The Development and Psychometric Assessment of Medication Literacy Scale for Hypertensive Patients

Zhuqing Zhong[1,2,3], Aijing Luo[2,*], Wenzhao Xie[1,2], Siqing Ding[1,3], Shuangjiao Shi[1,3], Yinglong Duan[1] and Feng Zheng[1]

[1]*Third Xiangya Hospital, Central South University, Tongzipo Road, Yuelu District, Changsha 410013, China*
[2]*Key Laboratory of Medical Informatics Research, Central South University, College of Hunan Province, Changsha 410013, China*
[3]*Xiangya Nursing School, Central South University, Tongzipo Road, Yuelu District, Changsha 410013, China*

Keywords: Hypertension, Medication Literacy, Scale, Reliability, Validity.

Abstract: Objective: To develop the medication literacy scale for patients with hypertension, and to test the reliability and validity of the scale. Methods The initial draft of the scale was formulated based on a theoretical framework of medication literacy with four domains of knowledge, attitude, skill and practice, and developed through procedures of literature review, expert meetings and consultations, patient interviews and focus group discussions. In this study, 260 patients with hypertension in Changsha city of China were selected to conduct a pilot survey. After item selection by a series of statistical analysis method and item re-wording according to patients' feedback, the scale was revised to form a formal investigation scale with four domains and 37 items. A formal investigation was carried out on 650 patients with hypertension selected purposively in a tertiary general hospital and two community health service centers in Changsha city. The reliability and validity of the scale were analyzed. Results: Finally, the formal scale consists of four dimensions on knowledge, attitude, practice and skills, 11 loading factors and 37 items in total. S-CVI of the scale was 0.968, and the I-CVI for each item ranged from 0.833 to 1.000, indicating good and acceptable content and face validity. The Cronbach's α coefficient was 0.849 for the overall scale and ranged from 0.744 to 0.783 for 4 dimensions. The Pearson correlation coefficient between each of the four dimension and the total scale was 0.530-0.799. Besides, the Pearson correlation coefficient among each dimension of the scale ranged from 0.157 to 0.439. The split-half reliability coefficient was 0.893 for the total scale and ranged from 0.793 to 0.872 for four dimensions. The test-retest reliability coefficient of the total scale was 0.968 and ranged from 0.880 to 0.959 for four dimensions. 11 common loading factors were extracted through exploratory factor analysis, and the cumulative variance contribution rate of individual domains were 56.111%-64.419%. The confirmatory factor analysis showed the fit indices of the four-dimension 11-factor model as follows (χ^2/df=2.629, GFI=0.804, AGFI=0.777, RMR=0.012, IFI=0.746, RMSEA=0.066, PNFI=0.599, PCFI=0.689), which indicated good model fit. Conclusions: The medication literacy scale for hypertensive patients has good reliability and validity, which is suitable and acceptable for evaluating the medication literacy level of hypertension patients in China. In the future, English translation of this scale is required, so that this scale can be further validated and applied worldwide.

1 INTRODUCTION

Medication safety problem has always been the focus of healthcare providers and public health community scholars. Researches across the globe reported that there were certain safety problems in medication taking process for hypertensive patients (Rahmawati, 2017; Liu, 2016).

Medication literacy is the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medications to make informed medication and health decisions in order to safely and effectively use their

* Corresponding author

Zhong, Z., Luo, A., Xie, W., Ding, S., Shi, S., Duan, Y. and Zheng, F.
The Development and Psychometric Assessment of Medication Literacy Scale for Hypertensive Patients.
DOI: 10.5220/0008916300560065
In *Proceedings of the 13th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2020) - Volume 5: HEALTHINF*, pages 56-65
ISBN: 978-989-758-398-8; ISSN: 2184-4305

medications, regardless of the mode by which the content is delivered (e.g. written, oral and visual), and there are four domains of knowledge, attitude, skill, and practice included by medication literacy which were extracted from its definition and connotation (Sauceda, 2012; Shi, 2019). Safe and correct self-medication was a leading contributor to the optimal blood pressure control for hypertensive patients (Hu, 2010), and the effectiveness of medication therapy depends mainly on patients' understanding of related knowledge about medication, attitudes to antihypertensive medication taking, skills on how they should administer the prescribed medication as well as adherent medication taking behavior and practice with appropriate adverse reaction and blood pressure monitoring (Shi, 2019). In addition, the awareness of the utilization of health support system could be a facilitator to promote hypertensive patients' blood pressure control. Therefore, it is of great significance to assess the level of medication literacy of hypertensive patients, which could be a pivotal step to prevent from medication safety problems, ameliorating the condition of suboptimal blood pressure control and long-term challenging disease state. However, there is a dearth of specific medication literacy scale for hypertensive patients currently, though several medication literacy measurements for general population have been found (Sauceda, 2012; Yeh, 2017; Horvat, 2017). Hence, based on previous theory research and analysis on medication literacy, a specific assessment scale of medication literacy for Chinese hypertensive patients has been developed in the present study, and four domains of knowledge, attitude, skill, and practice were included, the reliability and validity test were also performed.

