

Original Research Article

The Minimal Important Difference of the Fecal Incontinence Quality of Life (FIQL) Questionnaire for Patients with Posterior Compartment Prolapse: A Prospective Cohort Study

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Abstract

Objectives: The minimally important difference (MID) of the Fecal Incontinence Quality of Life (FIQL) scale has never been determined. Thus, in this study, we aimed to estimate the MID of the Japanese FIQL for patients with posterior compartment prolapse (PCP).

Methods: For 3-months after surgery, we followed a prospective cohort of 136 patients with PCP combined with fecal incontinence (FI) who had undergone ventral rectopexy between 2012 and 2018. Usable data from 114 patients were analyzed. Patients have both completed the FIQL and the 36-Item Short Form Health Survey (SF-36) before and after surgery. Distribution-based MID values were estimated at 1/2 SD and the standard error of measurement (SEM) for domain and total scores across time points. Changes in the domain scores anchored to changes in a SF-36 overall health assessment question were used to estimate anchor-based MID. To be interpreted as true change, the median, anchor-based MID values that were greater than the corresponding SEM were proposed as estimates of the MID for the FIQL.

Results: Distribution-based MID of 1/2 SD for each domain and total score ranged between 0.3 and 0.4, whereas SEM ranges were between 0.2 and 0.3. The anchor-based approach resulted in the median MID estimates of 0.4 to 1.0. Final estimates of MID for each FIQL and total score were as follows: lifestyle (0.6-1.1), coping/behavior (0.8-1.4), depression/self-perception (0.4-0.8), embarrassment (1.0-1.6), and total score (0.7-1.1).

Conclusions: The results provide a basis for clinically important differences in FIQL scores after surgery for patients with PCP and FI.

Keywords

Fecal Incontinence Quality of Life scale, minimally important difference, posterior compartment prolapse
J Anus Rectum Colon 2022; 6(1): 16-23

Introduction

The Fecal Incontinence Quality of Life (FIQL) scale has been identified as the most commonly employed patient-reported outcome (PRO) instrument for assessing a patient's perception of fecal incontinence (FI)[1]. The FIQL is composed of 29 items that evaluate 4 domains, that is, lifestyle, coping/behavior, depression/self-perception, and embarrass-

ment[1]. The scale has been widely used to assess changes in quality of life (QOL) among patients with FI who have undergone different types of treatment[2-4].

Previous studies have generally based clinical effectiveness on the statistical differences in PRO, including health-related QOL, but the values for clinically significant changes remain unknown[5,6]. The minimal important difference (MID) was first proposed by Jaeschke et al.[7] as the mini-

imum difference in a scoring measure that the patient perceives as a beneficial or harmful difference after receiving a treatment. Thus, the MID serves as an important indicator for judging the treatment effectiveness from patients' perspective. However, until now, the MID values of FIQL have not been estimated.

External rectal prolapse (ERP) and internal rectal prolapse (IRP) and/or rectocele (RC) are categorized as posterior compartment prolapse (PCP); these are frequently experienced by patients with PCP and FI[4,8]. Among the surgical treatments for patients with PCP, laparoscopic ventral rectopexy (LVR) has recently been regarded as an effective treatment for not only correcting anatomical abnormalities, but also relieving the associated FI[9]. We previously reported that 39 patients with PCP who underwent LVR, experienced an improvement of FI after surgery, which was supported by a statistically significant improvement in FIQL scores[4]. However, the MID values of FIQL were not assessed. Thus, in this study, we aim to determine a range of MID values for FIQL in a larger sample of patients with PCP combined with FI after undergoing LVR.

Methods

We performed a retrospective analysis of prospectively collected data of patients with PCP and FI who underwent LVR between 2012 and 2018. Patients were included in the analysis if their follow-up FIQL assessment (3 months post-surgery) was available for evaluation. The diagnosis of ERP was made clinically, when possible; when clinical diagnosis was not possible, it was based on evacuation proctography. An ERP was an absolute indication for LVR. The diagnosis of IRP and/or RC was suggested based on a history of FI and/or obstructed defecation (OD) and clinical examination and confirmed by evacuation proctography. Symptoms of OD included incomplete evacuation, straining, digitation, sensation of anorectal obstruction, and repetitive visits to the toilet. Indications for surgery were IRP and/or RC at proctogram with symptoms of FI and/or OD and failure of standard medical management. Informed consent was obtained from all the patients. This study was approved by the Ethical Committee of Kameda Medical Center (approval number: 20-144).

