



Validity and reliability of patient section of evidence-based medical records about doctor-patient building through integrated therapy of traditional Chinese and Western medicine (DPEBMR-P) in patients with gastrointestinal diseases

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Background: We developed an evidence-based medical record for doctor-patient relationship building through an integrated therapy of traditional Chinese and Western medicine (DPEBMR) to assess the efficacy in patients with digestive system diseases. The instrument was categorized into a doctor section and a patient section. In this article, our main goal was to test the validity and reliability of the patient's section for DPEBMR (DPEBMR-P).

Methods: One hundred patients were recruited. Doctors and patients used a predefined format to jointly record the illness. Cronbach's α and factor analysis were used to evaluate the reliability and structure validity, respectively.

Results: Cronbach's α of all 12 items from DPEBMR-P was 0.906, which demonstrated high reliability. The Kaiser-Meyer-Olkin value was 0.811 and Bartlett's spherical test value was 452.2 ($P < 0.05$), which meant it was suitable for performing factor analysis. A total of 3 items were identified as factors, and each had high loading: items of mental status (0.584 to 0.833), items of therapeutic effect (0.518 to 0.797), and items of appetite (0.857 to 0.882).

Conclusions: The DPEBMR-P indicated substantial reliability and structure validity.

Keywords: Gastrointestinal diseases; reliability; validity

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Introduction

The definition of health-related quality of life (HRQoL) is a multidimensional concept, which includes physical, mental, and social dimensions (1-4). The assessment of patients'

HRQoL could assist clinicians in evaluating the efficacy of the interventions. In the field of gastrointestinal diseases, there are many disease-specific HRQoL instruments; however, they all have limitations. For instance, GERD-

After one month's treatment, I feel that... (Please tick on the item you agree with)

	Sure	Sometimes like that	None
No. 1 At least two persons said I look good			
No. 2 I think I look good			
No. 3 I feel strength all over the body			
No. 4 At least two persons think I'm energetic when doing things			
No. 5 At least two persons think I'm not so irritable			
No. 6 I think I'm in a better mood			
No. 7 At least two persons said I eat more than before			
No. 8 I think I eat more than before			
No. 9 At least two persons said I had accept Traditional Chinese Medicine (TCM) treatment			
No. 10 I accept TCM treatment			
No. 11 At least two persons think I complain less of pain			
No. 12 I feel that there are less symptoms.			

Patient's signature	Date

Physician's signature	Date

Figure 1 Items of patient section of evidence-based medical record about doctor-patient building through integrated therapy of traditional Chinese and Western medicine (DPEBMR-P).

HRQL assessed the symptom's severity rather than HRQoL (5). The Reflux questionnaire mixed HRQoL and symptoms (6). GERD-QOL was a pure HRQoL instrument (7), but its social domain was vague, and it only recruited patients with GERD who had received esomeprazole.

To overcome these limitations, we developed a new instrument titled the evidence-based medical record about doctor-patient building through integrated therapy of traditional Chinese and Western medicine (DPEBMR) which could be applied in patients with gastrointestinal diseases who received any of the possible therapies. The instrument was categorized as into a doctor section and a patient section. In this article, our main goal was to test the validity and reliability of patients section for DPEBMR (DPEBMR-P).

Methods

The study measured the reliability and validity of the

DPEBMR-P among 98 patients with gastrointestinal diseases. DPEBMR-P contains 12 items, and the details of these items are in *Figure 1*.

Participants

The inclusion criteria were the following: adults with functional dyspepsia, gastroesophageal reflux disease, chronic non-atrophic gastritis, precancerous lesions of gastric carcinoma, peptic ulcers, irritable bowel syndrome, ulcerative colitis or chronic constipation which were diagnosed through gastroscopy, enteroscopy or biopsy. The exclusion criteria were the following: a diagnosis was made at least 6 months before, any co-morbidity with 2 or more systems, patients with major mental illness.

