Validation of a symptoms distress scale in a cirrhotic population using the item response theory

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## Background



- Liver cirrhosis (LC) is an irreversible chronic liver disease characterized by the replacement of liver tissue by fibrosis, scar tissue, and regenerative nodules, which leads to loss of liver function.
- 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, insomnia, itching of the skin, loss of appetite, nausea, and pain.
- These distressing symptoms might decrease the level of daily activities, increase psychological distress, and impair the quality of life.







## Assessment of Symptoms Distress

### Child-Pugh Score

- Assessing severity of liver dysfunction (Pugh, Murray-Lyon, Dawson, Pietroni, & Williams, 1973).
- Content: encephalopathy, ascites, serum albumin, a prolonged prothrombin time, and the level of serum bilirubin
- Pros and Cons
  - Pros
    - important indicators
    - simple and easy
  - Cons
    - Only five symptoms included
    - Non-subjective assessment instrument

	1 point	2 points	3 points
Encéphalopathie (grade)	Absente	Grade I et II	Grade III et IV
Ascite	Absente	Minime	Modérée
Bilirubine totale (µmol/l)	<35	35 à 50	> 50
Albumine (g/l)	> 35	28 à 35	< 28
Taux de prothrombine (%)	> 50	40 à 50	< 40

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## Assessment of Symptoms Distress

### • Symptoms distress scale (SDS)

- Advantages
  - Self-perceived distress stems from symptoms of LC
  - Various symptoms of LC i.e., vomiting, ascites, edema, dyspnea, dry mouth, itching, pain, cramps, fatigue bruising, tarry stools, and drowsiness
- Limitation
  - Inconsistent results between two Validities of symptoms distress of LC the SDS ?
    - Drowsiness (1.62 vs. 4.3), pair
      difficulties (0.53 vs. 4.0).

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## Methods of validating a scale

- Methods
  - Classical test theory (CTT)
    - Exploratory analysis factor / Confirmatory factor analysis
  - Item Response Theory (IRT)
- Differences in the two methods
  - CTT
    - Item-orientated method: item's appropriateness depends on model fit
  - IRT
    - Item-independent method: item appropriateness depends on independent item

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## Item Response Theory

- The probability that how a participant responds to an item can be explained by an estimated latent trait (a person's latent ability, e.g. symptoms distress)
- The correlation between the ability of a study participant and probabilities of responses to each item can simultaneously be illustrated:
  - Item difficulty: a 50% probability of responding at or above the latent ability
    - lower item difficulty value is considered to be expected to be endorsed at a lower ability level (a low level of symptoms distress)
  - Item discrimination: the ability of an item to discriminate different levels of the underlying trait among people.
    - lower item discrimination is considered to have a poor ability to discriminate the latent ability.

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### Importance

- An accurate and efficient assessment of symptoms distress with LC depends on the appropriateness of each item in the symptoms distress scale.
  - IRT: to examine the difficulty and discrimination of each item to identify item appropriateness in the symptoms distress scale
- Examining item difficulty and item discrimination of each item can help professionals assess symptoms distress in different disease stages by choosing appropriate items to provide suitable management for improving symptoms distress.





## Aims

- To examine the item appropriateness of symptoms distress scale in assessing symptoms distress in patients with Liver cirrhosis
  - Exploring the performance of each item of symptoms distress
    - Item difficulty and Item discrimination
  - Identifying the symptoms distress scale can be used
    appropriately to assess symptoms distress in patients with LC

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## Methods

- Study design
  - Cross-sectional study
- Study participants
  - Convenience sampling
  - Outpatient department of a medical hospital
  - Inclusion criteria
    - (1) aged more than 20 years, (2) non-alcoholic LC at least 6 months previously, (3) normal cognitive function as assessed by a short portable mental state questionnaire.
  - Exclusion criteria
    - Those patients with psychiatric disorders, a cancer diagnosis, and the use of antidepressants and antianxiety medications

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## Measurements

- Demographic
  - Age, Sex, Marital status, Education, Religion, Employment, and Monthly household income.
  - Lifestyle factors: cigarette smoking and alcohol consumption
- Disease characteristics
  - Disease duration, severity of LC assessed by Child-Pugh score



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## Symptoms distress

- Symptoms distress scale
  - 21 symptoms:
    - anorexia, nausea/vomiting, dyspepsia, ascites/edema, shortness of breath/dyspnea, dry mouth, itching, bodily pain, fatigue, dark urine, urinary difficulty, bruising, tarry stools, drowsiness, decrease in memory, and change in appearance.
  - Three dimensions: Frequency, Intensity, Distress
  - Scoring:
    - 0 (never experienced) to 3 (extremely frequent/strong/distressful occurrence)
    - High scores indicate severe symptoms distress

