Research paper

Reliability and validity of a pattern identification diagnostic tool for climacteric and postmenopausal syndrome pattern identification: A clinical study of a newly developed questionnaire

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ABSTRACT

Introduction: Traditional Korean Medicine (TKM) can be used to manage symptoms associated with the menopause, but effective treatment depends on diagnosis, which could be facilitated with an appropriate diagnostic tool. This study aimed to verify the reliability and validity of a diagnostic tool for climacteric and postmenopausal syndrome pattern identification (CaPSPI) by identifying seven major patterns and 10 syndrome elements.
Methods: This study was conducted between June and October 2018, in two University Korean Medicine Hospitals. To investigate the construct validity, 275 women aged 45–60 years experiencing menopausal symptoms (Kupperman index ≥ 20) answered a 75-item questionnaire regarding menopausal symptoms. To investigate the tool's criterion validity, a previously developed pattern identification questionnaire (DSOM) was administered to 107 participants. Subsequent analysis examined construct validity using factor analysis, reliability using Cronbach's alpha, and criterion validity using Pearson's correlation.
Results: For construct validity, the factor loading of the seven patterns was ≥ 0.452, and Cronbach's coefficient was ≥ 0.759. For the 10 syndrome elements (證素), the factor loading of the four disease locations (病位) was ≥ 0.519, and the associated Cronbach's coefficient was ≥ 0.790, while the factor loading of the six disease natures (病性) was ≥ 0.468, and the associated Cronbach's coefficient was ≥ 0.700. The criterion validity of the DSOM was also verified (p < 0.001).
Conclusions: The results confirmed the construct validity and reliability of the seven patterns and 10 syndrome elements proposed by the CaPSPI. The criterion validity of the DSOM was also verified. These results suggest that this may be an effective tool for diagnosing menopausal symptoms.

1. Introduction

Postmenopausal symptoms are often experienced over many years and there is a need to ensure good health and quality of life for women after the menopause [1]. The clinical approach in oriental medicine to premenopausal and postmenopausal periods, uses pattern identification and treatment methods (辨證論治), and include perspectives regarding the whole condition of the human body, such as vascular motion symptoms [2].

Pattern differentiation, or "zheng," is a unique traditional Chinese

medicine (TCM) concept that summarizes the nature, location, and pattern of diseases corresponding to the World Health Organization's definition. According to each individual pattern, specific TCM treatment can be prescribed precisely to maximize its effectiveness [3].

Research has studied the nature of patterns and the symptoms associated with each pattern [4,5], studies of specific patient groups [6–10], and expert surveys [11]. Based on these studies, the authors developed a pattern identification diagnostic tool for menopausal disorders as part of the development of clinical practice guidelines to standardize oriental medicine clinical practice [2].

This study was undertaken to perform a pattern identification (辨證) diagnosis of women with menopausal disorders and postmenopausal syndromes. In Phase I of the study, we developed a diagnostic questionnaire (hereinafter referred to as CaPSP) that included the symptoms of seven patterns, to be used in the pattern diagnosis of menopausal and postmenopausal conditions. In addition, 10 syndrome elements were selected via literature review and expert Delphi research to determine whether the seven major patterns selected in the study of menopausal symptoms were satisfied by the pattern diagnosis of menopausal symptoms [2]. This paper describes a clinical study which had the aim of establishing and verifying the reliability and validity of a pattern identification diagnostic tool developed in 2018, and reports the results of our analysis.

2. Methods

2.1. Participants

This study was conducted from June 1, 2018, to October 18, 2018, at the Dong-Eui University Korean Medicine Hospital (OpUMC-2018-6M-04-3) and Cheonan Korean Medicine Hospital of Daejeon University (DJUMC-2018-BM-04-2) after IRB approval was obtained. A total of 305 patients were targeted. However, because of recruitment difficulties, the final target group was composed of 275 patients, including 215 patients from Dong-Eui University Korean Medicine Hospital and 60 patients from Cheonan Korean Medicine Hospital of Daejeon University. All participants were recruited using posters that introduced the clinical research in two university-affiliated oriental medicine hospitals in Busan and Daejeon, South Korea, where clinical research is conducted.

