The Developed Patient Healthy Questionnaire-8 with a Greater Impact on Quality of Life Compared with the Somatic Symptom Scale-8 in Functional Dyspepsia

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Abstract

Background: To adapt insufficiencies of the Somatic Symptom Scale-8 (SSS-8) measuring somatization in functional dyspepsia (FD) to develop PHQ-8, of which reliability, validity and the effects of somatization evaluated by the developed PHQ-8 on quality of life (QoL) were further assessed.

Methods: 612 FD patients completed a 25 items questionnaire. 8 items were selected from 25 items to constitute the PHQ-8 by discrete degree, correlation coefficient, factor analysis and Cronbach coefficient four methods. Reliability and validity for the PHQ-8 and the SSS-8 were compared by principal component and confirmatory factor analysis. The effects of somatization, depression and anxiety on the Nepean Dyspepsia Index (NDI) for QoL were explored by Pearson correlation coefficient and linear regression analysis.

Results: Cronbach's α coefficients for the PHQ-8 and the SSS-8 were 0.601, 0.553, and cumulative contribution rates of three extracted factors were 55.103%, 51.666%, respectively. Somatization evaluated by the PHQ-8 ($r=0.309$, $P<0.001$) and the SSS-8 ($r=0.281$, $P<0.001$) were related to the NDI. The model for the PHQ-8 showed $\chi^2=31.247$, $RMR=0.01$, $RMSEA=0.042$, $GFI=0.984$. Linear regression analysis showed that somatization measured by the PHQ-8 ($\beta=0.270$, $P<0.001$), anxiety ($\beta=0.163$, $P<0.001$) and depression ($\beta=0.136$, $P=0.003$) were determinants of the NDI; somatization measured by the SSS-8 ($\beta=0.250$, $P<0.001$), anxiety ($\beta=0.156$, $P<0.001$) and depression ($\beta=0.155$, $P=0.001$) were determinants of the NDI.

Conclusions: The developed PHQ-8 had a better reliability and validity, which assessing somatization appeared to have a greater impact on QoL than that of the SSS-8. These results suggested that the developed PHQ-8 might improve to study the effects of somatization on QoL instead of the SSS-8 in specific FD patients.

Background

The pathogenesis and subtypes of functional dyspepsia

The prevalence of functional dyspepsia (FD) can be as high as 20~30%[1,2]. Its pathogenesis may be environmental exposure such as H.pylori infection[1-6], diet[1,7,8], and gastric acid[1,9,10], delayed gastric emptying, impaired proximal gastric accommodation[1,11-13], visceral hypersensitivity[1,14-16], duodenal inflammation [1,17-18], genetic factors [19,20], psychosocial factors (anxiety, depression, stress,etc) [19-25]. These factors may interact with each other under the participation of brain-gut axis, FD is a disorder of gut-brain interaction [1,3,15]. Rome IV classified FD into three subtypes: (1) epigastric pain syndrome (EPS): upper abdominal pain and/or burning discomfort of upper abdomen; (2) postprandial distress syndrome(PDS): postprandial fullness and early satiety ; (3) The overlapped group of EPS and PDS[2].

FD patients with common somatization symptoms

In addition, FD patients often have dizziness, back pain, sleep disorders, fatigue [26] and other digestive system symptoms that cannot be explained by biochemical and structural abnormalities. Clinically, these symptoms are called somatization symptoms [27,28]. Somatization is defined as a chronic mental disorder characterized by the presence of one or more frequently changing somatic symptoms, involving multiple systems and organs of the body [29]. The severity of dyspepsia was affected by somatization. Patients often had incorrect understanding or excessive attention to these symptoms, and had too much anxiety about their physical condition. They repeatedly sought medical help for these, consuming financial cost[30]. Somatization can coexist with other medical diagnoses such as anxiety and depression, and should be given equal attention to other comorbid diseases, because it often makes other diseases more complex and changeable [31]. FD patients had more somatic symptoms and worse quality of life (QoL) [32,33].

Limitations of questionnaires for somatization

The Patient Health Questionnaire Symptom Group (Patient Healthy Questionnaire-15, PHQ-15) was most widely used to assess somatization symptoms [34]. In FD patients, some items overlapped with FD gastrointestinal symptoms. Therefore, the Patient Healthy Questionnaire-12(PHQ-12) with the removals of three gastrointestinal symptoms was used, but the dysmenorrhea or other menstrual discomfort items in the PHQ-12 and the PHQ-15, which made the gender score different. The item of syncope was relatively rare, of which the incidence rate was low [34-36]. In addition, FD patients often had symptoms such as throat discomfort and dry mouth that were not included in the PHQ-15, which might lead to neglect these symptoms by clinicians.