2 METHODS PHASES OF DEVELOPMENT

2.1 Initial Item Pool Establishment

Knowledge-Attitude-Practice model (Alzghoul, 2015), health belief model (Peng, 2014), plan behavior theory (Cheng, 2012), health literacy (Sorensen, 2012), and patients' skills in the medication administration process were incorporated into conceptualization of medication literacy. Methods of derivation, synthesis, and theory analysis developed by Walker (Butcher, 2006; Walker, 2010) were used for nursing theory construction, then medication literacy was conceptualized and constructed. According to its definition, in essence, medication literacy was a recurring process of medication information acquisition, understanding, evaluation, and medication administration. Knowledge, skill, attitude, and practice are four core elements of medication literacy and are playing critical roles in different stage of dealing with information of medication. Based on the concept of medication literacy and its four core elements, the theoretical framework of medication literacy for hypertensive patients was established and the initial item pool of this scale was identified. Methods for development of initial item pool: a. related literature review of existing researches about instruments of general medication literacy, some items were extracted from or referred to existing measurements of hypertension treatment adherence; b. expert panel meeting was convened, related experts specialized in cardiovascular research and pharmaceutical research were invited to examine the clarity of drafted items as well as each item's relevance and appropriateness to its belonging construct. Some inappropriate items were removed and some highly relevant extra items suggested by experts were supplemented; c. interview for hypertensive patients: after items were revised according to the advises in expert meeting, the items of the initial assessment scale from above were applied to the interviews performed to 5 recruited hypertensive patients. The questions as well as suggestions about each item of the scale put forward by participants were recorded, according to which related items were revised. Then, an initial assessment scale including 52 items has been reached; d. focus group discussion: the advices of experts and the results of interviews for hypertensive patients were integrated and synthesized through discussion by research group, then a primary assessment scale involving 41 items assessing hypertensive patients' medication literacy level was accomplished.

2.2 Content and Face Validity

6 experts have been invited to appraise on the construct and items of the primary assessment scale with 41 items in this study. Based on every expert's understanding of the definition and connotation of hypertensive patients' medication literacy, constructive amendments and item suggestions were required to be given. Therefore, supplements, expurgations, and revisions to some items or contents could be made accordingly. Inclusion criteria for experts: a. with over 10 years of work experience in the cardiovascular department; b. with Doctoral degree or above; c. with profession title of associate

professor or deputy director or above; d. experts who master in the development and psychometric assessment of a scale; e. experts who were interested in this research and willing to offer advices or suggestions. Finally, 2 clinical professionals, 2 nursing professionals, and 2 pharmaceutical professionals were involved. The authority coefficient of each expert has been calculated in a comprehensive way, including experts' level of academic research, judgmental basis, and their familiarity degree to the concept of medication literacy for hypertensive patients and each item of this scale. The intended meaning and clarity of each item, as well as its relevance to its belonging domain were checked and graded by experts based on response options of Likert 4 ranking scale (highly relevant, relevant, slightly relevant, irrelevant), 4 indicating strong correlation and high relevance between each item and its corresponding domain and the overall scale, 3 indicating correlation, 2 identified weak correlation, and 1 was no correlation. Furthermore, content validity for each item as well as CVI (content validity index) was calculated (Hambleton, 1978; Martuza, 1977). Significant items were retained whereas non-significant items were excluded. After random consistency was calibrated by applying with Kappa value (K^*) (Polit, 2007), items with I-CVI (item level CVI) <0.78 were excluded (Lynn, 1986; Shi, 2012). The face and content validity were established at this point.

2.3 Pilot Survey

Purposive sampling was applied, and a total of 260 hypertensive patients from a tertiary hospital and a community health service center in Changsha city of China were participated in this pilot survey. Inclusion criteria: a. diagnosed as hypertension according to the 2016 revised version of guidance for hypertension prevention and treatment in China, which is systolic BP>=140mmHg or diastolic BP>=90 mmHg; b. the patient has been on antihypertensive treatment and taking antihypertensives for at least 2 weeks, these included both newly diagnosed and treated hypertensive patients and those who were already on antihypertensive medication treatment for a longer period of time; c. aged over 18; d. who can communicate with others and have the ability of reading and comprehension; e. who were willing to participate in this study and signed the consent forms; Exclusion criteria: a. who were diagnosed with psychologically and mentally ill by ICD or have been on a mental pharmacotherapy; b. who have severe or acute hypertension or other uncontrolled cardiovascular and cerebrovascular diseases such as New York Heart Association Class III or IV heart failure, or unstable angina. c. who have dementia or cognitive impairment, severe disease of other organs or systems, such as cancer. d. Patients with hearing and communication disability. The language, understanding and wording as well as construct of the assessment scale were checked, and questions about the clarity and accuracy of the expression of items were recorded. Meanwhile, collected data were statistically analyzed using IBM SPSS 23.0 for items selection, so that a complete and final research scale can be developed. During questionnaire distribution, participants' timely feedback on questionnaire problem was focused on to improve the questionnaire. Items that were questionable or confusing for participants were given appropriate revision or excluded.