The sample size was calculated as shown below.

2.1.1. Basis of calculation

For construct validity of the tool, the sample size was calculated using the sample number calculation formula [12] for confirmatory factor analysis. Via RMSEA (root mean square error of approximation) fit index, the number of participants was 275 (significance level 5%, power 85%, d = 14 [degrees of freedom]). The dropout rate was 10%, and the final number of participants was 305.

Criterion validity was analyzed to examine the correlation between the newly developed tool and one or more other measurement methods for the factors being investigated. Because there is no pattern identification diagnostic tool for climacteric syndrome, we examined the correlation between the new tool and DSOM [13], a tool developed for TKM diagnosis.

To calculate the sample size for the correlation test (criterion-related validity), calculations were run on 96 participants based on a significance level of 5%, power of 85%, correlation coefficient (0) under the null hypothesis, and correlation coefficient (0.3) under the alternative hypothesis. Taking into account the dropout rate (10%), the final number of participants was 107. The sample size was calculated using G*power 3.1.9.

2.1.2. Criteria for inclusion and exclusion of participants
2.1.2.1. Inclusion criteria

1) Women aged 45–60 years
2) Women with irregular menstruation for at least 3 months or having amenorrhea lasting at least 3 months
3) Women experiencing significant menopausal symptoms (Kupperman index ≥ 20)
4) Those who received sufficient explanation of the clinical trial and have voluntarily consented to participate through a signed agreement

2.1.2.2. Exclusion criteria

1) Those diagnosed with psychogenic climacteric syndrome
2) Those who had taken hormones within the previous 3 months
3) Those having symptoms or illnesses that could affect the pattern identification diagnosis as follows:
   - Patients who had malignant tumors in the present or past
   - Patients who had thyroid disease or were taking medication for thyroid disease
   - Liver function abnormality (acute chronic hepatitis/cirrhosis)
   - Patients with uncontrolled high blood pressure
   - Patients who had diabetes with complications/diabetic patients undergoing treatment using insulin injections and/or pumps
   - Patients suffering from neurological diseases, severe cardiovascular diseases, tuberculosis, and infectious diseases
4) Those deemed unable to prepare forms related to the conduct of research
5) Those judged to be unsuitable participants by the clinical trial manager

2.2. Methods

Two examiners helped the subjects in the process of the survey with a 75-item CaPSP and a demographic survey administered to participants experiencing menopausal symptoms (Kupperman index ≥ 20), and one examiner collected data from the four examination methods of inspection, listening and smelling examination, inquiry, palpation(望聞問切). A pathologist not involved in this research team shared each method with them 4 times, and actual practices were carried out for real. Although the CaPSP initially contained 76 items, the final CaPSP eliminated the 59th question, resulting in a total of 75 items [5]. Additionally, 107 of 275 total participants completed the DSOM [6] questionnaire. Analysis was carried out for each of the 107 participants (Fig. 1).

2.3. CaPSP

In order to devise a diagnostic tool for menopausal disorders, an examination of the literature was conducted on patterns and symptom elements of menopausal disorders. Afterwards, a combination of a consultation with an expert in Korean medicine and the Delphi method was used to determine the main patterns of menopausal disorders and the major symptoms of each. The seven selected patterns are liver qi depression (肝鬱), kidney yin deficiency (腎陰虛), kidney yang deficiency (腎陽虛), liver-kidney yin deficiency (肝腎陰虛), non-interaction between the heart and kidney (心腎不交), dual deficiency of the kidney yin-yang (腎陰陽兩虛), and dual deficiency of the heart-spleen (心脾兩虛). The syndrome elements are disease locations (liver [肝], heart [心], spleen [脾], and kidney [腎]) and six disease natures (yin deficiency [陰虛], qi stagnation [氣滯], blood deficiency [血虛], yang deficiency [陽虛], qi deficiency [氣虛], and heat [火熱]) [2] (Supplementary 1).

