

INCONCLUSIVE PSYCHOMETRIC PROPERTIES OF THE VAIZEY SCORE IN FECALLY INCONTINENT PATIENTS: A PROSPECTIVE COHORT STUDY

Hypothesis / aims of study

To determine the psychometric properties of the total Vaizey score and its individual items, used to evaluate a pelvic floor rehabilitation (PFR) program in a group of patients with fecal incontinence (FI), and to justify its use in research and routine clinical practice. Determining the minimally important change (MIC) in physiotherapy trials would facilitate future sample size calculations and help define successful outcome.

Study design, materials and methods

The study was conducted as part of a large prospective cohort study assessing the outcome of a PFR program in patients with FI. Consenting eligible patients with FI visiting one of 16 participating Dutch hospitals were consecutively included. Patients received a standardized PFR program with weekly sessions of at least 35 minutes' duration for nine weeks. The PFR program was evaluated by calculating each Vaizey item and the total Vaizey score at baseline and at three months following PFR. The global perceived effect (GPE) score was obtained from patients who had recently completed PFR when rating their present situation relative to their level of incontinence before treatment. Ceiling and floor effects, test-retest reliability, internal consistency and responsiveness were assessed. Three methods were used to estimate the MIC: (1) the 'mean change' method, (2) the ROC method, and (3) the 95% limit cut-off point. These MIC values were compared to the SDC accounting for measurement error.

Results

194 patients were analyzed, 53 of whom provided data on the GPE score. PFR resulted in a significant reduction of the total Vaizey score (-3.01, p=0.00) and most individual items. The total Vaizey scores changed in agreement with the GPE scores. Although the total Vaizey score was responsive (Spearman r=-0.55, p=0.00), some individual items yielded inconsistent results. The weighted kappa assessment of the test-retest reliability of the total Vaizey score was performed on the unchanged group and was adequate with 0.55. Most subscale items also had adequate estimates, except for urge (poor) and medication (excellent). The internal consistency of the total Vaizey score was low at baseline (Cronbach's alpha: 0.30), in contrast to the follow-up (0.71) and change scores (0.69). The estimates for the MIC and SDC yielded moderately consistent results. An MIC of -5 points seemed preferable and yielded the lowest misclassification rate.

Interpretation of results

The Vaizey score is a brief outcome measure with promising psychometric properties, however not convincing for the internal consistency at baseline, the floor and ceiling effects and the variable MIC values. To support clinical-decision making, we suggest that the Vaizey scale structure should be revised in case of a low internal consistency or in case of non-responsive items. Including non-responsive items in a severity scale may cause underestimation of the effectiveness of the intervention program. Furthermore, future research should elucidate which type of FI is most responsive to PFR, to achieve both easier selection of patients suitable for PFR and more realistic expectations from PFR.

To interpret meaningful improvement or change, future research is needed to determine which value represents the MIC in the Vaizey score best.

Concluding message

More research with larger samples is required to confirm conclusions on the psychometric properties of the total Vaizey score and its individual items, and to justify its use in research and routine clinical practice.

Specify source of funding or grant	NONE
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	The Medical Ethics Committees of the 16 participating medical centres in the Netherlands approved the study.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes