The original publication is available at www.springer.com. This article was published in Quality of Life Research, 2007;16(2):331-43. doi: 10.1007/s11136-006-9005-3.

The development of a new measure of quality of life in the management of gastro-oesophageal reflux disease: the Reflux Questionnaire

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INTRODUCTION

Gastro-oesophageal reflux disease (GORD) is responsible for some of the most frequently reported symptoms in both primary and secondary care: between 20-30% of adults in developed countries experience reflux symptoms intermittently[1-3]. Diagnosis is usually based on related symptoms, such as "heartburn", acid regurgitation and dysphagia. The major objectives of treatment are control of symptoms, with reduction in the frequency and duration of reflux and pain, and improvement in health related quality of life (HRQOL).

GORD and its management represent a significant health care cost. The yearly budget within the British National Health Service for PPIs is £300million[4,5], approximately 30% of which is for treatment of oesophagitis and reflux symptoms. The majority of patients with significant GORD remain on long-term treatment.

Medical treatment for GORD depends on the severity of symptoms; thus it often escalates from self-administered antacids through lifestyle changes to the intermittent use of acid suppression therapy followed by continuous use of H_2 receptor agonists (H_2RAs) or more commonly proton pump inhibitors (PPIs). Whilst PPIs are usually highly effective and are generally assumed to be safe, there are concerns about the long-term use of acid suppression treatments. Patients with persistent GORD uncontrolled by PPIs, or who do not wish long-term medical treatment, may be offered surgery.

Surgical treatment for GORD takes the form of fundoplication, in which the upper part of the stomach (fundus) is wrapped around the lower oesophagus, and may be performed either as a minimal access (laparoscopic) or an open procedure. Although fundoplication is effective in controlling GORD it is unclear whether the benefits in controlling GORD outweigh the potential risks and side effects of the surgery[6, 7].

The REFLUX (Randomised Evaluation oF Laparoscopic sUrgery for refluX) trial is a large multicentre trial, funded by the NHS R&D Health Technology Assessment Programme, which aims to compare the clinical and cost effectiveness of minimal access surgery with best medical treatment for patients with GORD, for whom both treatments are acceptable options. As the diagnosis and management of GORD is largely based on patient reporting of symptoms, the primary outcome measure in the trial is patient-reported HRQOL.

Although several GORD-specific or gastro-intestinal-specific symptom scales and quality of life scales have been developed[8-16], none captures the experience of patients receiving alternative treatments in sufficient detail for evaluating outcomes in the REFLUX trial. Of particular concern was that these measures do not reflect patients' experience of the side effects of surgery for GORD, which include general gastro-intestinal symptoms as well as reflux itself[14]. A new condition-specific outcome measure was therefore developed for use within the trial. The aim of this measure was not only to assess the symptoms of GORD, but also the side effects of both medical and surgical treatment for GORD, and the effect these have on HRQOL. There were three requirements for the new measure: it had to measure health-related quality of life not merely symptom experience; its content had to cover the effects of treatment for GORD as well as the symptoms of GORD; and it had to summarise data in a form suitable for economic evaluation. This paper reports on the development and assessment of the new measure.

METHOD

Questionnaire development

Between May and September 2000, a series of one to one interviews and focus groups were carried out with patients in two cities, Leeds and Aberdeen, in order to identify those themes and issues related to GORD and its treatment that were important to them. Thirty-one people were interviewed, 15 receiving medical treatment, and 16 who had received surgery. In addition, two focus groups were conducted, each with six patients, one in Aberdeen and one in Leeds. Both focus groups included only patients who had received surgery for their GORD symptoms, identified via their gastroenterologist or surgeon.

Both the interviews and focus groups followed the same general format. Patients were asked questions about the types and severity of the symptoms they experienced, how best to describe their symptoms, whether they felt their symptoms were best described by their frequency, duration and level of distress, and about the impact their symptoms had on their daily lives.

All interviews and focus groups were audio taped and transcribed. These transcripts underwent thematic analysis by three members of the trial team. Emerging themes and issues

suggested potential questionnaire items. Wherever possible the language used by patients was used when devising the items. The transcripts showed frequency and effect of symptoms on patients' quality of life were the two most common themes.

