Original Article

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Development, Validity, and Reliability of an Easy-to-Use Nutrition Counseling Tool for Thai Outpatients with Liver Cirrhosis

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Abstract:

Objective: We developed a simple nutritional counseling tool for adults with liver cirrhosis, aiming for doctors, nurses, and patients as the tool's primary users.

Material and Methods: The tool was created in a booklet design and based on the European Society of Parenteral and Enteral Nutrition guideline, which comprises four parts, knowledge about cirrhosis, consequences of malnutrition, nutritional recommendations, and calculation of dry body weight and appropriate daily nutritional requirements. Content validity was assessed by three hepatologists using the item objective congruence (IOC) index wherein a score ≥0.5 indicated valid content. Face validity was evaluated by three doctors, three nurses, one dietitian, and three patients for readability, coherence, understandability, and attractiveness using a rating score of 0-10. A reliability test to calculate dry body weight and carbohydrate and protein intake per meal using an intraclass correlation coefficient (ICC) was conducted to determine the agreement among seven doctors and three nurses (inter-raters) using a total of nine case scenarios.

Results: The contents of the booklet were valid (IOC: 1.00 for all 19 items). For face validity, the scores for readability, coherence, attractiveness, and understandability were 7.6, 8.6, 9, and 8.6 out of 10, respectively. The overall comments showed that the new instrument was attractive and convenient. All doctors and nurses correctly calculated the dry body weight, and carbohydrate and protein intake for nine case scenarios, indicating excellent agreement (ICC: 1.0, p-value<0.001).

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Conclusion: The novel nutritional counseling booklet is valid and shows excellent reliability among healthcare providers in calculating body status and nutritional requirements.

Keywords: booklet, counseling, liver cirrhosis, nutrition counseling, nutrition guideline, nutrition support

Introduction

Malnutrition has become increasingly common in patients with end-stage liver disease or cirrhosis[1]. The prevalence of malnutrition has been reported in a significant proportion of patients with cirrhosis, ranging from 10% to 100%, depending on the severity of hepatic decompensation and the modality used to diagnose malnutrition[2-4]. Despite the high prevalence, malnutrition remains underdiagnosed and ineffectively treated, leading to poor clinical outcomes[5-7]. Malnutrition in cirrhosis is linked to infection risks, hospitalization, surgical complications, poor candidacy for liver transplantation, and a prolonged length of stay in the hospital or intensive care unit[2,8,9].

The pathogenesis of malnutrition in patients with cirrhosis is multifactorial[2]. For instance, decreased oral intake occurs for several reasons, including anorexia, dysgeusia due to zinc deficiency, unpalatable diets due to sodium restriction, and/or inappropriate protein restriction in patients with hepatic encephalopathy or chronic renal insufficiency[2]. Additionally, patients with decompensated cirrhosis and ascites experience early satiety because of extrinsic compression of the gastrointestinal tract from the peritoneal fluid[2,5].

A recent systematic review of nutritional supplements for patients with cirrhosis showed that interventions significantly improved the nutritional status, muscle mass, strength, and physical function[7] of the patients. However, the effectiveness of nutritional counseling without the use of nutritional supplements is unknown[7]. Additionally, details regarding nutritional counseling in clinical trials of nutrition supplementation have not been clearly described, resulting in difficulty in the evaluation of counseling methods[7,10]. Several international organizations specializing in liver diseases and nutrition have also launched guidelines for the nutritional management of patients with liver cirrhosis, but with less emphasis on how to deliver information to these patients[6,10-13].

According to the guidelines set by the European Society for Clinical Nutrition and Metabolism (ESPEN) on clinical nutrition in liver disease, specific nutritional counseling by a multidisciplinary team should be implemented in cirrhotic patients to improve long-term outcomes and survival[5,6]. In the context of middle-income countries, like Thailand, with a large number of patients per healthcare professional, it is quite challenging to form a team for nutritional counseling as this would involve dietitians and other healthcare providers specialized in nutrition. Moreover, one session of counseling could take approximately 1-2 hour(s) for one patient (or group of patients). Furthermore, there are limited numbers of nutritional physicians and dietitians; thus, a simple tool for nutrition counseling is required.

The present study aimed to develop a simple nutritional counseling tool for outpatients with cirrhosis while also evaluating the practicality (e.g., ease of use and readability) of the tool.