In this pilot survey, a total of 252 completed questionnaires were collected, response rate is 96.60%. Statistical analysis methods of discriminant and convergent validity such as construct average factor loading, average variance and correlation coefficient between two constructs, as well as item discrimination of t-test, Cronbach's alpha (α) were calculated to re-screen items. a. Item Discrimination analysis: total scores of collected questionnaires were listed in sequence of numeric value from high to low, among which 27% of the highest score were defined as high score group, 27% of the lowest score were defined as low score group, then independent t-test was used, the difference of the score of each item between high score group and low score group was tested. Considering specialty practicalities, items with no significant difference between high score group and low score group were excluded; b. Correlation Coefficient Method: the Pearson correlation coefficient between the score of each item and the overall score of its belonging domain, as well as the correlation coefficient between the total score of each domain and the overall score of the whole scale were calculated. Considering the specialty practicalities, items with Pearson correlation coefficient r<0.3 were removed.

2.4 Formal Investigation

In formal investigation stage of this research, purposive sampling was used. 400 hypertensive patients were collected from inpatient and outpatient department of a tertiary hospital, 250 were collected from 2 community health services center in Changsha city of China from April to June, 2016. Therefore, a total of 650 eligible hypertensive patients participated

in this research. 650 questionnaires were handed out and 637 were collected back. The response rate was 98.00%, among which 336 were male participants (52.7%), aged from 18 to 90, the average age was (57.49±15.12); married 542 (85.0%); 149 with education level of primary school or below (23.4%); 462 were employed (72.5%); Duration of hypertension: 220 (34.5%) participants have been diagnosed as hypertension for more than 10 years; Family history of hypertension: 421 (66.1%) with family history. (Table 1).

Table 1: Patient Characteristics (n=637).

Items	Group	N	%
Age (years)*	18~45	131	20.6
	46~60	183	28.7
	61~90	323	50.7
Gender	male	336	52.7
	female	301	47.3
Education level	Primary and below	149	23.4
	Junior middle school	158	24.8
	High school	115	18.1
	Junior College	81	12.7
	College degree and above	134	21.0
Annual Household income Chinese RMB (¥)	<10,000/year	112	17.6
	10,000~29,999/year	131	20.6
	30,000~49,999/year	171	26.8
	50,000~99,999/year	101	15.9
	≧100,000/year	122	19.2
Marital status	married	542	85.0
	unmarried	35	5.5
	Divorced or widowed	60	9.5
Occupational status	employed	462	72.5
	retired	133	20.9
	unemployed	42	6.6
Registered residence	urban	380	59.7
	countryside	257	40.3
Duration of hypertension	<3years	187	29.4
	3- years	82	12.9
	5- years	146	22.9
	≧10 years	220	34.5
Family history of hypertension	yes	421	66.1
	no	216	33.9

*The mean for age was 57.49 years with a standard deviation of 15.12.

2.4.1 Validity Test

Content validity and Construct Validity were checked and tested. Content validity was assessed by calculating the content validity index of each item (I-CVI) and the content validity index of the whole scale (S-CVI), which have been figured out according to the results of expert panel consultation. Construct validity was assessed by calculating related indexes of exploratory factor analysis and confirmatory factor analysis. Convergent validity was assessed by calculating average factor loading of a construct. The validity for a construct was established if the average factor loading was greater than 0.7. Discriminant validity was also identified by calculating the average variance and squared correlation coefficient between two constructs. Discriminant validity for a construct was established if average variance was greater than squared correlation coefficient (Streiner, 1995; Bowling, 2009). The exploratory factor analysis and confirmatory factor analysis were applied to identify and confirm the construct and principal components of the scale. Amidst the 637 responses, half of the data was used to explore factor structure, and the rest half of the data was used to confirm factor structure with fit indices. Absolute fit indices namely χ^2/df, goodness of fit (GFI), absolute goodness of fit (AGFI), root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR) was calculated, a good model fit was highlighted by these indices (Jöreskog, 1993). In addition, incremental fit indices (IFI), parsimony fit index including PNFI, PCFI were also noted. A value of GFI, AGFI, and IFI was > 0.90, RMR < 0.05, IFI over 0.9, indicate good model fit. For RMSEA, the value ranges from 0.08 to 0.10 indicates acceptable model fit, value ranges from 0.05 to 0.08 suggests moderate model fit, value less than 0.05 shows great model fit. Generally, RMSEA, SRMR values < 0.07 indicate good model fit. (Pett, 2003; Hair, 2009; Shima, 2015). A value for parsimony fit index (PNFI, PCFI) > 0.5 was considered satisfactory (Mulaik, 1989). χ^2/df was an absolute fit index. For the χ^2/df, the smaller of the value, the better of the model fit, and χ^2/df<3 indicates a good model fit. (Knowledge cited from Chinese statistics book). Structure equation modeling was carried out using IBM SPSS AMOS version 25.

2.4.2 Reliability Test

Internal consistency was assessed using Cronbach's alpha (α) values. A value of 0.5 or greater was considered acceptable (Sushil and Verma, 2010). Split-half reliability was also calculated. The test-retest

reliability was measured by Pearson's correlation coefficient (ρ) between two time-points with a gap of 2 weeks in 40 randomly collected hypertensive patients. A value of (ρ) more than 0.75 and p-value < 0.05 was considered significantly strong correlation (Lahey, 1983; Cohen, 1988; De Vellis, 1991).

2.4.3 Scoring Criteria

This research scale measured medication literacy level of hypertensive patients across four domains namely knowledge about hypertension disease, treatment, and antihypertensive medication, attitude, skill and practice for medication administration. For items in domains of knowledge and skill, answering right for each item scores 1, and answering wrong scores 0. A 5-point Likert response option for each item in domains of attitude and practice was used, in which scores of 1.0, 0.75, 0.5, 0.25, 0 were applied (totally agree, agree, not sure, disagree, totally disagree; always, often, sometimes, seldom, never).

In addition, there were 5 items in the attitude domain and 1 item in practice domain scoring reversely. The summed total score on this 37-item scale ranged from 0 to 37, with higher scores indicating higher medication literacy level.

3 RESULTS

3.1 Scale Construct and Items Generation

An initial entry pool of 52 items was established in this study at the beginning, then the primary medication literacy scale for hypertensive patients with 41 items was developed after 11 items were excluded through the focus group discussion. Subsequently, scale with 39 items for pilot survey has been formed after 2 items being excluded according to suggestions generated from the 2-round expert consultation. Finally, 2 items with low discrimination were excluded after analysis of item discrimination and correlation coefficient method on the collected data from pilot survey. （item A4: I am willing to try traditional popular prescription; item A10 : I worry about the side effects of long-term antihypertensive treatment）. After pilot study and item re-screening, a formal medication literacy scale for hypertensive patients has been accomplished, and 4 domains with 37 items were identified. Knowledge domain (K) includes 9 items, attitude domain (A) involves 8 items, skill domain (S) 7 items, and practice domain (P) 13 items.

3.2 Validity Analysis

3.2.1 Content and Face Validity

Based on the expert panel feedback, 2 items in the attitude domain were removed. The results showed that the individual authority coefficient of each expert ranged from 0.79 to 0.97, the integrated authority coefficient of all experts was 0.92. The expert positive coefficient in two rounds of expert consultation was 1. The I-CVI (Item Level Content Validity Index) of each item ranged from 0.833-1.000; the S-CVI (Scale Level Content Validity Index)for the knowledge domain of the scale was 0.962, S-CVI for the attitude domain was 0.979, S-CVI for the practice domain was 0.961, S-CVI for the skill domain was 0.976; the S-CVI for the total medication literacy scale was 0.968, and the K^* values of each item were over 0.74, indicating that good validity assessment for items were identified.

3.2.2 Exploratory Factor Analysis

Exploratory factor analysis (EFA) was conducted. Principle component analysis with Varimax rotation was employed to analyze the construct and factor structure of this scale and each domain. 257 collected data were randomly abstracted from total questionnaires of 637 to conduct the exploratory factor analysis for the scale. Therefore, the construct and component factor of the total scale and its each domain were identified. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was reported at 0.765, 0.766, 0.713, and 0.808 with significant result for Bartlett's test of sphericity, i.e., *p*-value < 0.001. A 4-domain model construct of this scale was obtained with eigenvalues above 1.0. For demonstration of a clear model structure, items with factor loadings greater than 0.4 on a component, and non-salient loading less than 0.4 on other components, were considered as a single domain (Zwick, 1986; Toll, 2007). Domain 1 (knowledge) contained 9 items, domain 2 (attitude) contained 8 items, domain 3 (skill) contained 7 items and domain 4 (practice) contained 13 items. There were 3 common factors extracted from knowledge domain and its cumulative variance contribution rate was 64.419%, 4 items loaded on factor 1 measured knowledge for antihypertensive medication, factor 2 contains 3 items that measured knowledge for hypertension disease, factor 3 had 2 items that measured knowledge for hypertension treatment (Table 2). 2 common factors were extracted from attitude domain and its cumulative variance contribution rate was 60.914%, 5 items loaded on

factor 1 measured patients' attitude to antihypertensive medication, factor 2 had 3 items that represented attitude to hypertension disease (Table 3).

4 common factors were extracted from practice domain and its cumulative variance contribution rate was 59.474%, 4 items loaded on factor 1 represented antihypertensive compliance behavior, factor 2 had 3 items that measured medication decision making behavior, 3 items loaded on factor 3 represented patients' disease control behavior and adverse effects surveillance after medication administration as well as blood pressure monitoring practice, factor 4 contained 3 items that represented antihypertensive medication information-seeking and dissemination behavior (Table 4). 2 common factors were extracted from skill domain and the cumulative variance contribution rate was 56.111%, 4 items loaded on factor 1 measured patients' ability of reading and comprehension for the prescription and medication instruction, factor 2 contained 3 items that measured patients' ability to numeric calculation for dosage of medication, medication administering or prescription refill time (Table 5). This 4-domain with 11 factors model was then confirmed in the rest sample by conducting a confirmatory factor analysis (CFA).

Table 2: Exploratory Factor Analysis on Knowledge Dimension of ML for Hypertensive Patients (n=257).

Items	Factors		
	1	2	3
K1		0.688	
K2		0.867	
K3		0.813	
K4			0.614
K5			0.866
K6	0.776		
K7	0.747		
K8	0.761		
K9	0.795		
Eigenvalues	2.473	2.008	1.317
Variance contribution rate (%)	27.481	22.306	14.631
Factors designation	Sub-domain 1	Sub-domain 2	Sub-domain 3

Note: ML: Medication Literacy K: Knowledge dimension of ML; KMO (Kaiser-Meyer-Olkin) Measure of Sampling Adequacy Value=0.765, Bartlett's test:χ^2 (Chi square test value) =627.670; df (degree of freedom) =36; *P*=0.000.

Table 3: Exploratory Factor Analysis on Attitude Dimension of ML for Hypertensive Patients(n=257).

Items	Factors	
	1	2
A1		0.690
A2		0.826
A3		0.808
A4	0.763	
A5	0.776	
A6	0.767	
A7	0.727	
A8	0.785	
Eigenvalues	2.971	1.902
Variance contribution rate (%)	37.134	23.780
Factors designation	Sub-domain 1	Sub-domain2

Note: A: Attitude dimension of ML; KMO Measure of Sampling Adequacy Value=0.766, Bartlett's test:χ^2 (Chi square test value) =723.104; df (degree of freedom) =28; *P*=0.000.

Table 4: Exploratory Factor Analysis on Practice Dimension of ML for Hypertensive Patients (n=257).

Items	Factors			
	1	2	3	4
P1				0.489
P2				0.652
P3				0.671
P4		0.789		
P5		0.722		
P6		0.713		
P7.1	0.766			
P7.2	0.803			
P7.3	0.766			
P7.4	0.757			
P8			0.476	
P9.1			0.659	
P9.2			0.654	
Eigenvalues	2.512	1.988	1.762	1.469
Variance contribution rate (%)	19.327	15.294	13.553	11.300
Factors designation	Sub-domain 1	Sub-domain 2	Sub-domain 3	Sub-domain 4

Note: P: Practice dimension of ML; KMO Measure of Sampling Adequacy Value=0.713, Bartlett's test: χ^2 (Chi square test value) =874.831; df (degree of freedom) =78; *P*=0.000.

Table 5: Exploratory Factor Analysis on Skill Dimension of ML for Hypertensive Patients (n=257).

	Factors	
Items	1	2
S1		0.704
S2		0.750
S3		0.643
S4	0.600	
S5	0.789	
S6	0.739	
S7	0.821	
Eigenvalues	2.275	1.653
Variance contribution rate (%)	32.503	23.608
Factors designation	Sub-domain 1	Sub-domain 2

Note: S: Skill dimension of ML; KMO Measure of Sampling Adequacy Value=0.808, Bartlett's test:χ^2 (Chi square test value) =373.837; df (degree of freedom) =21; *P*=0.000.

3.2.3 Confirmatory Factor Analysis

380 questionnaires, of the rest part of the 637 collected questionnaires, were used to test the 4-domain with 11 factors model of the scale. Fit indices were calculated. The values obtained for fit indices in CFA were; IFI = 0.746, i.e., near to 0.9. The value for RMSEA and RMR was 0.066 and 0.012, respectively, i.e., less than 0.07. The values for GFI, AGFI were 0.804, 0.777, and values for PCFI and PNFI were 0.689 and 0.599, i.e., > 0.50. In our results, the value of χ^2/df was 2.629, i.e, < 3. All these values confirmed an acceptable 4-domain 11-factor model fit (Table 6), and the structure equation modeling was showed in Figure 1. For convergent validity and discriminant validity, in our results for this scale, the average factor loadings for each construct were reported larger than 0.7. Therefore, the convergent validity was established; the average variance and squared correlation coefficients between two constructs were also calculated and the results showed that the average variance values between every two constructs were greater than their respective squared correlation coefficients. This means that the discriminant validity was identified.

