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Research paper

Selecting diagnostic parameters of functional dyspepsia based on pattern identification: Step 1—Systematic literature review and expert consensus process

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ABSTRACT

Introduction: Although there have been many efforts to diagnose functional dyspepsia (FD), an objective diagnosis is not easily made. Korean medicine (KM) doctors have attempted to study parameters for diagnosing FD in clinical studies. The aim of this study was to select diagnostic parameters of FD based on pattern identification in KM.

Methods: First, we searched the relevant literature with Korean authors, recorded in 7 databases, from their inception to May 2016. Second, we consulted expert opinion to extract the diagnostic parameters from a standard questionnaire of pattern identification for FD in KM. Finally, we selected the diagnostic parameters from literature review findings and expert consensus process.

Results: We selected data on diagnostic parameters (including medical imaging parameters, such as gastric emptying time, mapping of skin surface temperature, and geometry and color information of the upper abdomen; biosignal detection, such as pressure pain threshold, pressure pain changes, and pain reduction change after thermal stimulation; medical laboratory testing such as oral moisture on the buccal mucosa, submandibular salivary flow, and saliva pH; and a self-reporting standard questionnaire based on pain visual analogue scale, frequency, and duration of pain in the upper abdomen) of FD obtained through literature review and expert consensus.

Conclusions: This study is important because it presents the diagnostic parameters of FD based on pattern types in KM. This is a significant first step toward quantitative assessment for the development of a diagnostic device.

1. Introduction

The prevalence of functional dyspepsia (FD) is as high as 11.5%–29.2% [1]. FD is defined as chronic or recurrent pain, or discomfort centered in the upper abdomen [2]. According to the Rome III consensus, the diagnostic criteria of FD include symptoms such as bothersome postprandial fullness, early satiation, epigastric pain, or epigastric burning. Patients must have had one or more of these symptoms for the previous 3 months, with symptom onset at least 6 months prior to diagnosis; moreover, they must have no evidence of organic, systemic, or metabolic disease that can explain these symptoms, including any condition detected by upper endoscopy [3–5]. FD can be subdivided into postprandial distress syndrome (PDS) and epigastric pain syndrome (EPS) [3].

Although many efforts have been made to diagnose FD, it is not easy to obtain an objective diagnosis, as FD has many different symptoms and pathogenic factors [6]. Over the past decade, there has been a dramatic change in how FD has been conceptualized because symptoms and signs are very important to diagnose FD [7]. Korean medicine (KM) doctors have tried to diagnose diverse symptoms and signs that can be included in FD by categorizing them according to pattern identification through traditional literature and clinical experience. As a result, a standard questionnaire of pattern identification (SQPI) for FD that can be applied to clinical research has been developed [8]. The following are the 6 patterns, based on different clinical symptoms and signs of FD: (1) disharmony between the liver and stomach, (2) retention of undigested food, (3) dampness – heat in the spleen and stomach, (4) simultaneous occurrence of cold and heat syndromes, (5) deficiency and cold of the spleen and stomach, and (6) insufficiency of stomach yin. It is essential to identify chest and abdominal symptoms and signs

through abdominal examination (AE), especially in FD. According to the World Health Organization (WHO) international standard terminologies, AE involves touching and pressing of the chest and abdomen in combination with other examinations for the purpose of diagnosing a morbid condition [9]. In comparison with other diagnostic methods such as inspection, listening and smelling, and inquiry, AE has relatively high quantitative attributes. However, since diagnoses are susceptible to various subjective factors related to the KM doctor's experience and knowledge, it is important to quantify and objectify each of the symptoms and signs.

A new glove-type touch sensor was developed that quantitatively captures touch data when a Kampo doctor palpates a patient's abdomen during an AE, contributing to the detection of sub-health–related issues in Japan [10]. In China, a ZF-Ib-type sensor was developed that measures the degree of abdominal wall tension into five grades [11]. However these instruments only measure some abdominal symptoms or signs and are not useful for diagnosing FD.

KM doctors have attempted to identify the diagnostic parameters of FD in clinical studies [12–15]. To identify patterns in FD, the diagnostic parameters are generally extracted from abdominal, pulse, and tongue examinations. Above all, there is a need to select measurable, standardized diagnostic parameters that provide quantitative, reproducible results. The aim of this study was to select diagnostic parameters of FD based on pattern types in KM through literature review and expert consensus process.

2. Methods

The workflow comprised the following specific steps (Fig. 1).

2.1. Literature review

2.1.1. Design overview

We performed a literature review of methods of diagnosis of FD that use diagnostic tools, and not the "four examinations" (inspection, listening and smelling, inquiry, and palpation). The inclusion criteria were as follows: 1) clinical studies, including observational studies and randomized controlled trials; and 2) studies reporting information on diagnostic tools and parameters, with an abstract or full text available. However, we excluded studies on the effectiveness and safety of therapeutic interventions and pharmacologic treatments, such as drugs, herbal medicines, and acupuncture, for FD. The subjects in the studies evaluated in this review included adults and pediatric patients, and the selection was limited to studies of FD patients.