Interventions

The study did not restrict the treatment regimens of

included patients. However, our hospital had standard therapies for the relevant diseases. For patients who had *Helicobacter pylori* infections, they received quadruple therapy if they were allergic to amoxicillin. Otherwise, they were treated with a sequential therapy. More detailed information can be found in supplementary. For patients without *Helicobacter pylori* infection, Chinese traditional medicine (lianzhuliyi pill and huaganjian) was prescribed if they had no heartburn or regurgitation, or we chose step-down therapy—initial two weeks: proton pump inhibitor; following two weeks: Chinese traditional medicine (lianzhuliyi pill and huaganjian). For patients with precancerous lesions of gastric carcinoma, another Chinese traditional medicine (sijunzi soup, banxiaxiexin soup, xiaoyao powder, xiangsu drink and zhishu pill) was used.

Statistical analysis

All data were analyzed using the SAS software, version 9.2. All statistical inferences were made of two-sided test, and a value of $P < 0.05$ was considered to be statistically significant. For missing data, the Last Observation Carried Forward method was used to impute. The inter-item correlation matrix was performed to evaluate the repeatability of the item. Principal components factor analysis and Cronbach's alpha were used to calculate the construct validity and internal consistency, respectively. If the initial eigenvalue of the item was larger than 1, it was regarded as a factor (8). If the value of Cronbach's alpha was larger than 0.7, it meant internal consistency was high (9).

Results

Of the 100 patients recruited, 98 completed the fourth follow-up. The mean age of these patients was 48.6 (SD: 14.7). More than half of them were female (57.1%). Most of them (79.6%) received only traditional Chinese medicine (TCM), some (18.4%) accepted both TCM and western drugs, and the rest (2%) were treated by only western drugs. The results of the inter-item correlation matrix failed to find any large correlation coefficients among the different items, which indicated the repeatability of the item was low.

Construct validity

The score of the Kaiser-Meyer-Olkin Measure of Sampling Adequacy was 0.811 (more than 0.5), which indicated sufficient common factors among variables. Meanwhile, the

Bartlett's test of sphericity had a significant result ($P < 0.05$). Thus, it was appropriate to conduct a principal component factor analysis test. A total of 3 items were identified as factors, and they accounted for 68% of the total variance. Then, we conducted a principle component analysis test with a varimax rotation to test the 3 factors.

The results (*Table 1*) indicate that each item had a high loading: items of mental status (0.584 to 0.833), items of therapeutic effect (0.518 to 0.797), and items of appetite (0.857 to 0.882).

Internal consistency

Table 2 displays the results of the reliability test. The Cronbach's alpha for overall scale was 0.906 and sub-scales ranged from 0.894 to 0.905. Thus, DPEBMR-P had a high internal consistency.

Discussion

Our study developed a new 12-item instrument to assess the efficacy of therapies in patients with gastrointestinal diseases. The patient section has a high degree of internal consistency and construct validity.

Our study has several strengths: first, our study was a real-world study which means that the results can be applied more extensively in patients with gastrointestinal diseases. Moreover, previous studies only focused on specific patients: GERD (5-7,10,11), dyspepsia or irritable bowel syndrome (12), and esophagitis (13). Our tool was more practical than the previous ones. Furthermore, our study considered others' sayings towards patients which previous studies had paid little attention to. Previous studies even with the generic instrument SF-36 and the EQ-5D did not include the items related to what the others said towards the patients (14,15). However, our feelings or thoughts might be influenced by others' sayings (16). Thus, it is necessary to include items about what the others are saying because HRQoL as an instrument is a multidimensional tool which should include any factors which can influence the patients' health status. Finally, to the best of our knowledge, our study was the first to recruit patients who received TCM treatment. TCM has been proven to be an effective intervention in treating patients with GERD (17,18), and so it was necessary to include patients who received TCM.