2.4. DSOM

DSOM recognizes the concepts of qi-blood yin-yang fluid and humor pattern identification, visceral pattern identification, and cold-heat dry-dampness, which are the most basic units of syndromes in Oriental
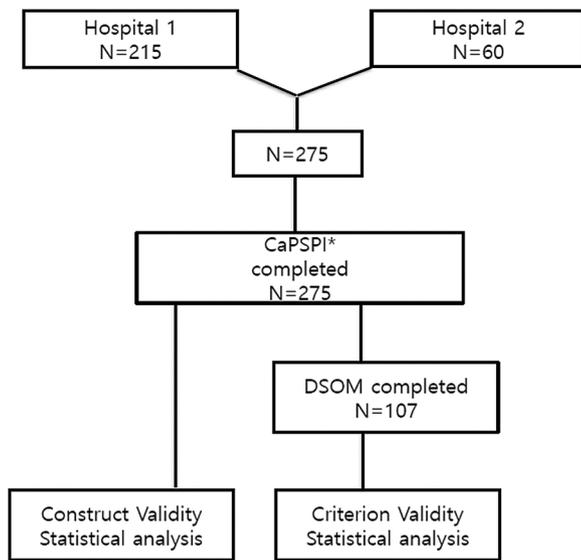
Fig. 1. Flow Chart of the Research Method.

*CaPSPI : diagnostic tool for climacteric and postmenopausal syndrome pattern identification.

medicine. It is an online survey-form diagnostic system that selects 16 pathogenic factors (病機) from these patterns, asking about each of them as a questionnaire item. There are 140 items [13]. Here, the term "pathogenic factor" means "important factor" in the development of a disease. We divided the patterns into the most basic units. There are 16 pathogenic factors: qi deficiency (氣虛), blood deficiency (血虛), qi stagnation (氣滯), blood stasis (血瘀), yin deficiency (陰虛), yang deficiency (陽虛), cold (寒), heat (熱), dampness (濕), dryness (燥), phlegm (痰), liver (肝), heart (心), spleen (脾), lung (肺), kidney (腎) [14].

In a study on the reliability and validity of DSOM in 2005 [15], the Cronbach coefficient of the pathogenic factors was 0.7 or higher, and the cumulative data of a total of 13,121 persons were analyzed in 2011, making some changes in the questionnaires according to gender [13].

2.5. Statistical analysis

The SAS 9.4 (SAS Institute Inc., Cary, NC, USA) software was used for calculating sample sizes and IBM SPSS 24.0 (IBM Corporation Software Group, Somers, NY, USA) software was used for data analysis. The number, percentage, means, and standard deviations were calculated to determine the general characteristics and menopause-related characteristics of the participants. A factor analysis (FA) was used to provide proof of the scale's construct validity [16]. For reliability of the measurement tool, Cronbach's a coefficients were obtained. For criterion validity, Pearson correlation coefficients between our diagnosis tool and DSOM pathogenic factors were calculated.

3. Results

3.1. General characteristics of participants

Table 1 shows the general characteristics and menopause-related data of 275 people who were studied. There were no other underlying conditions that affected the diagnosis.

3.2. Questions of patterns and syndrome elements

Table 2 lists the questions relating to the 7 major patterns and syndrome elements in CAPSI. The 4 major disease locations were identified according to the questions shown in Table 3. Table 4 shows the questions associated with categorizing the major disease natures.

3.3. Construct validity of the seven-pattern identification

The items for the seven major patterns of menopausal syndrome were derived by preliminary research for a menopausal diagnostic tool. The factor loading coefficient of all patterns was ≥0.452, and Cronbach's alpha was ≥0.579. Although one item from the kidney yang deficiency (腎陽虛), two items from the heart-kidney noninteraction (心腎不交), and three items from kidney yin and yang deficiency (腎陰陽兩虛) were dropped, there were at least seven questions associated with every pattern (Table 5).

3.4. Construct validity of the 10 syndrome elements

Ten syndrome elements were selected through a literature review,

Table 1

General Characteristics of Subjects and Menopause-related Characteristics of Subjects.

