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Feasibility study of structured diagnosis methods for functional dyspepsia in Korean medicine clinicsJeong Hwan Park^a, Soyoung Kim^{a,b}, Jae-Woo Park^c, Seok-Jae Ko^c, Sanghun Lee^{a,b,*}^a Korean Medicine Fundamental Research Division, Korea Institute of Oriental Medicine, Daejeon, Korea^b University of Science & Technology (UST), Korean Medicine Life Science, Daejeon, Korea^c Department of Gastroenterology, College of Korean Medicine, Kyung Hee University, Seoul, Korea

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ABSTRACT

Background: Functional dyspepsia (FD) is the seventh most common disease encountered in Korean medicine (KM) clinics. Despite the large number of FD patients visiting KM clinics, the accumulated medical records have no utility in evidence development, due to being unstructured. This study aimed to construct a standard operating procedure (SOP) with appropriate structured diagnostic methods for FD, and assess the feasibility for use in KM clinics.

Methods: Two rounds of professional surveys were conducted by 10 Korean internal medicine professors to select the representative diagnostic methods. A feasibility study was conducted to evaluate compliance and time required for using the structured diagnostic methods by three specialists in two hospitals.

Results: As per the results of the professional survey, five questionnaires and one basic diagnostic method were selected. An SOP was constructed based on the survey results, and a feasibility study showed that the SOP compliance score (out of 5) was 3.45 among the subjects, and 3.25 among the practitioners. The SOP was acceptable and was not deemed difficult to execute. The total execution time was 136.5 minutes, out of which the gastric emptying test time was 129 minutes.

Conclusion: This feasibility study of the SOP with structured diagnostic methods for FD confirmed it was adequate for use in KM clinics. It is expected that these study findings will be helpful to clinicians who wish to conduct observational studies as well as to generate quantitative medical records to facilitate Big Data research.

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* Corresponding author at: Korea Medicine (KM) Fundamental Research Division, Korea Institute of Oriental Medicine, 1672 Yuseong-daero, Yuseong-gu, Daejeon 34054, Republic of Korea.

E-mail address: ezhani@kiom.re.kr (S. Lee).

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1. Introduction

Functional dyspepsia (FD) that degrades quality of life is a common disorder affecting 1–3 out of 10 people in the general population.¹ In Korea, FD is the seventh most common disease, according to the statistics published by the Health Insurance Review and Assessment Service in 2015.² Functional dyspepsia, also known as non-ulcer dyspepsia, is characterized by various gastrointestinal symptoms such as chronic epigastric pain, bloating, early satiety, nausea, vomiting, and belching without evidence of organic, systemic, or metabolic disease.³ It is known as a heterogeneous symptom complex involving various pathophysiologies. Therefore, a therapeutic approach based on pathophysiology is difficult, and there is no standard treatment. In Korea, in addition to western medicine (WM), alternative treatment and symptom relief are increasingly being sought from Korean medicine (KM) modalities such as herbal medicine, acupuncture, and moxibustion.

Functional dyspepsia is classified either as epigastric pain syndrome (EPS) or as postprandial distress syndrome (PDS) in WM.⁴ In KM, FD is classified into six pattern identification categories.⁵ Several studies have attempted to find the appropriate diagnostic parameters or assessment tools that have diagnostic value in FD. Clinically, the severity of each symptom of FD is assessed through several pattern identification questionnaires and the Rome IV diagnostic criteria.⁶ To diagnose FD, there have been attempts to also use various diagnostic devices in clinical studies.⁷

Despite the increasing popularity of KM clinics for FD treatment and the large number of medical records accumulated, these records have a limited research utility, since they are unstructured and incomplete, and also appropriate assessment tools are usually not applied.

To overcome these problems, this study aimed to provide a feasible standard operating procedure (SOP) including appropriate diagnostic methods and documentation guidelines for the clinical treatment of FD. It is expected that standardized and uniform recording and reporting of quantitative medical data will facilitate Big Data research, and help KM doctors conduct valuable observational studies with ease.

