Data driven identification and classification of Chinese medicine syndrome types among functional dyspepsia patients: latent tree analysis (abridged secondary publication)

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KEY MESSAGES

1. Eight pattern differentiation rules for functional dyspepsia were derived by latent tree analysis using data from 250 and 150 patients in Hong Kong and Hunan, respectively.
2. At least one traditional Chinese medicine diagnostic pattern was identified in 70.7%, 73.6%, and 64.0% of the participants in the overall (n=400), Hong Kong (n=250), and Hunan (n=150) samples, respectively.
3. Cold-heat complex (59.8%) and liver qi invading the stomach (77.1%) were the most prevalent diagnostic patterns in Hong Kong and Hunan samples, respectively.
4. Spleen-stomach deficiency cold was highly likely to co-exist with spleen-stomach qi deficiency.
5. Participants with severe anxiety tended to exhibit liver qi invading the stomach.

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Introduction

Functional dyspepsia (FD) is a disorder of gut-brain interaction characterised by postprandial fullness, early satiety, epigastric burning, and/or epigastric pain. These symptoms are unexplainable by routine gastrointestinal examinations such as oesophagogastroduodenoscopy and *Helicobacter pylori* testing. Predominant postprandial fullness and early satiety are classified as postprandial distress syndrome (PDS), a subtype of FD, whereas predominant epigastric burning and epigastric pain are classified as epigastric pain syndrome (EPS), another subtype of FD. Patients with FD may also exhibit an overlapping PDS and EPS subtypes.

The symptoms of FD resemble those of stomach pain and stomach stuffiness and fullness, observed in traditional Chinese medicine (TCM). Herbal medicine is recommended, and its effectiveness has been supported by network meta-analyses.[1,2] A key difference between TCM and conventional medicine is that treatment strategies in TCM are guided by pattern differentiation, which involves comprehensive analysis of a patient's clinical features to determine the location, cause, and nature of disease. Nonetheless, standardised rules for pattern differentiation have not been established for any medical conditions. Thus, the TCM diagnostic process is likely to have low inter-rater agreement, leading to substantial variations in diagnostic-to-treatment decisions and quality of care. The incorporation of pattern differentiation into TCM clinical research is also hindered by the lack of standardised TCM diagnostic instruments. Variations in TCM diagnostic patterns across

different clinical and geographical characteristics suggest that the use of a single standardised diagnostic instrument is not always appropriate.

In this diagnostic cross-sectional study of FD patients, we aimed to (1) establish score-based differentiation rules using latent tree analysis, (2) identify co-existing TCM diagnostic patterns and their distributions, (3) assess associations between TCM diagnostic patterns for FD and common comorbidities, and (4) compare the prevalences of individual TCM diagnostic patterns in Hong Kong and Hunan, as well as geographical variations in clinical features constituting the same patterns.

Methods

We recruited consecutive patients with FD who presented to the gastrointestinal outpatient departments of Prince of Wales Hospital in Hong Kong (n=250) or Xiangya Hospital in Hunan (n=150) between December 2020 and May 2021. Patients were screened for eligibility by trained TCM practitioners; medical records were then reviewed to confirm eligibility. Inclusion criteria were (1) completion of oesophagogastroduodenoscopy within 10 years with *H pylori*–negative results, or a history of *H pylori* positivity with completed eradication therapy; (2) presence of symptoms that met the reference standard for FD without subtype restrictions (ie, PDS, EPS, or overlapping); (3) age ≥18 years; and (4) provision of written informed consent. Exclusion criteria were (1) a diagnosis of organic oesophageal or gastric disease within the preceding month (including oesophagitis, gastro-oesophageal reflux disease, peptic ulcer, and predominant heartburn or acid regurgitation); (2) presence of unremoved stomach polyps; (3) a history of major abdominal surgery (ie, appendectomy, gastrectomy, gastric lymph node removal, cholecystectomy, or abdominal cancer removal); (4) pregnancy at the time of enrolment; (5) presence of major physical illness (ie, malignancy or serious infection); or (6) refusal to provide written informed consent.

