated liver cirrhosis from progressing to hepatorenal syndrome by application of RFH-NPT in Indian subjects and the impact of nutritional therapy on RFH-NPT scores in patients with decompensated.

Study design

This was a randomized controlled trial study.

Study duration

The course of the study was over sixteen months, between July 2022 and November 2023.

Study place

The study was carried out in two different medical college hospitals one located in Kolar and another in Bangalore, districts of Karnataka, India.

Participants

Male and female patients of 1-70 years with decompensated liver cirrhosis who visited the general medicine and medical gastroenterology departments were included after obtaining consent and agreed to comply with dietary recommendations throughout the specified period of study.

Exclusion criteria

Patients with a history of other chronic diseases that may affect their nutritional status, such as cancer or chronic kidney disease and gastrointestinal surgeries. Patients with a history of food allergies or intolerances, especially to high protein diet. Pregnant or lactating women.

Randomization and blinding

A computer-generated randomised sequence was applied in opaque, sequentially numbered envelopes with sealed flaps to guarantee allocation concealment. Healthcare providers, researchers and study participants were blinded to the groups to which they were assigned.

Intervention

In this trial, participants were required to complete the RFH-NPT at baseline and at the completion of 4 months.

While the control group was advised to consume a conventional polymeric diet, the intervention group received both a standard polymeric diet and a peptide-based ONS for 4 months. Standard medical care was consistently provided to both groups. The participants in both groups were trained to track the amount of food in reference to the standard diet prescribed and the intervention group subjects were instructed to track ONS consumed on a daily basis. The information was gathered frequently to track compliance through weekly phone calls and monthly hospital visits.

Sample size calculation

The sample size was estimated by our statistician with reference to the study by M-L.S. Tai et al.²² A total of 128 subjects were required with a 20% dropout rate assumed, an effect size of 15%, a power of 90% and a significance level of 0.05.

Data tools

Apart from the RFH-NPT screening tool, a validated questionnaire containing demographic, disease, comorbid conditions, anthropometric, diet history, biochemistry and ascites details was administered at baseline and at the end of the study. Participants were graded into three categories based on the severity of malnutrition as per the RFH-NPT component cumulative scores for low (score=0), moderate risk (score=1) and high risk (score =2-7).

Statistical applications

A Microsoft Excel spreadsheet was used to enter the data and IBM SPSS version 23.0 was used for statistical analysis. To describe the features of the study population, descriptive statistics were employed. The mean values between the two groups were compared using independent t-tests.

The averages within each group were compared using paired t-tests. Student's t tests were used to determine the averages and mean differences between the two groups. Chi-square tests, multivariate correlations and regression analyses were used to assess the strength of the relationships between anthropometric indices, dietary status and RFH-NPT scores. Every test was run at 95% confidence intervals, with $p < 0.05$ regarded as statistically significant.

RESULTS

Random assignments were made for the 128 patients who were included in the trial, 63 patients were assigned to the control group and 65 patients were assigned to the intervention group. With an attrition rate of 14.06%, all female patients were lost to follow-up. A total of 110 patients completed the study Figure 1. Eighteen subjects who were lost to follow-up due to death, dropout and not complaint with diet were excluded. There were no obvious

differences between the baseline characteristics of the two groups. The average age of the participants was 49.51 ± 11.74 years. Alcohol abuse was the most common primary cause of cirrhosis (97.23%). All patients received standard medical care, but most hospitalisation involved mild ascites, oedema, portal hypertension, jaundice, fever and loss of appetite.



Figure 1: Study consortium flow chart for subject recruitment.

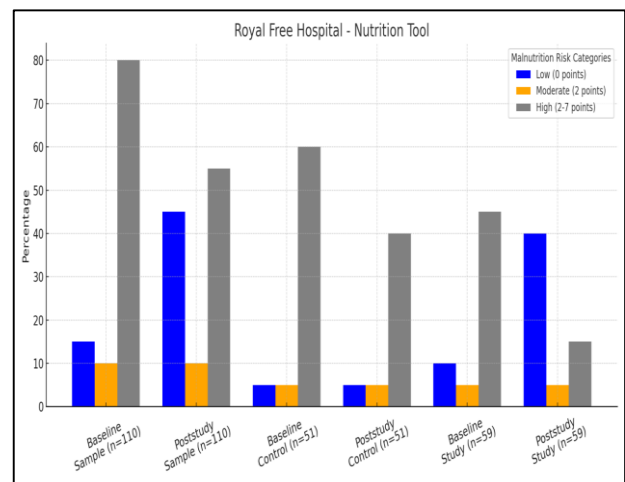


Figure 2: Malnutrition risks categories as per Royal free hospital tool.

