Reliability, validity and responsibility of the Postoperative Clinical Evaluation Criteria for Gastrointestinal Motility

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Research

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Abstract

Background and purpose

Abdominal surgery is the main department of gynaecology operation. Accelerating the recovery of gastrointestinal function after surgery can not only make patients early recovery diet, but also can reduce the common complications such as pelvic adhesion. It's important to the rehabilitation and prognosis of patients. The Chinese medicine has been proven to accelerate the recovery of bowel function after the gynecologic abdominal surgery. Most of the indicators used to evaluate gastrointestinal motility recovery are scattered, and there is no standardized evaluation criterion so far. We found that there is not a scale for evaluating the gastrointestinal motility in perioperative period after reviewing a large number of literatures. The Postoperative Clinical Evaluation Criteria for Gastrointestinal Motility (PCECGM) became the local standard of Guangdong province (DB44/t 1581-2015) issued by the quality supervision bureau of Guangdong province in 2015, and a clinical evaluation now is necessary.

Study design

Cohort study (Diagnostic); Level of evidence, 2.

Methods

This prospective study was performed in the department of gynecology department at the Guangdong Province Traditional Medical Hospital from Mar. 2015 and Jun. 2017. Patients who diagnosed with benign lesion after laparoscopic total hysterectomy were included in this study. The purpose of this research was to evaluate reliability, validity and responsiveness of the PCECGM.

Results

202 patients were included in this study, and the response , completion rate, complete time of the scale were 100%, 99.01% and 95.49 16.69 min, showing the good acceptability. The Cronbach's Alpha coefficient and spearman-brown were 0.62 and 0.71 respectively. KMO is 0.58, and Bartlett's Test of Sphericity is 181.01, P<0.001. Two factors were extracted according to the factor analysis, and the cumulative contribution rate is 56.33%. The total score of the patients after treatment was significantly higher, P<0.001, and standardized effect value and standardized reaction mean were all 1.32, indicating a high degree of reactivity.

Conclusions

The properties of "Postoperative clinical evaluation criteria for gastrointestinal motility" are acceptable. It is an effective tool for the evaluation of gastrointestinal motility after the gynecologic abdominal surgery. Introduction Perioperative gastrointestinal dysfunction refers to the perioperative gastrointestinal function of all aspects such as sports secretion defense digestion absorption excretion disorders or weakened. Gastrointestinal motility disorder is the main cause of postoperative gastrointestinal dysfunction. At present, there is no uniform standard for postoperative gastrointestinal motility evaluation in clinical

practice. It's important to the rehabilitation and prognosis of patients. The Postoperative Clinical Evaluation Criteria for Gastrointestinal Motility (PCECGM) became the local standard of Guangdong province (DB44/t 1581-2015) issued by the quality supervision bureau of Guangdong province in 2015.

Introduction

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At present, there is no uniform standard for postoperative gastrointestinal motility evaluation in clinical practice. It's important to the rehabilitation and prognosis of patients. The Postoperative Clinical Evaluation Criteria for Gastrointestinal Motility (PCECGM) became the local standard of Guangdong province (DB44/t 1581–2015) issued by the quality supervision bureau of Guangdong province in 2015.

Purpose

The purpose of this study was to evaluate the the reliability, validity and responsibility of PCECGM, so as to provide scientific evaluation criteria.

Materials And Methods

Participants

This prospective study was performed at the Guangdong Province Traditional Medical Hospital from Mar. 2015 and Jun. 2017. Patients with the following criteria were included in this study: 1) Patients who have undergone surgery for gastric or colorectal cancer, or hysterectomy for hysteromyoma; 2) Age, 40–75 years old; 3) Duration of surgery, 1–5 h; 4) Time under anesthesia, 1.5–4.5 h; 5) Provision of signed, informed consent.

Evaluation of measurement properties

The PCECGM contains 6 items related to time to first flatus, time to first defecation, time to first bowel sounds, time to consuming liquid/semi-liquid/general diet, abdominal distention and pain, nausea and vomiting. The score ranges from 0 to 100, and the higher scores, the better recovery of the gastrointestinal function.