Material and Methods

The present study consisted of two phases: 1) tool development and 2) validation and reliability testing. The study was approved by the Institutional Human Research Ethics Committee at Prince of Songkla University (REC. 63-399-14-7). The counseling materials were designed in accordance with the recommendations for the conception and efficacy of educational tools, which included

recommendations about the content, language, organization, layout and illustrations, and motivating involved individuals to use the booklet as a learning tool[14]. The tool was designed in booklet format and the development of the tool was done through the following steps (Figure 1):

Development of the booklet and content validity

During the development of the counseling tool, we examined the nutritional recommendations of international institutions. All nutritional recommendations in the tool were based on the ESPEN and the European Association for the Study of the Liver (EASL) guidelines[5,6,12]. This step was initially conducted by NS and CC.

The booklet comprised four parts:

- General knowledge on liver function and cirrhosis
- The importance of nutrition in cirrhosis and the consequences of malnutrition
- Nutritional recommendations, which are based on patient requirements, including food choices, portion size, timing, frequency, and foods to avoid such as high-salt foods
- The assessment of body status and calculation of nutritional requirements.

Quantitative and qualitative assessment of content validity was assessed by PS, NC, and one other hepatologist in Songklanagarind Hospital, all of whom are experts in the field. The item objective congruence (IOC) index was used for the quantitative assessment of content validity to determine whether the items (contents) and objectives are congruent[15]. The experts rated the individual

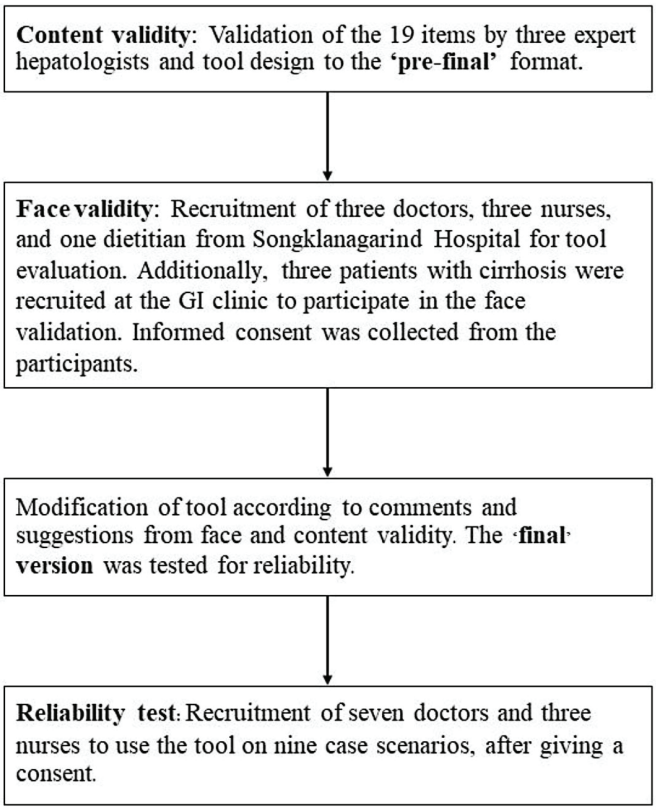

Figure 1 Study protocol

items on the degree to which they agreed or did not agree with the specific objectives. The ratings for each item were 1 for clear representation of the objective, −1 for unclear representation, and 0 for unclear objective. The scores given by the experts on each item were tallied and divided by the number of evaluating experts to give the IOC index for each item. An IOC index of at least 0.5 indicated valid content. We utilized three experts to evaluate the IOC index based on the recommendations by Crocker et al.[16].

Face validity/cognitive assessment of the tool

Considering that the booklet was designed for use by both healthcare professionals and patients, all parts of the pre-final format tool were read and evaluated for readability, coherence, attractiveness, and understandability by doctors, nurses, and dietitians, while patients with cirrhosis conducted the same process for parts 1-3 of the pre-final format tool. A mixed method was employed for the face validity. A rating scale from 0 to 10 was used, with 0 indicating 'least satisfactory' and 10 indicating 'most satisfactory'. Qualitative feedback was also collected. Modifications were made accordingly, and subsequent design of the tool to 'final' format was done.

Reliability test

This step was conducted to evaluate whether there was agreement among doctors and nurses (inter-raters) when using the tool for assessment of body status and calculation of nutritional requirements, as well as delivery of key messages for nutritional recommendations to patients. The variables for the reliability test were as follows:

Calculated dry body weight in kilograms (body weight after subtracting fluid retention, i.e., ascites and pitting edema in patients with cirrhosis). Dry body weight is calculated following consideration of ascites and edema; thus, 5%, 10%, or 15% is subtracted from the actual weight in the presence of mild, moderate, or severe ascites, respectively, with an additional 5% subtracted for pedal edema[17].