Participants were asked to complete an online questionnaire consisting of four sections. The first section collected data regarding basic demographic and clinical characteristics. The second section evaluated FD subtype (using the Ford et al reference standard for FD) and irritable bowel syndrome status (using the Rome IV Diagnostic Questionnaire for Adult Functional Gastrointestinal Disorders). The third section contained a 55-item Traditional Chinese Medicine Clinical Feature Questionnaire for Functional Dyspepsia (TCMQ-FD), which was designed to collect self-reported clinical feature data. Participants were asked to rate the severity of each clinical feature on a five-point Likert scale; a higher numerical rating indicated greater severity. To facilitate identification of TCM diagnostic patterns, the questionnaire items were developed using two sources: (1) a systematic review of TCM diagnostic instruments for FD[3] and (2) the 2017 Chinese Medicine Expert Consensus on Functional Dyspepsia Diagnosis in China. The fourth section assessed psychiatric comorbidities and disease-specific quality of life. Depression and anxiety symptoms were measured by validated Chinese versions of the Patient Health Questionnaire-9 and General Anxiety Disorder-7, respectively. Disease-specific quality of life was evaluated using the validated Chinese version of the Nepean Dyspepsia Index (NDI).

Data of TCMQ-FD from the overall (n=400), Hong Kong (n=250), and Hunan (n=150) samples were used to derive score-based pattern differentiation rules for TCM diagnostic patterns for FD. Latent tree analysis,[4] a quantitative approach consisting of five steps (Table 1), was conducted only for the overall sample. Pattern differentiation rules were derived for all three samples using soft labels.[5] Multivariate regression analyses were performed to assess correlations between individual TCM diagnostic patterns and between TCM diagnostic patterns and clinical and geographical variables.

Results

The basic characteristics of participants are presented in Table 2. Eight TCM pattern differentiation rules for FD were derived (Table 3): (1) spleen deficiency and qi stagnation, (2) cold-heat complex, (3) stomach heat, (4) liver qi invading the stomach, (5) spleen-stomach dampness-heat, (6) spleen-stomach qi deficiency, (7) spleen-stomach deficiency cold, and (8) spleen deficiency with dampness encumbrance. Using the derived pattern differentiation rules, at least one TCM diagnostic pattern was identified in 70.7%, 73.6%, and 64.0% of participants in the overall (n=400), Hong Kong (n=250), and Hunan (n=150) samples, respectively. Two or more diagnostic patterns were identified in 59.6% and 52.7% of participants in the Hong Kong and Hunan samples, respectively.

Spleen deficiency with dampness encumbrance was the most common TCM diagnostic pattern; its prevalence was 56.2%. Cold-heat complex and liver qi invading the stomach were the most common TCM diagnostic patterns in the Hong Kong (59.8%) and Hunan (77.1%) samples, respectively. Spleen-stomach dampness-heat was the least prevalent diagnostic pattern.

Of 14 pairs of TCM diagnostic patterns with positive association, three demonstrated exceptionally high adjusted odds ratios (AORs) [>5.00]: spleen-stomach deficiency cold plus spleen-stomach qi deficiency (AOR=53.23, 95% confidence interval [CI]=21.77-130.16) and their reverse pairing (AOR=49.61, 95% CI=20.96-117.44), spleen

TABLE 1. Latent tree analysis for traditional Chinese medicine (TCM) diagnostic patterns

Step	Procedure
Statistical pattern discovery	Build three independent global latent tree models in the Lantern software, choose the model with the best Bayesian information criterion score for subsequent steps, and obtain probabilistic co-occurring clinical features from each latent variable
Statistical pattern interpretation	Examine quantitative relationships between latent variables and clinical features constituting potential patterns by checking relevant probability distributions in the Lantern software, determine the TCM diagnostic pattern connotations for latent variables from a clinical perspective based on TCM expertise, and generate a list of potential TCM diagnostic patterns
Traditional Chinese Medicine diagnostic pattern identification	Based on TCM expertise, select only potential TCM diagnostic patterns that contain all essential clinical features for subsequent steps; discard patterns that do not contain all essential clinical features
Traditional Chinese Medicine diagnostic pattern quantification	Construct a latent tree model for each selected TCM diagnostic pattern in the Lantern software
Traditional Chinese Medicine pattern differentiation rule derivation	Use latent tree models to classify participants, assign a soft label to each participant based on the probability of exhibiting each TCM diagnostic pattern, and derive score-based differentiation rules according to a Naïve Bayes approach