The PCECGM reflects patients who make a subjective judgment about the meaning of change (improvement) following treatment. It is answered on a 3-point scale of 0 = not recovered; 10 = partial recovery; 20 = full recovery.

Measurement properties

We evaluated the acceptability, reliability, validity and responsibility of PCECGM. In addition, the quality of the PCECGM was also evaluated by current updated criteria for good measurement properties.

Acceptability

The feasibility is evaluated by the qualified, recovery and the average time required to fill in the form. Generally, it shows good acceptability when the qualified rate > 70% and recovery rate > 90%. The more concise the content is, the more understandable the topic language is, and the shorter the time it takes to fill in the form, the higher the acceptability of the subject.

Reliability

This domain contains three measurement properties, i.e., internal consistency, test-retest reliability, and measurement error. Internal consistency is considered as a measure of scale reliability and evaluates how closely related a set of items are as a group. Also, test-retest reliability is the closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement. To avoid testing patients with the unstable condition or occurring recall bias, the re-test was performed after 4 weeks after the primary test. At last, the measurement error was calculated by using the standard error of measurement (SEM).

Validity

This domain also contains three measurement properties, i.e., content validity, criterion validity and construct validity. Content validity mainly examines the measurement aim, the target population and the concepts of the questionnaire. Construct validity was assessed by testing predefined specific hypotheses; that is, how many results are in accordance with predefined hypotheses.

Responsiveness

Responsiveness has been defined as the ability of a questionnaire to detect clinically important change over time in the construct to be measured.

We calculated the PCECGM change scores of the between baseline (pre-surgery) and post-surgery with the time interval of 3 days.

Statistical analysis

All analyses were performed with the Epidata3.0 and calculated by SPSS20.0

Results

General Data Analysis

Age

The patients included in this survey were between 40 to 67 years old, among those 45 to 49 years old patients were the majority with a total of 97, accounting for 48.5%. (See Table 1 for details)

Table 1 The distribution of the patients' age

Age	40-44	45-49	50-54	55-59	60-64	65-69
Number of cases(Case)	27	97	48	17	9	2
Proportion (%)	13.50	48.50	24.00	8.50	4.50	1.00

Basic diseases and surgical history

36 out of the 200 patients were associated with various basic diseases, among them 4 were gastrointestinal diseases, accounting for 2% of the total. 61 out of the 200 patients had a history of various surgeries, including 49 cases involving pelvic and abdominal cavity surgery, accounting for 24.5%.

Major diseases of surgical treatment

The main disease of surgical treatment in 200 patients was uterine fibroids with a total of 131 cases, accounting for 65.5%; followed by adenomyosis, attachment lesions, endometrial lesions, cervical intraepithelial neoplasia, complete hydatidiform mole. (See Table 2 for details)

Table 2
Distribution of major diseases in surgical treatment

Disease name	**Uterus Fibroids**	**Myopathy endometrium**	**Cervical epithelium**	**Internal tumor attachment**	**Lesion completeness**	**Hydatidiform mole**
Number of cases(Case)	131	37	10	6	15	1
Proportion (%)	65.50	18.50	5.00	3.00	7.50	0.50

Anesthesia period, Surgery period, Postoperative exhaust time, Postoperative defecation time

The patient's anesthesia period in surgery varied from 1.25 to 5.25 hours; the surgery period were from 1.0 to 5.0 hours; the longest postoperative exhaust time (from the end of anesthesia to the first postoperative exhaust time, the same below) was 59.50 hours while the shortest was 12.03 hours; the longest postoperative defecation time was 98.83 hours and the shortest was 19.67 hours. (See Table 3 for details)

Table 3
Anesthesia period, surgery period, Postoperative exhaust and defecation time

	Anesthesia period	Surgery Period	Exhaust time	Defecation time
Average (hour)	3.20 ± 0.92	2.46 ± 0.76	26.69 ± 8.70	46.92 ± 15.41
Maximum (hour)	5.25	5.0	59.50	98.83
Minimum value (hour)	1.50	1.0	12.03	19.67

Postoperative hospital stay

The minimum of postoperative hospital stay was 3 days, and the longest was 14 days. The postoperative hospital stay was mainly 5 or 6 days, accounting for 25.5% and 30.5% separately. The cases of postoperative hospital stay less than 7 days accounted for 87%. (See Table 4 for details)