According to the MELD scores, 30.01% of the total subjects had a 19.6% mortality risk at 3 months and the CTP score was between Class A and Class B. The laboratory results assessed the severity of the disorders with abnormal liver function tests ranging from 2.9–3.3 g/dl for serum albumin, 8.3–11.2 mg/dl for haemoglobin

and 0.3–1.2 mg/dl for serum creatinine. The daily output of urine varied from 750 to 1100 ml (Table 1).

Nutrition history: In the presence of decompensation and decreased food intake, 52.34% of the participants had a weight loss history. The patients in the intervention group had an average weight of 59.39 kg and a BMI of 21.31 kg/m², while those in the control group, had an average weight of 58.95 kg and a BMI of 21.41 kg/m². At baseline, most subjects ate three regular meals a day and non-vegetarians accounted for 58.94% of the subjects. Ninety-one patients had mild appetite loss, whereas those with ascites and low serum albumin (<3.0 g/dl) showed moderate to severe appetite loss.

Inadequate food intake was noted in 53.9% (n=69) of the population, with an imbalance in energy, protein and micronutrients. Many patients had self-restricted intake of fat, non-vegetarian foods, certain vegetables, fruits and spices in their diet. In addition, 43.29% of patients with ascites transitioned from a normal diet to semisolid diet. The diet also included limits on fat, salt and fluid intake, resulting in an average daily intake of approximately 1500 kcal of calories and 48 g of protein. No oral nutritional supplements or multivitamins were prescribed among this population because of financial constraints.

Malnutrition was prevalent in both groups at baseline and moderate malnutrition was observed in 57.03% (n=73) of the subjects in the presence of decompensation and reduced food intake (Figure 1). A past history of weight loss >5% was noted in 52.34% of the total population at the time of recruitment. At the conclusion of the trial, the mean RFH-NPT scores in the intervention group dramatically improved ($p<0.05$), from 2.49 ± 1.7 to 0.64 ± 1.20 , while those in the control group worsened, from 2.75 ± 1.57 to 4.76 ± 1.70 (Table 2).

The control group patients showed a significant large difference when compared before and after the study with regard to body weight ($M=66.6$, $SD=7.4$), ($M=50.7$, $SD=8.3$), $t(50)=26.7$, $p<0.001$ and BMI ($M=21.4$,

$SD=1.7$), ($M=18.4$, $SD=2.1$), $t(50)=19.3$, $p<0.001$, respectively. The study group differed by a non-significantly tiny amount with both body weight, ($M=59.4$, $SD=6.2$), ($M=59.2$, $SD=6.2$), ($M=21.3$, $SD=1.6$) and BMI, ($M=21.2$, $SD=1.8$), ($t(58)=0.6$, $p=.541$) and $t(58)=0.7$, $p=0.479$ indicating that weight was maintained.

The post-study multiple linear regression results for the control and study groups revealed a very weak collective non-significant effect on the associations between energy, body weight and NPT scores ($F(1, 49)=0.87$, $p=0.357$, $R^2=0.02$, $R^2\text{ adj}=0$) and ($F(1, 57)=1.05$, $p=0.309$, $R^2=0.02$, $R^2\text{ adj}=0$, respectively). The post-study individual components of the screening tools significantly varied for both groups (Table 3).

However, the RFH-NPT score showed a significant difference between the pre- and post-treatment periods in the study group ($M=2.5$, $SD=1.8$ and $M=0.6$, $SD=1.2$), $t(58)=9.4$, $p<0.001$. Dietary compliance was 78.45% in the intervention group and 63.98% in the control group. The control group had a compliance of 89 ± 15.3 diet days and 93 ± 28.5 days in the study group compared with 120 total study days. Compared with the controls, the intervention group had improved dietary intake (2552 kcals vs 1399 kcals, 86.31 g vs 48.93 g) over 4 months.

Patients who consumed 100% or more of the prescribed protein and calories showed an increase in serum albumin levels during the study duration, with a mean increase from 2.98 to 3.49 g/dL ($p<0.05$). As the serum albumin concentration increased, the patients' ascites significantly decreased. Other laboratory parameters, MELD and CTP scores also improved notably in the intervention group compared with those in the control group. Comparatively, the control group had worsening dietary variables, higher rates of ascites, complications and repeated hospitalisation. These factors negatively affect food consumption, weight and overall nutritional status. Improved food intake and body weight positively influenced the nutritional tool scores in the intervention group.

Table 1: Baseline characteristics of the subjects at the time of enrolment.

