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# THE CLINICAL VALIDATION OF A NEW SHORT FAECAL INCONTINENCE MEASURE FOR EPIDEMIOLOGICAL AND OUTCOMES RESEARCH

### Hypothesis / aims of study

The Revised Faecal Incontinence Scale (RFIS) contains three items from the Wexner Faecal Continence Grading Scale (WFCGS) and two other faecal incontinence items (1). All items were administered in a large community survey (N=2915) (2). The RFIS was developed from an examination of item psychometric properties and consists of the following self-report items:

### *In the past 4 weeks*

- Do you leak, have accidents or lose control with solid stool? (WFCGS)
- Do you leak, have accidents or lose control with liquid stool? (WFCGS)
- Do you leak stool if you don't get to the toilet in time?
- Does stool leak so that you have to change your underwear?
- Does bowel or stool leakage cause you to alter your lifestyle? (WFCGS)

Scoring is by simple summation, and the range is 0-20 with 0 indicating no incontinence.

The community survey data indicated the internal consistency reliability of the RFIS = 0.85 and the RFIS had superior measurement properties compared with the WFCGS (2). This suggested the RFIS would be useful for evaluation and epidemiological research but further validation would be required in clinical settings. This study reports an interim validation of the RFIS in clinical settings for incontinence treatment.

### Study design, materials and methods

Patients were recruited consecutively from 11 continence clinics (specialist and community) across 4 Australian States. The study examined clinical and patient definitions of incontinence status, treatment outcomes and success across 4 treatment types (Continence Advising, Physiotherapy, Surgery and Combined Treatments).

Based on baseline (recruitment, pre-treatment) and follow up (3 months post treatment), and an assumed effect size of 0.5 on the RFIS, where the test size was 0.05, power set at 0.80, the calculated sample size was 84 cases. This paper reports an interim analysis on the first 56 cases with complete baseline data and 27 faecal incontinence participants with full data (pre-post) available.

The study protocols contain the RFIS, other urinary incontinence items and questionnaires (e.g. WFCGS; St Marks (3)), incontinence impact and health related quality of life measures, and patient global ratings of severity and improvement.

### Results

Baseline: for all 56 cases the mean RFIS score was 9.59 (SD = 4.94). When examined by patient rating of the severity of faecal incontinence the means for those in a normal/mild state 7.14 (SD = 4.00, N = 22) and for those with moderate/severe incontinence 11.38 (SD = 4.88, N = 32) ( $F = 11.32$ , df = 1, 52,  $p < 0.01$ ). When examined by a general item on health status there were no significant differences between those in Excellent/Very Good, Good, or Fair/Poor Health; similarly there were no statistically significant associations by gender, education level, age group or BMI.

### Pre-treatment to Post-treatment change scores

At follow up the mean RFIS score was 6.03 (SD = 5.01, N = 30). Of these cases, 27 had pre-post scores. When examined by patient post treatment severity ratings there was a significant difference ( $F = 7.69$ , df = 27, 1,  $p = 0.01$ ) in RUIS mean scores between the less severe (4.44, SD 3.74, N= 18) and the more severe incontinence groups (9.18, SD 5.51, N=11).

Change scores on the RFIS (pre-post) ranged from an improvement of 18 points to a deterioration of 7 points. Examination of pre-post mean scores revealed a statistically significant improvement of 4.22 RFIS scores (SD = 4.9, paired t-test,  $t = 4.47$ , df = 27,  $p < 0.01$ ).

When examined by the pre-treatment patient rating of the severity of faecal incontinence there was no statistically significant difference in RFIS change scores for those with normal/mild incontinence (4.29, SD = 6.12, N = 14) and for those with moderate/severe incontinence (4.14 SD = 3.56, N = 12) ( $F = 0.04$ , df = 1, 24,  $p < 0.05$ ). This indicates there was no significant difference in the degree of improvement during treatment based on the initial patient severity rating. When these scores were dichotomized (improvers vs. no change/deterioration) and examined there were no significant differences by patient severity at baseline, health status, gender, education, age group or BMI.

### Reliability data

RFIS pre-treatment internal consistency reliability alpha = 0.81, N=56. The pre-treatment alpha for both the WFCGS = 0.67 and the St Marks = 0.69 which are considered marginal as they are less than 0.7. Post-treatment RFIS alpha = 0.88, N = 29 compared with WFCGS = 0.76 and St Marks = 0.68. Initial RFIS test-retest reliability was  $r = 0.76$  ( $p < 0.01$ ) N = 11 although more cases are currently being collected.

**Correlations with other measures:**

Pre-Treatment RFIS with WFCGS  $r = 0.88$  ( $p<0.01$ ); with St Marks  $r = 0.86$  ( $p<.01$ ); RFIS with the pre-treatment Patient Incontinence Severity Rating  $r = 0.57$  ( $p<0.01$ ). Correlations between RFIS with Wexner Type Specification (impact) items were all significant at the  $p<0.01$  level save for sexual relations ( $p>.05$ ) and church attendance ( $p>0.05$ ). The correlation of RFIS with Faecal Incontinence Quality of Life (FIQL) coping items  $r = 0.58$  ( $p<.01$ ). The RFIS correlation with the Physical Function Scale of the SF-36V2 was  $r = -0.19$  ( $p>0.05$ ) at pre-treatment which, although not significant, is consistent with findings in the literature showing a negative association between faecal incontinence and generic measures of HRQOL.

**Interpretation of results**

The RFIS has good internal consistency reliability as compared with the internal consistency reliability of the WFCGS and the St Marks and good interim test-retest reliability. The RFIS is sensitive to change as a result of treatment indicating it can be used to assess patient outcomes.

The RFIS possessed evaluative discrimination by patient assessed incontinence severity but did not discriminate by health or socio-demographic variables. Similarly, the RFIS appears to be responsive over time to changes in incontinence status. These two findings suggest it has both content and construct validity; i.e. it assesses the underlying condition of faecal incontinence and this assessment appears to be independent of possible confounders.

These findings regarding discrimination and responsiveness were observed despite the fact that this was an interim analysis with a sample size well under the calculated study sample size. Although this implies the findings may change once the full study is completed, the current findings suggest that the RFIS may prove to be even more discriminatory and responsive than indicated by these interim findings.

No flatus item is included in the RFIS as it confounds prevalence estimates for epidemiological research (2). Internal consistency reliability of the WFCGS at pre-treatment is also improved (from 0.67 to 0.71) if this item is removed. However, clinicians could use the WFCGS flatus item in addition to the RFIS for flatus assessment.

**Concluding message**

Initial indications are that the RFIS is performing well in clinical settings demonstrating good internal consistency reliability; correlations with other measures are in the expected directions; and there is evidence that it is sensitive to changes in continence status as a result of treatment making it suitable for outcome evaluation.

**References**

1. Dis Colon Rectum 1993; Vol. 36; 77-97
2. Refining Continence Measurement Tools 2006; Centre for Health Service Development, University of Wollongong and Department of Psychiatry, The University of Melbourne.
3. Gut 1999; Vol. 44, 1; 77-80

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<b>Is this a clinical trial?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Ethics Committee of the University of Wollongong
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes