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Research paper

Development and validation of a new pattern identification scale for *Stomach Qi Deficiency*

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ABSTRACT

Introduction: This study aimed to develop pattern identification scale for *Stomach Qi Deficiency* (SSQD) and investigated whether this questionnaire satisfied adequate reliability and validity.
Methods: To develop SSQD, we extracted major symptoms of *Stomach Qi Deficiency* (SQD) syndrome and requested an expert group to take part in a Delphi survey. The questionnaire was modified by the opinion of the expert group. For the analysis of reliability and validity and investigation of cut-off value, 30 participants who had dyspepsia and diagnosed as SQD and 30 healthy control participants were evaluated.
Results: Of the 13 questions in the SSQD, 1 question had negative effects on reliability and validity, therefore, it was excluded on further inspection. Overall Cronbach's α coefficient of SSQD was 0.87. Construct validity was analyzed by factor analysis resulting 3 major factors. Using receiver operating characteristic curve analysis, the optimal cut-off value of SSQD was defined as 14, and its sensitivity and specificity were 93.33% and 86.67%, respectively. There were statistically significant positive correlation between SSQD and other dyspepsia severity scales.
Conclusions: The newly developed SSQD can provide fundamental reliability and validity as a specific pattern diagnosis questionnaire and can help diagnosing SQD. However, further studies will be needed to further confirm its specificity.

1. Introduction

Pattern identification is a unique method for diagnosis in Traditional medicine (TM) commonly used in China, Korea, Japan, and elsewhere around the world [1]. It is defined as the process of overall analysis of clinical data to determine the location, cause and nature of a patient's disease and achieving a diagnosis of a pattern syndrome [2]. A pattern in TM refers to the complete clinical presentation of the patient at a given moment in time including all findings [3]. Among these patterns, *Stomach Qi Deficiency* (SQD) is a pattern characterized by decreased appetite and impaired digestion, and is explained by weakness of stomach qi, affecting its function [4]. Practitioners in TM differentiate a pattern using information acquired with unique diagnostic methods such as inspection, auscultation and olfaction, inquiry, and pulse-taking and palpation [5]. This process of diagnosis has subjective features, therefore diagnostic devices and questionnaires for overcoming this subjectivity have been developed [6]. Recently, there has been some research on the standardization of pattern identification that has utilized a simple and objective method to diagnose a specific pattern identification that is also highly applicable in clinical use including pattern identification questionnaire for cold-heat [7], blood stasis [8], phlegm and fluid retention [9], food retention [10], spleen qi deficiency pattern [11] and questionnaire for herbal decoctions like *Pyungweesan* [12] and *Bojungikgitang* [13].

Particularly, objective diagnostic data on pattern identification accumulated through above mentioned questionnaires can be utilized as the baseline for health care informatics to support evidence-based medicine, by providing data for clinical research, and provide data to confirm clinical efficacy of diagnosis and treatment in TM for major diseases and symptoms [14].

Dyspepsia is a pain or an uncomfortable feeling referable to the gastroduodenal region of the upper gastrointestinal tract, and functional dyspepsia (FD), a relapsing and remitting disorder, is the most common cause of these symptoms [15].

Accompanying the increasing need for pattern identification questionnaires in TM, this study aimed to develop a new pattern identification questionnaire on SQD pattern, which is clinically important and frequently diagnosed in dyspeptic patients. First, questionnaire model

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appropriate for diagnosing SQD was developed through agreement within the expert panels and literature searches. Subsequently, 30 participants in the SQD group and 30 participants in the healthy control group were tested to determine the reliability and validity of the developed questionnaire to confirm how much the questionnaire can explain and determine SQD. Additionally, the optimal cut-off value for diagnosis of SQD was deducted for objectification of pattern identification. Relationship of a newly developed questionnaire with previously developed and generally used dyspepsia-related questionnaires was analyzed for application in clinical use.

2. Methods

2.1. Fundamental development of pattern identification scale for Stomach Qi Deficiency pattern (SSQD)

2.1.1. Selection of literature

For development of preliminary form for SSQD, literature was searched to gather symptoms related to SQD. From previous related research articles and medical textbooks published from Korea and China, a total of 35 references with explanations on SQD were identified.

