Validation of the short-form REFLUX-QUAL® (RQS®), a gastro-esophageal reflux disease (GERD) specific quality of life questionnaire

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SUMMARY

Introduction — Being an easy-to-use (eight items) quality of life questionnaire specific to GERD, the Reflux-Qual Short form (RQS®) was developed for use in everyday practice. The purpose of this study was to assess the psychometric properties of the RQS®.

Methods and materials — The reliability of the RQS® was measured by the Cronbach’s alpha coefficient and its clinical validity by comparing the RQS score for increasing clinical severity groups. The RQS® discriminative power was compared with that of the SF-12. Sensitivity to change over time was measured by calculating effect-sizes.

Results — The reliability and validity of the questionnaire were assessed on a sample of 1195 patients. Its psychometric properties were very satisfactory: Cronbach alpha = 0.84; RQS score significantly reduced for the worst-affected patients; the discriminative power was up to 5 times higher when compared with the SF-12. Sensitivity to change over time, evaluated with 362 patients, showed highly significant differences between groups with different levels of clinical progression (P = 0.0001).

Conclusion — The RQS® is a quality of life measurement instrument specific to GERD which is short, reliable, valid, and sensitive to within and between-subject differences.

Gastro-esophageal reflux disease (GERD) represents a major problem for public health because of its high incidence and impact on Quality of Life (QoL), which can be considerable. GERD is a chronic disease and prevalence of symptoms in the general population is very high with up to 10-20% of adults presenting heartburn or regurgitations weekly [1]. After 5 to 10 years of follow-up, two thirds of patients complain of persistent symptoms, requiring intermittent or continuous treatment. Only a minority of these patients develop severe esophagitis or complications [2].

Although GERD is not related to higher death rates, the impact of this disease on the QoL of patients has been clearly demonstrated [3-5]. Consequently, in this disease, where effectiveness of care in everyday practice is measured essentially on the basis of patients’ complaints and experience, use of a QoL questionnaire is extremely beneficial.

The recommendations on GERD healthcare management made at the 1999 Franco-Belgian Consensus Conference [6] advocated for “the individual management of patients, the panel suggests development of specific and simple questionnaires completed by doctors or, better still, by patients” [7].

Therefore, measurement of GERD-related QoL in everyday practice depends on the existence of measurement instruments that are not only easy to use, and hence short, but are also valid, reliable and sensitive.

A validated QoL questionnaire specific to GERD, the Reflux-Qual®, is currently in use in clinical research and has been shown to have excellent psychometric properties [8, 9]. Improved QoL with treatment has been demonstrated in a randomized clinical trial, the CILANCE study [10]. However, the number of included

RÉSUMÉ

Validation du questionnaire REFLUX-QUAL® simplifié (RQS®), un questionnaire de qualité de vie spécifique du reflux gastro-œsophagien.

Michel AMOURETTI, Bernard NALET, Michel ROBASZKIEWICZ, Jean-Pierre WAINSTEN, Christine de la LOGE, Khadra BENMEDJAHED, Carla DIAS-BARBOSA, Sylvie BRIN, Bernard SCHATZ

(Gastroenterol Clin Biol 2005;29:793-801)

Introduction — Un questionnaire spécifique du RGO facile à utiliser, le Reflux-Qual Simplifié (RQS®), a été développé pour une utilisation en pratique médicale courante. L’objet de cette étude était de vérifier les propriétés psychométriques du RQS®.

Méthodes et matériels — La fiabilité du RQS® a été évaluée par le calcul du coefficient alpha de Cronbach et sa validité par comparaison du score RQS pour différents niveaux de sévérité de la mala-
die. Le pouvoir discriminant du RQS® a été comparé à celui du SF-12. La sensibilité aux changements dans le temps a été mesurée en calculant des effect-sizes.

Résultats — La fiabilité et la validité du questionnaire ont été évaluées sur un échantillon de 1195 malades. Ses propriétés psychométriques étaient satisfaisantes : coefficient alpha de Cronbach = 0,84 ; le score RQS était significativement diminué pour les malades les plus affectés ; le pouvoir discriminant était jusqu’à 5 fois plus important que celui du SF-12. La sensibilité aux changements dans le temps, mesurée sur 362 malades, montre des différences hautement significatives entre groupes de malades ayant une progression clinique différente (P = 0,0001).