2. Methods

The various steps taken, including the preliminary research for the selection of diagnostic methods, the questionnaire survey and the feasibility study are described below. The overview of the flow chart showing the specific steps is shown in Fig. 1.

2.1. Preliminary research

To select the candidate KM diagnostic methods, we reviewed the electronic medical records (EMRs) of KM Hospital (Kangdong KyungHee University) and extracted all diagnostic methods regardless of the disease type. To select the candidate WM diagnosis methods and questionnaires, we searched PubMed, Google scholar, and the Oriental Medicine Advanced Searching Integrated System (OASIS) databases. In the title and abstract for PubMed, the following search terms: (“func-

tional dyspepsia” OR “non-ulcer dyspepsia”) AND (“pattern identification” OR “syndrome differentiation” OR “questionnaire” OR “diagnostic criteria” OR “diagnosis examination”), were used. These search terms were slightly modified for Google scholar and translated into the Korean language for OASIS. All types of clinical studies, observational studies, and reviews, pertaining to the diagnosis of FD were included in this study. We also reviewed clinical practice guidelines (CPG) published by national and international agencies from the United States, United Kingdom, Korea, and the Asian consensus guidelines on FD.^{8–11} Three diagnostic experts of KM were contacted via email and asked whether these were the necessary pattern identification for FD, and we reviewed the articles that they returned to us in their responses.^{20,26,28}

2.2. Questionnaire survey

Surveys were conducted twice by 10 senior professors who completed internal medicine specialist training from 10 different KM colleges. In the first survey questionnaire, the respondents were asked about the required diagnostic methods for FD and to indicate the methods being used by them in everyday clinical situations. They were also asked to indicate their most preferred diagnostic method for FD between KM and WM, and the reason for their choice. Finally, they were asked to describe a diagnostic scenario using either the KM or the WM diagnostic methods. The diagnostic methods reported by the participants were extracted from the results of the first survey, and included as part of the second survey questionnaire, along with the contents of the first questionnaire. In the second round, respondents were asked to select diagnostic methods from the results of the first survey and to describe how these could be used to conduct or design an observational study on FD patients. The diagnostic methods pertaining to KM and WM reported by more than 70% of respondents in the second survey were selected as key elements to be included in an SOP.

2.3. Feasibility study

A simulated clinical trial was designed including the selected diagnostic methods, by two Korean internal medicine specialists. A virtual clinical trial design was delineated in a document titled “The correlation between KM pattern identification questionnaire and gastric emptying test, and the changes in gastric emptying time according to the variety in food intake.”. A case report form (CRF) and an SOP were developed. The SOP contained a structured documentation procedure with five questionnaires and included the ultrasonic gastric emptying test. However, the SOP excluded unstructured KM and WM diagnostic methods. Three KM doctors who have more than one year of experience in gastrointestinal diseases from two KM hospitals performed a feasibility study on each of three virtual patients according to the SOP. The average age of the nine virtual patients was 29.9 years. Women represented 77.8% of the participants. They had neither organic disease nor medical histories of peptic ulcers, reflux diseases, previous abdominal surgeries, however, two subjects had FD. Time required for each diagnostic method,

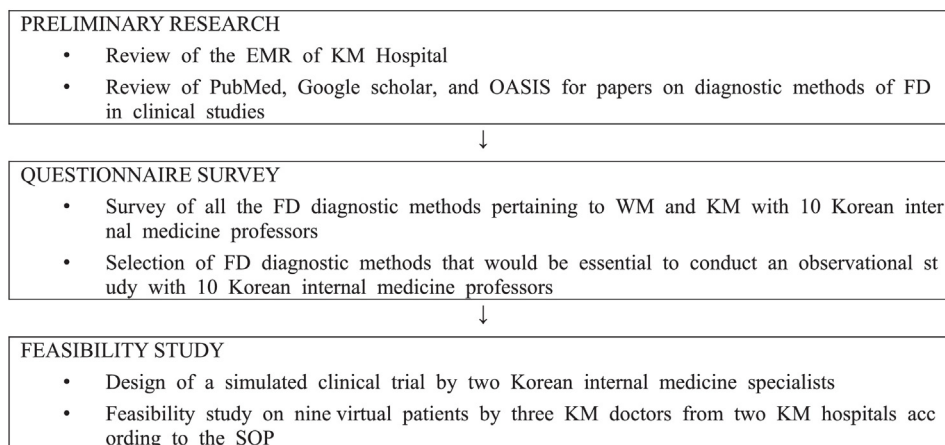


Fig. 1 – Overview of the flow chart. EMR, electronic medical records; FD, functional dyspepsia; KM, Korean medicine; OASIS, Oriental Medicine Advanced Searching Integrated System; SOP, standard operating procedure; WM, western medicine.

and the compliance of the subjects and the practitioners were measured on a 5-point scale. In addition, the reasons for the time delay and clinical suitability were ascertained by obtaining an unstructured description from the clinical practitioner.

3. Results

3.1. Preliminary review

Eleven methods (including abdominal examination) used in KM for the diagnosis of diseases of the digestive system accessible from EMRs of the last five years, were selected.

Through electronic search, a total of 1032 articles were identified. Of these, 295 duplicate records were removed. By screening the titles and abstracts of the identified literatures, we excluded 717 records that did not meet the inclusion criteria. Finally, 20 articles were included; 9 articles for WM diagnostic methods and 11 articles for questionnaires on FD (Fig. 2). For the selection of WM diagnostic methods, “Evidence-based clinical practice guidelines for functional dyspepsia” by Miwa et al. (2015),¹² “Regional cerebral blood flow during gastric balloon distention in functional dyspepsia” by Vandenberghe et al. (2007),¹³ “Imaging for chronic abdominal pain in adults” by Mendelson et al. (2015),¹⁴ “Asian consensus report on functional dyspepsia” by Miwa et al. (2012),¹¹ “Validation of Rome II criteria for functional gastrointestinal disorders by factor analysis of symptoms in Asian patient sample” by Kwan et al. (2003),¹⁵ “Guidelines for the management of esophageal and gastric cancer” by Allum et al. (2011),¹⁶ “Gastrointestinal hormone abnormalities and G and D cells in functional dyspepsia patients with gastric dysmotility” by He et al. (2005),¹⁷ “Dynamic antral scintigraphy to characterize gastric antral motility in functional dyspepsia” by Urbain et al. (1995),¹⁸ and “Functional gastrointestinal disorders: history, pathophysiology, clinical features, and Rome IV” by Drossman (2016)⁶ were chosen as representative references. Fourteen diagnostic methods including gastroscopy were selected as candidates, based on the references mentioned above.

Questionnaires were extracted from “Fungiform papillae and its correlation with Rome III classification and spleen qi deficiency in functional dyspepsia” written by Choi et al. (2015),¹⁹ “Preliminary study on pattern questionnaire for damum patterns” written by Park et al. (2006),²⁰ “Development and validation of a Functional Dyspepsia-Related Quality of Life (FD-QOL) scale in South Korea” by Lee et al. (2006),²¹ “A study on a concept of food accumulation using multidimensional scaling-comparison between Pyungweesan Questionnaire and Health Related Questionnaires” by Lee et al. (2011),²² “GSRs—a clinical rating scale for gastrointestinal symptoms in patients with irritable bowel syndrome and peptic ulcer disease” by Svedlun et al. (1988),²³ “Large-scale randomized clinical study on functional dyspepsia treatment with mosapride or teprenone: Japan Mosapride Mega-Study (JMMS)” by Hongo et al. (2012),²⁴ “Development of instrument of pattern identification for functional dyspepsia” by Kim et al. (2010),⁵ “Validation of the Nepean dyspepsia index-Korean version” written by Lee et al. (2003),²⁵ “A validation study of the Questionnaire of Sasang Constitution Classification (QSCC)” by Kim et al. (1993),²⁶ “Study on the development of a standard instrument of diagnosis and assessment for spleen deficiency pattern” by Oh et al. (2014),²⁷ and “Development and validation of Yin-Deficiency Questionnaire” by Lee et al. (2007).²⁸ Fourteen questionnaires including Nepean dyspepsia index questionnaire-Korean (NDI-K) were selected on the basis of published literature relevant to FD. Table 1 shows the candidate KM and WM diagnostic methods and questionnaires selected.