3.3 Reliability Analysis

The Cronbach's α coefficient, split-half reliability, and test-retest reliability coefficient of the total scale

Table 6: The Results of Fitting Indices of Confirmatory Factor Analysis of 11-Factor Model of Medication Literacy Assessment Scale for Hypertensive Patients (n=380).

Parameters	11-factor model
χ^2/df	2.629
GFI	0.804
AGFI	0.777
RMR	0.012
IFI	0.746
RMSEA	0.066
PCFI	0.689
PNFI	0.599

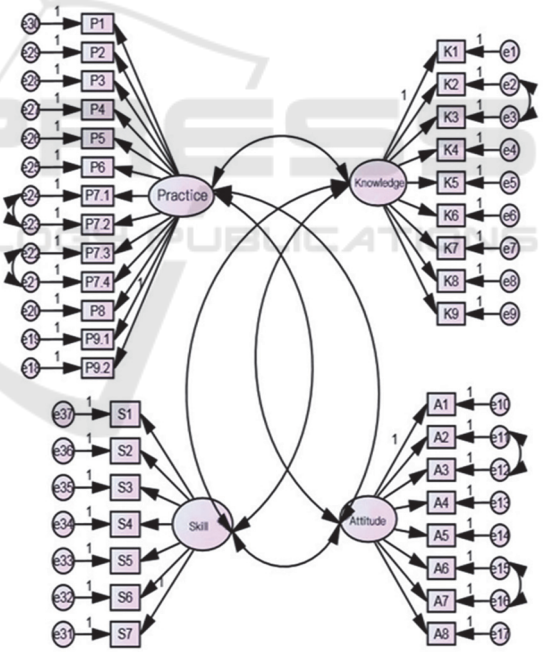

Figure 1: Structure equation modeling of 4-domain with 11 factors for medication literacy scale.

and among each domain on knowledge, attitude, practice, and skill were measured. The overall reliability of the scale for 37 items was 0.849. All items were positive correlated with each other. The Cronbach's α coefficients among each domain ranged from 0.744 to 0.783. The split-half reliability coefficient for the overall scale was 0.893, among

each domain ranged from 0.793-0.872. The test-retest Pearson's correlation coefficient for the overall scale was 0.968, among each domain of the scale ranged from 0.880-0.959 (P-value < 0.01). (Table 7). The Pearson correlation coefficient between each domain and the overall scale ranged from 0.530-0.799 (P<0.01), and the Pearson correlation coefficient among domains ranged from 0.157-0.439 (P<0.01). (Table 8). Therefore, good reliability of this scale was confirmed.

Table 7: The Reliability Coefficients of the Total Scale and among Each Dimension of Medication Literacy Assessment Scale for Hypertensive Patients (n=637).

Domains	Items	Cronbach's α coefficient	Split-half reliability	Test-retest reliability
KL	9	0.754	0.816	0.958
AL	8	0.783	0.872	0.959
PL	13	0.744	0.809	0.928
SL	7	0.763	0.793	0.880
ML	37	0.849	0.893	0.968

Table 8: Correlation Analysis between Each Domain of Medication Literacy and the Overall Assessment Scale for Hypertensive Patients (n=637).

	ML	KL	AL	PL	SL
ML	1				
KL	0.799**	1			
AL	0.530**	0.283**	1		
PL	0.746**	0.439**	0.334**	1	
SL	0.653**	0.370**	0.157**	0.216**	1

Note: **. Statistically significant Correlation with each other at level of 0.01(bilateral).
ML: Medication Literacy; KL: Knowledge Literacy; AL: Attitude Literacy; PL: Practice Literacy; SL: Skill Literacy.

4 DISCUSSION

This is the first study to develop and validate a self-reporting medication literacy scale specific for hypertensive patients, though, there were several existing medication literacy scales for general population, for example, Medication Literacy Assessment Scale in Spanish and English (MedLitRxSE) (Sauceda, 2012); Chinese Medication Literacy Measure (ChMLM) (Yeh, 2017); Medication Literacy Assessment Questionnaire (Horvat, 2017). For hypertensive patients, adherence to prescribed medication regimen and taking antihypertensives in a correct and safe way are prerequisites for achieving optimal blood pressure control. Medication literacy presents the knowledge and attitude to hypertension disease, treatment and antihypertensive therapy, as well as the skill and practice of taking antihypertensives in a correct and safe way. Therefore, medication literacy level assessment for hypertensive patients can be the first step to target gaps and patients' problems of pharmacotherapy, so that targeted counselling and interventions to prompt persistent, correct and safe antihypertensive therapy for patients could be implemented. The item generation in the development of the medication literacy scale for hypertensive patients was mainly based on a concept framework of medication literacy with four domains on knowledge, attitude, skill and practice. A comprehensive literature review about relevant literatures and existing medication literacy research tools was also conducted. Subsequently, an expert meeting, interviews for hypertensive patients, and focus group discussion for appraising the generated items were initiated and ended up with 41 items. After that, 6 experts were invited to have a content and face validity evaluation on the primary scale with 41 items, 2 items were removed by the experts. The measurement purification was carried out by item re-screen through statistical analysis with pilot study. Item discrimination analysis and correlation coefficient method were used to rescreen items, after which 2 items in the attitude domain were excluded. Finally, a scale with 37 items based on 4 domains were utilized to give a formal investigation in a sample of 650 participants. The evaluation of the scale was determined by study validity and reliability.