On the other hand, the Somatic Symptom Scale-8 (SSS-8) with good reliability and validity has been developed in the field of the DSM-5 to evaluate somatization symptoms [37-39], which was recommended to be a replacement for PHQ-15 in a limited time[40]. However, the items of the SSS-8 also overlap with gastrointestinal symptoms, and the SSS-8 is not a FD-specific scale for evaluating somatization.

Subsequently, we adapted the SSS-8 to develop the Patient Healthy Questionnaire-12(PHQ-8) by screening the somatic symptoms, and confirmed its reliability and validity, and demonstrated that somatization assessed by the developed PHQ-8 had a possible greater impact on QoL than that of the SSS-8 in specific FD patients.

Methods

Patients

Patients from June 2017 to June 2018, the outpatient department of gastroenterology, who were suspected to be FD, should improve the examination of digestive endoscopy, blood routine, biochemistry and abdominal ultrasonography. According to CONSORT guidelines, inclusion criteria: (1) Rome IV criteria[1]: upper abdominal pain, upper abdominal burning sensation, postprandial fullness, early satiety

of one or more symptoms, and no organic diseases' evidence that can explain the above symptoms; the above symptoms exist for at least 6 months, and nearly 3 months meet the above diagnostic criteria; (2) age $\geq$ 18 years old; (3) education level was primary school and above, and had a certain reading comprehension ability. Exclusion criteria: (1) gastroscopy revealed an organic disease of indigestion, including erosive esophagitis, Barrett's esophagus, etc; (2) B-ultrasound, blood routine and biochemical examination found systemic diseases, metabolic diseases and malignant tumors; (3) irritable bowel syndrome as main symptoms; (4) gastroesophageal reflux disease with acid regurgitation and heartburn as main symptoms; (5) a history of abdominal surgery, such as: cholecystectomy, intestinal resection, hysterectomy, appendectomy or any other abdominal surgery; (6) patients who had recently taken anticholinergic drugs, antispasmodic and analgesic drugs, hormones and nonsteroidal and anti-inflammatory drugs, etc; patients' upper abdominal symptoms disappeared after eradicating *H. pylori* infection; (7) pregnant and lactating women; (8) patients with psychosis and serious somatic diseases. Studies had shown that patients with anxiety and depression often have somatic symptoms as the main manifestation. In order to avoid the interaction effects of anxiety, depression and somatization, FD patients accompanied with anxiety and depression were excluded in developing PHQ-8. However, previous studies showed that anxiety, depression and somatization had mutual effects [21,33]. Thus the patients with anxiety and depression were included in the clinical application study of the PHQ-8.

Pool items for development of the PHQ-8

According to the SSS-8, the PHQ-15 and most common clinical somatization symptoms, 25 somatic symptoms formed the pool items of initial scale: 1 back pain 2 limb or joint pain 3 dysmenorrhea or menstrual other discomfort 4 headaches 5 chest pain 6 shortness of breath 7 dizziness 8 fainting 9 palpitations 10 sexual life pain or other discomfort 11 feeling tired or having low energy 12 insomnia or other sleep problems 13 numbness / stinging 14 fatigue 15 throat discomfort: foreign body sensation/ dryness/pain etc 16 dry mouth 17 excessive sweat 18 hand/foot heavy feeling 19 a burst of cold/fever 20 memory loss/forgetfulness 21 urinary frequency 22 urodynia / dysuria 23 blurred vision 24 neck and shoulder pain 25 muscle soreness. 12 items were included in the original PHQ-15[35], each item scored by three-level as 0 ("not bothered at all"), 1 ("bothered a little"), or 2 ("bothered a lot") (past 2 weeks). The items of the developed PHQ-8 were completed by discrete degree method, correlation coefficient method, factor analysis method and Cronbach's alpha.

All enrolled patients filled in the PHQ-15, the SSS-8, the Generalized Anxiety Disorder -7 (GAD-7) [41] for anxiety, the Patient Health Questionnaire (PHQ-9) [42] for depression, the Dyspepsia Symptoms Severity (DSS) [33], and the Nepean Dyspepsia Index-Short Form (NDI) [43] for QoL.