		N	Minimum value	Maximum value	Mean ± SD
Age		275	45	60	51.39 ± 3.98
Height		275	148	173	153.39 ± 4.59
Weight		215	44	88	58.16 ± 6.89
BMI		275	18.29	33.53	22.89 ± 2.54
Maximum BP		275	86	170	120.84 ± 13.94
Minimum BP		275	58	117	79.87 ± 10.01
Kupperman Index		275	20	147	44.5 ± 24.75
			Frequency	Effective percent	Cumulative Percent
Birth history	No		10	3.6	3.6
	Yes		265	96.4	100
	Sum		275	100	
Menopause	No		106	38.5	38.5
	Yes		169	61.5	100
Menopausal period (year)	1		50	25	25
	2		92	46	71
	3		57	28.5	99.5
	5		1	0.5	100
	Sum		200	100	
Menopause form	Induced menopause		2	0.7	39.3
	Natural menopause		167	60.7	100
	Sum		275	100	

Table 2

Questions used in CAPSI to categorise the 7 Major Patterns.

Liver Depression (肝鬱)	q14*, q18, q23, q28, q57, q60, q72
Kidney Yin Deficiency (腎陰虛)	q9, q12, q31, q36, q43, q54, q69
Kidney Yang Deficiency (腎陽虛)	q3, q30, q41, q45, q49, q53&q37, q76
Liver and Kidney Yin Deficiency (肝腎陰虛)	q6, q9, q18, q36, q50, q54, q69
Heart-Kidney Noninteraction (心腎不交)	q31, q52, q54, q69, q74, q68&q17, q36
Kidney Yin and Yang Deficiency (腎陰陽兩虛)	q9, q12, q30, q31, q36, q43, q45, q54, q69, q76
Dual Deficiency of Heart and Spleen (心脾兩虛)	q4, q17, q19, q27, q51, q62, q68, q71&q45

* q14 means the question No.14.

Table 3

Questions used in CAPSPI to categorise 4 Major Disease Locations(病位).

Liver(肝)	q6*, q24, q28, q56, q57, q58, q72
Heart (心)	q13, q16, q19, q20, q21, q50, q51, q68
Spleen (脾)	q1, q26, q27, q45, q66, q68, q71
Kidney (腎)	q9, q29, q31, q33, q35, q38, q49, q73

* q6 means the question No.6.

Table 4

Questions used in CAPSPI to categorise the 6 Major Disease Natures(病性).

Yin Deficiency(陰虛)	q8*, q15, q21, q31, q32, q36, q43, q54, q69, q74
Qi Stagnation (氣滯)	q22, q40, q44, q57, q58, q59
Blood Deficiency (血虛)	q5, q10, q34, q39, q42, q69, q70
Yang Deficiency (陽虛)	q5, q37, q41, q45, q48, q49, q53
Qi Deficiency (氣虛)	q61, q63, q64, q65, q67, q71, q75
Fire Heat (火熱)	q2, q7, q11, q15, q21, q43, q46, q55

* q8 means the question No.8.

and the expert Delphi method was carried out to determine these elements. Four disease locations (liver [肝], heart [心], spleen [脾], kidney [腎]) and six disease natures (yin deficiency [陰虛], qi stagnation [氣滯], blood deficiency [血虛], yang deficiency [陽虛], qi deficiency [氣虛], heat [火熱]) were selected.

3.4.1. Results of the factor analysis for disease locations

All questionnaire items pertaining to the disease locations were selected, with the exception of one item related to the liver (肝). Each location had at least seven items associated with it. The factor loading was ≥0.519, and Cronbach's alpha was ≥0.790 (Table 6).

3.4.2. Results of the factor analysis for disease natures

All items were selected, except for two that were related to yin deficiency (陰虛) and one for yang deficiency (陽虛). Five of the six major disease natures had at least seven items each, while Qi stagnation (氣滯) had only six items. The factor loading for disease natures was ≥0.468, and Cronbach's alpha was ≥0.814 for each, except that for yang deficiency (陽虛), with Cronbach's alpha of 0.700 (Table 7).

Table 6

Factor analysis for the four major disease locations (病位) accompanying climacteric and postmenopausal syndrome.