Content validity and construct validity were measured. A qualified scale requires I-CVI over 0.78, K^* over 0.74, and S-CVI over 0.9. In this study, the CVI of each item were over 0.78, and K^* over 0.74; S-CVI for the scale was 0.968 and for each domain ranged from 0.961-0.979. Therefore, good content validity of this newly developed medication literacy scale for hypertensive patients has been confirmed.

For construct validity, the scale was subjected to exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). 4-domain 11-factor modeling was explored and was then confirmed by subsequent CFA. The extracted 11 common factors from four domains of medication literacy scale for hypertensive patients were fundamentally identified in accordance with theory assumption of medication literacy and EFA results, which can be well interpreted by specialty practicalities. Besides, the cumulative variance contribution for each domain ranged from 56.111%-64.419%.

In the confirmatory factor analysis, χ^2/df, GFI, AGFI, RMR, IFI, RMSEA, PCFI and PNFI were calculated to test model fit in this study. In this study for the developed scale, the $\chi^2/df < 2$, the value of fit indices for GFI, AGFI and IFI were close to 0.9; RMR were less than 0.05 and RMSEA were less than 0.07; PCFI and PNFI were greater than 0.5. All these values indicated an acceptable model fit. Therefore, the construct validity of this scale was confirmed well.

In this study, the internal consistency of this scale was measured. The Cronbach's α coefficient of the overall scale for 37 items was 0.849. This was higher than alpha value reported by ChMLM scale among general population in Taiwan (Yeh, 2017) , i.e., 0.72, and was also higher than the total test reliability reported by 14-item English and Spanish MedLitRxSE tool for general population (Sauceda, 2012), i.e., (English: KR-20 = 0.81; Spanish: KR-20 = 0.77). In our results, the Cronbach's α value for individual domains ranged from 0.744 to 0.783, indicating a good internal consistency in this scale. The split-half reliability coefficient for the overall scale was 0.893, for its individual domains ranged from 0.793 to 0.872, indicating good split-half reliability of this scale. The test-retest reliability was 0.968, greater than 0.9, and for its individual domains were from 0.880 to 0.959 (P<0.001). In addition, this scale demonstrated a high acceptability among hypertensive patients with a response rate of 96.6% and 98%. Therefore, this newly developed scale is easy to use and fill in, which is pragmatic and applicable in assessing hypertensive patients' medication literacy.

The strengths established in this study: the developed scale is available in Chinese language, high patient acceptability, a rigorous and scientific procedure of measurement purification, validated and reliable constructs.

The validation of this newly developed medication literacy scale for hypertensive patients in other sample of population of China is still needed. Besides, English translation and validation is also required for its international utilization.

5 CONCLUSIONS

A newly self-reporting medication literacy scale for hypertensive patients was developed in Chinese language. The measurement property of this scale has been established, in which good reliability and validity was confirmed, suggesting its appropriateness and applicability to measure medication literacy level for Chinese hypertensive patients. Future study will be focused mainly on two aspects: first, English translation is needed, so that this scale application can be further validated worldwide; Then, large-scale investigation of hypertensive patients' medication literacy in China based on this scale is needed, so associated factors of hypertensive patients' medication level could be found.

REFERENCES

Alzghoul Bashar I,Abdullah Nor Azimah Chew. Pain Management Practices by Nurses: An Application of the Knowledge, Attitude and Practices (KAP) Model. [J]. Global journal of health science, 2015, 8(5).

Bowling, A. (2009). Research Methods in Health: Investigating Health and Health Services, 3rd Edn. London: Open University Press.

Butcher H K. Book Review: Strategies for Theory Construction in Nursing (4th ed.) [J]. Nurs Sci Q, 2006, 19 (2): 174-180.

Cheng Fang, Shi Huanhuan, Wang Wei. Theory of Planned Behavior and its application in nursing research worldwide[J]. Journal of Nursing Science, 2012, 27 (8): 91-94.

Cohen, J. S. (1988). Statistical power analysis for the behavioral sciences, 2nd Edn. New Jersey, NJ: Lawrence Erlbaum Associates Inc.

De Vellis, R. F. (1991). Scale Development: Theory and Applications, 26th Edn. Thousand Oaks, CA: Sage.

Horvat N, Vidic L, Kos M. Development and content validation of Medication Literacy Assessment Questionnaire [J]. International Journal of Clinical Pharmacy, 2017, 39 (3): 606-606.