Conclusion — Le RQS® est un instrument de mesure de la qualité de vie spécifique du RGO qui est court, fiable, valide et sensible aux différences intra et inter-sujets.
items (N = 37) precludes its use in everyday medical practice. As a result, a short form of the questionnaire (appendix), the RQS®, was developed [11, 12]. The RQS® consists of 8 items covering the principal domains of the patients’ QoL (Daily life — 2 items, Well-being — 2 items, Psychological impact — 2 items, Sleep — 1 item and Eating — 1 item). Using this questionnaire, a score is rapidly obtained that varies from 0 to 100, 0 corresponding to the lowest and 100 to the highest level of QoL.

The purpose of this study is to present the psychometric properties of the RQS® on a sample independent from that used in its development and to assess its responsiveness to change over time using clinical trial data.

Patients and methods

Creation of the RQS® / Item selection

The selection of Reflux-Qual® items to generate the RQS® was made on a sample of 539 patients using the Item Response theory model [13] (the study design, inclusion criteria and data collection procedures for this initial phase were similar to those described hereafter for the psychometric validation phase). The model was repeatedly applied to exclude redundant items and outliers (through infit statistics). Items were selected to cover, as much as possible, each dimension covered by the Reflux-Qual®. Further selection was made using investigators and patients’ choices. Item selection was also made so that the resulting questionnaire had the potential to discriminate all severity levels. Results of the regression analysis and correlation of the RQS score with the original Reflux-Qual® 37-items score indicated high concordance between the two scores (r = 0.95). Detailed results of this item selection phase are provided elsewhere [11, 12].

Finalization of the RQS® led to some modifications to simplify the RQS® scoring, such as renumbering the response choices from 0 to 4 so that a higher score always indicates a higher QoL. The RQS score, using the final version of the RQS® questionnaire, ranges from 0 (lowest QoL level) to 100 (highest QoL level) and is calculated as follows: RQS® score = mean value of the 8 items x 25.

Both the English and French versions of the RQS® instrument are presented in appendix although the psychometric properties provided in this manuscript were established for the French version.

Psychometric validation

DESIGN OF THE STUDY, PATIENTS AND DATA COLLECTION

A cross-sectional, multi-centre, observational study with completely anonymous data collection was carried out with general practitioners and gastroenterologists in order to validate the psychometric properties of the RQS®. A representative sample of general practitioners and gastroenterologists were obtained by random selection from the “TVF” register (supplied by the TVF Company affiliated to the CEGEDIM). This register is noted for its quality and updating in real time. A total of 300 general practitioners and 100 gastroenterologists throughout France were asked to include a sample of 1100 patients aged between 18 and 75, presenting GERD diagnosed either by typical symptoms, endoscopy or 24h pH test. Patients were not eligible if they suffered from GERD episodes.

In order to compare the progression of the two groups under treatment, the patients had to complete the Reflux-Qual® 37-item QoL questionnaire and the Gastrointestinal Symptom Rating Scale (GSRS), a questionnaire more sensitive to clinical differences compared with the SF-12 generic questionnaire.

Sensitivity to change over time of the RQS score

DESIGN OF THE STUDY, PATIENTS AND DATA COLLECTION

Sensitivity to change over time of the RQS score was studied on the basis of data from the CILANCE clinical trial [10]. The CILANCE study was a multi-centre, phase IV, randomized double-blind trial in parallel groups, one group receiving 1.5 mg of lanzoprazole in the morning and a placebo in the evening, the other group receiving 10 mg of cisapride in the morning and evening over a treatment period of 4 weeks. The trial consisted of two examinations, one at inclusion (W0) and a final examination 4 weeks later (W4). Seventy-six investigating centers took part in this trial and had to include 340 patients aged between 18 and 65. To be included, the patients had to have presented typical GERD symptomatology (heartburn and/or acid regurgitations) for at least 3 months. GERD had to be the main reason for the inclusion consultation, with heartburn occurring for at least 2 days during the week prior to inclusion.