Table 4
Distribution of postoperative hospital stay

Postoperative hospital stay(day)	3	4	5	6	7	8	9	10	11	12	13	14
Number of cases (case)	9	28	51	61	25	11	6	1	3	2	1	2
Proportion (%)	4.5	14.0	25.5	30.5	12.5	5.5	3.0	0.5	1.5	1.0	0.5	1.0

Comparison between the traditional gastrointestinal motility evaluation index and the scale of the total score

The three traditional indicators of postoperative exhaustion, postoperative defecation, and postoperative bowel sound recovery status were compared with the scale of the total score. Table 5 shows that there were 29 patients who have not been vented on the first day after surgery. The scores of the scale were "normal" with 14 cases and "poor" with 15 cases, suggesting that clinical intervention was required for those who have not been vented on the first day after surgery; 171 cases vented on the first day after

surgery and 159 of them recovered “good”, suggesting that those patients should not be intervened temporarily regardless of postoperative bowel movements but observation required; All patients who were included in the observation were exhausted on the second day, 199 cases were classified as “good”, suggesting that those patients did not require clinical intervention with or without defecation, only 1 case was rated as “general” and the others were all recovered of "good", suggesting that only one person should be given appropriate intervention to promote gastrointestinal motility recovery.

In Table 6, it can be seen that the postoperative defecation patient scale scores were all "good", suggesting that patients with postoperative bowel movements can be considered to have good gastrointestinal function recovery. There are still 2 cases who had no bowel movements on the third day after surgery, but the scale were all "good", suggesting that these two people did not require clinical intervention, and all patients had bowel movements within 4 days after surgery.

In Table 7, it can be seen that there were 97 cases whose bowel sounds recovered to normal on the first day after surgery, and 9 of them were classified as “normal”, suggesting that some patients should be appropriately intervened to promote gastrointestinal motility recovery. There were 3 cases classified as “poor”, suggesting that although a minority of patients recovered to normal bowel sounds after surgery, certain interventions were required to promote their gastrointestinal motility recovery.

Table 5
Comparison of postoperative exhaustion and scale scores

	Postoperative exhaust situation	Number of people (n)	Scale scores ($\bar{x}$ ±S)	scale classification		
				Good (n)	Normal (n)	Poor (n)
the first day after surgery	No exhaust	29	54.14 ± 7.78	0	14	15
	Exhausted	171	86.14 ± 9.27	159	11	1
The second day after surgery	No exhaust	0	0	0	0	0
	Exhausted	200	97.05 ± 6.45	199	1	0

Table 6

Comparison of postoperative defecation and scale scores

	Postoperative defecation	Number of people (n)	Scale scores ($\bar{x}$±S)	scale classification		
				Good (n)	Normal (n)	Poor (n)
the first day after surgery	no defecation	145	75.24 ± 11.77	104	25	16
	Have a bowel movement	55	98.00 ± 4.43	55	0	0
The second day after surgery	no defecation	32	82.97 ± 7.26	31	1	0
	Have a bowel movement	168	99.73 ± 1.57	168	0	0
The third day after surgery	no defecation	2	82.5 ± 2.50	2	0	0
	Have a bowel movement	198	100 ± 0	198	0	0
The forth day after surgery	no defecation	0	0	0	0	0
	Have a bowel movement	200	100 ± 0	0	0	0

Table 7

Comparison of postoperative bowel sound recovery and scale scores

	Postoperative recovery of bowel sounds	Number of people (n)	Scale scores ($\bar{x}$±S)	scale classification		
				Good (n)	Normal (n)	Poor (n)
the first day after surgery	None	2	45.00 ± 10.00	0	0	2
	weakened	101	74.50 ± 11.74	74	16	11
	Normal	97	89.54 ± 11.95	85	9	3
The second day after surgery	None	0	0	0	0	0
	weakened	16	83.44 ± 7.23	15	1	0
	Normal	184	98.23 ± 4.81	184	0	0

Characteristics evaluation results of gastrointestinal motility evaluation specifications after perioperative period

Feasibility

Acceptance rate

This study was conducted by a gynaecologist as an investigator with the one-on-one questionnaire. The questionnaire was finished between every one specialist and one patient. The questionnaire was issued in 202 copies and 202 were recovered. The recovery rate was 100%.