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## Statistical analysis

- Frequency of study variables
  - continuous variables: mean ± standard, deviation (SD)
  - categorical variables: frequencies, proportions
- Item appropriateness of symptoms distress scale
  - Item response theory (IRT)
    - IRT assumption examination
      - unidimensionality of the measured trait: Velicer's MAP test: one factor
      - local independence: Chen and Thissen's Chi-squared local dependence (LD) statistics (LD  $X^2$ ): ≥10
      - Item fit: Generalized standardized X<sup>2</sup> statistics: no significant

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## IRT

### • Item parameters

- Item difficulty: <u>-3 to 3</u>, lower item difficulty value is considered to be easier or expected to be endorsed at a lower ability level (a low level of symptoms distress)
- Item discrimination:
  - <u>1:</u> good item discrimination
    - $\leq 0.65$ : low item discrimination
    - > 1.35: high item discrimination
- Relationship between a person's ability and item difficulty
  - Wright maps
    - a person with severe symptoms distress would have a higher probability of answering items affirmatively

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## Reliability

- Reliability for the total scale is the summed item formation contributed by all items.
- A value of  $\geq 0.70$  indicates that the scale has acceptable reliability.



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## Results

Table 1. Demographic and disease characteristics of study participants (N=163)					
Variables	N	(%)	Mean	SD	
Demography					
Age			58.4	11.3	
Gender					
Male	112	(68.7)			
Female	51	(31.3)			
Marital status					
Married	127	(77.9)			
Others	36	(22.1)			
Educational level <sup>a</sup>					
Low	57	(35.0)			
Medium	73	(44.8)			
High	33	(20.2)			
Employment					
Yes	86	(52.8)			
No	77	(47.2)			

Disease characteristics				
Disease duration (years)			7.0	7.5
Severity of LC				
Child-Pugh Score				
Class A	114	(69.9)		
Class B	38	(23.3)		
Class C	. 11	( 6.8)		



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### Frequencies of responses for each item in the SDS

	Frequency		Intens	Intensity		Distress	
Item	•	$\geq$ 1	· · ·	≥1		$\geq 1$	
	M(SD)	N (%)	M(SD)	N (%)	M(SD)	N (%)	
1.anorexia	0.17(0.6)	16( 9.8)	0.16(0.5)	16( 9.8)	0.17(0.6)	15(9.2)	
2.nausea	0.10(0.4)	14(8.6)	0.11(0.4)	14(8.6)	0.13(0.5)	14(8.6)	
3.vomiting	0.09(0.3)	14( 8.6)	0.10(0.4)	14(8.6)	0.12(0.4)	14(8.6)	
4.dyspepsia	0.15(0.6)	15( 9.8)	0.15(0.5)	15( 9.8)	0.14(0.5)	15(9.2)	
5.ascites	0.21(0.6)	23(14.1)	0.20(0.6)	23(14.1)	0.21(0.6)	23(14.1)	
6.edema	0.17(0.6)	15( 9.8)	0.15(0.5)	15(9.8)	0.17(0.6)	15(9.2)	
7.shortness of breath	0.21(0.6)	25(15.3)	0.18(0.5)	25(15.3)	0.21(0.6)	25(15.3)	
8.dyspnea	0.25(0.6)	26(16.0)	0.22(0.6)	26(16.0)	0.23(0.6)	26(16.0)	
9.dry mouth	0.26(0.7)	27(16.6)	0.24(0.6)	27(16.6)	0.25(0.6)	27(16.6)	
10.itching	0.37(0.7)	43(26.4)	0.35(0.7)	42(25.8)	0.35(0.7)	42(25.8)	
11.bodily pain	0.53(0.8)	58(35.6)	0.51(0.8)	58(35.6)	0.52(0.8)	58(35.6)	
12.musice cramps	0.28(0.7)	31(19.0)	0.28(0.7)	31(19.0)	0.29(0.7)	31(19.0)	
13.RUQ pain	0.69(0.9)	69(42.3)	0.71(1.0)	69(42.3)	0.71(1.0)	69(42.3)	
14.dark urine	0.20(0.6)	22(13.5)	0.21(0.6)	22(13.5)	0.21(0.6)	22(13.5)	
15.fatigue	0.75(1.0)	72(44.2)	0.75(1.0)	72(44.2)	0.68(0.9)	71(43.6)	
16.urinary difficulty	0.25(0.7)	26(16.0)	0.25(0.7)	25(15.3)	0.17(0.4)	26(16.0)	
17.bruising	0.18(0.5)	20(12.3)	0.18(0.5)	20(12.3)	0.17(0.5)	20(12.3)	
18 tarry stools	0.21(0.6)	21(12.9)	0.20(0.6)	20(12.3)	0.17(0.5)	20(12.3)	
19.drowsiness	0.06(0.3)	6(3.7)	0.05(0.3)	6(3.7)	0.04(0.2)	6( 3.7)	
20.decrease in memory	0.42(0.8)	41(25.2)	0.42(0.8)	41(25.1)	0.39(0.8)	41(25.2)	
21.change in appearance	0.42(0.7)	54(33.1)	0.45(0.7)	54(33.1)	0.40(0.7)	52(31.9)	