In order to compare the progression of the two groups under treatment, the patients had to complete the Reflux-Qual® 37-item QoL questionnaire and the Gastrointestinal Symptom Rating Scale (GSRS), a

ABBREVIATIONS:

ES = Effect Size
GERD = Gastro-Esophageal Reflux Disease
GSRS = Gastrointestinal Symptom Rating Scale
MCS = Mental Component Summary
PCS = Physical Component Summary
QoL = Quality of Life
RQS® = Reflux-Qual Short form
SF-12 = Short Form 12

SPONSORS / GRANTS: This study has been realised with the help of the « Société Nationale Française de Gastro-entérologie » (SNFGE) and the pharmaceutical company AVENTIS. The pharmaceutical company AVENTIS holds the copyright of the original version and of the future translations of the questionnaire RQS®.

symptomatic measurement questionnaire specific to GERD [24, 25], at inclusion and after 4 weeks of treatment.

To study the sensitivity to change over time of the RQS® simplified score, this score was calculated on the basis of the 8 items taken from the long version (37 items) of the QoL questionnaire Reflux-Qual® [11, 12], then applied to the two groups of patients included in the CILANCE clinical trial.

**Analysis**

Sensitivity to change over time is defined as the capacity of the questionnaire to reveal a change in the clinical condition of the patients. This analysis, performed independently of treatment groups, studied the progression of the RQS score between inclusion and the end of the treatment period, according to the clinical progression of the patient [25, 26]. The descriptions were completed with paired tests of no progression and following dietary guidelines and a little less than half (47.9%) included in the study population, more than half (59.5%) were working full-time (table I).

More than half had not studied beyond GCSE advanced level and more than half were also working full-time (table I).

On average, GERD had lasted for 3.5 years (± 5.3) and 499 patients (41.7%) had GERD for less than a year. A very clear majority of the patients included in the study population presented at least one of the symptoms typical of GERD (94.3%): 841 patients (70.4%) were suffering from heartburn, 774 (64.8%) from acid regurgitations, and 626 (52.4%) were suffering from burning epigastric pains with upward irradiation (table II). Clinicians classified a minority of patients as suffering mainly from atypical symptoms (148 patients or 12.4%), and the percentage of patients suffering exclusively from atypical symptoms was only 5.7% (N = 68). Among the 1195 patients included in the study population, more than half (59.5%) were following dietary guidelines and a little less than half (47.9%) were on self-medication: antacids or alginites (85.7%). Among the 825 patients (69%) treated for their GERD at the time of the study, 50% were on a proton pump inhibitor at half dosage.

### RESULTS

**Psychometric validation**

**Characteristics of patients included**

Between October 2001 and June 2002, 1266 patients were included by 327 general practitioners and gastroenterologists. In all, 1245 patient questionnaires (RQS® and SF-12) were received and after exclusion of patients for whom one of the documents was missing or patients having completed their questionnaires more than 7 days after the consultation, 1195 records were taken into account in the analysis. The patients had a mean age of 51.4 (± 13.5) and 638 (53.4%) were men. The majority of the patients were living as a partner in a couple or as a member of a family. More than half had not studied beyond GCSE advanced level and more than half were also working full-time (table I).

On average, GERD had lasted for 3.5 years (± 5.3) and 499 patients (41.7%) had GERD for less than a year. A very clear majority of the patients included in the study population presented at least one of the symptoms typical of GERD (94.3%): 841 patients (70.4%) were suffering from heartburn, 774 (64.8%) from acid regurgitations, and 626 (52.4%) were suffering from burning epigastric pains with upward irradiation (table II). Clinicians classified a minority of patients as suffering mainly from atypical symptoms (148 patients or 12.4%), and the percentage of patients suffering exclusively from atypical symptoms was only 5.7% (N = 68). Among the 1195 patients included in the study population, more than half (59.5%) were following dietary guidelines and a little less than half (47.9%) were on self-medication: antacids or alginites (85.7%). Among the 825 patients (69%) treated for their GERD at the time of the study, 50% were on a proton pump inhibitor at half dosage.

#### Table I. Description of patients: socio-demographic characteristics per patients’ group (N=1195).

<table>
<thead>
<tr>
<th>Items</th>
<th>Predominant typical Symptoms</th>
<th>Predominant atypical Symptoms</th>
<th>Total Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>51.27 ± 13.29</td>
<td>53.09 ± 14.75</td>
<td>51.43 ± 13.50</td>
</tr>
<tr>
<td>STD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDa</td>
<td>8 (0.77)</td>
<td>8 (0.67)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>569 (54.82)</td>
<td>638 (53.39)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>461 (44.41)</td>
<td>549 (45.94)</td>
<td></td>
</tr>
<tr>
<td><strong>Domestic situation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDa</td>
<td>9 (0.87)</td>
<td>9 (0.75)</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>195 (18.79)</td>
<td>231 (19.33)</td>
<td></td>
</tr>
<tr>
<td>Living with partner or family</td>
<td>829 (79.87)</td>
<td>950 (79.50)</td>
<td></td>
</tr>
<tr>
<td>Other (commune, religious order etc)</td>
<td>5 (0.48)</td>
<td>5 (0.42)</td>
<td></td>
</tr>
<tr>
<td><strong>Level of education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDa</td>
<td>10 (0.96)</td>
<td>10 (0.84)</td>
<td></td>
</tr>
<tr>
<td>Basic secondary</td>
<td>534 (51.45)</td>
<td>614 (51.38)</td>
<td></td>
</tr>
<tr>
<td>High school graduate</td>
<td>261 (25.14)</td>
<td>301 (25.19)</td>
<td></td>
</tr>
<tr>
<td>Higher education</td>
<td>233 (22.45)</td>
<td>270 (22.59)</td>
<td></td>
</tr>
<tr>
<td><strong>Working status during the study</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDa</td>
<td>10 (0.96)</td>
<td>11 (0.92)</td>
<td></td>
</tr>
<tr>
<td>Working full time</td>
<td>477 (45.95)</td>
<td>543 (45.44)</td>
<td></td>
</tr>
<tr>
<td>Working part time</td>
<td>71 (6.84)</td>
<td>80 (6.69)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>62 (5.97)</td>
<td>71 (5.94)</td>
<td></td>
</tr>
<tr>
<td>Retired (or early retirement)</td>
<td>322 (31.02)</td>
<td>379 (31.72)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>96 (9.25)</td>
<td>111 (9.29)</td>
<td></td>
</tr>
<tr>
<td><strong>Details of professional activity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDa</td>
<td>13 (1.25)</td>
<td>14 (1.17)</td>
<td></td>
</tr>
<tr>
<td>Farmer</td>
<td>53 (5.11)</td>
<td>65 (5.44)</td>
<td></td>
</tr>
<tr>
<td>Executive, higher academic profession</td>
<td>76 (7.22)</td>
<td>85 (7.11)</td>
<td></td>
</tr>
<tr>
<td>Intermediate-level profession (infant/primary school teacher, technician)</td>
<td>185 (17.82)</td>
<td>205 (17.15)</td>
<td></td>
</tr>
<tr>
<td>Clerk</td>
<td>154 (14.84)</td>
<td>169 (14.14)</td>
<td></td>
</tr>
<tr>
<td>Labourer (including farm labourer)</td>
<td>78 (7.51)</td>
<td>97 (8.12)</td>
<td></td>
</tr>
</tbody>
</table>

MDa: missing data

**Acceptability of the RQS® questionnaire**

The acceptability of the RQS® questionnaire was judged excellent since, out of the 1245 questionnaires received, 1227 (98.5%) were fully completed. The mean percentage of...
missing data per questionnaire was 0.9% (r = 9). No item of the RQS® presented a percentage of missing data higher than 1%.

**INTERNAL RELIABILITY, CONSTRUCT VALIDITY AND DISTRIBUTION OF THE RQS® QUESTIONNAIRE**

The internal consistency reliability of the RQS® questionnaire was satisfactory, with a Cronbach alpha coefficient value equal to 0.84.

All the RQS® items confirmed the convergent validity criterion. The correlation between each of the 8 items and the “adjusted” global score was higher than 0.40 (varying between 0.43 and 0.65), indicating good construct validity. Analysis of the distribution of the RQS score showed there was no ceiling or floor effect, no patient had a score equal to 0 (level of minimum QoL) and only 0.8% of patients had a score equal to 100 (level of maximum QoL), indicating that the RQS score had the potential for capturing an improvement or a worsening in the study patients as a whole.

**CONCURRENT VALIDITY**

The RQS® questionnaire presented a high correlation with the mental dimension of the SF-12 (r = 0.60, P < 0.0001) and a moderate correlation with the physical dimension (r = 0.46, P < 0.0001), indicating a high consistency between the two measures.

**CLINICAL VALIDITY**

**Frequency of GERD episodes assessed by the doctor (figure 1)**

The correlation level between the frequency of GERD episodes and the RQS score was moderate (r = 0.37, P < 0.0001, N = 1191). The difference in the mean RQS score between groups of patients defined on the basis of frequency of GERD episodes was highly significant. The higher the frequency of GERD episodes, the lower the RQS score.

**Severity of GERD episodes (figure 2)**

Considering the severity of GERD episodes measured by patients, the difference of the RQS score obtained between the severity groups was also highly significant. The severe patients had a mean RQS score of 41.1 (± 13.5), which was significantly worse, and 30 points lower, compared with not very severe patients (71.1 ± 12.1). Considering the severity measured by the doctor, the difference between groups was also highly significant and reached 20 points between the not very severe and very severe patients. It is interesting to note that the patients judged to...
be the least severe on inclusion by the doctors (not very severe episodes or lacking for some patients in remission from their symptoms on inclusion in the study) had a mean RQS score lower than that obtained for the same level of severity but measured by the patient personally (difference of 5 and 9 points, respectively). To a lesser degree, the tendency was the reverse for patients with very severe symptoms, that is, the doctors (in comparison to the patients) tended to over-estimate the severity of GERD episodes with the most severe patients.

Assessment of the psychological or physical handicap by the doctor (figure 3)

Again, the difference between severity groups was highly significant. Patients not suffering from a handicap presented a mean RQS score of 76.4 \pm 13.1, which is 34 points higher compared with that obtained by patients suffering “a great deal” on the psychological or physical level (42.0 \pm 15.6).

**Descriptive analysis of the RQS score according to other clinical and socio-demographic parameters**

The RQS score was also described and compared for other sub-populations defined on the basis of clinical and socio-demographic variables, in order to identify potentially confounding variables. From these additional analyses it appeared that men had a slightly higher RQS score (59.7 \pm 17.4) of 3 points compared with women (56.3 \pm 17.3) (P < 0.05). This tendency corresponds to what is commonly observed when QoL is measured [28-30]. No age factor was identified as all age groups had similar RQS mean scores. The other socio-demographic characteristics having a possible impact on the RQS score were living alone or as a member of a family, and having a higher education level.

The mean RQS score was higher for people living as a member of a family (59.0 \pm 17.4), compared with those living alone (54.4 \pm 16.9). The higher the education level, the higher also the QoL (a difference of more than 5 points between those with less than GCSE advanced level (56.7 \pm 17.5) and those going into higher education (61.1 \pm 17.3)). Finally, a very significant difference was noted (P = 0.0001) in the RQS score when comparing patients with typical symptoms exclusively, with atypical symptoms exclusively and with a mixture of typical and atypical symptoms (64.6 \pm 18, 60.2 \pm 19.6, and 56.6 \pm 16.8, respectively). This was linked notably with a size effect, given that patients with a mixture of symptoms were suffering from more symptoms compared to patients with exclusively typical symptoms, who in turn were suffering from more symptoms than patients with exclusively atypical symptoms.

**Comparison of the discriminant power of the RQS® with that of the SF-12**

The RQS® clearly showed higher discriminative power than the SF-12 questionnaire (F = [2.31-5.05]), especially when considering the severity of GERD episodes estimated by the patient, where the discriminative power of the RQS® was 5 times higher than that of the PCS score. The discriminative power of the RQS® was 3 times higher than that of the PCS and MCS scores when the severity of the GERD episodes was estimated by the doctor (table III).