Items for development of the PHQ-8 selected by four methods

Discrete degree method: when the degree of dispersion of the selected items is low revealing the poor ability for evaluation to distinguish, so the items with high degree of dispersion should be selected, and the degree of dispersion is measured by the standard deviation of the item scores, excluding the standard deviation of the items was < 0.5 [44].

Correlation coefficient method: an item with a correlation coefficient > 0.3 is selected according to Cohen's criteria [39].

Factor analysis: using the principal component method, the common factor is extracted according to the feature root greater than 1, and the variance is maximized by orthogonal rotation to select an item with a factor load greater than 0.4. The KMO and spherical test are performed. The KMO value < 0.5 is unsuitable for factor analysis, and Bartlett's spherical test $P < 0.01$ can negate the zero hypothesis that the correlation matrix is a unit matrix, that is, there is a significant correlation between the variables [45].

Cronbach α coefficient method: the items are screened from internal consistency, and the Cronbach α coefficient of the initial total scale is calculated. If the α coefficient is increased after the deletion of an item, it indicates that the existence of the item reduces the internal consistency [46].

Dyspepsia symptoms severity

The Dyspepsia Symptoms Severity (DSS) score is the sum of all eight symptoms: postprandial fullness, early satiation, epigastric pain, burning, bloating, belching, nausea and vomiting by 3-point scale (absent, mild, moderate, severe) [33]. The relationship between the DSS, the SSS-8 and the PHQ-8 were evaluated, and the effects of somatization, anxiety and depression on DSS were analyzed.

Measurements of psychological disorder

The PHQ-15 questionnaire for somatization, of which the severity of 15 symptoms were rated for the last 4 weeks to by three-level as 0 ("not bothered at all"), 1 ("bothered a little"), or 2 ("bothered a lot") [34]. The Somatic Symptom Scale-8 (SSS-8) composed of 8 somatic symptoms is applied by three-level as well as five-level as 0 ("not bothered at all"), 1 ("bothered a little bit"), or 2 ("bothered somewhat") 3 ("bothered quite a bit") 4 ("bothered very much") [38]. Generalized Anxiety Disorder 7-item scale (GAD-7) measure the generalized anxiety disorders and diagnosis anxiety co-morbidity (total score > 10 points) (past 2 weeks) [41]. The Patient Health Questionnaire (PHQ-9) is used to assess depressive disorders or co-morbidity (total score > 10 points), nine items are rated on Likert scales (0–3) (past 2 weeks) [42].

Disease-specific quality of life (QoL) measurement

The Nepean Dyspepsia Index-Short Form (NDI) measure the influence of dyspepsia symptoms on FD patients' QoL: inference with work/study, tension, inference with daily activities, disputation to daily eating/drinking, knowledge toward/control over disease symptoms over the past 2 weeks. Each item is assessed with a 5-point scale from 0 (not at all), 1 (a little), 2 (moderately), 3 (quite a lot) to 4 (extremely) [43]. The relationships between the NDI, the SSS-8, the PHQ-15 and the PHQ-8, and the effects of somatization, depression and anxiety on QoL were assessed in FD patient.

Statistical analysis

SPSS 24.0 statistical software was used. Quantitative data were expressed as (mean $\pm$ standard deviation), *t*-test was used for comparison between two groups, and one-way ANOVA was used for comparison above two groups. The qualitative data were expressed by rate, and chi-square test was used for comparison. Principal component analysis was used for exploratory factor analysis; AMOS 22.0 was used for confirmatory factor analysis; Pearson correlation coefficient was used for correlation analysis; influencing factors such as somatization, anxiety and depression on NDI were analyzed by linear regression analysis; Two-sided test, $P < 0.05$, the difference had statistically significant.

Results

Demographics for two somaticization scale scores in 471 FD patients

612 patients were diagnosed with FD according to Rome IV criteria. 17.3% (106/612) patients reached anxiety disorders, 13.6% (83/612) subjects had depression co-morbidity, 7.8% (48/612) patients were diagnosed with anxiety and depression co-morbidity. In 471 FD Patients without anxiety and depression co-morbidity, 63.5% (299/471) patients were female, 36.5% (172/471) male. The educational rates for primary school, middle school, high school, college or above were 22.7% (107/471), 47.3% (223/471), 14.4% (68/471), 15.5% (73/471), respectively. Mean age was 43.4 ± 10.3 years (range, 18-67). 20.6% (97/471) patients were diagnosed with EPS, 31.0% (146/471) with PDS, 48.4% (228/471) with EPS and PDS Overlap. In 471 FD patients the demographics for the PHQ-8 and the SSS-8 assessing somatization were shown in Table 1.