Piloting

The initial version of the questionnaire (31 items) was piloted on a sample of 21 patients from Aberdeen, some of whom had taken part in the interview phase. The questionnaires were posted out to the patients asking them to complete it. At a later date they were interviewed about its readability and acceptability. Specifically, they were questioned about whether they had problems understanding the items, whether the response categories were appropriate for them, and whether they thought anything was missing from the questionnaire. The questionnaire was modified following the feedback from these interviews. A small number of items (n=3) were discarded as unsuitable or potentially ambiguous, others were re-worded and 3 items that were not originally included in the initial version of the questionnaire, but were repeatedly mentioned by the patients and felt to be of importance, were added**.**

Final questionnaire

The 31 items that were included in the formally evaluated version of the questionnaire were grouped into 7 categories (Heartburn; Acid reflux; Wind; Eating and swallowing; Bowel movements; Sleep; and Work, physical and social activities) describing symptoms relating to GORD or side effects of treatment (table 1). For each category respondents were asked to show how often they had experienced problems with specified symptoms over the past two weeks, followed by how much they felt those symptoms had affected their quality of life, also over the past two weeks. The symptom items offered five responses from "not at all" to "every day" while the quality of life items offered five responses – "not at all", "a little", "moderately", "a lot" and "extremely". Items in the less clinical category 'Work, physical and social activities' offered six responses, including "not applicable" (Appendix).

Table 1 about here

Data

The new measure, along with two generic measures of HRQOL (EQ-5D[17] and SF-36[18]) and information on background, demographics and use of medicine, was included in a postal questionnaire, which was sent to all REFLUX trial participants. Trial participants were sent a questionnaire at baseline after they have agreed to take part in the trial, at first follow-up (3

months after surgery or its equivalent for non surgical participants) and at second follow-up (12 months after surgery or equivalent). This paper reports on data received by December 2004, when 794 participants had returned a questionnaire at baseline, 602 participants had returned a questionnaire at first follow-up, and 418 participants had returned a questionnaire at second follow-up. Most of the analysis presented here was performed on the baseline data, but analysis of sensitivity to change also used the first follow-up data.

Analysis

Developing a scoring system

We planned that the new measure would produce two different types of score:

- a Reflux quality of life score (RQLS) summarising the extent to which respondents' symptoms affect their quality of life, where 0 is the worst quality of life and 100 is the best; and
- a series of seven Reflux symptom scores which profile respondents' experience these categories groups of symptoms over the past two weeks.

While it is possible to generate summary scores by merely summing the raw scores on each item, this assumes that all items in the measure are equally important. It disregards the possibility that some items are more important than others and should therefore have a larger effect on the final score. So we have used two distinct methods of weighting items' contribution to total score.

The Reflux questionnaire contains seven quality of life items, each relating to one of its seven categories, that require participants to indicate how much they feel their symptoms on a particular dimension in the past two weeks have affected their general quality of life. Weights for the RQLS were estimated by assessing the influence of these items on participants' assessment of their general quality of life. We used the seven baseline quality of life items as independent variables in an ordinary least squares (OLS) regression model with participants' assessment of their general HRQOL, as measured by the EQ-5D visual analogue scale (EQ-5D VAS), as dependent variable. For modelling purposes we assumed that the data from these items were cardinal. EQ-5D VAS requires respondents to assess their current state of health on a 0-100 visual analogue scale, where 0 represents worst imaginable health and 100 best imaginable health. To remain in the model, regression coefficients did not have to be statistically significant but they did have to have the correct (negative) sign, i.e. a reported

detrimental effect on quality of life should be associated with a decrease in EQ-5D VAS score. The resulting coefficients were used as weighting factors to calculate a general quality of life summary score.

In contrast weights for the Reflux symptom summary scores were generated by entering the 31 baseline symptom items into a principal components analysis (PCA) with a Varimax rotation. We judged how many components or factors to extract by using a combination of the Kaiser criterion (include all factors with an eigenvalue greater than 1) and a 'scree plot' of those eigenvalues. The resulting factor loadings were used as the item weights to calculate a number of symptom scores.

Reliability, validity and sensitivity to change

We assessed the reliability of the Reflux quality of life and symptom scores by internal consistency, as measured by Cronbach's alpha. In contrast our assessment of the validity and responsiveness or sensitivity to change of the new measure concentrated on the quality of life score, as this was the main aim of the measure. The validity of the RQLS was assessed by comparing its performance against the SF-36. Sensitivity to change was assessed by the measure's ability to reflect changes in participants' condition, as assessed by self-reported change in prescribed medication between baseline and first follow-up. Participants were asked to give details of their prescribed medication use (PPIs, H_2RAs and anti-emetics) at baseline and at first follow-up. This information was used to classify whether their medication use had changed between these times or not.