TABLE 2. Baseline characteristics of participants

Baseline characteristic	Hong Kong sample (n=250)	Hunan sample (n=150)
Age, y	51.4±13.0	45.2±13.7
No. (%) of women	199 (79.6)	101 (67.3)
Body mass index, kg/m^2	20.8±7.7	22.1±4.6
Duration of symptoms, y	3.6±5.3	2.3±3.4
Functional dyspepsia symptom subtype		
Postprandial distress syndrome only	70 (28.0)	28 (18.7)
Epigastric pain syndrome only	18 (7.2)	28 (18.7)
Overlapping	162 (64.8)	94 (62.6)
Self-reported duration of symptoms, y		
≥5	57 (22.8)	18 (12.0)
<5	193 (77.2)	132 (88.0)
Patient Health Questionnaire score	7.0±4.9	7.1±6.4
Depression (cut-off=10)	67 (26.8)	51 (34.0)
Generalised Anxiety Disorder score¶	5.8±5.3	6.6±5.7
Anxiety (cut-off=10)	47 (18.8)	41 (27.3)
Nepean Dyspepsia Index		
Symptom severity	44.8±27.7	53.6±32.6
Eating/drinking	64.0±23.2	68.9±24.4
Sleep	62.9±29.6	67.8±30.0
Knowledge/control	70.2±21.0	67.7±24.7
Interference	69.3±20.0	70.2±21.7
Total quality of life score	66.6±20.0	68.6±21.6
Concomitant irritable bowel syndrome	45 (18.0)	26 (17.3)

deficiency and qi stagnation plus spleen-stomach deficiency cold (AOR=8.73, 95% CI=3.52-21.68) and their reverse pairing (AOR=8.66, 95% CI=3.52-21.30), and spleen deficiency and qi stagnation plus cold-heat complex (AOR=6.07, 95% CI=2.86-12.90) and their reverse pairing (AOR=6.03, 95% CI=2.84-12.80).

Compared with Hunan sample, Hong Kong sample was more likely to experience spleen deficiency and qi stagnation (AOR=2.59, 95% CI=1.05-6.40), spleen deficiency with dampness encumbrance (AOR=2.34, 95% CI=1.15-4.74), and cold-heat complex (AOR=2.23, 95% CI=1.18-4.21). Compared with participants with the overlapping subtype, those with the PDS subtype were more likely to have spleen-stomach qi deficiency (AOR=3.20, 95% CI=1.07-9.59). Participants with liver qi invading the stomach were likely to have a higher burden of anxiety symptoms (AOR=1.20, 95% CI=1.08-1.33). Regarding disease-specific quality of life, participants with spleen deficiency and qi stagnation (AOR=1.03, 95% CI=1.01-1.05) and stomach heat (AOR=1.02, 95% CI=1.01-1.03) were more likely to have higher NDI symptom severity. Participants with spleen-stomach deficiency cold (AOR=1.04, 95% CI=1.01-1.07) and spleen-stomach dampness-heat (AOR=1.03, 95% CI=1.01-1.05) were more likely to have a higher quality of life in terms of eating and drinking. Participants with spleen deficiency with dampness encumbrance (AOR=1.04, 95% CI=1.01-1.06) were likely to have better knowledge and control over dyspeptic symptoms.

Discussion

At least one of the eight TCM pattern differentiation rules for FD was identified in 70.7% of the overall sample. However, the clinical appropriateness of this diagnostic approach should be validated in consultations, during which diagnostic decisions can be confirmed, adjusted, or rejected based on

TABLE 3. Score-based differentiation rules of traditional Chinese medicine diagnostic patterns for functional dyspepsia in the three samples

Overall sample (n=400)		Hong Kong sample (n=250)		Hunan sample (n=150)	
Clinical feature	**Score**	**Clinical feature**	**Score**	**Clinical feature**	**Score**
Spleen deficiency and qi stagnation					
Distension and fullness in the stomach	5.5	Distension and fullness in the stomach	7.6	Distension and fullness in the stomach	3.5
Oppression in the chest	4.2	Oppression in the chest	5.3	Lack of strength	2.9
Lack of strength	3.6	Lack of strength	4.1	Reluctance to speak	2.8
Reluctance to speak	3.6	Reluctance to speak	3.9	Oppression in the chest	2.6
Torpid intake	2.2	Torpid intake	1.8	Torpid intake	2.6
Lassitude of spirit	1.9	Belching	1.5	Lassitude of spirit	2.5
Belching	1.5	Lassitude of spirit	1.4	Belching	1.4
Unformed stools	0.9	Unformed stools	0.8	Unformed stools	0.8
Cold-heat complex					
Signs and symptoms exacerbated by pressure	6.9	Signs and symptoms exacerbated by pressure	7.6	Borborygmus	8.3
Borborygmus	6.5	Borborygmus	6.0	Signs and symptoms exacerbated by pressure	6.0
Bitter taste in the mouth	4.7	Bitter taste in the mouth	5.5	Vomiting and nausea	4.0
Signs and symptoms exacerbated by ingestion	4.3	Signs and symptoms exacerbated by ingestion	5.5	Bitter taste in the mouth	4.0
Gastric upset	4.0	Gastric upset	4.4	Unformed stools	3.2
Vomiting and nausea	3.5	Vomiting and nausea	3.1	Signs and symptoms exacerbated by ingestion	3.1
Unformed stools	3.0	Unformed stools	2.9	Gastric upset	2.5
Signs and symptoms exacerbated by cold	2.5	Signs and symptoms exacerbated by cold	2.7	Dry mouth	2.4
Dry mouth	2.2	Dry mouth	1.9	Signs and symptoms exacerbated by cold	2.2
Stomach heat					
Burning sensation in the stomach	9.6	Bitter taste in the mouth	8.5	Burning sensation in the stomach	7.7
Acid vomiting	8.5	Burning sensation in the stomach	7.7	Acid vomiting	6.9
Bitter taste in the mouth	7.7	Acid vomiting	6.2	Bitter taste in the mouth	6.6
Gastric upset	4.1	Fetid mouth odour	4.9	Gastric upset	5.6
Dry mouth	3.8	Gastric upset	3.7	Dry mouth	4.2
Fetid mouth odour	3.4	Dry mouth	3.6	Swift digestion with rapid hungering	2.7
Swift digestion with rapid hungering	3.2	Swift digestion with rapid hungering	3.6	Constipation	2.6
Yellowish urine	2.6	Yellowish urine	3.0	Fetid mouth odour	2.0
Constipation	2.4	Constipation	2.2	Poor sleep quality	2.0
Poor sleep quality	1.8	Poor sleep quality	1.7	Yellowish urine	1.8
Liver qi invading the stomach					
Depressed mood	10.7	Depressed mood	11.9	Depressed mood	7.0
Oppression in the chest	7.6	Oppression in the chest	8.3	Oppression in the chest	5.7
Acid vomiting	5.8	Acid vomiting	7.8	Acid vomiting	4.3
Irritability	4.7	Irritability	4.9	Irritability	4.2
Vomiting and nausea	3.5	Distension and fullness in the hypochondrium	3.3	Vomiting and nausea	4.0
Distension and fullness in the hypochondrium	3.4	Vomiting and nausea	2.9	Signs and symptoms exacerbated by mood	3.6
Signs and symptoms exacerbated by mood	2.9	Signs and symptoms exacerbated by mood	2.7	Distension and fullness in the hypochondrium	3.0
Hiccup	2.1	Distension and fullness in the stomach	0.7	Belching	2.5
Distension and fullness in the stomach	1.1	Hiccup	0.6	Hiccup	2.2
Belching	0.5	Belching	-0.3	Distension and fullness in the stomach	1.7

TABLE 3. (cont'd)