Calculated body mass index (BMI, kg/m^2): BMI is defined as the body weight (kg) divided by the square of the body height in meters.

Recommendations on carbohydrate (number of serving spoons of rice in each meal) and protein (number of tablespoons in each meal) intake based on dry body weight.

In Thailand, steamed rice is typically consumed as the major carbohydrate source, and to measure it, we use a serving spoon to transfer the rice from the rice cooker to the plate or bowl. This is the standard procedure to measure staple carbohydrate foods in Thailand. For protein, we often chop or slice meat into small pieces and cook it together with other ingredients. We don't typically consume meat like steak. As a result, in Thai culture it is simpler to estimate protein consumption in tablespoons.

Sample size calculation

To control the potential effect of literacy on reading comprehension, it was necessary to test face validity using a sample of lay people in addition to a sample of experts in the field. Face validation evaluates the appearance of the material in terms of readability, consistency of style and formatting, and the clarity of the language used. Face validity is based on subjective judgment and does not require sample size calculation. A review of face validity assessment by Hardesty & Bearden (2004) reported that most studies employed five judges, ranging from 3 to 52 judges[18]. Thus, we decided that use of 10 judges was suitable for this study. The judges were three doctors, three nurses, one dietitian, and three patients with cirrhosis. As the objective of this study was to develop a simple nutritional tool, we targeted doctors, nurses, and patients as the tool's primary users. Dietitians are already nutrition specialists; thus, we chose more doctors, nurses, and patients than dietitians. The cohort contained an equal number of doctors, nurses, and patients.

For the reliability test, the sample size was calculated based on the intraclass correlation coefficient (ICC). We used case scenarios instead of actual patients to investigate the reliability among doctors and nurses. This was intended to minimize the burden on patients because 10 raters (seven doctors and three nurses) would need to assess one patient at a time. We hypothesized the reliability coefficient among raters to be 0.95 with a minimum of 0.8. Thus, to achieve this coefficient, with a significance level of 0.05 (two-tailed), 80% power, and 10 raters, a total of nine different case scenarios (equivalent to nine patients) was required[19].

Statistical analysis

The content validity of the tool was done prior to ethics submission and the IOC index was calculated for the content validity, showing the IOC of 0.67 for two items and 1 for the other 17 items, indicating valid content. A reliability test was conducted using the ICC to determine the agreement among doctors and nurses (inter-rater) when calculating dry body weight, and carbohydrate and protein intake per meal for nutritional prescriptions. A p-value of <0.05 was deemed to indicate significance.

Table 1 IOC index of each item in the nutrition counseling tool

Objectives	Items	Expert 1	Expert 2	Expert 3	IOC index
To inform patients about their nutritional status, including body weight and body mass index	Height	1	1	1	1
	Body weight				
	Body mass index				
	Ideal body weight				
	In each meal, I should have:				
	Rice (serving spoons)	1	1	1	1
	Meat (tablespoons)	0	1	1	0.67
	I need a late-night snack	1	1	1	1
	I have ascites and/or leg edema	1	1	1	1
To inform patients of general knowledge on liver function and liver cirrhosis	Liver function and liver cirrhosis	1	1	1	1
	Ascites and leg edema	1	1	1	1
To inform patients on the importance of nutrition in cirrhosis and the consequences of malnutrition	Malnutrition in cirrhosis	1	1	1	1
	Risk factors for malnutrition	1	1	1	1
	Consequences of malnutrition	1	1	1	1
To educate and raise awareness about nutrition therapy in cirrhosis patients	Why is nutrition therapy important?	1	1	1	1
	The key to eating for cirrhosis	1	1	1	1
	"Eat at least 4 meals a day, 3 main meals, and 1 supplementary snack before bedtime. In some patients your doctor may add an extra snack at mid-morning or afternoon"	1	1	1	1
	Dietary options for snacking	1	1	1	1
	Foods to avoid	1	1	1	1
	Diet myths	1	1	1	1
To inform health care providers of the importance of nutrition therapy in patients with cirrhosis and to calculate the correct nutrition therapy	Why is there a need for a nutrition guide in patients with cirrhosis?	1	1	1	1
	How to use this counseling booklet	1	0	1	0.67
	How to calculate dry body weight	1	1	1	1

