

Translation and validation of the traditional Chinese version of the faecal incontinence quality of life scale

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Abstract

Purpose Psychometric evaluation with tools such as the faecal incontinence quality of life scale is an essential component of clinical assessment. Currently, there is no translated Traditional Chinese version of the scale. A validated translated version may help to improve the quality of healthcare received in countries with Chinese minorities (0.5, 1.2 and 4.0 % of the UK, USA and Australian population, respectively) as well as local population of Hong Kong. The purpose of this study is to validate the Traditional Chinese version of the faecal incontinence quality of life scale (FIQL).

Methods The FIQL questionnaire was translated into Traditional Chinese Language followed by linguistic validation. It was then tested on 55 patients with faecal incontinence and 93 controls in the colorectal outpatients clinic. Faecal incontinence severity index was also used for the assessment of disease severity.

Results Internal consistency was good/excellent for all scales (Cronbach's alpha >0.70, between 0.71 and 0.93). The intra-class correlation indicated a high stability over time with coefficients ranging between 0.78 and 0.90. Test and retest of all four scales found no significant differences of mean scores between baseline and retest. The mean faecal incontinence quality of life scale scores of all four domains improved

significantly after treatment of 10 patients whose faecal incontinence severity index scores decreased by 50 % of their pre-treatment scores, hence indicating good sensitivity.

Conclusions This study demonstrates the linguistic and psychometric validity of the traditional Chinese version of the faecal incontinence quality of life scale.

Keywords Faecal incontinence · Quality of life · Obstetric trauma · Pelvic floor dysfunction

Introduction

Faecal incontinence (FI) is defined as an involuntary loss of anal sphincter control resulting in an uncontrolled release of gas, liquid or solid stool [1]. The estimated prevalence of FI in the community is believed to be increasing with age and the female sex more likely to be suffering from it [2]. Aetiology such as obstetric trauma, previous anal surgery, rectal prolapse and elderly age are known to be associated with FI. The incidence of FI is thought to be under-reported, as sufferers may not seek medical help due to the embarrassing nature and the social stigma surrounding the disease.

Patients who seek help are initially assessed in specialised colorectal clinic where a detailed history and examination are carried out. The impact of FI on an individual should not only be measured by its severity but also on the quality of life of the individual. In general, the current recognised measurements on FI severity (Wexner's score [3], St. Mark's Incontinence scoring system [4] and the faecal incontinent severity index (FISI) [5]) focus the frequency of the loss of gas, liquid or solid stool, along with the impact on life style and use of medication. The measurement of quality of life can either be used with a generic scale, such as the Short-Form 36 Health Survey (SF-36) or a disease-specific quality of life measurement. Rockwood et al.

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initially developed the faecal incontinence quality of life scale (FIQL) in 2000 [6]. The instrument comprises of four domains (lifestyle, coping/behaviour, depression/self-perception and embarrassment) with a total of 29 items. This validated instrument was originally written in English but later translated into different languages (e.g. French [7], Norwegian [8], Italian [9], Japanese [10], Turkish [11] and Spanish [12]), with minor changes made to suit cultural diversities.

Hong Kong has a population of 7.18 million (94 % Chinese) with the majority of the population uses Cantonese as their spoken language and traditional Chinese characters as their written language. Traditional Chinese is also commonly used in Taiwan and Macau. Moreover, the Chinese community represent 0.5, 1.2 and 4.0 % of the UK, USA and Australian population, respectively. Therefore, a validated translated version of the FIQL may help to improve the quality of healthcare provided for local populations and ethnic minorities in Western countries. Translated version of the SF-36 is currently in use in Hong Kong [13]. However, as it is a generic scale, a more disease-specific scale such as a translated version of the FIQL will undoubtedly benefit FI patients in Hong Kong.

The aim of this study is to produce a validated Traditional Chinese version of the FIQL.

大便失禁生活質素問卷

1. 一般來說，你認為你的健康屬於：

- 1 非常好
- 2 很好
- 3 好
- 4 尚可
- 5 差

2. 以下各項，請指出有多少時間因為意外地大便失禁而受影響：

	常常如此	大部份時間	少部份時間	永不
a. 我害怕外出	1	2	3	4
b. 我避免外出探望朋友	1	2	3	4
c. 我避免晚上不留在家中	1	2	3	4
d. 外出活動如看電影及到教堂對於我來說是很困難的	1	2	3	4
e. 我會在外出前減少進食	1	2	3	4
f. 無論我任何時候不在家中，我也會盡量留在洗手間旁	1	2	3	4
g. 我需要每天計劃日常活動時間表以遷就我的大便習慣	1	2	3	4
h. 我避免旅遊	1	2	3	4
i. 我擔心不能及時到洗手間	1	2	3	4
j. 我感覺不能控制我的大便	1	2	3	4
k. 我往洗手間前沒有足夠的時間控制我的大便	1	2	3	4
l. 我不知道自己已大便失禁	1	2	3	4
m. 我嘗試留在最近洗手間位置，以避免意外地大便失禁	1	2	3	4

Method

Patients and measurements

The sample population consists of 55 patients with faecal incontinence and 93 controls with other gastrointestinal symptoms. Subjects were over 18 years of age, recruited among patients referred to the colorectal clinic at the Prince of Wales Hospital between the periods of January 2011 and January 2012.