Study measures and database collection

The primary end point was to estimate the MID of FIQL based on changes in the domain or total FIQL score across study time points. The Japanese version of the FIQL was validated in our previous study[10]. The FIQL scores ranged from 0 to 4 with higher scores corresponding to better functioning and health-related QOL.

The validated Japanese version of the 36-Item Short-Form Health Survey (SF-36) is a general health measure

that is widely used across disease and health conditions. It consists of 36 items which ask respondents about their general and mental health as well as their physical, emotional, and social function[11]. A single general health item was used as an anchor in this analysis. The Fecal Incontinence Severity Index (FISI) score quantifies the degree of incontinence on a scale of 0 to 61, with a score of 61 indicating total incontinence[12]. Symptoms of OD were evaluated using Constipation Scoring System (CSS)[13].

The FIQL and the SF-36 were handed out to patients by a nurse and self-administered in the outpatient clinic preoperatively and 3-months after LVR. Family members were allowed to fill out the questionnaires on behalf of the patients when self-completion was difficult. In the case of missing data, the scale scores were computed based on the average of the non-missing item responses, on the condition that at least half of the items in the scale had non-missing values. The FISI scores were also evaluated at the same patient visits. Responses from returned surveys were entered into a secured database and scored according to standard scoring algorithms for each instrument. We then collected demographic factors, disease characteristics, a list of previous surgeries, and follow-up clinical data (complications and recurrences).

MID estimates

There is still no consensus on the best method for estimating MID[5]. Therefore, in the interest of being thorough, we used three different approaches to estimate MID.

Distribution-based method

In the distribution-based method, 1/2 SD and 1 standard error of measurement (SEM) for MID were used in this study. The SEM was calculated as follows: $SEM = SD \times \sqrt{1 - r_{\text{test-retest}}}$, where r is the reliability of the domain[5]. Based on our previous study, the test-retest reliability representing the intra-class correlation coefficients was 0.93 for lifestyle domain, 0.86 for coping/behavior domain, 0.89 for depression/self-perception domain, 0.89 for embarrassment domain, and 0.92 for total score[10].

The anchor-based method

The anchor-based method used item 1 from the SF-36 questionnaire, "In general, would you say your health is" with corresponding 5-point Likert scale, with 1 being *poor*; 2, *fair*; 3, *good*; 4, *very good*; and 5, *excellent* (SF-36 original paper). This criterion item was supported for use as an anchor as described previously[14,15]. The MID was determined based on the changes of the SF-36 criterion item before and 3 months after surgery after completion of the FIQL and the FISI. The changes of the SF-36 criterion item were classified into five grades: greater than or equal to 2 scale-points improvement (≤ -2); 1 scale-point improvement

Table 1. Characteristics of Patients.

	ERP	IRP and/or RC	Total
No. of patients	71	43	114
Male/female	8/63	4/39	12/102
Median age (yr) (25–75%)	79 (72.5–85.5)	77 (70.5–83.5)	78 (71.9–84.1)
Symptoms			
FI alone	36	11	47
FI + OD	35	32	67
Prior abdominal or pelvic surgery	21	19	40

ERP external rectal prolapse, IRP internal rectal prolapse, RC rectocele, FI fecal incontinence, OD obstructed defecation

Table 2. Fecal Incontinence Severity Index Score.

	Baseline	3 months	P
ERP	35 (26.0–44.0)	12 (2.4–21.6)	<0.0001
IRP and/or RC	29 (22.5–35.5)	11 (1.9–20.1)	<0.0001
Total	32 (23.0–41.0)	12 (2.5–21.5)	<0.0001

ERP external rectal prolapse, IRP internal rectal prolapse, RC rectocele

Table 3. Summary of FIQL Scores at Baseline and 3 Months after Surgery.