Still, some limitations should be discussed. First of all, the sample size of our study was limited which might make the results unstable. However, our research was

Table 1 Factors loading

Item	Explanatory variable	Cumulative explanatory variable	Factor load capacity		
			Factor 1: mental status	Factor 2: curative effect	Factor 3: food intake
No. 3 I feel strength all over the body	24.833	24.833	0.833		
No. 2 I think I look good			0.820		
No. 4 At least two persons think I'm energetic when doing things			0.754		
No. 1 At least two persons said I look good			0.584		
No. 6 I think I'm in a better mood	24.275	49.108		0.797	
No. 10 I accept TCM treatment				0.778	
No. 11 At least two persons think I complain less of pain				0.604	
No. 9 At least two persons said I had accept traditional Chinese medicine (TCM) treatment				0.603	
No. 12 I feel that there are less symptoms				0.583	
No. 5 At least two persons think I'm not so irritable				0.518	
No. 7 At least two persons said I eat more than before	18.890	67.998			0.882
No. 8 I think I eat more than before					0.857
No. 3 I feel strength all over the body			2.980	2.913	2.267

Table 2 Results of reliability test

Item	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Squared multiple correlation	Cronbach's alpha if item deleted
No. 1 At least two persons said I look good	20.38	34.7	0.612	0.544	0.9
No. 2 I think I look good	20.56	34.866	0.708	0.675	0.895
No. 3 I feel strength all over the body	20.52	35.546	0.619	0.583	0.899
No. 4 At least two persons think I'm energetic when doing things	20.44	33.881	0.729	0.714	0.894
No. 5 At least two persons think I'm not so irritable	20.24	34.617	0.667	0.582	0.897
No. 6 I think I'm in a better mood	20.48	35.515	0.559	0.531	0.902
No. 7 At least two persons said I eat more than before	20.02	34.446	0.675	0.812	0.896
No. 8 I think I eat more than before	20.08	34.163	0.668	0.792	0.897
No. 9 At least two persons said I had accept traditional Chinese medicine (TCM) treatment	20.33	35.826	0.51	0.461	0.905
No. 10 I accept TCM treatment	20.98	37.431	0.608	0.507	0.901
No. 11 At least two persons think I complain less of pain	20.59	34.707	0.634	0.536	0.899
No. 12 I feel that there are less symptoms.	20.88	35.831	0.685	0.652	0.897

continuously performed, and we will recruit more patients in the future to make the results more robust. Also, the age range in our study was from 33.9 to 63.3. Thus, our results may not be applicable to older or younger patients.

Conclusions

DPEBMR-P is a useful tool to assess the efficacy of therapies in patients with gastrointestinal diseases.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by Ethics Committee from Xiyuan Hospital, China Academy of Traditional Chinese Medicine.

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Details of therapies

H. pylori test: positive. Initially, patients received eradication (Table S1).

If patients are sensitive to amoxicillin: quadruple chemotherapy for *Helicobacter pylori* infection (Table S2).

Table S1 Sequential therapy for helicobacter pylori infection

Medicine	Dosage	Direction (take orally)	Medication time (morning)	Medication time (night)	Before/after meal
1–7 day					
Rabeprazole sodium/ pantoprazole/omeprazole enteric tablet	20 mg	Twice	6 am	6 pm	Before
Colloidal bismuth subcitrate	0.3 g	Twice	6 am	6 pm	Before
Amoxicillin	1 g	Twice	8 am	8 pm	After
8–14 day					
Rabeprazole sodium/ pantoprazole/omeprazole enteric tablet	20 mg	Twice	6 am	6 pm	Before
Colloidal bismuth subcitrate	0.3 g	Twice	6 am	6 pm	Before
Carat enzyme dispersible tablets	0.5 g	Twice	8 am	8 pm	After
Tinidazole	0.5 g	Twice	8 am	8 pm	After

Table S2 Sequential therapy for helicobacter pylori infection in patients sensitive to amoxicillin

Medicine (1–14 day)	Dosage	Direction (take orally)	Medication time (morning)	Medication time (night)	Before/after meal
Rabeprazole sodium/pantoprazole/ omeprazole enteric tablet	20 mg	Twice	6 am	6 pm	Before
Colloidal bismuth subcitrate	0.3 g	Twice	6 am	6 pm	After
Carat enzyme dispersible tablets	0.5 g	Twice	8 am	8 pm	After
Tinidazole	0.5 g	Twice	8 am	8 pm	After