Among the somatic scores evaluated by the three scales, there was a significant difference in genders ($P < 0.05$). There were no significant differences between different educational levels and ages ($P < 0.05$).

Items for the developed PHQ-8 selected by four methods

By a discrete degree method dysmenorrhea or other discomfort during menstruation, chest pain, shortness of breath, fainting, palpitations, sexual life pain or other discomfort, numbness/tingling, sweating, heavy hands/foot, bursts of cold/fever, memory loss/forgetfulness, frequency of micturition, urodynia /dysuria, blurred vision, neck and shoulder pain, muscle pain were removed due to the standard deviation of the items was < 0.5 .

By a correlation coefficient method fainting ($r = 0.090$), dysmenorrhea or other menstrual discomfort ($r = 0.243$), hyperhidrosis ($r = 0.296$) and urodynia / dysuria ($r = 0.260$) removed.

According to factor analysis the KMO value of the initial scale was 0.668, and the Bartlett spherical test chi-square value = 366.894, $P < 0.01$, which was suitable for factor analysis showing that each item had a factor loading of more than 0.4 in its dimension except for headaches and chest pain.

A Cronbach α coefficient method showed that the α coefficient increased after removing fainting, urodynia / dysuria.

The screened items of the developed PHQ-8 were shown in Table 2 by the discrete degree, a Cronbach α coefficient, correlation coefficient method and factor analysis, including back pain, limb or joint pain, dizziness, fatigue, dry mouth, feeling tired or having low energy, insomnia or other sleep problems, throat discomfort.

Reliability analysis of the developed PHQ-8 and the SSS-8

Intrinsic reliability analysis

To measure whether the problem of the questionnaire is the same concept, The Cronbach coefficient is generally used to test the internal consistency. It is generally believed that when the coefficient is greater than 0.7, the reliability is good [47]. The Cronbach α coefficient of the developed PHQ-8 and the SSS-8 were 0.601, 0.553, respectively. The correlation coefficient between each item and the total score were 0.426–0.652, 0.359–0.573, respectively.

Criterion validity analysis

The PHQ-15 and the NDI as classic scales, the correlation coefficient between the total score of the PHQ-8, the SSS-8 and the PHQ-15 were ($r=0.739$, $P=0.000$), ($r=0.835$, $P=0.000$), respectively. Table 3 showed the Nepean Dyspepsia Index as a classic QoL criterion, the developed PHQ-8 appeared to be superior to the SSS-8.

Structural validity analysis for the developed PHQ-8 and the SSS-8

Exploratory factor analysis: the developed PHQ-8 had a KMO=0.668, Bartlett spherical test chi-square = 366.894, $P<0.01$; the SSS-8 had a KMO=0.680, Bartlett spherical test chi-square = 236.445, $P<0.01$, of which factor analysis was suitable. The exploratory factor analysis was carried out on the scale, and the principal component method was used to maximize the orthogonal rotation through the covariance matrix and the variance, and the common factor was extracted by using the Kaiser criterion (Eigen value > 1). 3 common factors of the developed PHQ-8 was extracted, the cumulative contribution rate was 55.103%, and the factor load range on the common factor. It was 0.482–0.802, which was higher than the minimum standard of structural validity test 0.4 [45,47]; 3 common factors for the SSS-8 were extracted, the cumulative contribution rate was 51.666%, and the factor load range on the common factor was 0.353–0.881. The PHQ-8 and the SSS-8 specific factor loads were shown in Table 4 and Table 5.

Confirmatory factor analysis: validation factor analysis models often use chi-squared values (χ^2), root mean square (RMR) of residuals, root mean square approximate error (RMSEA), goodness of fit index (GFI), adjusted the goodness fitting index (AGFI), comparative fitting index (CFI), Tucker-Lewis index (TLI), norm-fitting index (NFI) and other indicators are used to evaluate the fitting effect of the model. The smaller the value of χ^2 , GFI, AGFI, CFI, TLI, NFI > 0.9 indicate that the model fits well, the closer to the “1” fit, the better, RMR, RMSEA < 0.05 indicates that the model fits well, the closer to “0” fit The better. The developed PHQ-8 and the SSS-8 were separately performed by exploratory factor analysis, and 3

common factors were extracted. Two scales confirmatory factor analysis had a good 3-factor model fit, shown in Table 6.