FI patients and controls were asked to complete the translated version of the FIQL, FIS1 and the Chinese version of the SF-36 [13].

The FIQL comprises 29 items measuring four domains of health-related quality of life: lifestyle (10 items), coping/behaviour (9 items), depression/self-perception (7 items) and embarrassment (3 items). All items are rated on a scale from 1 to 4 points except two items in the depression/self-perception with ranges of 1 to 5 and 1 to 6 points. The score for each domain is the mean score of all the items within its domain.

The FIS1 is a 4-item scale to assess patient's symptom severity by the frequency (2 or more times a day; once a day; 2 or more times a week; once a week; 1–3 times a month; never) to loss of gas, mucus, liquid or solid stool [5].

3.

	強烈贊成	有些贊成	有些不贊成	強烈不贊成
a. 我感到羞愧	1	2	3	4
b. 我不能做太多自己想做的事	1	2	3	4
c. 我擔心意外地大便失禁	1	2	3	4
d. 我感到憂鬱	1	2	3	4
e. 我擔心其他人嗅覺到自己的大便	1	2	3	4
f. 我覺得自己不是健康的人	1	2	3	4
g. 我很少享受生活	1	2	3	4
h. 我很少有性生活	1	2	3	4
i. 我覺得跟其他人很不同	1	2	3	4
j. 我經常覺得意外地失禁是常會發生	1	2	3	4
k. 我害怕有性生活	1	2	3	4
l. 我避免乘搭飛機或火車旅行	1	2	3	4
m. 我避免外出進食	1	2	3	4
n. 無論到任何地方，我也要找到洗手間的位置	1	2	3	4

4. 在過去的一個月，你有沒有因為值得關注的問題而不開心、沮喪及絕望呢？

- 1 非常多
- 2 很多
- 3 有一些
- 4 一般
- 5 很少
- 6 沒有

Fig. 1 Traditional Chinese version of the faecal incontinence quality of life score

Several aspects of the translated questionnaire are tested. In order to avoid responder fatigue, some of the aspects are divided into subgroups for analysis.

This study was approved by the Local Survey and Behaviour Ethics Committee.

Linguistic validation of the translated FIQL

An independent translator translated the American version of the FIQL into a traditional Chinese version with Chinese as his mother tongue. The translated script was then inspected and confirmed by the authors (TWCM, WWL, DKYN). The questionnaire was then back-translated into American-English by a native independent translator with good command of the English language. The translated FIQL (Fig. 1) and FISI was then pilot tested on 10 patients (5 with FI and 5 controls) to verify that it is clear, understandable and acceptable (Fig. 2).

Psychometric properties

Reliability of the translated scale was established by measuring internal consistency and test-retest coefficients. The internal consistency of each domain was tested by means of Cronbach's alpha coefficient. Scores were considered poor if <0.5 , suspicious if between 0.5 and 0.69, acceptable if 0.7 and 0.8, good if 0.81 and 0.9 and excellent if >0.9 [14].

Test-retest aims to measure the temporal stability of the instrument. A subgroup of randomly selected FI patients was given the same questionnaire to complete at two time-points between 10 and 14 days without treatment. The second questionnaires were sent to the patients' home with a stamped addressed envelope. This was examined by calculating the intra-class correlations (ICC) for each scale with the corresponding 95 % confidence interval. $ICC > 0.8$ was considered acceptable.

Validity of the questionnaire was assessed on its convergent and divergent validity. The convergent validity was analysed by evaluating the correlation between the four scales

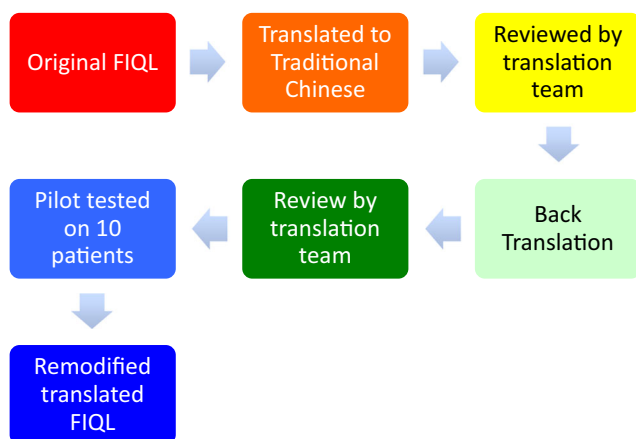


Fig. 2 Linguistic validation of the translated FIQL

Table 1 Demographics for patients with faecal incontinence and control populations

	Faecal incontinence	Other symptoms	<i>p</i> value
Number	55	93	
Age (mean±s.d.)	50.2±10.8	59.0±13.1	NS
Gender			
Male	12	41	
Female	68	53	<0.0001

and the appropriate dimensions of the SF-36. Scores of 0 to 0.25 were deemed very poor, 0.26 to 0.49 were judged poor, 0.50 to 0.69 were judged average, 0.70 to 0.89 were deemed strong and 0.9 or higher were judged very strong. On analysing the divergent validity, four scales of the translated questionnaire were correlated to the FISI.

Statistical analysis

The analysis of the internal validity was performed by Cronbach's alpha coefficients. The test-retest analysis was performed using the ICC. Analysis of validity of the translated FIQL with respect to the SF-36 and FISI was made using Pearson's correlation coefficients. Statistical analysis was performed using SPSS version 20.0 (IBM SPSS statistics, Somers USA). A *p* value <0.05 was considered significant.

Results

Of the 148 patients, 55 patients were referred first time with symptoms of FI and 93 patients with other gastrointestinal symptoms without faecal incontinence as controls. The demographics of the patient population are listed in Table 1.

In this study, 84 % of the FI patients completed the questionnaire. Of the uncompleted questionnaires, those which were <80 % completed were discarded (2/150; 1.3 %). The remaining partially completed questionnaires (10/148, 6.8 %; 2/55, 3.6 % FI group and 8/93, other GI group) were completed using the mean score method for each corresponding domain. Frequently missing items were related to their sexual

Table 2 Scales scored as means with standard deviation between faecal incontinence patients vs control

Scale	FI	Control	<i>p</i> value
Lifestyle	3.01±0.75	3.59±0.51	<0.0001
Coping/behaviour	2.46±0.78	3.36±0.59	<0.0001
Depression self-perception	2.64±0.77	3.38±0.62	<0.0001
Embarrassment	2.51±0.80	3.37±0.68	<0.0001

Table 3 Reliability test of the translated FIQL. Values of test and retest are expressed as means \pm standard deviation and the interclass correlation coefficient (ICC) as coefficients and 95 % confidence intervals

Scale	Test	Retest	ICC	Alpha
Lifestyle	3.01 \pm 0.75	3.01 \pm 0.77	0.89 (0.77–0.95)	0.93
Coping/behaviour	2.46 \pm 0.78	2.55 \pm 0.75	0.90 (0.79–0.96)	0.89
Depression self-perception	2.64 \pm 0.77	2.63 \pm 0.81	0.80 (0.59–0.90)	0.84
Embarrassment	2.51 \pm 0.80	2.54 \pm 0.71	0.78 (0.57–0.90)	0.70

history (3 h; 33 % and 3 k; 28 %). There were no significant correlations among incomplete items.

There were also significant differences in FIQL scores of all domains between FI patients and controls, indicating that it is disease specific (Table 2).

Psychometric analysis

Reliability

The internal consistency of the translated FIQL in 79 patients evaluated using Cronbach's alpha was found to range from acceptable to excellent in all four domains; 0.93 for lifestyle, 0.89 for coping/behaviour, 0.84 for depression/self-perception and 0.70 for embarrassment (Table 3).

A subgroup of 25 FI patients were randomly chosen for the test and retest study.

Intra-class correlation (ICC) for each scale was calculated which indicated high stability over time with coefficient; 0.94 for lifestyle, 0.95 for coping/behaviour, 0.88 for depression/self-perception and 0.78 for embarrassment (Table 3).

Convergent validity

The convergent validity of the questionnaire was analysed by evaluating the scales of the FIQL with the appropriate scales of the SF-36 (translated version). In total, 10 comparisons were examined and all were found to be statistically significant (Table 4). This confirms the validity of the translated questionnaire against the validated sensitivity of the SF-36.

To analyse the divergent validity, the scales of the FIQL were correlated with the FISI (translated version). Although

all four domains were found to have negative correlations, only two of the four domains were found to be statistically significant (Table 5).