3.2. Questionnaire survey

On the basis of the results of the first survey, 8 of 11 reported diagnostic methods pertaining to KM were shortlisted, and of these, three methods including abdominal diagnosis, pulse diagnosis, and tongue diagnosis were finally selected according to the results of the second survey. On the basis of the results of the first survey, all 14 diagnostic methods pertaining to WM were shortlisted, but only gastroscopy was finally selected as per the results of the second survey. In addition to

Table 1 – Candidate of Diagnostic Methods for Functional Dyspepsia (FD)

Category	Candidate of diagnostic methods	References
Korean medicine diagnostic methods (11 item)	Abdominal diagnosis	EMR of last five years on digestive system disease patient in KM hospital of Kyung Hee University
	Acceleration pulse wave test	
	Body composition analysis test	
	Cardiac function test	
	Computerized eight principle pattern identification test	
	Digital infrared thermographic imaging system	
	Heart rate variability (HRV)	
	Pulse diagnosis (includes tool)	
	Pulse wave velocity test	
	Tongue diagnosis (includes tool)	
	Transcranial doppler test	
Western medicine diagnostic methods (14 items)	Abdominal CT scan	Miwa H. Evidence-based clinical practice guidelines for functional dyspepsia. <i>J Gastroenterol</i> 2015 ¹²
	Abdominal MRI scan	Vandenberghe J. Regional cerebral blood flow during gastric balloon distention in functional dyspepsia. <i>Gastroenterology</i> 2007 ¹³
	Abdominal ultrasonography	Miwa H. Evidence-based clinical practice guidelines for functional dyspepsia. <i>J Gastroenterol</i> 2015 ¹²
	Abdominal X-ray examination	Mendelson R. Imaging for chronic abdominal pain in adults. <i>Austr Prescr</i> 2015 ¹⁴
	Biochemical blood test	Miwa H. Asian consensus report on functional dyspepsia. <i>J Gastroenterol Hepatol</i> 2012 ¹¹
	Colonoscopy	Kwan AC-P. Validation of Rome II criteria for functional gastrointestinal disorders by factor analysis of symptoms in Asian patient sample. <i>J Gastroenterol Hepatol</i> 2003 ¹⁵
	Complete blood count (CBC)	Miwa H. Evidence-based clinical practice guidelines for functional dyspepsia. <i>J Gastroenterol</i> 2015 ¹²
	Electrocardiogram (ECG)	Allum WH. Guidelines for the management of esophageal and gastric cancer. <i>Gut</i> 2011 ¹⁶
	Esophageal pressure test	Miwa H. Asian consensus report on functional dyspepsia. <i>J Gastroenterol Hepatol</i> 2012 ¹¹
	Gastrointestinal hormone test	He M-R. Gastrointestinal hormone abnormalities and G and D cells in functional dyspepsia patients with gastric dysmotility. <i>World J Gastroenterol (WJG)</i> 2005 ¹⁷
	Gastrointestinal motility test (Scintigraphy)	Urbain J. Dynamic antral scintigraphy to characterize gastric antral motility in functional dyspepsia. <i>J Nucl Med</i> 1995 ¹⁸
	Gastroscopy	Miwa H. Evidence-based clinical practice guidelines for functional dyspepsia. <i>J Gastroenterol</i> 2015 ¹²
	Stool examination (occult blood, white blood cells (WBC))	Miwa H. Evidence-based clinical practice guidelines for functional dyspepsia. <i>J Gastroenterol</i> 2015 ¹²
	Urine examination	Drossman DA. Functional gastrointestinal disorders: history, pathophysiology, clinical features, and Rome IV. <i>Gastroenterology</i> 2016 ⁵
Questionnaires (14 items)	Cold and heat questionnaire	Choi J. Fungiform papillae and its correlation with Rome III classification and spleen Qi deficiency in functional dyspepsia. <i>J Int Korean Med</i> 2015 ¹⁹
	Dam'um Questionnaire	Park J-S. Preliminary study on pattern questionnaire for damum patterns. <i>J Korea Inst Orient Med Diagn</i> 2006 ²⁰
	Deficiency and excess questionnaire	Choi J. Fungiform papillae and its correlation with Rome III classification and spleen Qi deficiency in functional dyspepsia. <i>J Int Korean Med</i> 2015 ¹⁹
	Functional dyspepsia (FD) related quality of life (FD-QoL),	Lee E-H. Development and validation of a Functional Dyspepsia-Related Quality of Life (FD-QOL) scale in South Korea. <i>J Gastroenterol Hepatol</i> 2006 ²¹
	Food retention questionnaire	Lee C-H. A study on a concept of food accumulation using multidimensional scaling-comparison between Pyungweesan Questionnaire and Health Related Questionnaires. <i>J Korea Inst Orient Med Diagn</i> 2011 ²²
	Gastrointestinal symptom rating scale (GSRS),	Svedlund J. GSRS—a clinical rating scale for gastrointestinal symptoms in patients with irritable bowel syndrome and peptic ulcer disease. <i>Dig Dis Sci</i> 1988 ²³