	Baseline	3 months	P
Lifestyle	2.8 (2.2–3.5)	3.6 (3.2–4.1)	<0.0001
Coping/behavior	2.4 (1.9–2.9)	3.2 (2.7–3.7)	<0.0001
Depression/self-perception	2.9 (2.1–3.5)	3.5 (3.0–4.1)	<0.0001
Embarrassment	2.3 (1.8–2.8)	3.2 (2.5–3.8)	<0.0001
Total score	2.6 (2.1–3.1)	3.4 (2.9–3.9)	<0.0001

FIQL fecal incontinence quality of life

(-1); no change (0); 1 scale-point deterioration (+1); and greater than or equal to 2 scale-points deterioration (≥ 2). The MID values were calculated as changes in the median QOL scores when the SF-36 criterion item was either improved or deteriorated by 1 point.

Receiver operating characteristic analysis

We used ROC curve analysis for changes in FIQL scores that differentiated patients with a 1-scale-point improvement of the SF-36 criterion item from those who had no improvement. An AUC (area under the curve) ≥ 0.70 for an outcome instrument suggests adequate accuracy[16].

Changes in the domain or a total FIQL score smaller than the corresponding SEM are more likely to represent an error of measurement than a real change[17,18]. To be interpreted as true change, therefore, the MID should thus be greater than the SEM. Data were expressed as median with interquartile range except for distribution-based MID values. Analysis was performed using the Mann–Whitney *U* test for unpaired data, and the Wilcoxon signed-rank test for paired data (two-sided *p* test). Spearman’s correlation coefficient was used between the changes in the domain or total FIQL score and change in the anchor. All analyses were performed using SPSS v26 (IBM Corp., Armonk, NY, USA). *P* < 0.05 was considered to indicate statistical significance.

Results

Of the 136 eligible patients in the study, 22 have failed to complete postoperative questionnaires and were excluded from the analysis. The reasons for non-completion were “not

contacted” (n = 18) and “lost” (n = 4). In total, 114 patients who completed both the baseline and 3-month follow-up FIQL measurement were included in the analyses. Their median age was 78 years, and 89% were females. Seventy-one patients (62%) had ERP. Forty-seven patients had FI alone, and 67 had mixed FI and OD (Table 1). One patient had a conversion to open surgery because of hemorrhage, and another patient required re-operation for a small bowel injury. During the 3 months before the follow-up, none of the patients had recurrent ERP.

An association of *r* = -0.32 (*P* = 0.001) was found between the change in the total score and change in the anchor. The FISII score in either patients with ERP or those with IRP and/or RC at the baseline was observed to have significantly reduced 3-months after surgery (Table 2). There was no significant difference in the change of FISII score between patients with FI alone and those with FI and OD [-23 (-33.6 to -12.4) versus -18 (-28.3 to -7.7), *P* = 0.12]. A summary of FIQL scores is presented in Table 3. Each of the FIQL domain or total scores at the baseline were significantly higher 3 months after surgery.

Figure 1 shows FIQL score changes stratified by anchor-based approaches as the point changes of SF-36 criterion item. There were significant differences in the changes of all FIQL domains and total scores when the SF-36 criterion item score change was greater than or equal to -2. In addition, significant differences in the changes of scores on depression/Self-perception and embarrassment domains were noted when the SF-36 criterion item score change was -1.