Correlation analysis of anxiety, depression, somatization and the DSS for the developed PHQ-8 and the SSS-8 scores in 612 patients

A further clinical application study was carried out, assessing anxiety, depression and somatization mutual effects for the DSS and the NDI, and somatization assessed by the PHQ-8 and the SSS-8 in 612 patients. Correlation analysis showed that anxiety, depression, and somatization were positively correlated with DSS (Table 7). The correlation coefficient between the DSS and somatization assessed by the SSS-8 appeared to be higher than that of the developed PHQ-8.

Linear regression analysis of the effects anxiety, depression, somatization on the DSS

Anxiety, depression and somatization as independent variable the DSS, the DSS was taken as dependent variable, and linear regression analysis was carried out by backward method to further study the effects of anxiety, depression and somatization on DSS. After adjusting for factors such as gender, age, FD type, education level and employment situation, Table 8 showed that depression and somatization were the influencing factors for the DSS, Three model adjusted R^2 for the PHQ-8 and the SSS-8 were 0.263, 0.263, respectively, all $p < 0.001$. The role of somatization might be more important than depression. The standardization β for the SSS-8 seemed to be higher than that for the PHQ-8.

Correlation analysis of anxiety, depression, somatization and QoL

Correlation analysis showed that anxiety, depression, and somatization were positively correlated with the NDI (Table 9). Compared to the SSS-8, the correlation coefficient between NDI and somatization for the developed PHQ-8 seemed to be higher.

Linear regression analysis for the effects of anxiety, depression, somatization on QoL

The Nepean Dyspepsia Index for QoL was taken as dependent variable, anxiety, depression and somatization as independent variable, and linear regression analysis was carried out by backward method to further study the effects of anxiety, depression and somatization on QoL. After adjusting for factors such as gender, age, FD type, education level and employment situation, Table 10 showed that anxiety, depression and somatization were the influencing factors for QoL, three model adjusted R^2 for the PHQ-8 and the SSS-8 were 0.224, 0.236, respectively, all $p < 0.001$. Somatization appeared to be more important than anxiety and depression. The standardization β for the PHQ-8 appeared to be higher than that for the SSS-8.

Discussion

Functional dyspepsia (FD) is the result of the interaction of physiological function and psychosocial factors through brain-gut axis changes[2,5]. Psychosocial factors such as somatization have effects on

health-related QoL after controlling for anxiety and depressive symptoms in FD patients[30,48]. Somatization manifestations can occur in multiple systems, patients often paid too much attention to symptoms and thought that their symptoms were caused by potentially serious physical diseases, thus aggravating anxiety and depression, leading to the deterioration of symptoms, resulting in repeated medical treatment and economic expenses [33]. The PHQ-15 is a good worldwide tool for assessing the severity of somatization and somatoform disorders, which has high reliability and validity not only in the disease population but also in the general population [34,49].

However, the PHQ-15 has some limitations in the study of FD patients. First, the PHQ-15 is not a specificity scale for FD patients, which has three items that overlap with gastrointestinal symptoms (stomach pain, nausea, flatulence or indigestion, diarrhea, loose stools or constipation). Secondly, there is a menstrual problem which is not applicable to menopausal women and cause gender differences. Thirdly, due to cultural differences, patients in the PHQ-15 has poor compliance with questions about sexual issues. Fourthly, the relative incidence of syncope items is low[35], in addition to the symptoms in the PHQ-15, FD patients often have other symptoms: dry mouth, fatigue, and throat discomfort, etc. Finally, most patients with somatic symptoms often visited a general outpatient clinic without non-psychiatric doctors, which may result in less satisfactory results. Therefore, in view of the PHQ-15 above limitations, it is necessary to use a more simple tool to assess FD patient's somatization symptoms and its severity, which is conducive to doctors to give patients better advice, diagnosis and treatment.