Variables	Total (n=110)	Control group	Study group	P value
Age (in years)	49.28 (± 11.23)	48.1 (± 11.93)	50.31 (± 10.59)	
Gender, N (%) - Male	100 (100%)	-	-	
Etiology				
Alcohol	107 (97.27%)	50 (98.03%)	57 (96.61%)	
Non-Alcohol	3 (2.72%)	1 (1.96%)	2 (3.38%)	
Complications				
Portal HTN	110 (100%)	51 (46.36%)	59 (53.64%)	
Hepatic encephalopathy	21 (19.09%)	17 (33.33%)	4 (6.78%)	
Infections	16 (14.54%)	8 (15.68%)	8 (13.56%)	
GI bleed	23 (20.90%)	11 (21.57%)	12 (20.33%)	
Ascites	57 (51.81%)			
Disease severity				
MELD	12.12 (± 3.74)	12.88 (± 3.72)	11.46 (± 3.66)	0.4651

Continued.

Variables	Total (n=110)	Control group	Study group	P value
CTP	7.61 (±1.03)	8 (±1.09)	7.34 (±1.01)	0.0013
Serum Albumin (g/dl)	2.94 (±0.31)	2.93 (±0.37)	2.95 (±0.24)	0.7341
Creatinine (mg/dl)	0.78 (±0.20)	0.81 (±0.19)	0.76 (±0.21)	0.4367
Height (cm)	166.34 (±8.23)	165.65 (±8.18)	166.93 (±8.30)	0.4186
Body weight (kg)	66.59 (±7.09)	66.59 (±7.41)	66.59 (±6.87)	1.0000
Body mass index (kg/m ²)	24.05 (±1.68)	24.22 (±1.68)	23.89 (±1.69)	0.3081
Abdominal girth (cm)	83.45 (1.95)	82.57 (±2.08)	82.51 (±1.94)	0.876
Length of stay (days)	12 (±2.9)	12 (±2.8)	12 (±2.7)	1.000
Diet and Nutrition				
Energy (kcal)	1514 (±140)	1490 (±170)	1470 (±160)	0.5267
Protein (gm)	48.6 (±7.39)	49 (±8.62)	49 (±9.10)	1.000

Table 2: Royal free hospital nutrition tool and malnutrition risk scores.

RFH-NPT variables	Control group (n=51, %)		Intervention group (n=59, %)		P value
Category	Baseline (N, %)*	Post study (N, %)	Baseline (N, %)	Post study (N, %)	
Ascites free	19 (37.25)	9 (17.65)	22 (37.29)	47 (79.66)	0.001
Ascites present	32 (62.75)	42 (82.35)	37 (62.71)	12 (20.33)	0.001
Royal free hospital- nutrition prioritising tool values (Mean±SD) [¶]					
Ascites free	2.84±1.86	6.79±1.87	2.32±1.93	1.54±1.18	0
Ascites present	3.28±1.08	4.16±1.27	3.22±1.16	0.7±1.22	0
Mean Score	3.12±1.12	5.14±1.98	2.88±1.54	1.02±1.22	0

*sample number (n) and percentages (%), [¶]- total sample mean and standard deviation (sd) with and without fluid.

Table 3: Individual Components of the Royal Free Hospital Nutrition Prioritising Tool.

S.no	Components	Total subjects (110)		Control group (n=51)		Study group (n=59)		P value
		Total	Post study	Base line	Post study	Base line	Post study	
1	DCLD	1±0	1±0	1±0	1±0	1±0	1±0	-
		(n=41)		(n=19)		(n=22)		
2	Fluid status	0	0.56±0.59	0	0.84±0.37	0	0.31±0.64	-
3	BMI Categories	0.29±0.6	0.63±0.89	0.26±0.56	0.84±0.37	0.31±0.65	0	0.04633
4	Unplanned weight loss	0.85±0.70	0.85±0.94	1.15±0.76	1.74±0.56	0.56±0.73	0.09±0.29	1.0000
5	Acute illness/no nutrition	0.39±0.8	0.98±0.01	0.42±0.84	1.79±0.63	0.36±0.79	0.27±0.7	0.0044
		(n=69)		(n=32)		(n=37)		
6	Fluid overload + Food intake	0.41±0.68	0.71±0.86	0.44±0.67	1.38±0.71	0.38±0.59	0.14±0.48	0.021
7	Weight loss in 3-6 months	1.83±0.38	0.81±0.83	1.78±0.42	1.34±0.6	1.86±0.35	0.35±0.72	5.551
8	Food intake reduced by 50%	1.01±1.01	0.81±0.99	1.06±1.01	1.44±0.91	0.97±1.01	0.27±0.69	0.2422

note: dclcd: decompensated chronic liver disease, bmi: body mass index.