**Sensitivity to change over time of the RQS score**

**Characteristics of patients included**

A total of 362 patients were included by 76 doctors. The mean age of the patients was 47.7 years old (\pm 11.6) and 56.1% were women. Heartburn had lasted for 68.3 months (\pm 82.1), which is approximately five and a half years. The mean number of days with reflux episodes during the 7 days preceding inclusion was 5.0 days (\pm 1.7). The most frequent symptoms on inclusion were acid regurgitations (92.5% of patients), burning epigastric pains (87.8% of patients), postural syndrome (71.5% of patients) and upper flatulence (63.8% of patients). Two thirds of the patients were following dietary guidelines (67.4% of patients) and a little over half had been treated for their GERD during the preceding 3 months (55.8% of patients).

The CILANCE clinical trial population was globally comparable with the cross-sectional population of the psychometric validation study presented above. However, it can be noted that in the CILANCE study patients were slightly younger (roughly 4 years) and that the history of the complaint was longer (mean of 5.5 instead of 3.5 years) than that in the present study.

**Analysis of sensitivity to change over time**

According to the change in the number of days with reflux episodes (figure 4, table IV)

Analysis of the change in the RQS® global score between W0 and W4 according to the clinical progression expressed in number of days with reflux episodes showed an improvement in QoL for all the groups, including stable or worsened patients. The difference between these groups was highly significant (P = 0.0001). The higher the improvement in terms of number of
days with reflux, the higher the progression of the RQS score; the
greatest mean improvement being 20.04 ± 15.97 points for
patients reducing from 5 to 7 days. The QoL improvement was
highly significant for all groups improving clinically [i.e. reduc-
tion in the number of days with reflux episodes] (P < 0.0001,
paired tests) and not significant for the stable or worsened
group. Effect-sizes were very high in all groups except the group
of stable or worsened patients that had a low effect-size
(< 0.20). This was the case for patients who gained 1 or 2 days
without reflux symptoms, which corresponds to a real clinical
improvement, and the resulting effect-sizes of 0.8 or more dem-
strated the good responsiveness of the RQS® questionnaire to
clinical change.

According to the change in the Reflux score of the GSRS scale

The mean change in the RQS® global score according to the
GSRS scale Reflux score between W0 and W4 also showed an
improvement for all groups, varying between 3.4 (± 13.4) and
24.9 (±14.7). This improvement was significant for all the cli-
nically improved groups (P < 0.0001, paired tests) and not signif-
ificant for stable or worsened patients. Calculation of effect-sizes
confirmed the good sensitivity of the RQS score with high values
in all groups (ES between 0.57 and 1.78) with the exception of
the group of stable or worsened patients that had a low effect-
size (0.20).

Discussion

Judgement criteria to clinically assess the impact of diseases
and the effectiveness of treatments usually combine collection
and analysis of symptoms expressed by the patients with data
from the physical examination and complementary investiga-
tions. In recent years, people have come to realize this approach
to be insufficient [31] as it does not adequately take into account
each patient’s personal experience. People’s expectations con-
cerning their health and capacity to adapt to a disease and the
limitations it imposes, differ widely. Two people whose health
condition is identical may have very different quality of life.

Taking into account quality of life is especially important in the
case of “mild” chronic diseases such as GERD, where only a minor-
ity of patients develop severe esophagitis or complications. With
this complaint, it is the patient’s experience that is the main clinical
criterion to be considered in assessing the impact of the disease
and in judging the efficacy of the therapeutic strategy adopted.

Table IV. – Effect sizes calculation for sub-groups of patients established
from the change in the number of days with reflux episodes
between week 0 and week 4 (N=324).

Effect sizes pour les sous-groupes de malades établis par
rapport à l’évolution du nombre de jours avec des épisodes de
reflux entre la semaine 0 et la semaine 4 (N=324).