IOC=item objective congruence

Table 2 Quantitative evaluation of 10 raters for face validity, readability, coherence, attractiveness, and understandability of the nutrition counseling tool

Items	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10	Mean (S.D.)
Readability	3	8	8	8	7	7	9	8	9	9	7.6 (1.7)
Coherence	8	10	8	10	8	7	10	7	9	9	8.6 (1.1)
Attractiveness	8	10	10	10	8	7	10	9	9	9	9.0 (1.0)
Understandability	8	9	9	9	8	6	9	10	9	9	8.6 (1.0)

R=Rater, S.D.=standard deviation

Figure 2 Illustration of the A5-sized portable booklet (Thai Ver)

Results

Tool development and content validity

The A5-sized booklet contained 8 double-sided pages (Figure 2). The first page was personalized dietary recommendations for rice (serving spoons) and meat (tablespoons) measurements. Pages 2 to 6 provide content to help the reader understand liver functions, liver cirrhosis, ascites, pitting edema, malnutrition in cirrhosis, benefits of nutrition support and late-night snacks, and foods that should be avoided. Foods to be avoided included salty foods or the use of fish sauce, fermented or preserved foods (high salt content), foods that could have aflatoxins such as dried ground peanuts or ground pepper, and finally, raw food or roughly cooked food.

Pages 7 and 8 of the booklet were designed for healthcare providers and provide information on the significance of nutrition in cirrhosis including an example of dry body weight calculation. Moreover, a table presents nutritional recommendations broken down by intervals of dry body weight. Healthcare providers can then recommend diets for patients in terms of the quantity of serving spoons of rice and tablespoons of meat for each meal (Figure 2).

For the booklet evaluation, content validity was verified by three hepatologists using the IOC index (Table 1). For 2 items, the IOC was 0.67, while the remaining 17 items had IOCs of 1.00 in the first round of evaluation. In the second round following the correction of the two items, the IOC index was 1.00 for all 19 items.

Face validity

Face validity was done through interviews involving three patients and seven healthcare providers for quantitative and qualitative feedback. For quantitative evaluation, the scores for readability, format coherence, attractiveness, and understandability were 7.6, 8.6, 9.0, and 8.6, respectively (Table 2). The overall qualitative feedback for the booklet was "very attractive and convenient to use." However, there were comments indicating some need for improvement which included "too small font size," "texts were too close together," "duplicate details," "use of difficult-to-understand medical terms," and "more photos or pictures were required."

Reliability

This step was performed to determine agreement among doctors and nurses (inter-raters) while using the tool to calculate dry body weight, BMI, and amount of carbohydrate and protein intake per meal. Ten healthcare providers (7 doctors and 3 nurses) conducted the reliability test and showed excellent agreement with an ICC of 1.0 (p-value<0.001).

Discussion

Printed educational materials have been utilized to improve patient knowledge, contentment, treatment adherence, and self-care[20]. The American Academy of Family Physician recommends employing educational materials created by healthcare professionals as a technique for verbal communication reinforcement[20]. An inadequate diet in patients with cirrhosis increases the infection risk, need for hospitalization, length of hospital stays, surgical complications, and the probability the patient will be a poor candidate for liver transplantation[8,9]. Appropriate nutrition is essential for patients with cirrhosis, and nutritional counseling is a technique to provide and encourage dietary improvements and, as a result, reduce morbidity and poor clinical outcomes. A study by Alavinejad, et al. reported that patients with cirrhosis who received nutritional education in the form of a guided booklet experienced a considerable improvement in their ascites, edema, and quality of life[21]. Furthermore, using a booklet as a means of enhancing the probability of the advice being followed has been shown to improve clinical outcomes in several studies with different populations such as pregnant women, older adults, or patients with type II diabetes[22-24]. For example, one study found that treatment adherence and HbA1c improved in

patients with type II diabetes who received a counseling booklet[24].

As mentioned, details regarding nutritional counseling were not clearly described in the various guidelines from related organizations. Our research aimed to develop a nutritional counseling tool to address the gap in delivering dietary recommendations. Before implementing the tool in an outpatient department, we ensured quality through a rigorous development process that included content validity and reliability tests. The ESPEN guideline recommends key components of nutrition principles in cirrhosis, including adequate energy and protein intake, avoidance of high-sodium foods, and small frequent meals with a late-night snack[6]. These suggestions were followed by the authors in creating the first edition of the booklet.

