Sigma Theta Tau International's 29th International Nursing Research Congress

Validation of a Symptoms Distress Scale in a Cirrhotic Population: Item Response Theory

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Introduction: Liver cirrhosis (LC) is a chronic liver disease characterized by fibrous scar tissue and regenerative nodules that gradually replace healthy liver cells. With the continuous development of fibrous scar tissue and nodules, patients with LC may experience progressive deterioration of liver function, followed by various symptoms, including fatigue, loss of appetite, nausea, pain, and itching of the skin. These distressing symptoms might decrease the level of daily activities, increase psychological distress, and impair the quality of life. The assessment of symptoms distress is an important strategy for symptoms management and treatment of patients with liver cirrhosis (LC); however, appropriate instruments are limited. Recently, two similar scales (i.e., the symptoms experience scale and physical symptoms scale) were adopted to assess symptoms distress in cirrhotic populations. These scales have two Advantages. First, self-perceived distress stems from symptoms of LC that can be measured by subjective instruments. Second, the two scales encompass various symptoms of LC. However, studies that adopted these scales to examine symptoms distress with LC showed inconsistent results and the validities of the two scales were only confirmed using a content validity index; the appropriateness of items for assessing symptoms distress in the two scales was not further examined by appropriate methods. Thus, the objective of this study was to validate a symptoms distress scale by confirming the appropriateness of each item using the item response theory (IRT).

Methods: A cross-sectional and convenience sampling was conducted to recruit eligible cirrhotic outpatients from the gastroenterology outpatient department of a single medical university hospital. The inclusion criteria for the study were: (1) being aged more than 20 years, (2) having been diagnosed with non-alcoholic LC at least 6 months previously, (3) having normal cognitive function as assessed by a short portable mental state questionnaire, and (4) being capable of communicating in Mandarin or Taiwanese. Those patients with a cancer diagnosis who might have prejudiced the assessments of symptoms distress were excluded. In total, 163 patients with LC completed the 21-item symptoms distress scale. The IRT with a graded response model was used with a two-parameter (discrimination and difficulty) logistic model for the data analysis.

Results: IRT models showed that most item difficulties in all responses were >1, indicating that a majority of cirrhotic patients with greater symptoms distress would respond to the items in the symptoms distress scale. Only four items, item 11 (bodily pain), item 13 (RUQ pain), item 15 (fatigue), and item 21 (changes in appearance), showed low item difficulty in the first response category ($\beta i1 < 1$), indicating that 50% of respondents may experience mild distress in the four items. However, three items, item 14 (dark urine), item 17 (bruising), and item 19 (drowsiness), showed extreme item difficulty (>3), indicating that cirrhotic patients with extremely high levels of symptoms distress would respond to these three items.

Regarding item discrimination, two items, item 14 (dark urine) (α =0.61) and item17 (bruising) (α =0.47) in the frequency dimension,, had low item discrimination. Three items in the intensity dimension, item 12 (muscle cramps) (α =0.63), item 14 (dark urine) (α =0.64), and item 17 (bruising) (α =0.49), and one item in the distress dimension, item 17 (bruising) (α =0.50), also showed low item discrimination, which indicated that the three items did not have acceptable discrimination for identifying symptoms distress in the LC population.

Wright map showed all items are located above an average symptoms distress ability of 0, indicating that all items might represent a high level of symptom distress; nevertheless, the majority of patients showed low levels of symptoms distress. Thus, the scale should be used with great caution when assessing an LC population with mild symptoms distress.

Conclusion:

The IRT model showed that the symptoms distress scale may be more sensitive at representing symptom distress in cirrhotic populations with greater symptoms distress than in those with few or mild symptoms distress. A possible explanation is that the initial stages of LC are asymptomatic. Cirrhotic patients in the early asymptomatic phase may experience slight distress from the symptoms of LC, so symptoms distress goes undiagnosed. However, self-observing symptoms is an important strategy for patients and clinicians to prevent the progression to further clinical stages and the advent of complications. Adopting an instrument that measures self-perceived symptoms distress rather than objective assessment such as Child-Pugh scores is an easy way to remind patients to examine the occurrence of LC symptoms. Thus, a validated self-rated symptoms distress scale comprising comprehensive symptoms of LC may be helpful for cirrhotic populations and clinicians to assess and examine the occurrence of symptoms distress during LC progression.

Results showed that three items of muscle cramps, dark urine, and bruising were highlighted in a cirrhotic population with more-severe symptoms distress. The progression of decompensated cirrhosis may be an explanation. Cirrhotic patients with a large range of liver cell dysfunction might be incapable of producing and metabolizing bilirubin and carrying out coagulation and fibrinolysis, which would result in high bilirubin serum levels and blood coagulation dysfunction. Because patients with decompensated cirrhosis might experience more-complicated and -severe symptoms; the three items can be used as specific indicators representing cirrhotic patients with serious symptoms distress.

Results showed that a small number of items, such as bodily pain, RUQ pain, fatigue, and changes in appearance, were appropriate for examining symptoms distress in cirrhotic patients with mild symptoms distress. Hepatomegaly and inflammation of liver tissues in the early phases of cirrhosis can result in various symptoms consisting of a <u>yellow discoloration of the skin and whites of the eyes, abdominal pain,</u> and fatigue. Previous studies found that most patients with cirrhosis did not receive adequate management and follow-up, because these symptoms are easily neglected during the early phases of the disease. Thus, these four items from the symptoms distress scale may benefit patients in the early stage of LC by enabling their symptoms distress to be quickly and accurately identified.

Consequently, the items of the symptoms distress scale can be useful for assessing symptoms distress at different levels of symptoms distress. By identifying item applications, the symptoms distress scale should be helpful in effectively assessing and examining symptoms distress during the progression of LC for clinicians. Although the items can be useful for assessing symptoms distress with different levels of symptoms distress; adopting the scale for assessing LC populations with mild symptoms distress should done with great caution.

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Keywords:

liver cirrhosis, symptoms distress and item response theory

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Abstract Summary:

Our study confirmed a valid and reliable instrument to measure symptoms distress of liver cirrhosis. By identifying item applications, the symptoms distress scale should be helpful in effectively assessing and examining symptoms distress during the progression of LC for clinicians.

Content Outline:

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- (1) The importance of assessing symptoms distress in cirrhotic populations.
- (2) Few appropriate instruments can be used to measure the symptoms distress of cirrhotic

populations

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- (1) Summary
- (2) The reasons explaining the issue that different items can be used to assess different levels
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- (3) Implications

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