DISCUSSION

This study highlights the efficacy of the RFH-NPT in diagnosing malnutrition and the value of nutritional therapy in enhancing clinical outcomes in patients with liver cirrhosis. In line with previous studies, men comprised the majority of study participants compared with women.²² The comorbidities, mortality risk and severity of the disease scores were all comparable with those of previous studies.^{23,24} Our study revealed that the

prevalence of malnutrition in patients with cirrhosis was greater than that reported in earlier research, which could be attributed to several factors, including the prevalence of alcohol as an aetiology, the rural setting, financial constraints and the unaffordability of speciality healthcare costs.^{25,26} Consistent with previous research, we noted that malnutrition in our study was associated with more comorbidities, such as weakened immune system, heightened susceptibility to infections, muscle atrophy, fatigue, cognitive impairment, multiple hospitalisations

from ascites and increased medical costs.²⁷⁻²⁹ The RFH-NPT tool revealed that scores ranging from moderate to severe indicated reduced food intake, severe weight loss, increased risk of complications and frequent hospitalisation. A greater proportion of these individuals had already experienced substantial weight loss, exceeding 10% in the last 3 months prior to enrolment and further loss of more than 5% or more triggered a functional disability state, especially in controls.

The body mass index and present body weight in the control group patients were challenging to measure, as it was difficult to pinpoint the weight fluctuations caused by the presence of ascites and oedematous fluid. Hence, dry weight was calculated based on ascitic fluid weight cut-off as referenced from Lamati et al and Alves et al.^{30,31} The intervention group's poststudy participants showed better management of dietary intake than did the control group, whose weight loss halted during the study duration and significantly improved the nutrition-related components of RFH-NPT. With the above results, the study confirmed that dietary intake was inversely proportional to RFH-NPT malnutrition scores.

The study examined each element of the Royal Free Hospital Nutrition instrument, which included the patient's body mass index (BMI), ascites, ailment, past body weight experiences and nutritional consumption. In controls, the mean scores of the components of the screening instrument revealed that weight loss and BMI were negatively impacted by an increase in disease severity scores, an increase in ascites grade and a considerable decrease in food intake. Following eighteen weeks of dietary and ONS support, the intervention group had increased nutritional intake with progressive improvements in serum albumin levels, ascites and comorbidities. In contrast, the control group did not experience any appreciable changes in these nutritional metrics. BMI and weight loss were inversely correlated with the degree of illness, ascites grade and extreme dietary self-limitation by the patients.

The consumption of protein and energy in both groups at baseline was much lower (34% of energy) than the standard recommendations. Compared with controls, the intervention group significantly improved to the recommended levels of food intake over 2-3 weeks, leading to an overall improvement in all aspects of malnutrition scores.³² The dietary intake of the control group patients further decreased by 19.45% (>280 kcal, 9.1 g protein) during the study and these patients with severe ascites experienced a decrease in activities of daily living. The worsening malnutrition scores of the control group were influenced by several disease-related factors, apart from a low-sodium diet, abdominal distension and the influence of complimentary therapies.¹⁶

The RFH-NPT scores improved in intervention subjects (69.49% vs 1.96%) compared with controls who were fed a high-protein, high-calorie diet and monitored regularly.

Additional support for this finding tends to come from improvements in labs, quality of life and albumin levels, which are important measures of liver health and nutritional status. These findings indicate that patients with cirrhosis who receive consistent nutritional intervention should anticipate improved outcomes. The study results recommend the application of RFH-NPT, which is a simple, sensitive, validated and easy-to-use technique that can help prioritise nutritional therapy and improve nutritional status and other therapeutic outcomes by determining their risk of malnutrition.¹¹

Implications for practice

As demonstrated by the study's findings, hospitalised cirrhosis patients can receive better nutritional therapy and have a lower chance of developing malnutrition-related problems if the RFH-NPT screening tool is used regularly. Timely nutritional intervention can lead to better patient outcomes and lower health care costs; therefore, a registered clinical dietician should be consulted for further evaluation and treatment. In gastrointestinal settings in India, where the subjective global assessment (SGA) tool is currently used, the RFH-NPT can be used for screening cirrhosis patients and is an ideal tool for detecting malnutrition.

One concern is that health care professionals in India are not always using screening tools consistently due to a lack of interest. It is also important to remember that the RFH-NPT is mostly intended for adult patients and might not be suitable for use in younger or older people. Despite various drawbacks, this trial offers early proof that individuals with liver cirrhosis may benefit from RFH-NPT in terms of their nutritional status and other clinical outcomes. Larger, multicentre investigations are required to further validate these results in Indian gastro-hepatic settings.

CONCLUSION

The RFH-NPT score improved in patients with cirrhosis who followed a high-calorie, high-protein diet, as per our RCT results. This research indicates that the validated RFH-NPT may be able to predict outcomes in patients receiving nutrition for cirrhosis by accounting for a range of nutrition-related characteristics. Further evidence included improved albumin levels and quality of life, which are critical markers of nutritional condition and liver health.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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