

Original article

# Development of a valid and reliable food retention questionnaire

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## Abstract

**Objectives:** Food retention (FR) is a pathological process which manifests as epigastric or abdominal fullness or pain, dyspepsia, water brash, sickness, languidness, edema, weight gain, or joint pain. The present study was conducted to examine the reliability and validity of a food retention questionnaire (FRQ) and to define its optimum cut-off score.

**Methods:** A total of 194 outpatients (62 men, 132 women) were asked to complete the FRQ. Thirteen clinicians determined whether or not the 194 outpatients exhibited FR. We estimated the internal consistency and construct validity for the FRQ. The total scores from the FRQ and clinicians' diagnoses of the patients were used to perform receiver operating characteristics (ROC) curve analyses and to define an optimum cut-off score for the FRQ.

**Results:** The FRQ exhibited a satisfactory internal consistency ( $\alpha=0.852$ ). In the test of construct validity using principal component analysis, a total of four factors (gastrointestinal distress, Dampness, food hypersensitivity, and stool–urine–pain) were extracted (total percentage of variance = 53.2%). ROC curve analyses showed that the FRQ had a moderate discriminative ability for FR (sensitivity = 70.7%, specificity = 76.8%, and AUC = 0.788). The optimum cut-off score was defined as six points.

**Conclusions:** Our results suggest that the FRQ is a valid and reliable instrument for evaluating FR.

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**Keywords:** Pattern diagnosis; Questionnaire; East Asian medicine; Korean medicine

## Introduction

Food retention (FR) is a pathological process, which manifests as epigastric or abdominal fullness or pain, dyspepsia, water brash, sickness, offensive odor of stools, and a thick tongue coating [1]. In addition to gastrointestinal symptoms and signs, FR is associated with general symptoms and signs including languidness, edema, weight gain, and joint pain [2]. FR is induced by uncontrolled eating habits including overeating and selective eating, which result in food retention in the stomach [3]. When food is retained in the stomach, pathogenic Dampness is generated in the spleen and stomach [2]. Dampness may be stagnant or flow through overall regions of the body through the

Meridians or Triple Energizers. Therefore, it is possible that FR induces Dampness pathogen-related problems as well as gastrointestinal symptoms or signs.

A few self-rated questionnaires for gastrointestinal problems have been developed. Utilizing these questionnaires, the gastrointestinal symptom score (GIS) was developed to assess symptom intensities in patients with functional dyspepsia (FD) [4], and the gastrointestinal symptom rating scale (GSRS) was developed to assess gastroesophageal reflux disease (GERD) [5]. Together with GIS and GSRS, the Nepean dyspepsia index (NDI) was developed to assess health-related quality of life in patients with dyspepsia or FD [6]. From a therapeutic point of view, Hayakawa et al. reported that Liu Jun Zi Tang, one of the herbal prescriptions used to eliminate pathogenic Dampness that has stagnated in the spleen, promoted gastric adaptive relaxation and relieved FD [7]. Many symptoms of FD are similar to those of FR such as epigastric pain, water brash, and dyspepsia. However, as mentioned above, the clinical spectrum of FR is wider than that of FD. Symptoms or signs of languidness, weight gain, edema, and joint pain occur specifically in the

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etiology of FR. Therefore, developing a tool to determine FR based on East Asian medical pathophysiology would be useful. Such a questionnaire would also be helpful in determining the clinical use of FR-eliminating herbal prescriptions such as Ping Wei San [8]. However, few studies have developed questionnaires to determine the presence of FR.

In a previous study, Lim et al. identified the pilot version of a FRQ consisting of 20 items using the Delphi method [2]. However, the pilot version was not validated and did not define the optimum cut-off point. Thus, the purpose of this study was to examine the reliability and validity of the pilot version of the FRQ and to define the optimum cut-off point using receiver operator characteristics (ROC) curve analysis.