RESULTS

Sample characteristics

Between March 2001 and June 2004 a total of 810 participants had been recruited into the REFLUX trial, of whom 799 had completed and returned their baseline questionnaires. By December 2004 602 participants out of 649 (93%) had returned a first follow-up questionnaire, and 418 out of 447 (94%) a second follow-up questionnaire. At baseline, 64% of the sample was male and the median age at trial entry was 46 years (range 18 to 74).

Scoring

Generating weights for the Reflux quality of life score (RQLS).

All 727 participants with complete baseline data on the Reflux quality of life items and EQ-5D VAS were included in the analysis. Though coefficients for three of the seven quality of life items were not statistically significant, we kept them in the regression model for completeness. In contrast we excluded the Wind item from the RQLS model as the coefficient consistently showed the wrong sign and was not statistically significant. In effect the Wind item will receive a weight of zero when calculating the final score. The Work, physical and social activities item had the largest coefficient and thus had most effect on the EQ-5D VAS,, and the Sleep item the smallest coefficient. The final model is in table 2.

Table 2 about here

The coefficients from this model were used as weights for calculating the quality of life score by multiplying the response to each quality of life item (coded from 0 "not at all" to 4 "extremely") by the corresponding weight (i.e. the coefficient from table 2) and subtracting these values from the constant term in the following model:

a) Raw RQLS = 90-(heartburn quality of life x 1.35) - (acid reflux quality of life x 1.70) - (wind quality of life x 0) - (eating quality of life x 1.10) - (bowel movement quality of life x 1.95) - (sleep quality of life x 0.35) - (activities quality of life x 2.15).

The score was then standardised to a scale from 0 (worst quality of life) to 100 (best quality of life) as follows:

b) Standardised RQLS = (Raw RQLS - 55.6) x 2.91

Figure 1 presents the frequency distribution of quality of life scores for patients at baseline. The mean score was 65.0 with a standard deviation of 24.3.

Figure 1 about here

Generating weights for the Reflux symptom scores

PCA identified five components that accounted for 57% of the variance in the items (table 3). In general the component structure reflected the themes identified when the items were developed. However Component 1 grouped together heartburn-like symptoms and sleep disruption into something like general discomfort (table 3). The first component after rotation explained 19% of the total variance and included seven items with loadings above 0.4.

Component 2 explained 12% of the total variance and included six main items. The remaining 3 components accounted respectively for 10%, 9% and 8% of the total variance. Component loadings were used to construct a profile of five Reflux symptom scores to summarise an individual's symptom experience. In the first instance we suggest the following labels for these components: 1 = general discomfort; 2 = wind & frequency; 3 = nausea & vomiting; 4 = activity limitation; and 5 = constipation & swallowing.

Table 3 about here

Each symptom score was calculated by multiplying the response to each of the symptom items in that score (coded from 0 "every day" to 4 "not at all") by the corresponding weight (i.e. the coefficient from table 3) and then summing across the items. For the four items in activity limitation we grouped the response codes "not applicable" and "no my symptoms do not affect me" as 4, and recoded the other categories from 3 "my symptoms have affected me but I still work/perform these activities" to 0 "I no longer work/perform these activities because of my symptoms". Symptom scores were then standardised to a scale from 0 (worst symptom score) to 100 (best symptom score) as follows:

General discomfort = 5.24 x ((item A1 x 0.674) + (item A2 x 0.643) + (item B1 x 0.654) + (item D2 x 0.421) + (item F1 x 0.777) + (item F2 x 0.814) + (item F3 x 0.791)) .

Wind & frequency = 6.59 x ((item C1 x 0.738) + (item C2 x 0.553) + (item C3 x 0.568) + (item C4 x 0.515) + (item E1 x 0.722) + (item E3 x 0.696))

Nausea & vomiting = 9.84 x ((item B2 x 0.734)+(item B3 x 0.556)+(item B4 x 0.541) + (item B5 x 0.709))

Activity limitation = 9.58 x ((item G1 x 0.695) + (item G2 x 0.571)+(item G3 x 0.755) + (item G4 x 0.588))

Constipation & swallowing = 13.72 x ((item D1 x 0.338) + (item E2 x 0.839) + (item E4 x 0.645))

Table 4 presents the mean symptom scores at baseline. There were pronounced ceiling effects for nausea & vomiting, constipation & swallowing, and activity limitations: 26%, 25% and 17% respectively of the sample had a maximum score of 100. In contrast wind & frequency showed a more normal distribution.