Disease locations	Evaluation item number	Number of selected items	Factor loading coefficient	Reliability (Cronbach's coefficient)
Liver (肝)	8	7	0.519~0.811	0.836
Heart (心)	8	8	0.546~0.856	0.861
Spleen (脾)	7	7	0.567~0.761	0.800
Kidney (腎)	8	8	0.556~0.748	0.790

3.5. Criterion validity

The correlation results showed that the DSOM index and correlation coefficient with the 10 syndrome elements increased to ≥0.34, and all were statistically significant at a significance level of 0.05.

Of 16 pathogenic factors from DSOM, there were 10 matches (肝, 心, 脾, 腎, 氣虛, 血虛, 氣滯, 陽虛, 陰虛, 熱) with the newly developed tool in terms of disease locations. When correlation analysis was performed between those 10 pathogenic factors and the four disease locations, all correlations were found to be significant (p = 0.001) (Tables 8 and 9).

4. Discussion

The development of this new menopausal diagnostic tool occurred as part of a project for the development of TKM clinical guidelines for climacteric and postmenopausal syndrome.

From among several candidate patterns selected through literature review and consultations with experts in Oriental medicine physiology, pathology, and diagnosis, the main patterns of menopause disorder were determined by the Delphi method [2]. In practice, however, the clinical symptoms of menopausal disorder are complex; therefore, there are many other forms of pattern identification, each overlapping with the others, which makes it difficult to establish treatment measures [17,18]. To determine whether the seven major patterns selected for the tool satisfy the diagnostic pattern of menopausal disorder, or whether other patterns had been missed, the major syndrome elements (證素) of menopausal disorder were confirmed in the same way as that in the process of finalizing the modulation patterns at the questionnaire production stage [2]. "Syndrome element" is a new pattern

Table 5

Factor analysis for seven major patterns of climacteric and postmenopausal syndrome.

Patterns	Evaluation item number	Number of selected items (%)	Factor loading coefficient	Reliability (Cronbach's coefficient)
Liver depression (肝鬱)	7	7	0.592~0.798	0.844
Kidney yin deficiency (腎陰虛)	7	7	0.556~0.761	0.785
Kidney yang deficiency (腎陽虛)	8	7	0.506~0.751	0.759
Liver and kidney yin deficiency (肝腎陰虛)	7	7	0.552~0.749	0.781
Heart-kidney noninteraction (心腎不交)	9	7	0.649~0.735	0.852
Kidney yin and yang deficiency (腎陰陽兩虛)	13	11	0.452~0.790	0.856
Dual deficiency of heart and spleen (心脾兩虛)	8	8	0.556~0.713	0.844

Table 7

Factor analysis for six major disease natures (病性) accompanying climacteric and postmenopausal syndrome.

Disease natures	Evaluation item number	Number of selected items	Factor loading coefficient	Reliability (Cronbach's coefficient)
Yin deficiency (陰虛)	12	10	0.558~0.755	0.864
Qi stagnation (氣滯)	6	6	0.601~0.824	0.822
Blood deficiency (血虛)	7	7	0.536~0.820	0.831
Yang deficiency (陽虛)	8	7	0.483~0.687	0.700
Qi deficiency (氣虛)	7	7	0.580~0.864	0.882
Fire Heat (火熱)	8	8	0.468~0.753	0.814

Table 8

Correlation coefficients between DSOM * pathogenic factors (病機) and disease locations of diagnostic tool for climacteric and postmenopausal syndrome pattern identification.

		Pathogenic factors of DSOM			
		Liver (肝)	Heart (心)	Spleen (脾)	Kidney (腎)
Disease locations	Pearson correlation	0.716*	0.694*	0.641*	0.524*
	N	107	107	107	107

#DSOM: Diagnosis System of Oriental Medicine.
P-value: * p = 0.001.

Table 9

Correlation coefficients between DSOM [#] pathogenic factors (病機) and disease natures of the diagnostic tool for climacteric and postmenopausal syndrome pattern identification.