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## Assumption examination of IRT Model

- Unidimensionality of the measured trait
  - Velicer's MAP test: one factor
- Local independence
  - $\text{ LD } X^2 :\ge 10$
- Item fit
  - Generalized standardized X<sup>2</sup> statistics: no significant

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### Item parameters

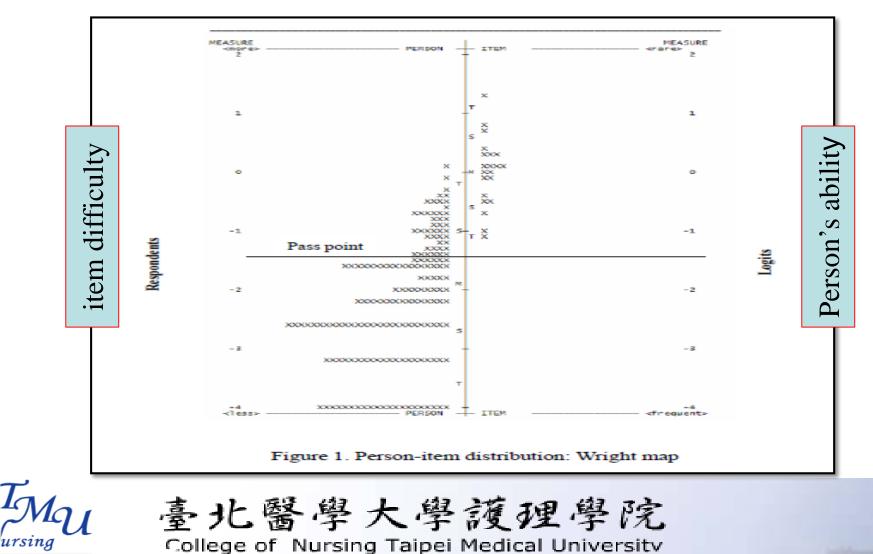
### • Item difficulty

- <1: low item difficulty (low level of symptoms distress)
  - item 11 (bodily pain), item 13 (RUQ pain),
    - item 15(fatigue), and item 21 (changes in appearance)
- ->3: extreme item difficulty (high level of symptoms distress)
  - item 14 (dark urine), item 17 (bruising), and item 19 (drowsiness)
- Item discrimination
  - low item discrimination (< 0.65)</li>
    - item 12 (muscle cramps), item 14 (dark urine), and

item 17 (bruising)

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## Relationship between a person's ability and item difficulty





## Reliability

- Three dimensions of symptoms distress scale
  - Frequency: 0.75
  - Intensity: 0.74
  - Distress: 0.73

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## Summary

- Three items were reported in cirrhotic patients with severe symptom distress
  - muscle cramps, dark urine, and bruising
- Four items can appropriately be represented in cirrhotic patients with mild symptoms distress
  - bodily pain, RUQ pain, fatigue, and changes in appearance
- The majority of items in the symptoms distress scale represented a high level of symptoms distress

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## Symptoms distress of cirrhotic population

- Cirrhotic patients in the early asymptomatic phase may experience slight distress from the symptoms of LC, so symptoms distress goes undiagnosed.
- 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 Child-Pugh scores is an easy way to remind patients to examine the occurrence of LC symptoms.

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## Conclusion

 Symptoms distress scale, a validated <u>self-rated symptoms distress</u> <u>scale</u>, comprising <u>comprehensive symptoms of LC</u> may be helpful for cirrhotic populations and clinicians to assess and examine the occurrence of symptoms distress during LC progression.



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# Thanks for your attention



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