Table 1 (Continued)		
Category	Candidate of diagnostic methods	References
	Gastrointestinal symptom scale (GIS)	Hongo M. Large-scale randomized clinical study on functional dyspepsia treatment with mosapride or teprenone: Japan Mosapride Mega-Study (JMMS). <i>J Gastroenterol Hepatol</i> 2012 ²⁴
	Questionnaire of pattern identification for FD	Kim J-B. Development of instrument of pattern identification for functional dyspepsia. <i>J Physiol Pathol Korean Med</i> 2010 ⁵
	Nepean Dyspepsia Index Korean version (NDI-K)	Lee S. Validation of the Nepean dyspepsia index-Korean version. <i>Kor J Neurogastroenterol Mot</i> 2003 ²⁵
	Sasang Constitutional Examination	Kim SH. A validation study of the Questionnaire of Sasang Constitution Classification (QSCC). <i>J Sasang Const Med</i> 1993 ²⁶
	Short Form (SF)-36 Health survey	Hongo M. Large-scale randomized clinical study on functional dyspepsia treatment with mosapride or teprenone: Japan Mosapride Mega-Study (JMMS). <i>J Gastroenterol Hepatol</i> 2012 ²⁴
	Spleen Qi Deficiency Questionnaire	Oh H-W. Study on the development of a standard instrument of diagnosis and assessment for spleen deficiency pattern. <i>J Korean Med</i> 2014 ²⁷
	World Health Organization (WHO) Quality Of Life Scale	Hongo M. Large-scale randomized clinical study on functional dyspepsia treatment with mosapride or teprenone: Japan Mosapride Mega-Study (JMMS). <i>J Gastroenterol Hepatol</i> 2012 ²⁴
	YIN Deficiency Questionnaire	Lee S. Development and validation of Yin-Deficiency Questionnaire. <i>Am J Chin Med</i> 2007 ²⁸

the diagnostic methods, participants were surveyed for choice of questionnaires used in FD cases. On the basis of the results of the first survey, 11 of 14 questionnaires were shortlisted, but only the pattern identification FD questionnaire and NDI-K were finally selected in accordance with the results of the second survey. In addition, among the four types of test methods which were additionally reported by participants in the first round of surveys, three items were selected per the survey results: ultrasonic gastric emptying test,²⁹ adequate relief

questionnaire,³⁰ and Visual Analog Scale (VAS) for overall dyspeptic symptoms¹⁹ (Table 2).

