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MINIMUM IMPORTANT DIFFERENCES FOR SCALES ASSESSING SYMPTOM SEVERITY AND QUALITY OF LIFE IN PATIENTS WITH FECAL INCONTINENCE

Hypothesis / aims of study

The minimum important difference (MID) is the smallest change in questionnaire score associated with clinically meaningful change.(1) The MID of a questionnaire is essential to determine whether group differences in patient-centered outcomes are clinically meaningful since statistically significant differences are not always synonymous with clinically meaningful change. The MID of a commonly used fecal incontinence (FI) symptom severity scale, the Fecal Incontinence Severity Index (FISI), and several commonly used quality of life scales including: the Colorectal Anal Distress Inventory (CRADI) subscale of the Pelvic Floor Distress Inventory (PFDI), the Colorectal Anal Impact Questionnaire (CRAIQ) subscale of the Pelvic Floor Impact Questionnaire (PFIQ), and the Modified Manchester Health Questionnaire (MMHQ) have not been determined. The aims of the study were to estimate the MIDs of the FISI, CRADI, CRAIQ, and the MMHQ.

Study design, materials and methods

This was an ancillary analysis of the Adaptive Behaviors among women with Bowel Incontinence (ABBI) study, a multi-center prospective cohort study involving seven clinical sites and a data coordinating center. This study investigated adaptive behaviors among women receiving non-surgical and surgical management for FI. Women were eligible if they had a primary complaint of FI consisting of liquid stool, solid stool, or mucous occurring at least monthly for 3 consecutive months and they were planning to have treatment for FI. Informed consent was received. Treatment included behavioral techniques, pelvic floor muscle exercises, medications, surgery, or a combination of these methods. At baseline, 3 and 12 months after starting treatment, subjects completed several self-administered questionnaires to assess bowel symptoms and quality of life including the FISI, PFDI, PFIQ, and MMHQ. A Global Impression of Change scale was also completed at the 3 and 12-month visits. ABBI patients who received treatment and completed their baseline and 3-month evaluations were the subjects of this study.

A variety of methods have been used to determine MID and no single one has proven to be superior.(1) Anchor-based methods are most commonly used to determine MID, however distribution-based methods also have value.(1,2) Recently, an integrated system that combines anchor- and distribution-based methods has been recommended.(1) Both approaches were used in this analysis.

The changes in score from baseline to 3 months in the FISI, CRADI, CRAIQ and MMHQ were used in each of the analyses described below. The results from each approach were compared and the MID (or a range of MID) for each scale is reported. For the anchor-based approach we evaluated the MID of the FI measures using the Global Impression of Change (3). MID was defined as the difference in mean change from baseline of those who indicated that they where “a little better” and those who reported “No change” on the Global Impression of Change scale at 3 months. For the distribution-based approach, we determined the change in score of the scales that correspond to medium (0.5 SD) effect size, which is considered a conservative estimate of MID, and 1 standard error of measurement (SEM), another estimate of MID, and compared these to the results of the anchor-based approach.

Results

Of the 133 subjects who enrolled in the ABBI trial, 65% (86/133) completed at least one of four FI measures at both the baseline and 3-month evaluations and are the subjects of this analysis (65% for FISI, 64% for CRADI, 59% for CRAIQ, and 51% for MMHQ). There were no significant differences in demographics, medical history, bowel characteristics, or treatments for fecal incontinence between patients who followed up at the 3-month evaluation and patients who did not follow up. Three months after initiating treatment there were significant improvements in FISI, CRADI, CRAIQ and MMHQ scores (all P<.0001). Mean changes (SD) from baseline to 3 months after treatment in FISI, CRADI, CRAIQ and MMHQ scores were -8 (12), -52 (70), -63 (91), and -12 (19), respectively. The table presents the change in FISI, CRADI, CRAIQ, and MMHQ by Global Impression of Change response category. Anchor-based MIDs (95% CI) based on the global rating were -3.6 (-10.6, 3.4), -11.4 (-51.7, 28.8), -18.1 (-69.1, 32.9), and -3.2 (-10.5, 4.2) for the FISI, CRADI, CRAIQ, and MMHQ, respectively. MID estimates (95% CI) based on the distribution-based criteria for the FISI, CRADI, CRAIQ, and MMHQ were: 0.5 SD corresponded to an improvement in score of -6.1 (-7.2, -5.3), -40.4 (-47.6, -35.1), -60.0 (-71.1, -51.9), and -12.3 (-14.9, -10.6) points and 1 SEM corresponded to -8.1 (-9.0, -7.2), -32.1 (-36.0, -28.6), -19.2 (-24.1, -14.4), and -5.9 (-6.9, -4.9) points, respectively.

Global Impression of Change Category and Change in FISI, CRADI, CRAIQ, & MMHQ

		FISI-Patient Wt. (range 4-59)	CRADI (range 0-400)	CRAIQ (range 0-400)	MMHQ (range 0-100)
Global Impression of Change	N	3 Months - Baseline Mean (SD)	3 Months - Baseline Mean (SD)	3 Months - Baseline Mean (SD)	3 Months - Baseline Mean (SD)
Very Much Better	20	-16.75 (14.86)	-91.94 (64.00)	-106.86 (93.79)	-25.92 (24.77)

		FISI-Patient Wt. (range 4-59)	CRADI (range 0-400)	CRAIQ (range 0-400)	MMHQ (range 0-100)
Global Impression of Change	**N**	**3 Months - Baseline Mean (SD)**	**3 Months - Baseline Mean (SD)**	**3 Months - Baseline Mean (SD)**	**3 Months - Baseline Mean (SD)**
Much Better	23	-11.52 (8.47)	-76.62 (88.67)	-90.85 (103.75)	-16.99 (21.68)
A Little Better	26	-4.73 (8.31)	-27.84 (33.26)	-43.58 (65.55)	-6.57 (9.08)
No Change	12	-1.17 (12.76)	-16.41 (60.97)	-25.49 (81.15)	-3.41 (9.68)
MID*	38	-3.56	-11.43	-18.09	-3.15
95% CI		(-10.56, 3.43)	(-51.66, 28.80)	(-69.09, 32.90)	(-10.52, 4.21)

* MID for improvement: difference in 'A Little Better' and 'No Change' category means

Interpretation of results

This study has determined reasonable estimates of MID for four commonly used fecal incontinence scales. The Global Impression of Change, the most commonly used anchor for MID determination, represents the best measure of the significance of change from an individual perspective and it is recommended that this patient's perspective be given the most weight when determining the MID. The MID from this anchor-based approach is, as predicted, less than that for 0.5 SD, a conservative estimate for MID and consistent with the one estimated by using the 1 SEM distribution-based approach. As such, the distribution-based methods for determining MID support the MID derived from the anchor-based approach. These estimates should be replicated and refined in larger studies.

Concluding message

Reasonable estimates of MID are 4, 11, 18, and 3 points for the FISI, CRADI subscale of the PFDI, CRAIQ subscale of the PFIQ, and MMHQ, respectively. Statistically significant improvements that meet these thresholds can be interpreted as being clinically important.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board and each participating institution**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**