## Methods

### Subjects and data collection

One hundred ninety-four outpatients (62 men, 132 women) who were randomly selected from all of the outpatients in 13 oriental medicine clinics in Seoul were asked to complete the FRQ. The age range for men was between 20 and 76 years (mean  $\pm$  SD = 46.92  $\pm$  13.04 years), and that for women was between 19 and 77 years (mean  $\pm$  SD = 44.89  $\pm$  14.13 years). There were no significant differences in age between genders. We asked the two hundred clinicians of the Association of Korean Medical Etiology to participate in the FRQ validations by e-mail or fax. Thirteen of them, each with more than five years of clinical experience, agreed to determine the presence or absence of FR for each patient in their oriental medicine clinics. The outpatients completed the FRQ before the clinicians' determinations of FR. Clinicians were asked to determine the presence or absence of FR using traditional diagnostic tools such as inspection, listening and smelling, inquiry, and palpation without the results of the FRQ. Therefore, the results of the FRQ were not influenced by the clinicians' determinations, nor were the clinicians' determinations of FR influenced by the FRQ. The results of the FRQ were essentially double-blind for the clinicians and outpatients. Among the 194 outpatients, 99 were diagnosed with FR and 95 were diagnosed as non-FR. Double-blinded FRQ scores and clinicians' determinations were used to determine the sensitivity and specificity of the FRQ and to define an optimum cut-off point using a ROC curve analysis to minimize the interactions between questionnaire scores and clinicians' determinations. Fig. 1 depicts the entire process of FRQ development used in this study. Informed consent was obtained from all subjects prior to enrollment in the study.

### Measures

#### FRQ

In a previous study, Lim et al. researched the medical literature, finding articles including Yi Xue Ru Me (An Introduction to Medicine), Dong Eui Bo Gam (An Oriental Medical Treasure), Jing Yue Quan Shu (Jing Yue's Medical Encyclopedia), and Bing Yin Bing Ji Xue (Cause and Mechanism of Disease) with references to FR [2]. Subsequently, two iterations of the

Delphi method were performed by asking 53 clinicians who were all members of 'The Association of Korean Medical Etiology' to rate the importance of each extracted item in diagnosing FR based on the medical literature. All of the clinicians agreed upon the 20 items for the pilot version of the FRQ (Table 1). In the present study, two of the 20 items relating to leucorrhea and after-drinking diarrhea were excluded from the pilot version of the FRQ because these items were thought to be inappropriate to answer. Ultimately, 18 items were compiled in order to examine reliability and construct validity. Each item was rated on a 7-point Likert scale: 1 = disagree very strongly; 2 = disagree strongly; 3 = disagree; 4 = neither agree nor disagree; 5 = agree; 6 = agree strongly; and 7 = agree very strongly. Additional scoring of the FRQ was carried out using a dichotomous response system similar to the general health questionnaire (GHQ) [9] and Phlegm pattern questionnaire (PPQ) [10]. Based on the dichotomous response system, we transformed Likert scores of 1, 2, 3, and 4 to 0 points and Likert scores of 5, 6, and 7 to 1 point. The totals of the 194 outpatient dichotomous FRQ scores, in combination with the FR determinations from the clinicians, were used to examine sensitivity and specificity and to define an optimum cut-off score for the FRQ.

### Statistical analyses

Internal reliability was examined using both Cronbach's coefficient alpha and the corrected item-total correlations. A low alpha value ( $\alpha < 0.600$ ) or item-total correlation ( $r < 0.300$ ) suggests that some items either had very high variability or that the items were not all measuring the same variable [11]. Construct validity was examined using principal component analysis (PCA) with varimax rotation. We retained factors with eigenvalues greater than 1.0. An optimum cut-off score on the FRQ was defined using a ROC curve analysis. We determined the cut-off point for the FRQ at the maximum Youden index ( $J = \text{sensitivity} + \text{specificity} - 1$ ) level [12]. Together with the Youden index, we examined the area under the curve (AUC), which serves as a discriminative tool to determine FRQ [12]. All statistical analyses were performed with SPSS 15 for Windows (SPSS, Chicago, IL, USA). Values are presented as mean  $\pm$  standard deviation (SD), and  $P < 0.05$  indicated statistical significance.

## Results

In the reliability tests, Cronbach's coefficient alpha was 0.852 for the 18 items. However, one item, 'greedy for food,' showed an item-total correlation below 0.3 (Table 2). These results indicate that this item did not measure the same things as the other items, and it was therefore excluded from the validity tests [11].

To examine construct validity, 17 items (excluding 'greedy for food') were subjected to PCA. As a result, four factors were extracted, and the total percentage of variance was determined to be 53.2% (Table 3). The four factors extracted were as follows: factor 1 consisted of gastrointestinal items (gastrointestinal distress factor); factor 2 consisted of Dampness pattern-related

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