2.1.2. Data sources and searches

The following 7 electronic databases were searched from their inception to the end of May 2016: PubMed, Korea MED, Korean Medical Database (KMbase), Korean Studies Information Service System (KISS), National Discovery for Science Leaders (NDSL), and DataBase

Periodical Information Academic (DBpia). In addition, the traditional medicine-specific database, the Oriental Medicine Advanced Searching Integrated System (OASIS), was used. The search terms were divided into 2 parts: "functional dyspepsia," (e.g., non-ulcer dyspepsia, or nonulcer dyspepsia) and "diagnosis" (e.g., examination, parameter, pattern, element, or measure). There was no language restriction for these studies. Only data from papers with full text available were reviewed, and only papers written by Korean authors who conventional Western and Korean medical doctors were selected. We focused on the selection of diagnostic parameters to be able to objectively and reproducibly collect data regarding Korean medicine doctors' experience and knowledge. The search strategy was modified appropriately according to the databases. The search was performed between May 9 and 31, 2016.

2.1.3. Data collection and analysis

Two independent reviewers selected the studies according to the above inclusion and exclusion criteria and extracted the articles for inclusion by title and abstract. In the case of eligible studies with incomplete data, we attempted to contact the investigators and corresponding authors to obtain more detailed information. One reviewer read the full text of the selected articles and extracted the data using a standard data extraction form. Another reviewer then rechecked the data to ensure that the data had been extracted appropriately. Any disagreement between the 2 reviewers was resolved by discussion and consensus.

2.1.4. Outcome

Extracted data were the diagnostic tools used, the parameters used to decide the clinical significance for diagnosing FD, the potential diagnostic parameters for diagnosing FD, and the diagnostic value of each potential diagnostic parameter for FD.

2.2. Expert opinion

We reviewed an SQPI for FD that can be applied to clinical research, which was published by an advisory committee of 11 experts of Korean Division of Gastroenterology from Korean medical colleges nationwide (Appendix A) [8]. The SQPI had been developed previously by an advisory committee by consensus discussions based on clinical opinion and a review of 20 textbooks, including Korean gastroenterology, Chinese gastroenterology, Chinese internal medicine, practical traditional Chinese internal medicine, Chinese diagnostic medicine, and Chinese gastroenteropathy encyclopedias.

We divided individual component symptoms or signs from 45 groups of conditions in the SQPI. For instance, the condition "My upper abdomen is pain and bloating" was divided into two component symptoms, "epigastric pain" and "epigastric bloat." All the measurable diagnostic parameters were extracted from these component symptoms and signs by 4 Korean medical doctors (KMDs) and 5 biomedical
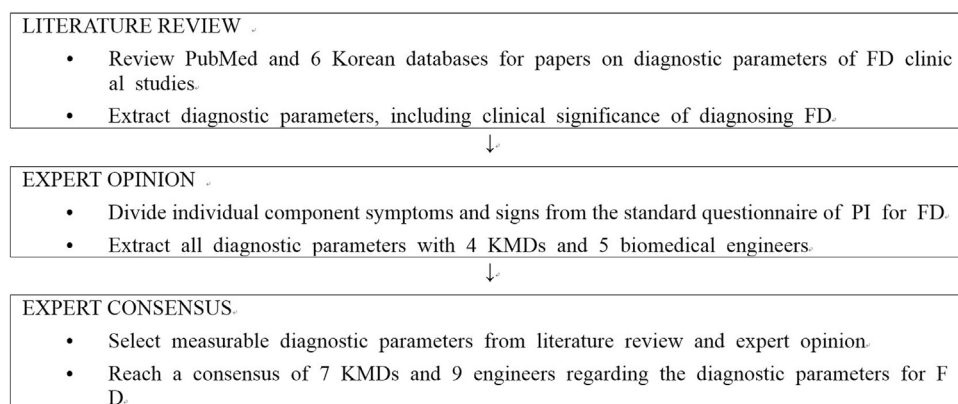
Fig. 1. Overview of the flowchart.

LITERATURE REVIEW
• Review PubMed and 6 Korean databases for papers on diagnostic parameters of FD clinical studies
• Extract diagnostic parameters, including clinical significance of diagnosing FD

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EXPERT OPINION
• Divide individual component symptoms and signs from the standard questionnaire of PI for FD
• Extract all diagnostic parameters with 4 KMDs and 5 biomedical engineers

↓

EXPERT CONSENSUS
• Select measurable diagnostic parameters from literature review and expert opinion
• Reach a consensus of 7 KMDs and 9 engineers regarding the diagnostic parameters for FD