<table>
<thead>
<tr>
<th>Clinical status according to change in number of days with reflux episodes</th>
<th>Number of patients</th>
<th>Effect size 1 (ES1) = (Mean W4–Mean W0) / STD (W0)</th>
<th>Effect size 2 (ES2) = (Mean W4–Mean W0) / STD (W4–W0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High improvement [7;5]</td>
<td>127</td>
<td>1.30</td>
<td>1.25</td>
</tr>
<tr>
<td>Moderate improvement [4;3]</td>
<td>100</td>
<td>1.11</td>
<td>1.17</td>
</tr>
<tr>
<td>Slight improvement [2;1]</td>
<td>53</td>
<td>0.79</td>
<td>0.95</td>
</tr>
<tr>
<td>Stable or worsened [0;5]</td>
<td>43</td>
<td>0.16</td>
<td>0.24</td>
</tr>
</tbody>
</table>

where:

- **ES1** = Effect size 1 = (Mean W4–Mean W0) / STD (W0)
- **ES2** = Effect size 2 = (Mean W4–Mean W0) / STD (W4–W0)
Development of a quality of life measurement questionnaire specific to patients suffering from GERD therefore seemed essential.

To meet this need, a questionnaire, the 8-item RQS® was developed and validated. The instrument is a short version of the 37-item Reflux-Qual® questionnaire already used in medical research. Development of the Reflux-Qual® and the RQS® followed up-to-date methods: the Reflux-Qual® items were created from patient interviews and the selection of items for the short form was performed taking into account measurement aspects as well as patients and clinicians preferences.

The resulting questionnaire consists of a one-page document with 8 items that cover a wide range of domains specific to GERD (see appendix 1). The RQS score is calculated as the mean of these 8 item scores multiplied by 25; it ranges from 0 (lowest QoL) to 100 (highest QoL).

The validity, reliability and sensitivity of the French version of the RQS® questionnaire have been demonstrated with patients suffering from GERD. Indeed, it was confirmed that the RQS® questionnaire exhibits excellent psychometric properties. To begin with, the very low level of missing data observed in the study showed the excellent acceptability of the RQS® by patients. The bell shaped distribution of the RQS score showed no concern for ceiling or floor effects, indicating that the questionnaire has the potential to capture both an improvement and deterioration in patients’ QoL for the whole study population. Internal consistency reliability of the RQS® questionnaire was good since the Cronbach alpha coefficient was equal to 0.84. Construct validity of the 8 items as a whole was very good since each item had a correlation of more than 0.40 with the global score calculated for the other items.

The statistical results also showed good concurrent validity, correlations between the RQS score and the MCS and PCS scores of the SF-12 indicating good convergence between these two measures. Moreover, the RQS® clearly showed a higher discriminative power compared with the SF-12 questionnaire whatever the clinical criterion considered. Finally, the high sensitivity of the RQS score to clinical severity differences (between patients) and to change over time (within patients) was clearly demonstrated. However, concerning the sensitivity of the scale to change over time, as this was assessed using the 37-item Reflux-Qual® questionnaire, we would recommend analysing this property further when the RQS® is used longitudinally. Although we do not believe that completing the 37-item version rather than the 8-item version will have a major impact on the answers provided to the 8 items of the RQS®, this has not been demonstrated and should therefore be checked.

With regards to the statistical significance levels obtained, it should be noted that these are particularly related to the large size of the sample studied. Interpretation of results should therefore not be restricted to the thresholds of statistical significance observed. Certain factors such as gender, married life and education level, also seemed to be linked to the QoL measurement.

Although the differences between men and women, between people living alone and those in a family or between education levels are clearly smaller than those observed between groups of clinical severity, they are not negligible. Additional multivariate exploratory analyses would be useful to better understand latent relationships between these different confounding factors, the symptoms and the patients’ QoL.

The Reflux-Qual® questionnaire is already available in Dutch (for the Netherlands and Belgium), English (United Kingdom and the United States), German, Italian, and Mexican Spanish for the United States; the RQS® could therefore be readily available in these languages also.

In conclusion, these results indicate that the RQS® questionnaire has all appropriate features to be used by clinicians in their everyday practice, helping them to better adapt their care strategy according to patients’ desires and needs, thereby contributing to the doctor-patient dialogue. A user manual has been developed to provide the doctors with key instructions for using the questionnaire and to assist in the interpretation of scores. The RQS® should give doctors a better understanding of the impact of the disease on the QoL of their patients at a given moment, and help them follow the progression of this QoL over time. In this way they can better assess the effectiveness of treatment strategies and the quality of care provided, whilst involving the patients more directly in the decisions that concern them.

REFERENCES

Appendix. – English version of the RQS®. copyright© Laboratoire Aventis, 2003, All rights reserved. Questionnaire RQS

1. During the past 4 weeks, have you been bothered by your digestive problems when gardening, doing odd jobs or doing housework?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

2. During the past 4 weeks, because of your digestive problems, have you done less than usual?

- Never
- Rarely
- Sometimes
- Often
- All the time

3. During the past 4 weeks, have you felt satisfied with your life in general even though you have digestive problems?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

4. During the past 4 weeks, considering your digestive problems, have you enjoyed food?

- Never
- Rarely
- Sometimes
- Often
- All the time

5. During the past 4 weeks, have you been worried because of your digestive problems?

- Never
- Rarely
- Sometimes
- Often
- All the time

6. During the past 4 weeks, because of your digestive problems, have you been in a bad mood?

- Never
- Rarely
- Sometimes
- Often
- All the time

7. During the past 4 weeks, have your digestive problems kept you awake most of the night?

- Never
- Rarely
- Sometimes
- Often
- All the time

8. During the past 4 weeks, have you avoided eating large meals because you were afraid of having digestive problems?

- Never
- Rarely
- Sometimes
- Often
- All the time
1. Au cours des 4 dernières semaines, vos troubles digestifs vous ont-ils gêné(e) pour jardiner, bricoler, effectuer vos tâches ménagères ?

<table>
<thead>
<tr>
<th>Pas du tout</th>
<th>Un petit peu</th>
<th>Moyennement</th>
<th>Beaucoup</th>
<th>Enormément</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

2. Au cours des 4 dernières semaines, à cause de vos troubles digestifs, avez-vous fait moins de choses que d’habitude ?

<table>
<thead>
<tr>
<th>Jamais</th>
<th>Rarement</th>
<th>Quelquefois</th>
<th>Souvent</th>
<th>En permanence</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>

3. Au cours des 4 dernières semaines, avez-vous été satisfait(e) de votre vie en général malgré vos troubles digestifs ?

<table>
<thead>
<tr>
<th>Pas du tout</th>
<th>Un petit peu</th>
<th>Moyennement</th>
<th>Beaucoup</th>
<th>Enormément</th>
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<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>

4. Au cours des 4 dernières semaines, compte tenu de vos troubles digestifs, avez-vous mangé avec plaisir ?

<table>
<thead>
<tr>
<th>Jamais</th>
<th>Rarement</th>
<th>Quelquefois</th>
<th>Souvent</th>
<th>En permanence</th>
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<td>4</td>
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5. Au cours des 4 dernières semaines, vous êtes-vous fait du souci à cause de vos troubles digestifs ?

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<thead>
<tr>
<th>Jamais</th>
<th>Rarement</th>
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<th>Souvent</th>
<th>En permanence</th>
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<td>4</td>
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<td>2</td>
<td>1</td>
<td>0</td>
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6. Au cours des 4 dernières semaines, vos troubles digestifs vous ont-ils mis(e) de mauvaise humeur ?

<table>
<thead>
<tr>
<th>Jamais</th>
<th>Rarement</th>
<th>Quelquefois</th>
<th>Souvent</th>
<th>En permanence</th>
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<td>4</td>
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<td>1</td>
<td>0</td>
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7. Au cours des 4 dernières semaines, à cause de vos troubles digestifs, êtes-vous resté(e) éveillé(e) une grande partie de la nuit ?

<table>
<thead>
<tr>
<th>Jamais</th>
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<th>Souvent</th>
<th>En permanence</th>
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8. Au cours des 4 dernières semaines, avez-vous évité de faire des repas copieux par crainte d’avoir des troubles digestifs ?

<table>
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<tr>
<th>Jamais</th>
<th>Rarement</th>
<th>Quelquefois</th>
<th>Souvent</th>
<th>En permanence</th>
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