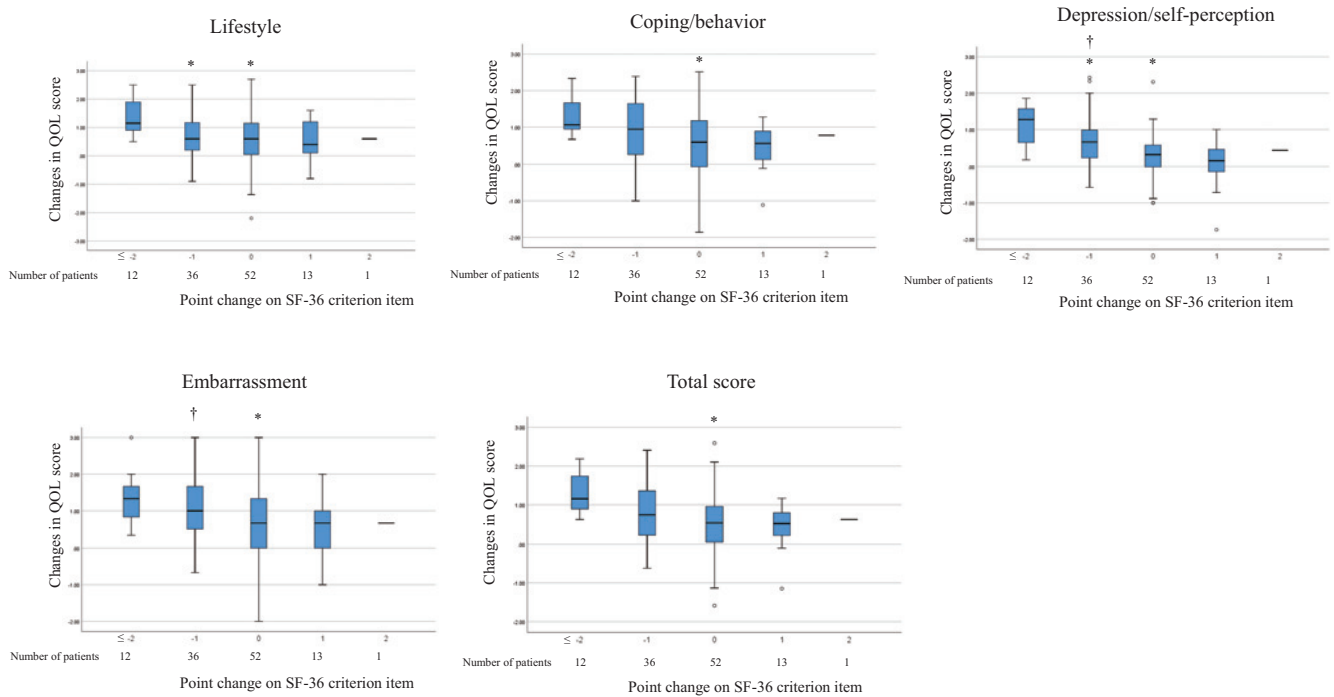


Figure 1. FIQL score changes based on the point changes on SF-36 criterion item. Boxes show median values with upper and lower quartiles. The vertical line extends from the minimum to the maximum values. * $P < 0.05$ versus ≤ -2 point change on the criterion item. † $P < 0.05$ versus a 0-point change on the criterion item. P -values were determined by using the Mann–Whitney U test.

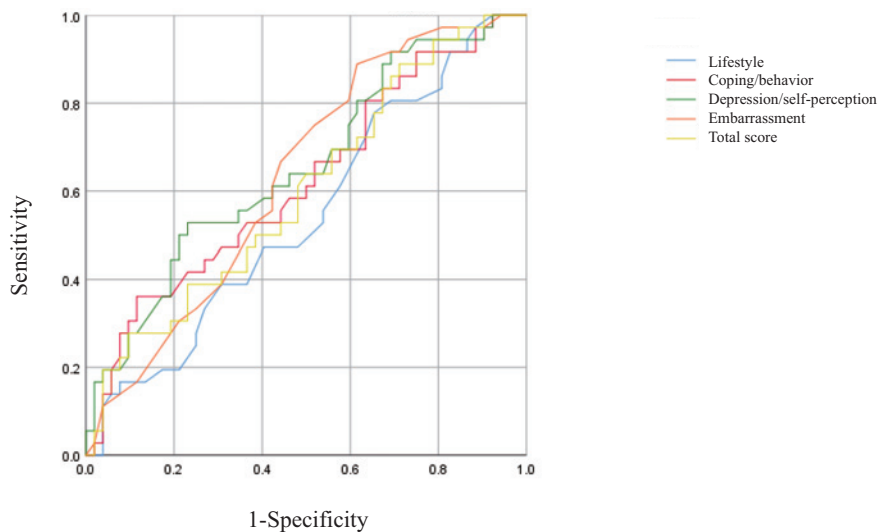


Figure 2. ROC curve analysis for changes in FIQL scores that differentiated patients with a 1-scale-point improvement of the SF-36 criterion item from those who had no improvement.

There were no significant changes of FISI scores when SF-36 criterion item score change was +1, -1, or greater than or equal to -2. The CSS score at the baseline was significantly reduced 3-months after surgery [versus 11.5 (7.5 to 15.5) versus 7 (1 to 13), $P < 0.0001$], but there were no significant changes of CSS scores when SF-36 criterion item score

change was +1, -1, or greater than or equal to -2.

The AUC values in ROC analysis were 0.55 to 0.67 for each domain and total score, respectively, which were both lower than 0.7, thereby suggesting inadequate accuracy (Figure 2). For all domains, the half SDs or SEMs estimated either at baseline or 3 months after surgery were smaller

Table 4. Summary of All MID Estimates (n = 114).

	Lifestyle	Coping/ behavior	Depression/ self-perception	Embarrassment	Total score
Anchor-based					
Number of used estimates (n = 49)					
25%	0.01	0.19	0.07	0.42	0.24
Median	0.56	0.78	0.43	1.00	0.66
75%	1.11	1.37	0.79	1.58	1.08
Distribution-based					
Baseline					
½ SD	0.41	0.36	0.38	0.38	0.34
SEM	0.22	0.27	0.25	0.25	0.19
3 months					
½ SD	0.42	0.40	0.38	0.44	0.37
SEM	0.22	0.30	0.25	0.29	0.21
Final MID range	0.6–1.1	0.8–1.4	0.4–0.8	1.0–1.6	0.7–1.1

MID minimal important difference, SD standard deviation, SEM standard error of measurement

Table 5. Summary of MID Estimates in Patients with ERP (n = 71).

	Lifestyle	Coping/ behavior	Depression/ self-perception	Embarrassment	Total score
Anchor-based					
Number of used estimates (n = 32)					
25%	-0.04	0.41	0.01	0.17	0.08
Median	0.60	0.83	0.48	0.83	0.66
75%	1.24	1.25	0.91	1.50	1.24
Distribution-based					
Baseline					
½ SD	0.42	0.37	0.40	0.39	0.36
SEM	0.22	0.28	0.26	0.26	0.20
3 months					
½ SD	0.32	0.34	0.34	0.40	0.31
SEM	0.17	0.18	0.26	0.27	0.17
Final MID range	0.6–1.2	0.8–1.3	0.5–0.9	0.8–1.5	0.7–1.2

MID minimal important difference, ERP external rectal prolapse, SD standard deviation, SEM standard error of measurement

than the corresponding median anchor-based values. Therefore, final MID range was determined using median and 75 percentile anchor-based values. Namely, the estimated MID score ranges were 0.6 to 1.1 for lifestyle domain, 0.8 to 1.4 for coping/behavior domain, 0.4 to 0.8 for depression/self-perception domain, 1.0 to 1.6 for embarrassment domain, and 0.7 to 1.1 for total score (Table 4). The MID values for patients with ERP were almost identical to those for patients with IRP and/or RC (Table 5, 6).

Discussion

To the best of our knowledge, this study was the first to investigate the MID for the FIQL specifically for patients with PCP and FI who had undergone LVR. Given that the

use of multiple methods for determining the MID values may refine the interpretability of any particular QOL instrument[5], we determined the MID of FIQL using three independent approaches. Distribution-based methods are generally regarded as inferior to anchor-based methods because they depend on only statistical criteria and rely solely on the characteristics of a specific study[19]. We concur with the general agreement that the distribution-based method should only be used to support estimates derived from anchor-based methods[17,20]. Additionally, as described above, any changes in the QOL score that are smaller than the corresponding SEM are more likely to represent a measurement error than a real change[17,18]. In our study, the MID values using the distribution-based method were smaller than those using the anchor-based method. Therefore, there was a

Table 6. Summary of MID Estimates in Patients with IRP and/or RC (n = 43).

	Lifestyle	Coping/behavior	Depression/ self-perception	Embarrassment	Total score
Anchor-based					
Number of used estimates (n = 17)					
25 %	0.13	-0.08	-0.02	0	0.2
Median	0.50	0.56	0.29	1.00	0.59
75 %	0.88	1.20	0.76	1.50	0.98
Distribution-based					
Baseline					
½ SD	0.38	0.35	0.34	0.36	0.31
SEM	0.20	0.26	0.23	0.24	0.18
3 months					
½ SD	0.38	0.36	0.36	0.39	0.35
SEM	0.20	0.27	0.26	0.26	0.20
Final MID range	0.5–0.9	0.6–1.2	0.3–0.8	1.0–1.5	0.6–1.0

MID minimal important difference, IRP internal rectal prolapse, RC rectocele, SD standard deviation, SEM standard error of measurement

reduced likelihood of error in the distribution-based method in estimating MID. We also used ROC curve analysis to identify the MID, but the AUCs were too low to determine the MID values using the Youden index (the farthest point from the diagonal line) or the closest point to the top-left (closest Euclidian distance).