Overall sample (n=400)		Hong Kong sample (n=250)		Hunan sample (n=150)	
Clinical feature	**Score**	**Clinical feature**	**Score**	**Clinical feature**	**Score**
Spleen-stomach dampness-heat					
Tenesmus	7.6	Tenesmus	8.1	Tenesmus	6.9
Passing stools with difficulty	5.0	Passing stools with difficulty	6.1	Unformed stools	4.0
Unformed stools	4.8	Unformed stools	5.3	Diarrhoea	3.8
Foul-smelling stools	3.9	Foul-smelling stools	4.4	Passing stools with difficulty	3.4
Diarrhoea	3.4	Diarrhoea	3.3	Foul-smelling stools	3.1
Yellowish urine	2.0	Borborygmus	2.2	Yellowish urine	1.8
Borborygmus	1.9	Yellowish urine	2.1	Vomiting and nausea	1.4
Vomiting and nausea	1.4	Thirst without desire to drink	1.6	Borborygmus	1.1
Thirst without desire to drink	1.0	Vomiting and nausea	1.4	Torpid intake	-0.4
Torpid intake	-0.1	Torpid intake	0.0	Thirst without desire to drink	0.0
Spleen-stomach qi deficiency					
Reluctance to speak	8.6	Lack of strength	9.9	Lack of strength	6.2
Lack of strength	8.1	Reluctance to speak	8.8	Reluctance to speak	5.5
Stomach heaviness	5.5	Sallow complexion	6.5	Stomach heaviness	4.6
Sallow complexion	5.4	Stomach heaviness	5.4	Sallow complexion	4.1
Undigested food in stools	3.8	Undigested food in stools	4.6	Lassitude of spirit	4.0
Hard stools followed by soft stools	3.8	Hard stools followed by soft stools	4.5	Weight loss	3.1
Weight loss	3.0	Foul-smelling stools	2.7	Hard stools followed by soft stools	2.9
Lassitude of spirit	2.9	Lassitude of spirit	2.6	Undigested food in stools	2.8
Foul-smelling stools	2.3	Weight loss	2.3	Torpid intake	2.6
Unformed stools	1.6	Signs and symptoms relieved by pressure	1.9	Foul-smelling stools	1.8
Signs and symptoms relieved by pressure	1.6	Unformed stools	1.8	Unformed stools	1.4
Torpid intake	1.3	Torpid intake	0.4	Signs and symptoms relieved by pressure	1.2
Spleen-stomach deficiency cold					
Reluctance to speak	8.1	Lack of strength	8.0	Reluctance to speak	5.3
Lack of strength	6.5	Reluctance to speak	7.3	Lack of strength	5.0
Sallow complexion	3.9	Sallow complexion	4.6	Body heaviness	3.5
Body heaviness	3.4	Bland taste in the mouth	3.6	Lassitude of spirit	3.4
Bland taste in the mouth	2.9	Body heaviness	3.3	Sallow complexion	3.1
Lassitude of spirit	2.7	Lassitude of spirit	2.4	Torpid intake	2.5
Dull pain in the stomach	2.1	Cold hands and feet	2.2	Bland taste in the mouth	2.2
Aversion to cold	2.1	Dull pain in the stomach	2.1	Aversion to cold	2.1
Cold hands and feet	1.8	Aversion to cold	2.1	Dull pain in the stomach	1.9
Signs and symptoms exacerbated by cold	1.7	Signs and symptoms exacerbated by cold	2.0	Signs and symptoms exacerbated by cold	1.5
Signs and symptoms relieved by pressure	1.5	Signs and symptoms relieved by pressure	1.8	Cold hands and feet	1.4
Torpid intake	1.2	Unformed stools	0.7	Signs and symptoms relieved by pressure	1.2
Unformed stools	0.8	Torpid intake	0.5	Unformed stools	0.9
Spleen deficiency with dampness encumbrance					
Unformed stools	5.2	Unformed stools	5.4	Tenesmus	4.7
Tenesmus	4.8	Bland taste in the mouth	5.4	Unformed stools	4.6
Bland taste in the mouth	4.4	Tenesmus	4.9	Bland taste in the mouth	3.5
Excessive phlegm or salivation	4.4	Excessive phlegm or salivation	4.8	Foul-smelling stools	3.5
Foul-smelling stools	3.8	Passing stools with difficulty	4.3	Excessive phlegm or salivation	3.5
Vomiting and nausea	3.7	Foul-smelling stools	3.9	Vomiting and nausea	3.3
Passing stools with difficulty	3.6	Vomiting and nausea	3.8	Diarrhoea	3.0
Heavy-headedness	3.2	Heavy-headedness	3.4	Heavy-headedness	2.7
Dizziness	2.7	Dizziness	3.4	Passing stools with difficulty	2.5
Diarrhoea	2.7	Foreign body sensation in the throat	2.6	Borborygmus	2.3
Borborygmus	2.5	Borborygmus	2.5	Foreign body sensation in the throat	2.2
Foreign body sensation in the throat	2.5	Body heaviness	2.5	Body heaviness	2.2
Body heaviness	2.4	Diarrhoea	2.4	Dizziness	2.0
Thirst without desire to drink	1.6	Thirst without desire to drink	1.5	Thirst without desire to drink	1.6
Torpid intake	0.8	Torpid intake	0.5	Torpid intake	1.2