3.3. Feasibility study

A simulated clinical trial was designed including the selected diagnostic methods, by two Korean internal medicine specialists, and conducted as per the SOP created. Three KM doctors from two KM hospitals performed a feasibility study

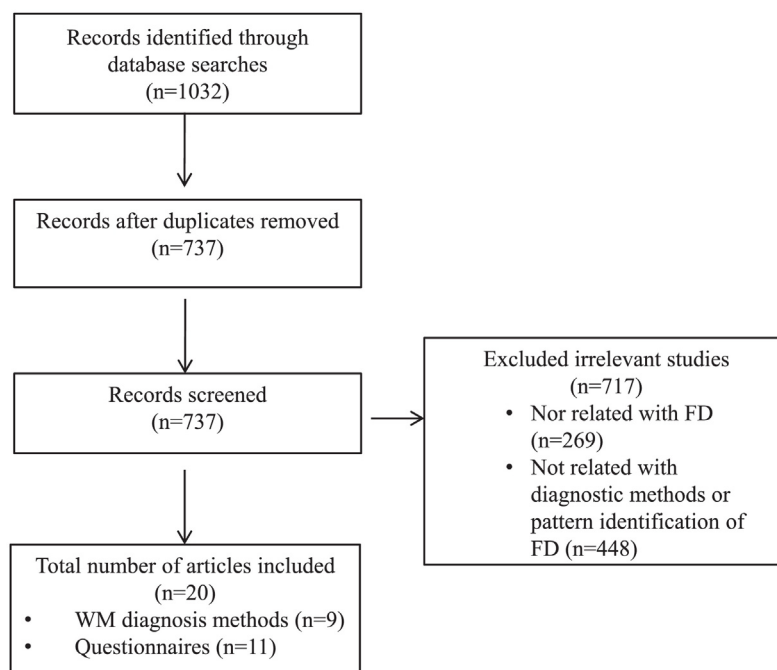


Fig. 2 – Flow diagram of literature search. FD, functional dyspepsia; WM, western medicine.

Table 2 – Selection of Functional Dyspepsia (FD) Diagnostic Methods Through Survey Questionnaires

Category	Preliminary survey	First questionnaire	Second questionnaire
Korean medicine diagnostic methods	Abdominal diagnosis	Abdominal diagnosis	Abdominal diagnosis
	Acceleration pulse wave test	Acceleration pulse wave test	
	Body composition analysis test	Body composition analysis test	
	Cardiac function test	Cardiac function test	
	Computerized eight principle pattern identification test		
	Digital infrared thermographic imaging system	Digital infrared thermographic imaging system	
	Heart rate variability (HRV)	Heart rate variability (HRV)	
	Pulse diagnosis (includes tool)	Pulse diagnosis (includes tool)	Pulse diagnosis(includes tool)
	Pulse wave velocity test		
	Tongue diagnosis (includes tool)	Tongue diagnosis (includes tool)	Tongue diagnosis (includes tool)
Western medicine diagnostic methods	Transcranial doppler test		
	Abdominal CT scan	Abdominal CT scan	
	Abdominal MRI scan	Abdominal MRI scan	
	Abdominal ultrasonography	Abdominal ultrasonography	
	Abdominal X-ray examination	Abdominal X-ray examination	
	Biochemical blood test	Biochemical blood test	
	Colonoscopy	Colonoscopy	
	Complete blood count (CBC)	Complete blood count (CBC)	
	Electrocardiography (ECG)	Electrocardiography (ECG)	
	Esophageal pressure test	Esophageal pressure test	
Questionnaires	Gastrointestinal hormone test	Gastrointestinal hormone test	
	Gastrointestinal motility test (scintigraphy)	Gastrointestinal motility test (scintigraphy)	
	Gastroscopy	Gastroscopy	Gastroscopy
	Stool examination (occult blood, WBC)	Stool examination (ocult blood, WBC)	
	Urine examination	Urine examination	
	Cold and heat questionnaire	Cold and heat questionnaire	
	Dam'um Questionnaire	Dam'um Questionnaire	
	Deficiency and excess questionnaire	Deficiency and excess questionnaire	
	Functional dyspepsia related quality of life (FD-QoL)	Functional dyspepsia related quality of life (FD-QoL)	Functional dyspepsia related quality of life (FD-QoL)
	Food retention questionnaire	Food retention questionnaire	
Others (addition)	Gastrointestinal symptom rating scale (GSRS)	Gastrointestinal symptom rating scale (GSRS)	
	Gastrointestinal symptom scale (GIS)	Gastrointestinal symptom scale (GIS)	
	Nepean dyspepsia index Korean version (NDI-K)	Nepean dyspepsia index Korean version (NDI-K)	Nepean dyspepsia index Korean version (NDI-K)
	Questionnaire of pattern identification for FD	Questionnaire of pattern identification for FD	Questionnaire of pattern identification for FD
	Sasang constitutional examination	Sasang constitutional examination	
	Short form (SF)-36 health survey		
	Spleen qi deficiency questionnaire	Spleen qi deficiency questionnaire	
	World Health Organization (WHO) quality of life scale		
	Yin deficiency questionnaire	Yin deficiency questionnaire	
	Adequate relief questionnaire	Adequate relief questionnaire	Adequate relief questionnaire
Others (addition)		Electrogastrography (EGG) test	
		Ultrasonic gastric emptying test	Ultrasonic gastric emptying test
		VAS for overall dyspeptic symptom	VAS for overall dyspeptic symptom

