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Integrative Medicine Research

journal homepage: www.imr-journal.com

Original Article

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

ARTICLE INFO

Article history:

Received 14 August 2017

Received in revised form

25 September 2017

Accepted 12 October 2017

Available online 17 October 2017

Keywords:

Big Data

Dyspepsia

Korean medicine

Feasibility studies

Observational study

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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<https://doi.org/10.1016/j.imr.2017.10.001>

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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,

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