		Pathogenic factors for DSOM					
		Yin deficiency (陰虛)	Qi stagnation (氣滯)	Blood deficiency (血虛)	Yang deficiency (陽虛)	Qi deficiency (氣虛)	Fire Heat (火熱)
Disease natures	Pearson correlation	0.682*	0.710*	0.655*	0.706*	0.639*	0.349*
	N	107	107	107	107	107	107

#DSOM: Diagnosis System of Oriental Medicine.
P-value: * p = 0.001.

identification term coined by a Chinese professor Wen Feng Zhu and represents a basic element of pattern identification. It consists of disease location and disease nature and is determined through the differentiation of syndromes, physical evidence, and pathological information [19]. The reliability and validity of the 10 syndrome elements were investigated in the same way as that of the seven major patterns of the menopausal disorder.

Regarding participants' general characteristics, while some participants had high or low blood pressure, no other diseases with the potential to affect the diagnosis were present. The participants' ages and Kupperman index scores met all required conditions (Table 1). Through the expert agreement process conducted based on the literature search by patterns, seven or more items were recognized as valid through the FA. All items had factor loading coefficients of at least 0.452, and Cronbach's alpha of all patterns was ≥0.579. These results indicate acceptable levels of reliability and construct validity for the tool in light of the general criteria for reliability and composition (reliability of 0.6 or higher and factor of 0.4 or higher) (Table 5) [20,21].

As for the results for the 10 syndrome elements (證素), the reliability of all four disease locations was ≥0.790, and factor loading coefficients appeared to be ≥0.519, making it acceptable in light of the general criteria for reliability and composition (reliability of 0.6 or higher and factor of 0.4 or higher) (Table 6). In contrast, the disease natures showed appropriate reliability and validity, with a reliability of ≥0.7, and all items had a factorial inventory coefficient of 0.468 (Table 7).

The results of the correlation analysis between the four disease locations (肝, 心, 脾, 腎), the six disease natures (陰虛, 陽虛, 血虛, 氣滯, 氣虛, 火熱), and pathogenic factors (病機) from the DSOM revealed that all correlations were significant (p = 0.001). This result indicates that the criterion validity of the tool is acceptable (Tables 8 and 9).

Several studies are being planned in the future to use the tools developed for clinical use. First, we plan to carry out a study to decide the cut-off value in order to produce the results of the pattern identification diagnosis. We will make it available online to conveniently check survey results and accumulate a large amount of data. It is believed that collecting data from several other regions or countries in this manner will enable many studies of the health conditions of menopausal women as well as the diagnosis of menopause disorders.

4.1. Limitations

The diagnosis in the study was based on the statistical results; therefore, in the future, studies for concordance with expert diagnosis are required. Further, this study was conducted in two metropolitan cities in the central and southern areas of South Korea and included 275 women in premenopausal or postmenopausal period from the two regions of South Korea. Further studies including larger number of samples from other countries and regions are warranted.

5. Conclusion

In summary, this clinical study of women experiencing mild or more severe menopausal symptoms has demonstrated the appropriateness of the items of patterns and syndrome elements of CaPSPI and its reliability and validity. These results can be attributed to the several processes in the selection of the final questionnaire. The processes include choosing patterns and syndrome elements by sufficient advanced studies, selecting each item by several expert agreements, and translating items by Korean medicine specialties and psychological experts to minimize error. As the newly developed menopausal syndrome diagnostic tool demonstrates acceptable construct validity and criterion

validity, the suitability of its use in a clinical setting has been confirmed.

Authors' contribution

All authors participated in this study.

In-Seon Lee drafted the paper.

Chang-Wan Kang was responsible for the statistical analysis of data.

In-Seon Lee, Jong-Won Kim, and Soo-Hyung Jeon were responsible for the study concept and design.

In-Seon Lee, Yong-Tae Lee, Gyoo-Yong Chi, and Jong-Won Kim were responsible for data analysis and interpretation.

In-Seon Lee supervised the study.

Soo-Hyung Jeon and Ji-Yeon Lee were responsible for acquisition of data.

All authors approved the final paper.

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Declaration of Competing Interest

There are no conflicts of interest to declare.

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