The SSS-8 has been used to quickly assess somatization symptoms and their severity, avoiding gender differences caused by menstrual abnormalities, sexual life problems caused by cultural differences, and low incidence of syncope items insufficient [38], but which is a non-specific scale of FD patients and has gastrointestinal overlap symptoms in the clinical application. In view of the SSS-8 limitations, in this study, the items of the developed PHQ-8 screened by discrete degree, correlation coefficient, factor analysis and Cronbach coefficient four methods had back pain, limb or joint pain, dizziness, fatigue, dry mouth, feeling tired or mentally poor, insomnia or other sleep problems, throat discomfort dryness, foreign body sensation etc.

The results showed that menstrual abnormalities, sexual life, syncope related items and the total score of the scale were poorly correlated. The removal of these three items improved the reliability of the developed PHQ-8, each item of which was significantly related to the total score, showing the reliability of the PHQ-8 appeared be better than that of SSS-8. The Cronbach coefficient of the PHQ-8 and the SSS-8 suggested the internal consistency of the PHQ-8 might be also superior to SSS-8. In the calibration validity analysis, the PHQ-15 and the SSS-8 had been widely used as a classic somatic symptom assessment scale, and NDI which were obviously related. In the exploratory factor analysis, the PHQ-8 had a higher cumulative contribution rate than the SSS-8. Common factor 1 "neurological discomfort" includes dizziness, feeling tired or mentally poor, insomnia or other sleep problems, fatigue; common factor 2 "pain discomfort" includes back pain, limb or joint pain; common factor 3 "general discomfort" including throat discomfort, dry mouth. Gierk et al. [40] used confirmatory factor analysis to analyze the validity of SSS-8, and the results showed that the 3-factor model was better than the 1-factor model.

Similarly, we performed a 3-factor model confirmatory analysis for the PHQ-8 and the SSS-8. The 3-factor model fitting of the SSS-8 seemed to be better than that of the PHQ-8, while the SSS-8 contained gastrointestinal discomfort entries in FD patients.

The developed PHQ-8 score was further evaluated in order to compare with the SSS-8 in 612 FD patients including anxiety or depression, because previous studies showed that anxiety, depression and somatization had mutual effects [21,33]. Correlation and linear regression analysis found that somatization assessed by SSS-8 might play a larger role on the DSS than that by the PHQ-8. However, somatization assessed by the PHQ-8 might play a larger influence on QoL than that by the SSS-8, because of the fact that the PHQ-8 had been removed overlap gastrointestinal symptoms in FD patients.

However, there were some shortcomings in the research process. First, the subjects with FD included in this study were all composed of patients with tertiary hospitals. These patients may have severe symptoms, limiting the prevalence of other people with FD, and whether other FD patients from the community can get the same conclusion required a large scale study. Secondly, this study mainly analyzed the evaluation of specific somatization symptoms of FD patients by the developed PHQ-8, which was not used in other disease patients and healthy people. In addition, only patients with IBS, GERD as main symptoms were excluded. Thirdly, the PHQ-8 had not been tested for retest reliability in all cases, so the external reliability of the scale need to be further analyzed in future large sample research. Fourthly, similar to the SSS-8, the PHQ-8 was used to assess the severity of somatoform disorders, rather than the diagnostic tool for somatoform disorders [34]. Accordingly, further more studies were needed to improve the rationality of the developed PHQ-8 in future.

FD patients' somatization was an independent risk factor for impaired QoL, proximal gastric accommodation, gastric emptying and *H.pylori* infection were not risk factors in a 5-year follow-up study [33]. Thus, evaluating somatization is important in a long follow-up study. Our results showed the correlation between the PHQ-8 and QoL appeared to be higher than that of the SSS-8. Further a horizontal study was conducted, in which anxiety, depression and somatization were the influencing factors for the NDI. Compared with the SSS-8, somatization evaluated by the PHQ-8 seemed to have a greater impact on QoL in specific FD patients.

Conclusions

The PHQ-15 and the SSS-8 have overlap gastrointestinal symptoms in specific FD patients, the SSS-8 was recommended to be a replacement for the PHQ-15 in a limited time. The developed PHQ-8 without overlap gastrointestinal symptoms had good reliability and validity. Somatization assessed by the developed PHQ-8 might have a possible greater impact on QoL of FD patients than that of the SSS-8. These results suggested that the developed PHQ-8 might be more effective evaluating influences of somatization on QoL instead of SSS-8, which may be helpful to further verify the developed PHQ-8 and study the effects of somatization on QoL for FD patients in a limited time in future.