Hu Dayi. The Social Practice Significance of the "Guidelines for Prevention and Treatment of Hypertension in China" (2009 Grass-roots Edition) [J]. China J hypertension, 2010, 18(1): 9-10.

Hambleton RK, Swaminathan H, Algina J, etal. Criterion-referenced testing and measurement: Review of technical issues and developments [J]. Rev Educat Res, 1978, 48(1):11‑22.

Hair, J. F. Jr., Black, W. C., and Babin, B. J. (2009). Multivariate Data Analysis. Anderson RE, 7th Edn. New York, NY: Prentice Hall.

Jöreskog, K., and Long, J. S. (1993). "Introduction," in Testing Structural Equation Models, eds A. Kenneth, J. Bollen, and J. Scott Long (Newbury Park CA: Sage).

Liu He, Xu Shuiyang, Wang lei, et al. The health literacy and influencing factor of hypertension patients (15-69 years old) in Zhejiang province [J]. Chinese Journal of Prevention and Control of Chronic Diseases, 2016, 24 (5): 343-347.

Lahey, M. A., Downey, R. G., and Saal, F. E. (1983). Intraclass correlations: there's more there than meets

the eye. Psychol. Bull. 93, 586–595. doi: 10.1037/0033-2909.93.3.586.

Lynn MR. Determination and quantification of content validity [J]. Nursing Res, 1986, 35(6):382‑385.

Martuza VR. Applying norm-referenced and criterion-referenced measurement in education [M]. Boston: Allyn and Bacon, 1977:275‑293.

Mulaik, S. A., James, L. R., Van Alstine, J., Bennet, N., Lind, S., and Stilwell, C. D. (1989). Evaluation of goodness-of-fit indices for structural equation models. Psychol. Bull. 105, 430–445. doi: 10.1037/0033-2909.105.3.430.

Peng Xiangdong, Zhu Yongqiang, Sa Zhihong, et al.Health behavior theory: from health belief model to risk perception and health behavior decision making [J].Chinese Journal of Health Education, 2014, 30 (6): 547-548.

Polit DF, Beck CT, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations [J]. Res Nurs Health, 2007, 30(4):459‑467.

Pett, A. M., Lackey, N. R., and Sullivan, J. J. (2003). Making Sense of Factor Analysis: The use of Factor Analysis for Instrument Development in Health Care Research. Thousand Oaks, CA: Sage. doi: 10.4135/9781412984898.

Rahmawati R, Bajorek B V. Self-medication among people living with hypertension: a review [J]. Family Practice, 2017, 34 (2):1-7.

Shi S J, Shen Z Y, Duan Y L, et al. Association Between Medication literacy and medication adherence among patients with hypertension [J]. Frontiers in Pharmacology, 2019, 10:822. doi: 10.3389/fphar.2019.00822.

Sauceda J A, Loya A M, Sias J J, et al. Medication literacy in Spanish and English: psychometric evaluation of a new assessment tool [J]. Journal of the American Pharmacists Association, 2012, 52 (6): e231-e240.

Sorensen K,Van den Broucke S, Fullam J, et al. Health literacy and public health: A systematic review and integration of definitions and models[J]. BMC Public Health, 2012, 12 (1): 1-13.

Shi Jingcheng, Mo Yakun,Sun Zhengqiu.Content validity index in scale development[J].Journal of Central South University (Medical Science) , 2012, 37 (2): 152-155.

Yeh Y C, Lin H W, Chang E H, et al. Development and validation of a Chinese medication literacy measure [J]. Health Expect, 2017, 20 (6): 1296-1301.

Sushil, S., and Verma, N. (2010). Questionnaire validation made easy. Eur. J. Sci. Res. 46, 172–178.

Streiner, D. L., and Norman, G. R. (1995). Health Measurement Scales: A Practical Guide to their Development and use, 2nd Edn. New York, NY: Oxford University Press Inc.

Shima, R., Farizah, H., and Majid, H. A. (2015). The 11-item Medication Adherence Reasons Scale: reliability and factorial validity among patients with hypertension in Malaysian primary healthcare settings. Sing. Med. J. 56, 460–467. doi: 10.11622/smedj.2015069.

Toll, B. A., McKee, S. A., Martin, D. J., Jatlow, P., and O'Malley, S. S. (2007). Factor structure and validity of the Medication Adherence Questionnaire (MAQ) with cigarette smokers trying to quit. Nicot. Tob. Res. 9, 597–605. doi: 10.1080/14622200701239662.

Walker L, Avant K. Strategies for Theory Construction in Nursing, CourseSmart eTextbook [J]. Pearson Schweiz Ag, 2010, 44 (44): 434-436.

Wu Minglong. Structural equation model: AMOS's operation and application [M]. Chongqing: Chongqing University Press, 2009.

Zwick, W. R., and Velicer, W. F. (1986). Comparison of five rules for determining the number of components to retain. *Psychol. Bull.* 99, 432–442. doi: 10.1207/s15327906mbr1702_5.