Completion rate

Since this scale is for gynecological specialist on-site interview and physical examination, and then filled out by specialist doctors, only 2 copies of the scale with a completion rate of less than 95%, the total completion rate is about 99.01%. In the analysis, 200 scales were used after deleting those two copies.

Completion time

The minimum completion time of this scale is 61 seconds, the longest is 120 seconds, and the average time is 95.49 seconds. Therefore, the completion time of the scale is (95.49 ± 16.69) seconds.

Based on the data above, the recovery rate of the gastrointestinal motility after perioperative period scale was 100%, the completion rate of the scale was 99.01%, and the completion time of the scale was (95.49 ± 16.69) seconds. From the data above, the scale is of good acceptability.

Reliability

Cronbach's Alpha

The total Cronbach's Alpha coefficient of this scale is 0.519, and the Alpha coefficient calculated after standardization is 0.620, which is between 0.60 and 0.65, suggesting that the reliability of this scale is among the acceptable range. (See Table 8)

Table 8 Total Cronbach alpha coefficient of the scale

Cronbach’s Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
0.516	0.620	6

Split-half reliability coefficient

Spearman-Brown formula is used to calculate the split-half reliability coefficient of the scale. The items are divided into two parts according to odd and even order. The unequal-length Spearman-Brown is 0.706, split-half reliability is between 0.7 and 0.8, indicating that the split-half reliability of the scale is better (see Table 9).

Table 9
split-half reliability of the scale

	N of Items	Cronbach's Alpha	Spearman-Brown Equal Length	Coefficient Unequal Length
Part 1	3	0.250	0.706	0.706
Part 2	3	0.098		
Note: Part 1: anal exhaust, bowel sounds, nausea; Part 2: anal defecation, abdominal pain, vomit.				

Sensitivity analysis of the item

The sensitivity analysis of the item is to remove one of the items in the scale and then calculate its Cronbach's Alpha coefficient. If the value of the coefficient is larger, the influence of the item on the relevant statistics is greater. Thus, this item is the first consideration of adjustment [96]. The sensitivity of the item "vomiting" in this scale is low and is an item that can be considered for optimization after the perioperative gastrointestinal motility scale. (See Table 10)

Table 10
Sensitivity analysis of item

	Remove the mean of the total score of the current item scale	Remove the variance of the total score of the current item scale.	Remove the Cronbach's Alpha coefficient of the total score of the current item scale.
1. Anal exhaust	63.325	104.090	0.414
2. Anal defecation	76.300	119.407	0.471
3. Bowel sound	69.250	166.018	0.419
4. Abdominal pain	62.125	159.909	0.427
5. Disgust	65.675	200.421	0.512
6. Vomit	65.450	207.585	0.531

Validity

Face validity and content validity

During the preparation of this scale, the Chinese and foreign databases were reviewed, including CNKI, CQVIP, Wanfang, China Biomedical Literature Database, Medline, Pubmed, EMBASE, etc.. A large number of Chinese and Western medical literatures were obtained, among which there is a total of 1640 articles were retrieved and read, among which 687 articles related to postoperative gastrointestinal motility evaluation index. Relevant evaluation indicators were extracted and entered into the database to obtain 9 symptoms and signs.