Table 4 about here

Both the RQLS and Reflux symptom scores were calculated only for individuals with complete data. However there were few missing data. Reflux scores could be calculated for over 95% of patients at baseline. Missing data rates for symptom items ranged between 1 and 2% and for quality of life items between 3 and 5%.

Reliability

The reliability coefficient (Cronbach's alpha) measuring the internal consistency of the RQLS was 0.90. For the Reflux symptom scores alphas were: general discomfort 0.87; wind & frequency 0.78; nausea & vomiting 0.75; activity limitations 0.68; and constipation & swallowing 0.56. Apart from the last item, all alphas are greater than 0.7, which is generally considered satisfactory[19].

Validity

Table 5 presents the relationship (Pearson's r) between the RQLS and the eight SF-36 dimension scores. Social functioning and bodily pain showed the best relationship with the RQLS, and the mental health dimension the worst.

Table 5 about here

Table 6 presents the proportion of respondents who had a score of 100 (best health) on the SF-36 dimensions as a percentage of those who had a best score of 100 on the RQLS. While 96% of those who had the maximum score on the SF-36 physical functioning dimension also had a score of 100 on the RQLS, only 31% of those who had a score of 100 on the SF-36 bodily pain dimension also had a score of 100 on the RQLS.

Table 6 about here

Figure 2 plots the mean RQLS against the SF-36 physical component score (PCS) and mental component score (MCS) grouped into fifths. The mean RQLS increases steadily and significantly between successive PCS groups. There is a similar pattern for MCS groups except that respondents in the highest fifth have a lower mean RQLS than those in the next lower fifth.

Figure 2 about here

Sensitivity to change

Participants reported whether they were being prescribed medication at baseline and first follow-up. This information was used to classify them into four groups: those prescribed medication at baseline and follow-up (N=293); those prescribed medication at baseline but not follow-up (N=186); those who prescribed medication at follow-up but not baseline (N=3); and those not prescribed medication at all (N=7). As the last groups are reassuringly small, Figure 3 presents mean change in RQLS (baseline score - follow-up score) for the first two groups

Figure 3 about here

A negative score indicates an improvement in quality of life. Although the RQLS improved for both groups (paired t-tests showed significant change), patients whose medication status changed between baseline and follow-up (medication at baseline but not at follow-up) showed a greater improvement in their RQLS than patients whose medication status stayed the same (medication at baseline and follow-up).

DISCUSSION

Principal findings

This paper describes a new outcome measure for use with patients with gastro-oesophageal reflux disease (GORD). The Reflux questionnaire comprises 31 items and generates a single score (RQLS) measuring the extent to which individual participants feel that their GORD symptoms, and any side effects of treatment, affect their quality of life. The 31 items also generate five Reflux symptom scores measuring the extent to which those participants experienced clusters of symptoms over the past two weeks. Thus the RQLS provides a single index that can be used to record change for evaluation, while the symptom scores provide a descriptive profile that describes whether respondents experience problems in specific clusters. The data presented provide evidence that the new measure is valid, reliable and sensitive to change.

Strengths of the study

The Reflux questionnaire was designed as a patient-centred self-completed postal questionnaire. Items were generated by using GORD patients as key informants, rather than relying on the views of clinicians or other experts. So the Reflux questionnaire covers those elements of their illness that GORD patients indicated were important in determining their quality of life. A patient-centred approach also underlies the scoring system used to generate the RQLS. The weights used to create this score were based on the relationship between participants' reports of their scores on seven quality of life items and of their general health status on a visual analogue scale. The score takes account of patients' preferences through their self-reported effect on quality of life. In contrast the Reflux symptom scores, not intended as measures of HRQOL, used essentially statistical weights, generated from principal components analysis of symptom frequencies rather than patients' views.

The performance of a measure may also be assessed by its acceptability to respondents. Although the Reflux questionnaire has 31 items, it suffered very few reported difficulties or missing item responses within the REFLUX trial. During the pilot modifications were based on patient feedback on the acceptability and readability of items.

Weaknesses of the study

The most common method of establishing the validity of a measure is to analyse its association with a criterion of known validity that is accepted as a 'gold standard'. However there is no gold standard for quality of life in, or disease severity in, GORD by which to determine validity[14]. Nevertheless the REFLUX trial does use SF-36 and EQ-5D, two reputable measures of generic HRQOL, though not designed for use with GORD patients. As we had used the EQ-5D VAS to generate the RQLS, we used the SF-36 to establish construct validity. The RQLS showed good correlations with the SF-36 dimensions of bodily pain and social functioning, topics common to both measures, and weaker correlations with mental health and energy, topics not included in the Reflux questionnaire. Though we used self-reported change in medication to assess the sensitivity of the RQLS to change, this assumes that changing from being prescribed medication to not being prescribed medication necessarily shows improved health status.

