

## A SIMPLE QUALITY OF LIFE QUESTIONNAIRE FOR PATIENTS WITH FAECAL INCONTINENCE.

### Hypothesis / aims of study

Faecal incontinence affects 2% of the adult general population. Current assessment tools only record the frequency and type of incontinence, with no measure of the effect on the patient's quality of life. Clinicians routinely underestimate the degree of lifestyle disruption in patients with faecal incontinence<sup>(1)</sup>. There is therefore a great need for a reliable and objective measure of quality of life in this patient group.

A simple quality of life questionnaire was designed to triage patients with faecal incontinence to the most appropriate level of support, investigation and treatment.

### Study design, materials and methods

A questionnaire was developed to include a 'symptom' score, similar in content to St Mark's questionnaire<sup>(2)</sup> and a 'bothersome' score (Questionnaire 1). A pilot study (34 patients) assessed the clarity of questions (content validity). It was carried out among patients with and without symptoms of faecal incontinence in an outpatient setting. Once content validity was established the questionnaire was sent to 360 patients who attended a pelvic floor clinic. Its external validity was assessed against the SF-36 and the Manchester Health Questionnaires and ease of use assessed using a separate form.

Each letter contained the following:

1. Patient information sheet
2. Demographic and incontinence questions
3. Three questionnaires: SF-36, Manchester Health and 'new' bowel control self assessment
4. Questions about ease of use
5. A stamped, self-addressed envelope.

A minimum correlation coefficient of 0.35 was shown during validation of the Manchester Health questionnaire<sup>(3)</sup>. Using Pearson's correlation coefficient it was calculated that a sample size of 63 or more was needed to demonstrate correlation between the new and reference questionnaires at 80% power using a two-tailed 5-percent level of significance.

### Results

Of the 360 patients, 86 replied, with a mean age of 56 years (range 26-86, 66 female). The questionnaire was shown to be reliable both by measurement of its internal consistency, (Cronbach's alpha statistic (0.9)) and by test-retest analysis (Spearman's Correlation Coefficient (SCC): 0.8 with  $p < 0.001$ ). There was a significant correlation between the scores of the new questionnaire and the Manchester Health Questionnaire, (SCC: 0.43 with  $p < 0.001$ ), as well as the SF-36 (SCC: 0.28 with  $p < 0.01$ ). Divergence validity, assessed by correlating the number of pads used and the overall 'symptom' score, was established (SCC: 0.5 with  $p < 0.001$ ). The new questionnaire was easiest and on average took 4 minutes to complete.

### Interpretation of results

We have demonstrated that the new questionnaire is reliable and valid. It is easy and quick to complete and assesses both severity and impact of symptoms.

29% of patients scored 1 or less in any of the domains. This is the group with minimal symptoms and low impact on the quality of life who can be reassured in the community. 17% scored a maximum of 2 in one or more domains, a moderately affected group and 54% scored 3 in at least one of the domains, a severely affected group. Those with moderate and severe symptoms should be considered for a referral to a specialist clinic.

### Concluding message

The National Institute for Health and Clinical Excellence (NICE) recommended development of a valid and reliable tool to measure patient-related outcomes including symptom severity and quality of life for people with faecal incontinence. The new bowel control self assessment questionnaire fits the criteria and we recommend its use in everyday clinical practice.

Questionnaire 1

### **Bowel control self assessment questionnaire**

Are you: Male  Female

Please answer the following questions about your bowels by putting the most appropriate number in the boxes provided for each question.

**Where:**

**0 = Not at all**

**1 = A little**

**2 = Moderately**

**3 = A great deal**

### **Over the last 4 weeks,**

1. When you have an urge to go to toilet to open your bowels do you have trouble holding on?

If yes, how much does it bother you?

2. Do you lose wind from your anus when you do not mean to?
- If yes, how much does it bother you?
3. Do you lose watery stool from your anus when you do not mean to?
- If yes, how much does it bother you?
4. Do you lose solid stool from your anus when you do not mean to?
- If yes, how much does it bother you?
5. Do you wear a pad or some form of protection for your bowel problem?
- If yes, how much does it bother you?

Thank you for filling in this questionnaire.  
Please return it to the nurse or to the doctor in clinic.

References

1. Incontinence. Plymouth:Health Publication Ltd 2002; 267-316.
2. Gut 1999; 44: 77-80.
3. BJOG 2001; 108: 1057-67.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Guy's and St Thomas' NHS Foundation Trust ethics committee</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>