Abbreviations

FD: functional dyspepsia; SSS-8: Somatic Symptom Scale-8; PHQ-8: Patient Healthy Questionnaire-8; QoL: quality of life; NDI: Nepean Dyspepsia Index; RMR root mean square ; RMSEA: root mean square approximate error; GFI: goodness of fit index; AGFI: adjusted the goodness fitting index; CFI: comparative fitting index; TLI: Tucker-Lewis index; NFI: norm-fitting index; EPS: epigastric pain syndrome; PDS: postprandial distress syndrome; PHQ-15: Patient Healthy Questionnaire-15; PHQ-12: Patient Healthy Questionnaire-12; GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9, DSS: dyspepsia symptoms severity

Declarations

Ethics approval and consent to participate

The study was approved by the ethics committee of Affiliated Hospital of North Sichuan Medical College. All patients signed informed consent form.

Consent for publication

Not applicable.

Availability of data and materials

The data and materials can be available from the corresponding author on reasonable request.

Competing interests

There were not competing interests in this study.

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None.

Authors' contributions

Yuan C and Yong G: conducted conception and design, analysis and interpretation of data, and wrote the manuscript; Wang X: collected and analyzed the data, drafted the manuscript; Xie T, Wang C: participated in analyzing data, editing the manuscript and final approval of the version to be published; Yuan Y: edited and approved the manuscript; He G: planned and conducted study concept and design, statistical analysis and edited and approved the manuscript.

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Tables

Table 1. Demographics for two somatization scales scores in 471 FD patients (Mean±SD)

	PHQ-8	<i>t/F</i>	<i>P</i> -value	SSS-8	<i>t/F</i>	<i>P</i> -value
Gender		2.484	0.013		3.322	0.001
Male(n=172)	4.32±2.78			4.30±2.29		
Female(n=299)	4.97±2.65			5.04±2.39		
Age(years old)		1.439	0.231		1.987	0.115
18-29(n=45)	3.96±2.49			3.98±2.03		
30-44 (n=201)	4.78±2.61			4.84±2.33		
45-59 (n=211)	4.87±2.85			4.90±2.48		
≥60 (n=14)	4.57±2.62			4.50±2.47		
Education		1.669	0.173		2.428	0.065
Primary school (n=107)	5.15±2.96			5.25±2.76		
Junior high school (n=223)	4.46±2.71			4.54±2.24		
High school (n=68)	4.87±2.63			4.96±2.48		
College or above (n=73)	4.82±2.38			4.62±2.03		

Table 2 The developed PHQ-8 development by screening 25 items by four methods

Items	Degree of dispersion	Correlation coefficient	Factor analysis	Cronbach coefficient
Back pain	0.679	0.427	0.722	0.746
Pain in your arms,legs,or joints	0.557	0.403	0.673	0.746
Dysmenorrhea or other discomfort during menstruation	0.464(×)	0.243(×)	0.617	0.754(×)
Headaches	0.577	0.403	0.380(×)	0.746
Chest pain	0.496(×)	0.395	0.362(×)	0.745
Shortness of breath	0.497(×)	0.448	0.427	0.742
Dizziness	0.581	0.490	0.650	0.739
Fainting	0.112(×)	0.090(×)	0.609	0.755(×)
Palpitation	0.480(×)	0.386	0.514	0.746
Sexual pain or other discomfort	0.294(×)	0.313	0.511	0.749
Feeling tired or having low energy	0.687	0.543	0.731	0.735
Insomnia or trouble sleeping	0.694	0.378	0.623	0.751
Numbness/tingling	0.470(×)	0.341	0.731	0.749
Fatigue	0.628	0.509	0.780	0.738
Throat discomfort	0.763	0.457	0.434	0.746
Dry mouth	0.674	0.375	0.636	0.751
Excessive sweat	0.466(×)	0.296(×)	0.757	0.751
Hand/foot heavy feeling	0.364(×)	0.322	0.409	0.749
A burst of cold / fever	0.447(×)	0.464	0.505	0.741
Memory loss/forgetfulness	0.493(×)	0.415	0.724	0.744
Urinary frequency	0.449(×)	0.364	0.717	0.747
Urinary pain/dysuria	0.242(×)	0.260(×)	0.740	0.751
Blurred vision	0.419(×)	0.309	0.739	0.750
Neck and shoulder pain	0.487(×)	0.382	0.645	0.746
Muscle pain	0.374(×)	0.396	0.729	0.745

Note: × indicated that the item was removed.