Responsiveness

The mean FIQL scores improved with statistical significance in all four domains after treatment of a pilot study carried out in our unit to investigate the efficacy of transcutaneous electric nerve stimulation on acupuncture points (Acu-Tens) on faecal incontinence where 8 out of 10 patients whose FISI scores decreased by 50 % from their pre-treatment scores, hence indicating good sensitivity (Table 6) [15].

Discussion

This present study demonstrates sufficient validity and reliability of the traditional Chinese version of the FIQL. Traditional Chinese characters are a written form of Chinese character set that does not contain the newly created characters, simplified Chinese characters, which were formed after 1946. Traditional Chinese characters are commonly in Taiwan, Hong Kong, Macau and many overseas Chinese ethnic communities in United Kingdom, Australia, USA and Canada. Hence, a validated translated traditional Chinese version of the FIQL may help to improve the quality of healthcare received in ethnic Chinese minorities in these countries.

The FIQL has been translated into many different languages for patient suffering from faecal incontinence in different countries. The size of the study population for re-validation in other studies varies from 50 patients (Portuguese version [16]), 76 patients (Norwegian version [8]) to 119

Table 4 Convergent validity of 10 comparisons between translated FIQL to SF-36

Scale	Physical role	General health	Vitality	Social functioning	Emotional role	Mental health
Lifestyle	0.47**			0.34***	0.34***	
Coping/behaviour						0.42**
Depression self-perception		0.64 [^]	0.42**			0.35***
Embarrassment	0.35*			0.41**		0.32***

[^] $p < 0.0001$; * $p < 0.001$; ** $p < 0.01$; *** $p < 0.05$

Table 5 Pearson's correlation coefficients between translated FIQL and FISI

Scale	<i>r</i>
Lifestyle	−0.32 ^a
Coping/behaviour	−0.34**
Depression self-perception	−0.45*
Embarrassment	−0.30 ^a

p*<0.01; *p*<0.05^aNS

patients (Japanese version [17]). In this study, 55 patients with faecal incontinence were recruited which seemed to be sufficient for the study.

All of the patients were recruited from our outpatient colorectal clinics. Patients who agreed to participate completed their questionnaire in a quiet room with on-hand support if any questions arise. This method we believe allows a higher completion rate with a more accurate respond from the patient. However, for the reliability study, the retest questionnaires were sent to the patients' address with a stamped address envelope. Although a 100 % return of these retest questionnaires were received, we were unable to know the time taken to complete the questionnaires and also to provide on-site assistance should queries arise.

We have found a significant proportion of unanswered questions related to sexual relations/behaviour, which were similar to the Norwegian study [8]. These questions are culturally sensitive and can be regarded as items that are 'missing not at random'. Missing data are common in quality of life questionnaires. The personal mean score method to deal with missing data appears to be appropriate with insignificant bias [18].

Similar to the French [7], Norwegian [8] and Japanese [17] FIQL studies, the psychometric analysis of the FIQL indicated high internal consistency for three of the four scales with the lowest being the domain of embarrassment. Cronbach's alpha has been known to be sensitive to the number of items, and this has been reflected in the value for the embarrassment domain, which has only three items. However, in this study, the Cronbach's alpha value for embarrassment (0.70) still remains to be in the acceptable range.

Table 6 Pre- and post-FIQL mean scores of patients who had successful Acu-Tens treatments for faecal incontinence

	Pre-treatment	Post-treatment	<i>p</i> value
Lifestyle	1.99±0.49	3.70±0.32	<0.001
Coping/behaviour	1.77±0.39	3.40±0.57	<0.001
Depression self-perception	1.90±0.48	3.31±0.76	<0.01
Embarrassment	2.10±0.32	3.63±0.45	<0.005

The stability over time has shown to be good for this translated FIQL, with the intra-class correlations between 0.78 and 0.90 for all scales. The variability in results in other studies may be influenced by the time interval between the tests. Tsunoda et al. suggested that a shorter time interval may minimise the risk of changes in clinical status, which could therefore affect the quality of life score. We have chosen in this study for the time interval to be between 10 and 14 days without treatment, as used by Rockwood et al. in the original paper [6]. This time interval seemed to be a reasonable time frame as it has also been used in other studies [11, 12, 17].

In this study, we also correlated the FIQL with the FISI score. Negative correlations were found, indicating severity of the disease having a negative impact on the patient's lifestyle, coping/behaviour, depression/self-perception and embarrassment. However, two of the four domains were not statistically significant, which may be due to type II error.

The correlations between the four scales of the traditional Chinese version and the scales of SF-36 were examined. We have selected 10 comparisons and found all of them to be statistically significant. This confirmation would allow this translated FIQL to be used in the assessment of outcomes in clinical trials.

In conclusion, this traditional Chinese version of the FIQL presents sufficient psychometric properties to be used in clinical and research settings for patients with faecal incontinence.

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