This evaluation specification has gradually formed through eight rounds of expert consultation: after the first round of expert consultation, bowel sounds, anal exhaust, anal defecation, abdominal distension, nausea and vomiting were the main clinical evaluation indicators; after the second round of experts consultation, the subjective and objective indicators were scored according to the 20-point scale, and the scores of “bloating” were greater than “disgusting” and “vomiting”, and “anal exhaust” was greater than “intestinal sounds” and “anal defecation”; after the third round of expert consultation, the index of each indicator and the corresponding score are determined, and the comprehensive evaluation criteria are determined as “good” (80-100 points), “normal” (60-79 points), and “poor” (0-59 points); the evaluation criteria indicators formed by the fourth and fifth rounds of expert consultation (ie, preliminary evaluation specifications); and the sixth to eighth round of expert consultations formed the draft standard for evaluation. The draft was evaluated by a small sample clinical evaluation related disciplines such as surgery, gynecology, orthopedics and etc.. The data show that the evaluation results of the standard are consistent with the evaluation results of postoperative exhaust and defecation indicators. At the same time, it is possible to scientifically evaluate the comprehensive recovery of gastrointestinal function in patients after surgery, including not only the objective indicators of postoperative anal exhaust, defecation, and the time of bowel sounds recovering to normal, but also the recovery of subjective indicators such as nausea, vomit, and abdominal pain. In the case, the recovery of gastrointestinal function reflected is more comprehensive and comprehensive. This form was submitted to the Provincial Quality Supervision Bureau after being approved by the expert group. Finally, it was approved by the Provincial Quality Supervision Bureau on April 16, 2015 and officially implemented on July 16, 2015.

Structural validity

KMO test and Bartlett's spherical test

From Table 11, the KMO (Kaiser-Meyer-Olkin) value of the scale is 0.581, which is greater than 0.5, indicating the validity of the factor analysis. According to Kaiser (1974), the scale is suitable for factor analysis; in Bartlett's spherical test, the value of the test is 181.005, the free degree is 15, $P < 0.001$, indicating that the correlation coefficient matrix of the factor is a non-integral matrix, which can extract the

least factor at the same time and explain most of the variance, suggesting validity. (See Table 11 for details)

Table 11
KMO test of the scale and Bartlett's spherical test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy	Bartlett's Test of Sphericity		
	Approx. Chi-Square	df	P
0.581	181.005	15	<0.001

Factor analysis

The principal component analysis method and the maximum variance rotation method were used to analyze the factors. It can be seen from the following table that the factor is extracted according to the characteristic value > 1, two common factors are extracted, and the cumulative contribution rate is 56.331% (see Table 12 for details). After the revolve of the shaft, they were combined into two types of factors, the subjective symptom factor and the objective symptom factor, covering the main contents of the scale, suggesting that the structure of the scale is good (see Table 13). As can be seen from Table 16, the first common factor is the subjective symptom factor (including abdominal pain, nausea, vomit), and the second common factor is the objective symptom factor (including exhaust, defecation, bowel sounds).

Table 12
Factor analysis of the scale

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total
1	2.116	35.273	35.273	2.116	35.273	35.273	1.859
2	1.263	21.057	56.331	1.263	21.057	56.331	1.734
3	0.889	14.819	71.150				
4	0.833	13.883	85.032				
5	0.480	7.994	93.026				
6	0.418	6.974	100.000				

Table 13
Common factor extraction results after maximal variance of all factors revolved

Item	factor 1	factor 2
Postoperative exhaust		0.515
Postoperative defecation		0.814
Postoperative abdominal pain score	0.740	
Postoperative nausea score	0.801	
Postoperative vomiting score	0.606	
Postoperative bowel sounds		0.788
Extraction Method: Principal Component Analysis. Rotation Method: Promax with Kaiser Normalization. a. Rotation converged in 3 iterations.		

Analysis of reactivity

The paired rank sum test was performed on the total scores of the post-treatment and post-treatment scales of the postoperative patients. The original hypothesis indicates that the median of the difference between pre-treatment (ie, the first test total score on the first postoperative day) and the post-treatment (ie, the first, second and third postoperative day) was equal to 0, and $P < 0.001$ was calculated. The original hypothesis was rejected, indicating that there are significant statistical differences of the total score before treatment and the first day, the second day, and the third day after treatment (see Table 14–18 for details).

Table 14
The paired rank sum test of the third test of before treatment and the first day after treatment

N	Test Statistic	Standard Error	Standardized Test Statistic	P
200	780.00	66.23	5.89	< 0.001

Table 15
The paired rank sum test of the third test of before treatment and the second day after treatment

N	Test Statistic	Standard Error	Standardized Test Statistic	P
200	10270.00	487.51	10.51	< 0.001

Table 16
The paired rank sum test of the third test of before treatment and the third day after treatment

N	Test Statistic	Standard Error	Standardized Test Statistic	P
200	12246.00	553.55	11.06	< 0.001

Table 17
The paired rank sum test of the third test of the first day and second day after treatment

N	Test Statistic	Standard Error	Standardized Test Statistic	P
200	9284.50	455.26	10.16	< 0.001

Table 18
The paired rank sum test of the third test of the second day and third day after treatment

N	Test Statistic	Standard Error	Standardized Test Statistic	P
200	630.00	59.81	5.27	< 0.001

Standardized effect size (ES)

It is the ratio of the absolute value of the mean difference between before and after treatment to the standard deviation before treatment. It is calculated that the standardized effect value of the total score of this scale is 1.32, indicating that the scale has a high degree of reactivity.