The anchor-based method requires a reasonably strong linear relationship between the anchor and the variable of interest[19]. A previous review recommended statistically significant absolute value of ≥ 0.3 as appreciable[17]. In this study, the correlation was correct but may not be optimal, which is the most likely explanation for the low values of AUC. Another factor that may be related to this suboptimal correlation value is how the formation of the anchor question influences its relation to the score difference. A single general health item (SF-36) was used as an anchor and adjusted to the measured content (FIQL) in this study. Although the SF-36 criterion items had satisfactory correlation with the SF-6D generic instrument[21], it may not be well-adjusted for symptom-specific QOL instruments like the FIQL. A general one-item anchor may be less sensitive or responsive to changes in health status or less uniform directional agreement between the anchor and the FIQL. Additionally, patients may experience difficulties other than FI after surgery. While postoperative improvement of FI may cause an increase in FIQL domain scores, the patients may also experience other issues, such as pain, fatigue, or socio-economic distress after surgery, which may cause an increase in the SF-36 criterion item score.

In this study, final estimate range of MID for total score was 0.7–1.1. When the smallest value (0.7) was selected to assess the proportion of patients who would have perceived as a beneficial difference, it was 54% (61/114). This was an approximate value to the frequency of FI improvement [65%

(74/114)] using the symptom score, when the improvement is defined as a reduction of at least 50% in FISI scores[4].

Our study subjects were patients with PCP and FI who underwent LVR; hence, we must consider whether our determined MID values are relevant only to this treatment or if they may be relevant to other treatment modalities for these patients as well. At present, there is no agreement on whether an MID has relevance to a particular treatment or various treatment methods. The degree of change in FIQL scores after LVR may differ from the change after a perineal procedure because the technique's impact on postoperative continence should be variable. LVR for PCP has been considered to be a more effective technique in terms of recurrence as well as postoperative continence than the perineal procedures for ERP or IRP and/or RC[22,23]. Therefore, perineal procedures may not produce a significant improvement in FIQL scores after surgery, which would make it difficult to estimate the MID values and they may be different from our determined MID values. Thus, further studies are needed to estimate the MID using different treatment modalities.

The quality of the anchors may influence the consequences when using an anchor-based analysis, and different anchors may yield widely different MID values for the same instrument[19]. MID values may also change in different patient populations and conditions. It is recommended that multiple relevant anchors be applied to determine the MID. A limitation of our study was that we used only one anchor to adjust the FIQL. Another limitation includes the mixed cohort of patients with ERP and IRP and/or RC, although the MID estimates in both groups of patients were almost identical in this study (Table 5, 6).

The strength of this study is that we maintained a considerable level of standardization as diagnoses, surgeries, and

measurements were all performed in one referral hospital, applying the same situations and measurement series and using the same equipment. We then identified ranges of MID estimates of FIQL, although results are expressed as absolute figures in most studies determining a MID. When calculating the MID other than the absolute MID, the range of MID should be estimated, especially when the AUC values of the QOL score are not appreciable.

In conclusion, this study provides an initial range of MID values across FIQL domains for patients with PCP and FI as estimated ranges indicating clinically important differences and/or changes in scores. Although these results should be validated in further studies, these provide a basis to estimate clinically important differences and changes in the FIQL scores of patients with PCP and FI after surgery.

Acknowledgements

The authors thank Yuko Tsunoda for her assistance with the statistical analysis.

Conflicts of Interest

There are no conflicts of interest.

Author Contributions

Conceptualization: [Akira Tsunoda, Tomoko Takahashi]; Methodology: [Akira Tsunoda]; Formal analysis and investigation: [Akira Tsunoda, Tomoko Takahashi]; Writing - original draft preparation: [Akira Tsunoda]; Writing - review and editing: [Akira Tsunoda, Tomoko Takahashi]

Approval by Institutional Review Board (IRB)

Institutional review board: Ethical Committee of Kameda Medical Center

Review board approval number: 20-144

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