To evaluate whether the contents were valid and had met the objectives of the counselling tool (content validity), all the information in the booklet was verified by three specialists. Initially, we found that parts regarding protein intake and key principles for using the tool were not fully correlated with the tool's objectives. After modifications, a second round of evaluation showed an IOC of 1.00 for all the contents in the tool, confirming the content validity and meeting of objectives of the tool. There are several ways to measure content validity including qualitative and quantitative methods[22,23,25,26]. Burke et al. and Joshi et al. utilized qualitative (subjective) evaluations of content validity for the educational booklets in their studies aimed at promoting healthy lifestyles in older adults and providing information about ureteric stents, respectively[22,25]. In contrast, de Oliveira et al. and Sapkota et al. used the content validity index (CVI) as a quantitative evaluation of content validity for their educational booklet for pregnant women[23,26]. The CVI requires several judges and a more complex calculation, while the IOC, as in the present study, requires a smaller number of judges (at least three judges). Moreover, the IOC appears to be a more practical method than the CVI[15]. Both the CVI and IOC are based on the principle that a predetermined number of judges, such as 2 out of 3 judges, or >0.5, have reached consensus on the objective-representing criteria.

Other studies have reported that layout, design, and graphic illustrations of a booklet were the key points to motivate reading and learning[22,23]. We, therefore, used attractive illustrations and fonts to gain the attention of the patients. Face validation was conducted to evaluate the presentation of the booklet in four dimensions, readability, format coherence, attractiveness, and understandability. The judges were the target users of the tool, including patients, doctors, nurses, and dietitians. At the first round of evaluations, all the judges showed interest in the booklet and their mean scores for each dimension of the booklet was 7 or higher out of 10 points. The overall consensus was that this was an attractive and convenient nutrition counseling tool. However, one patient provided a score of 3/10 in readability because the text size was too small. This indicates that presentation is essential for reading and understanding. The font must be appropriately sized and legible. For different purposes, different colors and font sizes can be used to differentiate different topics or contents. Thus, feedback was recorded and we proceeded to a new version of the tool[27].

It is important for healthcare professionals to deliver the correct amount of energy and protein requirements to patients. Therefore, we conducted reliability tests on the new tool. All healthcare professionals correctly calculated the body weight status and the amount of nutrition intake, indicating excellent inter-rater reliability. This ensured that our booklet was standardized and all healthcare professionals who would potentially use the booklet could deliver the correct information. Generally, healthcare professionals who are attempting to maximize outcomes for their patients may face challenges since patients with cirrhosis lack important knowledge about managing their disease[28]. Bridging the knowledge gap between patients and physicians with a simple educational intervention could

enhance patient understanding and their ability to access the required information, resulting in better clinical outcomes[21,29].

The strength of the present study is that the counseling tool was designed using a rigorous methodology, and its validity and reliability were tested prior to its implementation in routine health care. Our booklet is also comprehensive and covers all aspects of nutrition self-care for patients with cirrhosis, including nutritional requirements, food choices, portion sizes, timing and frequency of meals, and foods to avoid. The tool could be used to enhance patient understanding, adherence to nutritional recommendations, and their ability to care for themselves.

To put nutritional recommendations into practice and reduce the time required for intricate calculations of each patient's energy and protein needs, we created a table depicting the number of serving spoons for rice and tablespoons of meat in relation to the patient's dry body weight. We believe this is the novelty of our study. This makes the tool easy for both healthcare professionals and patients to follow. The booklet may be used by physicians, nurses, or dietitians because reliability has been evaluated and confirmed by a variety of health care specialists.

The most notable limitation of this study is that the booklet has never been assessed for its effectiveness in nutritional counseling in enhancing clinical or nutritional outcomes in patients with liver cirrhosis, such as weight gain or reduced infection rate. Consequently, it is essential to establish the efficacy of the booklet for patients with liver cirrhosis. In addition, only 3 patients evaluated the face validity of the booklet, which might not be a representative sample of patients with cirrhosis. Thus, face validation could be evaluated again after implementing the tool in clinical practice with a larger sample size.

Conclusion

The newly developed nutrition counseling booklet is valid and shows excellent reliability among healthcare providers in calculating body status and nutritional requirements. Well-designed and randomized controlled studies are required to further validate the clinical efficacy of this tool.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as potential conflicts of interest.

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