Standardized response mean (SRM)

It is the ratio of the mean of the differences before and after treatment to the standard deviation of before and after treatment. It is calculated that the mean standard response of the main symptom scores of this scale is 1.32, which also indicates that the scale has a high degree of reactivity.

Discussion

Feasibility

In this study, the scale survey was conducted by gynecological clinicians during postoperative hospitalization, which could be conducted simultaneously with the daily ward rounds. The compliance of investigators and survey subjects was good, and the quality of filling in the form was controllable and the

recovery rate was high. The scale is concise and easy to understand. The average time spent on answering questions is 95.49 seconds, which does not take up too much time of investigators and survey subjects in clinical practice. All the above advantages indicate that the feasibility of this scale is good.

Reliability

The Cronbach's Alpha of this scale was 0.620. According to Robert f. DE Willis (2004), is the acceptable range. The low alpha coefficient of the scale is affected by the following factors: off-center average score, negative correlation between items, low item-scale correlation, weak correlation between items, and small variability in grades. The split-half reliability is to test the consistency between the two scales. The unequal-length Spearman-Brown is 0.706, split-half reliability is between 0.7 and 0.8, indicating that the split-half reliability of the scale is better. In addition, due to the improvement of surgical operation level, there are fewer patients with obvious gastrointestinal disorders after gynecological laparoscopic surgery, which may be one of the reasons for the low confidence coefficient in the sensitivity analysis of this test. In the future, we can increase the evaluation in clinical application of gynecological surgery with longer operation time and larger operation scope, such as malignant tumor surgery and gastrointestinal surgery, so as to improve the reliability by increasing the performance variability.

The total Cronbach's Alpha coefficient calculated after standardization is 0.620, and the unequal-length Spearman-Brown is 0.706, which can be considered that the scale has stability and reliability. For low sensitivity analysis, further studies are needed, and further gastrointestinal surgery samples can be taken for testing in the future.

Validity

In strict accordance with the preparation requirements of the scale, this evaluation standard has good surface validity after preliminary positioning, expert consultation and selection of items by clinical and scientific teams.

The principal component analysis method and the maximum variance rotation method were used to analyze the factors, and two common factors are extracted, and the cumulative contribution rate is 56.331%. The scale included the subjective symptom factor (including abdominal pain, nausea, vomit), and the objective symptom factor (including exhaust, defecation, bowel sounds), which covered all contents of the scale, suggesting that the scale was well structured.

Reactivity

In this study, we conducted oral Chinese medicine intervention for eligible patients. Intervention time was 9 and 16 points on the first day after surgery. The intervention method was oral Chinese medicine granules. Before intervention, the patients were evaluated for the first time (time: 08:00–08:30), and the score was

taken as the total score before treatment. Afterwards, they were evaluated on time as the score after treatment. In this study, paired rank sum test,standardized effect size and standardized response mean was performed after multiple time (longitudinal) retesting, and the results indicated that the scale had a high degree of response.

Abbreviations

PCECGM
Postoperative Clinical Evaluation Criteria for Gastrointestinal Motility
SEM
standard error of measurement
KMO
Kaiser-Meyer-Olkin
ES
Standardized effect size
SRM
Standardized response mean

Declarations

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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Contributions

ZC, LC and HG have made substantial contributions to conception and design, analysis and interpreted of data, and drafting the manuscript. ZJ and QC also help to analysed and interpreted some important data, conducted surveys and collected the data from patients. HG, ZL, ZJ and QC revising it critically for important intellectual content. ZC and LC have a role for funding and supervised the study. All authors read and approved the final manuscript.