Ten Chinese textbooks related to diagnostics, pathology and internal medicine were selected with the exclusion of textbooks where the author and the publishing company were identical. A total of 257 Chinese articles were selected through the database website as China Knowledge Resource Integrated Database (CNKI) with search terms of '*Stomach Qi Deficiency*', 'shortage of *Stomach Qi*' and 'weak *Stomach Qi*', of which 5 references with explanations of SQD were selected.

Among textbooks on diagnostics, pathology and internal medicine about Korean medicine written in Korean, 20 textbooks were selected explaining SQD. Korean research articles were searched through the database websites; the Korean studies Information Service System (KISS) and the Oriental Medicine Advanced Searching Integrated System (OASIS), with search terms of '*Stomach Qi Deficiency*' and '*Stomach Qi Deficiency* pattern'. From our search results, 11 articles were selected, but none of these presented any symptoms or explanations realating to SQD. The whole selection process is shown below (Fig. 1).

Table 1
Selected symptoms for *Stomach Qi Deficiency* and results of importance inspection by Delphi method.

Question items	Importance (mean)	Rank
The upper abdomen is always uncomfortable and worse after meals.	4.462	1
Abdominal examination of a Korean medicine doctor (epigastric fullness, epigastric rigidity and sound of murmuring water)	3.846	2
No appetite for food	3.769	3
Pulse diagnosis of a Korean medicine doctor (fine and weak pulse)	3.769	4
Lethargy and weakness of body	3.692	5
Tongue diagnosis of a Korean medicine doctor (pale tongue with little coating)	3.615	6
Mild pain on the upper abdomen that is relieved by warmness	3.538	7
Time from onset	3.538	8
Frequent belching	3.231	9
Emotionally tired easily.	3.231	10
A sallow or pale face	3.154	11
BMI	3.153	12
Unable to distinguish the taste of foods	3.077	13
Loose stool	2.923	14
Sometimes nauseous or vomits	2.846	15
Frequent experience of acid reflux	2.462	16
Frequent hiccups	1.846	17

2.1.2. Selection of major symptoms

From each reference which listed the symptoms of SQD, major symptoms with high frequency were extracted. Fourteen major symptoms were extracted with exclusion of symptoms with a frequency of less than lower 30%. In addition to the extracted symptoms, 3 items of 'patient's Body Mass Index (BMI)', 'time from onset of symptoms' and 'abdominal examination (epigastric fullness, epigastric rigidity and sound of murmuring water)' were considered clinically important to be included in the major symptoms and a total of 17 major symptoms were confirmed (Table 1).

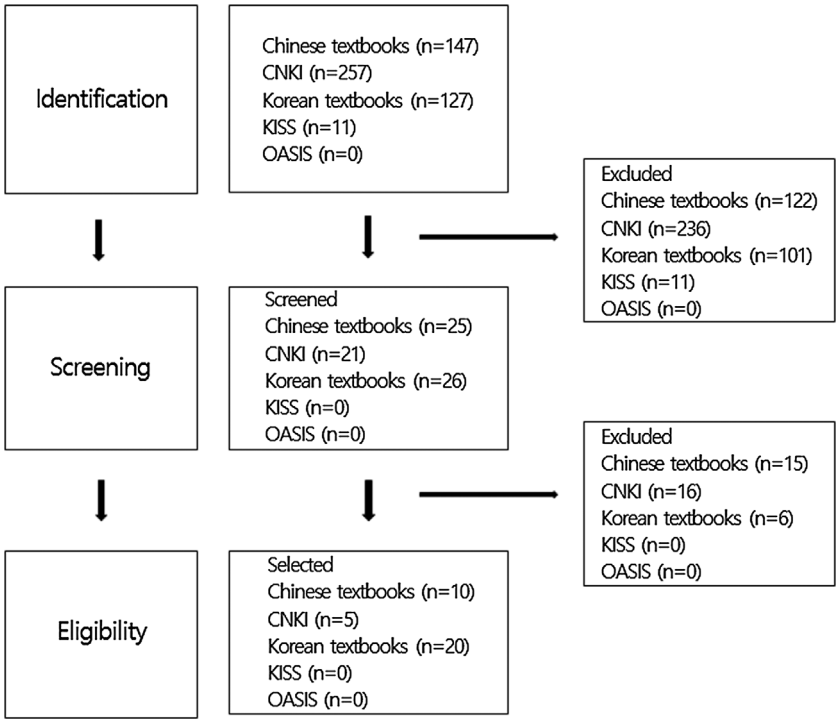

Fig. 1. Flow chart of literature selection.

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