Table 3. Correlation analysis between somatization and quality of life

Variable		FD (n=471)	PDS (n=146)	EPS (n=97)	Overlap (n=228)
PHQ-8	r	0.309	0.281	0.190	0.360
	P	<0.001	0.001	0.063	<0.001
SSS-8	r	0.281	0.236	0.197	0.317
	P	<0.001	0.004	0.053	<0.001

Table 4. Factors and loads analysis for the developed PHQ-8

Items	Factor 1	Factor 2	Factor 3
Feeling tired or having low energy	0.802		
Fatigue	0.769		
Insomnia or trouble sleeping	0.525		
Dizziness	0.482		
Back pain		0.797	
Pain in your arms, legs, or joints		0.719	
Throat discomfort dryness ,etc			0.728
Dry mouth			0.706

Table 5 .Factors and loads analysis for the SSS-8

Items	Factor 1	Factor 2	Factor 3
Back pain	0.713		
Pain in your arms, legs,or joints	0.695		
Headaches	0.495		
Chest pain or shortness of breath	0.494		
Insomnia or trouble sleeping		0.806	
Feeling tired or having low energy		0.767	
Stomach or bowel problems			0.881
Dizziness			0.353

Table 6. The developed PHQ-8 and the SSS-8 confirmatory factor analysis results

Scale	model	χ^2	df	RMR	RMSEA	GFI	AGFI	CFI	TLI	NFI
PHQ-8	3 factors	31.247	17	0.016	0.042	0.984	0.967	0.958	0.931	0.915
SSS-8	3 factors	17.251	17	0.010	0.007	0.991	0.981	0.998	0.997	0.927

Table 7.Correlation analysis of anxiety, depression, somatization and the dyspepsia symptoms severity

Variable		FD (n=612)	PDS (n=175)	EPS (n=112)	Overlap (n=325)
Anxiety	r	0.223	0.231	0.147	0.232
	P	<0.001	<0.001	<0.001	<0.001
Depression	r	0.323	0.296	0.322	0.333
	P	<0.001	<0.001	<0.001	<0.001
Somatization PHQ-8	r	0.374	0.396	0.293	0.346
	P	<0.001	<0.001	<0.001	<0.001
Somatization SSS-8	r	0.399	0.395	0.281	0.362
	P	<0.001	<0.001	<0.001	<0.001

Table 8. The effects of anxiety, depression and somatization on the dyspepsia symptoms severity

Variable	Unstandardization β	Standardization β	<i>t</i> -value	<i>P</i> -value
Depression	0.144	0.176	3.911	<0.001
Somatization PHQ-8	0.287	0.256	6.460	<0.001
Depression	0.154	0.188	4.218	<0.001
Somatization SSS-8	0.206	0.257	6.431	<0.001

Table 9. Correlation analysis of anxiety, depression, somatization and the Nepean Dyspepsia Index

Variable		FD (n=612)	PDS (n=175)	EPS (n=112)	Overlap (n=325)
Anxiety	<i>r</i>	0.327	0.258	0.268	0.367
	<i>P</i>	<0.001	<0.001	<0.001	<0.001
Depression	<i>r</i>	0.354	0.266	0.304	0.394
	<i>P</i>	<0.001	<0.001	<0.001	<0.001
Somatization PHQ-8	<i>r</i>	0.404	0.325	0.309	0.446
	<i>P</i>	<0.001	<0.001	<0.001	<0.001
Somatization SSS-8	<i>r</i>	0.389	0.285	0.345	0.418
	<i>P</i>	<0.001	<0.001	<0.001	<0.001

Table 10. The effects of anxiety, depression and somatization on the Nepean Dyspepsia Index

Variable	Unstandardization β	Standardization β	<i>t</i> -value	<i>P</i> -value
Anxiety	0.567	0.163	3.784	<0.001
Depression	0.490	0.136	3.986	0.003
Somatization (PHQ-8)	1.330	0.270	6.638	<0.001
Anxiety	0.541	0.156	3.580	<0.001
Depression	0.557	0.155	3.416	0.001
Somatization(SSS-8)	0.883	0.250	6.311	<0.001