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Ethics approval

The Ethical Committee of the Second Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine (Guangdong Provincial Hospital of Traditional Chinese Medicine) approved this study on 30 November 2012 (B2012-64-01). Written informed consent was obtained from all volunteers, and the study conformed to the ethical principles set forth by the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Figures

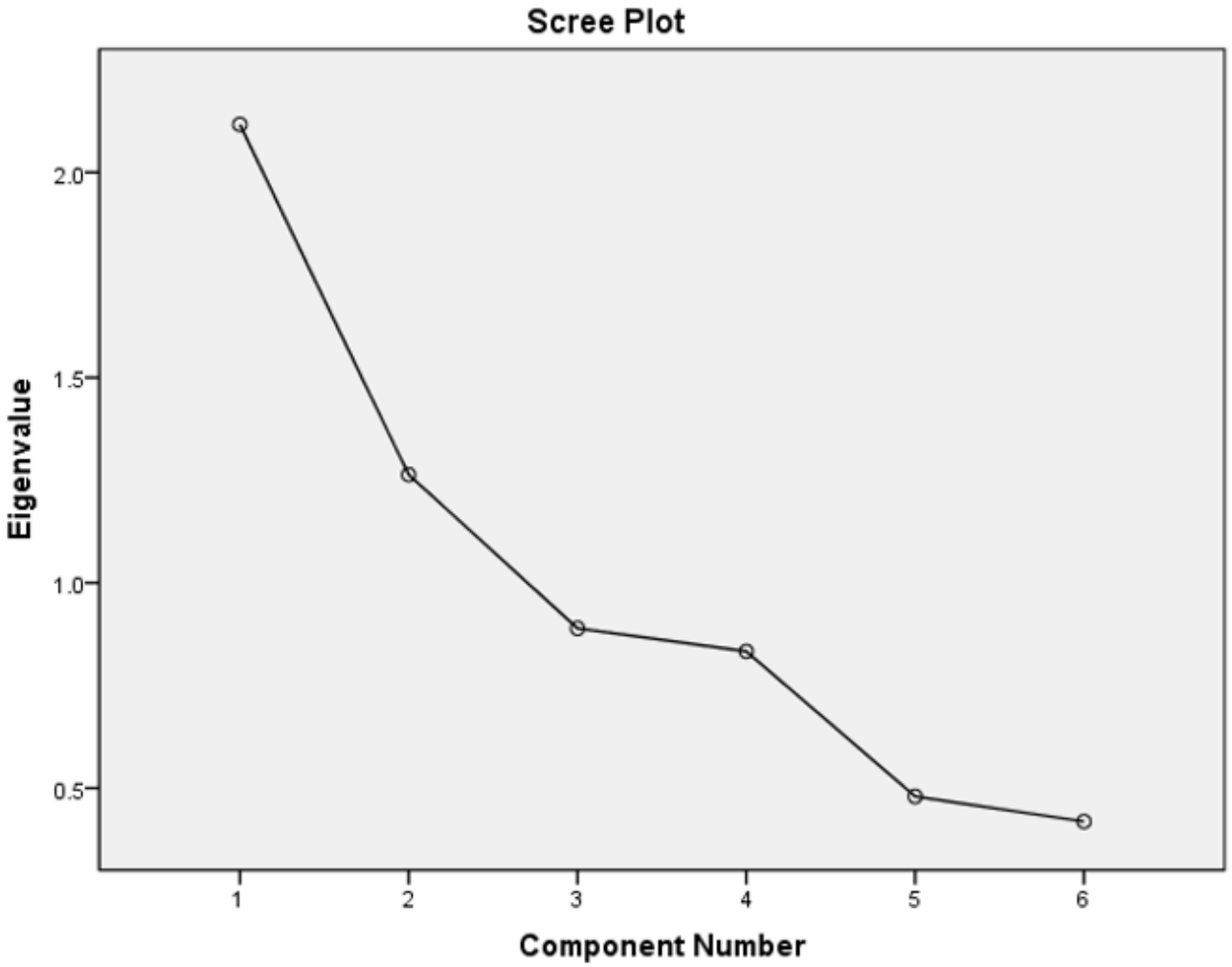

Figure 1

Gravel diagram