additional information from physical examinations, as well as pulse and tongue assessments. TCM diagnostic patterns for FD could be incorporated into computer-aided TCM diagnostic systems. This could streamline clinical decision-making by generating patient-specific recommendations based on clinical information and comorbidities, improve quality of care through accurate diagnoses and treatments, and update TCM practitioners about new evidence on diagnostic methods and treatment strategies. Nevertheless, implementation assessments are necessary to evaluate the capacity and preparedness of TCM practitioners and healthcare organisations in adopting these digital health applications.

There are limitations to this study. First, the TCMQ-FD only considers clinical features from the preceding 2 weeks; it may not capture the dynamic nature of TCM diagnostic patterns. Therefore, patients should complete the questionnaire immediately before follow-up consultations to facilitate accurate diagnoses. Second, although pulse and tongue features are essential for TCM diagnosis, these were not included in the latent tree analysis because of the lack of automated diagnostic apparatuses to objectively acquire such data. Third, the pattern differentiation rules derived from Hong Kong and Hunan samples may not be generalisable populations outside of these two regions. Fourth, climate may influence the distribution of TCM diagnostic patterns in a geographical region; the results might have differed if this study were conducted in summer when dampness is the dominant qi of the season.

To address these limitations, future research should focus on developing instruments that can reliably quantify tongue and pulse diagnostic features. Next, multicentre diagnostic cross-sectional studies should be conducted to collect TCMQ-FD data along with instrument-measured pulse and tongue data for assessment of geographic variation in TCM diagnostic patterns. Sampling and data collection during different seasons would help to quantify possible variability in diagnostic patterns attributable to climate factors. Incorporation of validated TCM diagnostic instruments into artificial intelligence–powered electronic health records could facilitate continuous monitoring of intra-patient diagnostic changes and support the development of prognostic models to inform treatment decisions.

Although the latent tree analysis demonstrated good performance in this study, its applicability among more complex patients with higher co-morbidity burdens is unclear. For example, in patients with dual complaints of FD and anxiety disorder, it is unclear whether the use of TCMQ-FD alone is sufficient, or whether an additional anxiety disorder–specific TCM diagnostic instrument is needed. According to classical TCM theory, both FD and anxiety disorder may share a common pathogenesis of liver qi stagnation, suggesting that TCMQ-FD may be sufficient to guide treatment. However, when a patient presents with two distinct complaints (eg, FD and knee osteoarthritis), a separate TCM diagnostic tool is probably necessary. From a practical perspective, TCM practitioners need to prioritise which condition to address, considering the patient's preferences and values. Therefore, clinician experience and judgement remain essential for TCM diagnosis.

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1. Ho L, Xu Y, Zhang NL, et al. Quantification of prevalence, clinical characteristics, co-existence, and geographic variations of traditional Chinese medicine diagnostic patterns via latent tree analysis-based differentiation rules among functional dyspepsia patients. Chin Med 2022;17:101.
2. Ho L, Zhang NL, Xu Y, et al. Latent tree analysis for the identification and differentiation of evidence-based traditional Chinese medicine diagnostic patterns: a primer for clinicians. Phytomedicine 2022;106:154392.
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