The second issue in establishing the validity of the Reflux questionnaire is that the analysis was based on patients with controlled symptoms, since one of the trial inclusion criteria was

"reasonable symptom control" with medication. Thus 10% of patients achieved the best possible RQLS at baseline, showing that their GORD was affecting quality of life "not at all", probably because medication provided complete symptom control. There is scope to ameliorate these ceiling effects in future.

The final issue relates to the interpretability of the five Reflux symptom scores, derived through multivariate statistical analysis. To interpret the resulting weights we have suggested five labels: general discomfort; wind & frequency; nausea & vomiting; activity limitation; and constipation & swallowing. Though the first four are easy to interpret, the fifth contains only three items – "difficulty in swallowing" and two relating to constipation. Although these appear heterogeneous, that is a common consequence of multivariate analysis, which takes full account of correlations between items. Furthermore these items play little part in the other four dimensions, and have been identified as potential side effects of surgical treatment. We have therefore retained this fifth dimension, more to assess changes after treatment rather than status at baseline.

Unanswered questions

The aim of this paper was to validate a new measure of the HRQOL of patients being treated for GORD. Further evidence about the performance of the measure will be available through detailed analysis of the REFLUX trial, due to be completed in 2006. Although our principal aim was to develop and validate an outcome measure for use in the REFLUX trial, we hope that the Reflux questionnaire will prove more widely applicable.

ACKNOWLEDGEMENTS

We thank the NHS R&D Health Technology Assessment programme for grant support of the Reflux Trial. We also thank all who took part in this study and gave generously of their time and views. The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Executive Department of Health. The views expressed are the authors', not necessarily the funders'.

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Figure 1. Distribution of RQLS

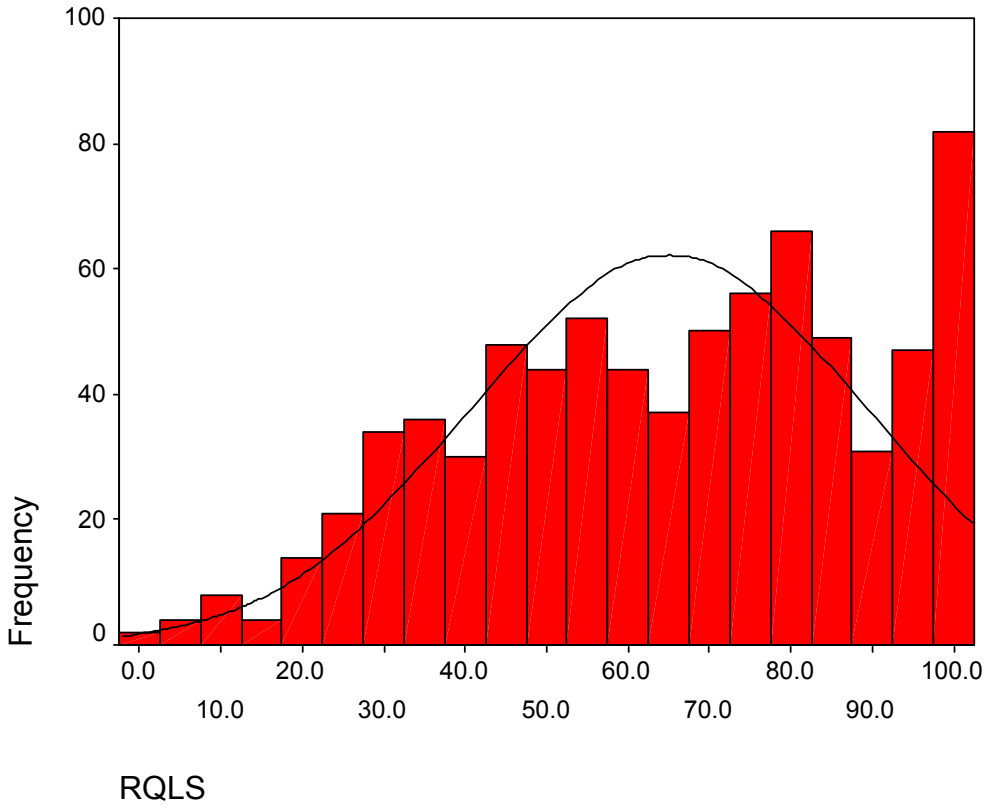


Figure 2. RQLS by SF-36 physical component summary score and mental component summary score (grouped in fifths)

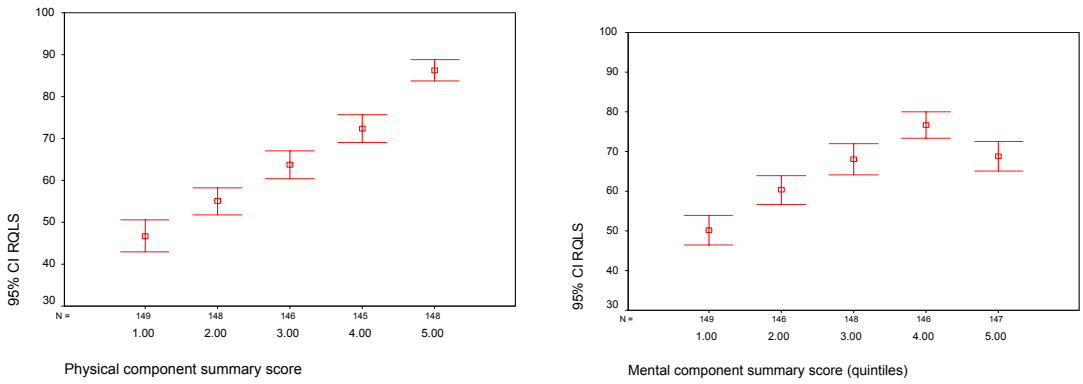


Figure 3. Change in RQLS by change in prescribed medication (baseline to follow-up)

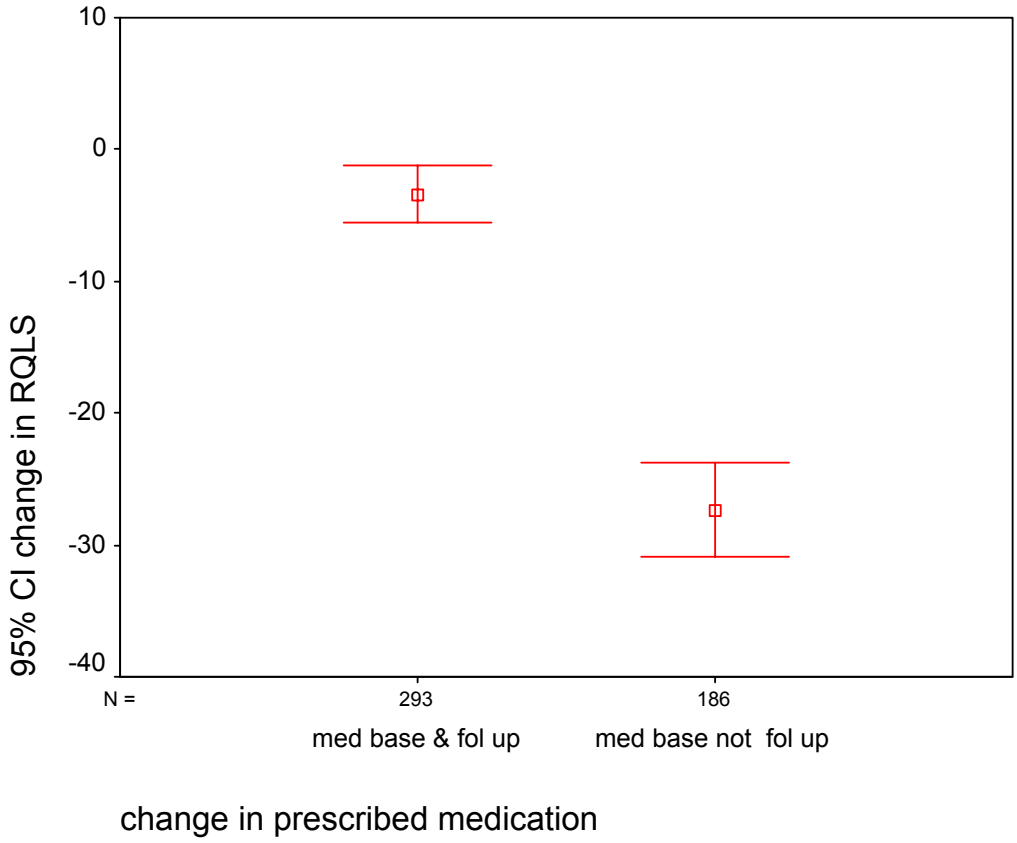


Table 1. Reflux categories

Category	Number of items
Heartburn	3
Acid reflux	6
Wind	5
Eating and swallowing	3
Bowel movements	5
Sleep	4
Work, physical and social activities	5

Table 2. Model coefficients used to calculate the Reflux Quality of Life Score (RQLS)

Reflux quality of life item	B	SE	Sig
Heartburn	-1.346	0.81	NS
Acid reflux	-1.700	0.70	<0.05
Eating and swallowing	-1.103	0.68	NS
Bowel movements	-1.954	0.61	<0.01
Sleep	-0.351	0.66	NS
Work, physical and social activities	-2.147	0.84	<0.05
Constant	89.995	1.51	<0.001

Adj R^2=0.22

Table 3. Component loadings used to calculate the Reflux symptom scores

Item	Component 1	Component 2	Component 3	Component 4	Component 5
A1: heartburn	0.674				
A2: discomfort in chest	0.643				
B1: acid reflux	0.654				
B2: vomiting			0.734		
B3: regurgitating			0.556		
B4: nausea			0.541		
B5: urge to be sick			0.709		
C1: flatulence		0.738			
C2: belching		0.553			
C3: feeling bloated		0.568			
C4: stomach gurgling		0.515			
D1: difficulty swallowing					0.338
D2: eating restricted	0.421				
E1: diarrhoea		0.722			
E2: constipation					0.839
E3: urgent need to go		0.696			
E4: feeling like bowels not emptied					0.645
F1: difficulty sleeping lying down	0.777				
F2: difficulty getting to sleep	0.814				
F3: disrupted sleep	0.791				
G1: paid/unpaid work				0.695	
G2: less strenuous activities				0.571	
G3: strenuous activities				0.755	
G4: social activities				0.588	

Note: Factor loadings <0.3 have been suppressed.

Table 4. Mean Reflux symptom scores at baseline

Reflux symptom dimension	Mean	SD	Median
General discomfort	59.4	25.6	60.3
Wind & frequency I	50.7	22.1	49.6
Nausea & vomiting	81.7	19.6	89.0
Activity limitation	79.2	16.5	81.5
Constipation & swallowing	77.7	20.6	79.6

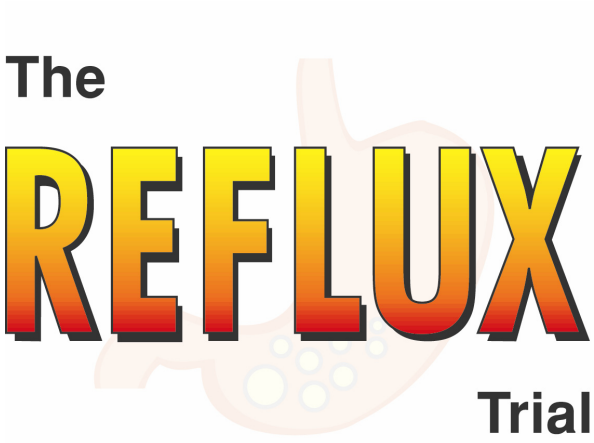
Table 5. Relationship (Pearson's r) between RQLS and SF-36 dimension scores

SF-36 dimension	RQLS
Physical functioning	0.42
Role limitations-physical	0.49
Bodily pain	0.56
General health perception	0.46
Energy/vitality	0.34
Social functioning	0.59
Role limitations-emotional	0.41
Mental health	0.18

Table 6. Percentage (n) of respondents with maximum RQLS with maximum score on the SF-36 dimensions

SF-36 dimension	% (n)
Physical functioning	96 (70)
Role limitations-physical	66 (48)
Bodily pain	31 (23)
General health perception	--
Energy/vitality	--
Social functioning	74 (54)
Role limitations-emotional	97 (71)
Mental health	--

Appendix



The Reflux Questionnaire

REFLUX QUESTIONNAIRE

For the following questions, please put a cross in the box which best describes how often your symptoms have occurred and the effect they have had on your quality of life.