on each of the three virtual patients according to the SOP. The results showed that, except the ultrasonic gastric emptying test, all diagnostic methods showed good compliance, scoring at least 3 points (on a 5-point scale), and the time required was

7.37 minutes, which was relatively short (Table 3). The ultrasonic gastric emptying test scored a relatively poor 2 points for compliance, and time required to perform the test was a relatively long 129 minutes.

Table 3 – Mean of Compliance Scores and Time Required for Each Diagnosis Method

Item	Mean of compliance ^a		Time required (mins)
	Subject	Practitioner	
Adequate relief questionnaire	4.0	4.0	0.07
VAS for overall dyspeptic symptom	4.0	3.0	0.14
Instrument of pattern identification for FD	3.8	3.5	1.80
Nepean dyspepsia index Korean version	3.3	3.5	2.33
FD related quality of life	3.3	3.5	3.10
Ultrasonic gastric emptying test	2.3	2.0	129

^a Diagnostic criteria for compliance on a 5-point scale with 4: very easy to perform and to follow directions; 3: no difficulties to perform and to follow directions; 2: some difficulty in performing, but possible to complete, sometimes need to repeat instruction; 1: difficult to perform, causes incompleteness, and difficult to follow repeated instructions; 0: cannot perform and follow instructions at all. FD, functional dyspepsia; VAS, Visual Analog Scale.

4. Discussion

Recently, owing to the external validity limitation of even well-designed clinical trials, the value of Big Data studies based on EMRs is emerging as a new way of obtaining valuable medical data to guide clinical decisions.³¹ However, quality control of the EMRs is essential for establishing evidence based on these clinical records. For example, data extracted from EMRs of diabetic patients were revealed to be unstructured, incomplete, and riddled with errors. Hence, a semi-structured EMR template was developed for EMR generation.³² In addition, a hybrid solution of manual curation and computer automation was developed to extract meaningful information from unstructured data in medical records.³³

Functional dyspepsia is one of the most common diseases of the digestive system encountered in KM clinics. However, despite the fact that a variety of clinical treatments are being administered and numerous medical records are being generated, these records have limited utility in clinical research, because the majority of clinicians lack experience in creating and using objective and quantitative clinical records. Thus, the success or failure of a treatment modality is not being recorded, analyzed, or reported in a format amenable for dissemination in scientific literature. The purpose of this study was to determine the essential diagnostic methods from existing clinical records of patients with FD at KM clinics, and provide a standardized documented guideline for clinicians who intend to conduct observational studies, as well as for generating quantitative medical records to facilitate Big Data research. Because of the surveys conducted, three KM diagnostic methods, one WM diagnostic method, five questionnaire-based diagnostic methods, and one basic examination tool were selected. The compliance and the time required for practical use in clinical practice were evaluated through a feasibility study. All selected diagnostic methods performed well in the compliance test (with reference to both subjects and practitioners), scoring more than 3 points out of 5, except for the ultrasonic gastric emptying test. This result implies that the selected methods have high applicability in the clinical setting. The ultrasonic gastric emptying test, with a compliance score of 2 or higher, was also deemed to have enough applicability in clinical use, though the time taken to perform the test was long, at 129 minutes. The relatively long time needed to perform the test may limit its applica-

tion to cases where it is absolutely essential for diagnosis. During the pilot study, a survey was also conducted to analyze time-delayed cases. We sought to understand the reasons behind time-delays observed in obtaining patient responses to the questionnaire, as well as time-delays for obtaining doctors' diagnoses. Our survey results revealed several aspects of medical questionnaires that were deemed confusing or difficult by patients. For instance, the pattern identification questionnaire for FD diagnosis mentions two symptoms in one question (question 1-4 and 1-5), leading to confusion and difficulty in providing an accurate answer. Similarly, since the NDI-K questionnaire is written in medical vernacular derived from Chinese characters, it is not easy to differentiate between frequency, strength, and pain level of dyspepsia symptoms, leading to difficulties in responding to this questionnaire. Considering these issues, developing improved versions of currently popular medical questionnaires may also help with ease of data collection, and improve data reliability.

Six diagnostic methods in this study were selected to be available for quantified clinical efficacy assessment in different areas. 'VAS for overall dyspeptic symptom' can help doctors to record the basic overall severity level of symptoms and the progress of symptoms of the patient. 'Nepean dyspepsia index Korean version (NDI-K)' can help doctors to record the severity level in more detail. 'Questionnaire of pattern identification for FD' can help doctors to produce the KM pattern identification data in a more quantified way. 'Functional dyspepsia related quality of life (FD-QoL)' can help doctors to produce the information of patient's life quality degraded by FD. 'Ultrasonic gastric emptying test' can help doctors to evaluate the therapeutic effect by quantifying the exercise capacity of the digestive organ. 'Adequate relief questionnaire' can help doctors to evaluate the therapeutic effectiveness of the treatment group by comparing the proportion of respondents with the control groups. The selection of representative and certified indicators for quantitative patient records in these various areas and the development of SOPs for such quantitative patient records will be helpful to KM doctors who want to explore different sources of evidences. Furthermore, this will serve as a basis for further research and may contribute to the development of KM techniques for FD.

This study has some limitations. The organic or systemic diagnostic procedure for FD was not included, because most patients with FD were admitted to the KM hospitals after obtaining test results and diagnoses from WM hospitals.

Therefore, the time required and the compliance parameters for organic or systemic diagnostic procedures were excluded from the study. The feasibility test was conducted on virtual patients, and the number of patients and doctors were small. Therefore, there is a possibility of overestimating the feasibility reported here. In addition, we did not conduct a feasibility study on all the KM and WM diagnostic methods, since such analysis would be beyond the scope of this study, and can only be determined by specialists in Korean internal medicine, by consensus.

However, this study provides the first standardized protocol for the systematic recording of clinical cases of FD in KM clinical practice. Although there have been a number of clinical studies of FD conducted in KM clinics, most of the protocols employed were meant for use in randomized controlled clinical trials, and were not suitable for KM doctors aiming to conduct observational studies.^{34,35}

In conclusion, the SOP for the structured diagnosis of FD, constructed using the results of this study, was confirmed to be adequate for use in KM clinics. It is expected that the results of this study may be helpful for KM practitioners who wish to publish reports and data of FD cases from their clinical practice. The SOP created here can be used as a reference for development of standardized EMRs for facilitating Big Data research.

Conflict of interest

The authors declare no conflict of interest.

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