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Bols E[1], Hendriks E[1], Berghmans B[2], Baeten C[1], de Bie R[1]
1. Maastricht University Medical Centre, 2. Pelvic care Center Maastricht - Maastricht University Medical Centre - the Netherlands

A CRITICAL EVALUATION OF THE VAIZEY SCORE, WEXNER SCORE AND THE FECAL INCONTINENCE QUALITY OF LIFE SCALE FOR CLINICAL USE IN PATIENTS WITH FAECAL INCONTINENCE

Hypothesis / aims of study

Reporting severity of faecal incontinence (FI) and its consequences on quality of life are of great relevance, although no consensus exists on the optimal patient-reported outcome (PRO). The application of the Vaizey and Wexner scores and the Fecal Incontinence Quality of Life Scale (FIQL) in evaluating patients with FI is hampered since the psychometric properties in terms of validity, reliability and responsiveness have not been rigorously evaluated before. In addition, it is unclear which change scores are minimally important, which is of significance in calculating the sample size of a trial and interpreting results of physiotherapy effectiveness studies. This study aims to assess the psychometric properties and minimally important change (MIC) of the Vaizey score, Wexner score and the FIQL for use in the evaluation of patients with FI.

Study design, materials and methods

We performed secondary analyses on a randomised controlled trial, which evaluated the add-on effect of rectal balloon training to pelvic floor muscle training. Adult patients with FI were included at the Maastricht University Medical Centre between August 2006 and May 2009 when they reported having had FI for more than six months, with a Vaizey score ≥12 (range 0–24) (1), and failure of dietary measures and medication. Baseline measurements consisted of medical history taking, physical examination, diagnostic work-up and three PROs, comprising the Vaizey score (primary outcome), Wexner score (range 0–20), and the FIQL (2). The 29-item FIQL (range 4–16) is composed of four multi-item subscales: Lifestyle, Coping/Behaviour, Depression/Self Perception and Embarrassment. After baseline measurement, patients were referred for a standardised physiotherapy program, comprising 12 sessions within nine weeks. The questionnaires were again completed at follow-up. Additionally, a nine-point global perceived effect (GPE) score asked patients to score their perceived change after physiotherapy treatment ('very much improved' to 'very much worse'). The PROs were tested for internal responsiveness (standardised response mean statistic) and external responsiveness by calculating the correlation coefficient (Pearson or Spearman r) between the change in the individual items and the total scores and the GPE. Longitudinal construct validity was assessed by correlating (Pearson r) the changes in the Vaizey score, Wexner score and FIQL, respectively. Two anchor-based methods were calculated to determine the MIC: the mean change method and the Receiver Operator Curve (ROC) analysis (3). Missing data were completed using the multiple imputation procedure. A two-tailed P-value of 0.05 indicated statistical significance.

Results

Eighty patients with FI with a mean age of 59.3 (SD ± 11.9) were enrolled in the randomised controlled trial. Patients were followed up at a mean of 6.8 weeks (SD=5.3). Ten patients (12.5%) discontinued physiotherapy treatment or dropped out. All total PRO scores proved to have both adequate to excellent responsiveness and longitudinal construct validity, and changes were in agreement with subjective improvement. Variability existed in the MIC estimates of the Vaizey and Wexner score, according to the different methods, whereas the estimates for the FIQL were rather consistent (Table 1). All PROs showed psychometric or practical limitations, especially with regard to the individual items (amongst others 'pad use') and the FIQL subscales.

Table 1. Simplified overview of study results

PRO properties	Vaizey	Wexner	FIQL	Lifestyle subscale	Coping subscale	Depression subscale	Embarrassment subscale
Internal responsiveness	++	++	+	-	+	-	+
External responsiveness	++	+	+	+	+	+	+
Longitudinal construct validity	+/++	+/++	+	+	+	-	+
Interpretability	+	+	+	NA	NA	NA	NA
Range MIC	-3 to -5	-2 to -3	1.1 to 1.2	NA	NA	NA	NA
Easy to sum up	++	++	-	-	-	-	-

PRO, patient-reported outcome; FIQL, Fecal Incontinence Quality of Life scale; MIC, minimally important change; NA, not applicable.
++=excellent, +=adequate, -=poor.

Interpretation of results
The instruments available to date to evaluate severity and quality of life in FI do not yet attain the highest levels of psychometric soundness. Given the limitations associated with the additional individual items that the Vaizey score assesses compared to the Wexner score, together with only minor differences in psychometric properties and the absence of another highly recommendable questionnaire, the Wexner score seems preferable to assess severity of FI. Due to variability in MIC estimates, they should be used as indicators. Choosing a specific MIC may depend on the PRO baseline value, consequences in patient care, such as type of intervention or the consequence of being misclassified.

Concluding message
Our study should be considered as a first step in improving our knowledge on the interpretation of the PROs and establishing their usefulness. As the focus of patients (embarrassment, fear, preventive measures) may differ from that of physicians (frequency and amount of lost stool, type of FI), it is recommended to include several measures for evaluation, such as the combination of a severity scale, subjective rating of improvement, and a quality of life instrument.

References
1. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. Gut 1999;44(1):77-80
2. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum 2000;43(1):9-16; discussion 16-7
3. Terwee CB, Roorda LD, Dekker J, Bierma-Zeinstra SM, Peat G, Jordan KP, et al. Mind the MIC: large variation among populations and methods. J Clin Epidemiol 2010;63(5):524-34.

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Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**