SECTION A - HEARTBURN

A1. In the last two weeks, how often have you experienced heartburn (a burning sensation which moves up from your chest to your throat)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

A2. In the last two weeks, how often have you experienced any discomfort or pain in your chest?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

A3. In the last two weeks, how much has the heartburn or discomfort/pain in your chest affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION B - ACID REFLUX

B1. In the last two weeks, how often have you experienced acid reflux and/or had an acid taste in your mouth?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

B2. In the last two weeks, how often have you been sick (vomited)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

B3. In the last two weeks, how often have you regurgitated (brought up) quantities of liquid or solids into your mouth?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

B4. In the last two weeks, how often have you experienced a feeling of nausea (without actually being sick or regurgitating)?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

B5. In the last two weeks, how often have you wanted to be sick but physically been unable to?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

B6. In the last two weeks, how much have these reflux symptoms affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION C – WIND

C1. In the last two weeks, how often have you experienced a lot of wind from the lower bowel?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

C2. In the last two weeks, how often have you experienced a lot of burping/belching?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

C3. In the last two weeks, how often have you experienced bloatedness and/or a feeling of trapped wind, in your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

C4. In the last two weeks, how often have you experienced loud gurgling noises from your stomach?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

C5. In the last two weeks, how much have these wind problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION D - EATING AND SWALLOWING

D1. In the last two weeks, how often have you experienced difficulty swallowing food or have you actually choked on food?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

D2. In the last two weeks, how often have your eating habits been restricted because of your condition? Examples might be eating more slowly, having smaller portions or eating different foods.

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

D3. In the last two weeks, how much have these problems with eating affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION E – BOWEL MOVEMENTS

E1. In the last two weeks, how often have you experienced diarrhoea and/or loose stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

E2. In the last two weeks, how often have you experienced constipation and/or hard stools?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

E3. In the last two weeks, how often have you felt an urgent need to have a bowel movement ?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

E4. In the last two weeks, how often have you had a feeling of not emptying your bowels?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most days ☐
- Every day ☐

E5. In the last two weeks, how much have these bowel problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION F – SLEEP

F1. In the last two weeks, how often have you experienced difficulty in lying down to sleep?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F2. In the last two weeks, how often have you experienced difficulty getting to sleep because of your reflux symptoms?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F3. In the last two weeks, how often have you been woken up because of your reflux symptoms?

- Not at all ☐
- Once a week ☐
- Two or three times a week ☐
- Most nights ☐
- Every night ☐

F4. In the last two weeks, how much have these sleep related problems affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐

SECTION G – WORK, PHYSICAL AND SOCIAL ACTIVITIES

For the following section, please put a cross in the box which best applies to you.

G1. In the last two weeks, have your reflux symptoms affected you at work (paid or voluntary)?

- Not applicable (I do not do paid or voluntary work) ☐
- No, my symptoms do not affect me ☐
- Yes, my symptoms have affected me but I still work ☐
- Yes, I have worked less often because of my symptoms ☐
- Yes, I have not worked in the last two weeks because of my symptoms ☐
- I no longer work because of my symptoms ☐

G2. In the last two weeks, have your reflux symptoms affected your ability to perform less strenuous activities (such as going for a gentle walk, shopping or housework)?

- Not applicable (I do not perform these activities, though this is not due to my reflux symptoms) ☐
- No, my symptoms do not affect me ☐
- Yes, my symptoms have affected me but I still perform these activities as often as ever ☐
- Yes, I perform these activities less often because of my symptoms ☐
- Yes, I have not performed these activities in the last two weeks ☐
- I no longer perform these activities at all because of my symptoms ☐

G3. In the last two weeks, have your reflux symptoms affected your ability to perform strenuous activities (such as brisk walking or swimming)?

- Not applicable (I do not perform these activities, though this is not due to my reflux symptoms) ☐
- No, my symptoms do not affect me ☐
- Yes, my symptoms have affected me but I still perform these activities as often as ever ☐
- Yes, I perform these activities less often because of my symptoms ☐
- Yes, I have not performed these activities in the last two weeks ☐
- I no longer perform these activities at all because of my symptoms ☐

G4. In the last two weeks, have you found that your reflux symptoms have affected any of your social activities (such as going out for meals, going out for drinks or socialising with other people)?

- Not applicable (I do not perform these activities, though this is not due to my reflux symptoms) ☐
- No, my symptoms do not affect me ☐
- Yes, my symptoms have affected me but I still perform these activities as often as ever ☐
- Yes, I perform these activities less often because of my symptoms ☐
- Yes, I have not performed these activities in the last two weeks ☐
- I no longer perform these activities at all because of my symptoms ☐

G5. In the last two weeks, how much has the effect of your symptoms on your work, physical or social activities affected your quality of life?

- Not at all ☐
- A little ☐
- Moderately ☐
- A lot ☐
- Extremely ☐