

This is a **Sample** version of the

Quality of Life Questionnaire for Functional Digestive Disorders (FDDQL)

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- FDDQL Overview information
- FDDQL Scoring/ Administration instructions
- FDDQL Complete Questionnaire Assessment (43 sets of question criteria)
- FDDQL Clinical Validity

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Validation of a specific quality of life questionnaire for functional digestive disorders

O Chassany, P Marquis, B Scherrer, N W Read, T Finger, J F Bergmann, B Fraitag, J Geneve, C Caulin

Abstract

Background—Dyspepsia and irritable bowel syndrome are suitable conditions for assessment of quality of life. Their similarities justify the elaboration of a single specific questionnaire for the two conditions.

Aims—To examine the process leading to the validation of the psychometric properties of the functional digestive disorders quality of life questionnaire (FDDQL).

Methods—Initially, the questionnaire was given to 154 patients, to assess its acceptability and reproducibility, analyse its content, and reduce the number of items. Its responsiveness was tested during two therapeutic trials which included 428 patients. The questionnaire has been translated into French, English, and German. The psychometric validation study was conducted in France, United Kingdom, and Germany by 187 practitioners. A total of 401 patients with dyspepsia or irritable bowel syndrome, defined by the Rome criteria, filled in the FDDQL and generic SF-36 questionnaires.

Results—The structure of the FDDQL scales was checked by factorial analysis. Its reliability was expressed by a Cronbach's α coefficient of 0.94. Assessment of its discriminant validity showed that the more severe the functional digestive disorders, the more impaired the quality of life ($p < 0.05$). Concurrent validity was supported by the correlation found between the FDDQL and SF-36 questionnaire scales. The final version of the questionnaire contains 43 items belonging to eight domains.

Conclusions—The properties of the FDDQL questionnaire, available in French, English, and German, make it appropriate for use in clinical trials designed to evaluate its responsiveness to treatment among patients with dyspepsia and irritable bowel syndrome.

(*Gut* 1999;44:527–533)

Keywords: digestive disorders; irritable bowel syndrome; dyspepsia; quality of life; clinical trial; validation

The need to assess subjective aspects of health related quality of life (QoL) under chronic conditions is now increasingly recognised. The prevalent functional digestive disorders (FDD), including functional dyspepsia (FD) and irritable bowel syndrome (IBS), constitute

suitable conditions for the use of a quality of life questionnaire. For FDD, there is no specific function impairment and therefore no yardstick for therapeutic evaluation.^{1,2} Current criteria such as pain score correlate poorly with the patient's own evaluation of health status.^{3,5} FDD are chronic non-life threatening conditions, but have been reported to have a strong impact on daily activities, wellbeing, social performance, and psychological status,^{6,7} even during symptom-free periods, because of the fear of the next bout of abdominal pain, the restrictions on social life and leisure, and the obligation to take drugs.⁸ QoL assessment explores the repercussions of the disease and the treatments as perceived by the patient.³ Like any other outcome criterion, a QoL questionnaire has to include psychometric data such as reliability, and content and construct validity.^{4,5,9} When planning a clinical trial involving quality of life, the major concern is to select the most relevant, valid, and responsive questionnaire, which should be available in several languages. Generic instruments are designed to compare health status among different populations, whatever the underlying condition.¹⁰ Their main drawback is their failure to stimulate responsiveness, as they do not focus specifically on the impact of a particular disease. They have rarely disclosed small but significant health status changes over time or during therapeutic trials. A disease specific questionnaire seems more pertinent to discrimination of the effect of a particular therapy on the QoL.¹⁰ An analysis of the literature did not show the existence of any specific questionnaire devoted to FDD when we started to elaborate our questionnaire. Our objectives were to draft and validate a specific questionnaire, which would be available in French, English, and German. Besides a short description of the initial steps in devising this functional digestive disorders quality of life questionnaire (FDDQL), we report here the results of the international psychometric validation study in 401 patients with FD or IBS.

Patients and methods

INITIAL DEVELOPMENT

A French self administered questionnaire of 74 items was generated by clinicians (O C, J F B, and C C) on the basis of the literature, from

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**SCALING AND SCORING OF THE
'FUNCTIONAL DIGESTIVE DISORDERS QUALITY
OF LIFE'
(FDDQL)**

The FDQQL is composed of 43 Items investigating 8 dimensions

DESCRIPTION OF THE QUESTIONNAIRE:

| Dimensions | Number of Items | Cluster of Items | Item Reversion | Direction of Dimensions |
|-----------------------|------------------------|-------------------------|-----------------------|--------------------------------|
| Daily activities (DA) | 8 | 1 – 8 | No | |
| Anxiety (AN) | 5 | 9 – 13 | No | |
| Diet (DI) | 6 | 14 – 19 | No | |

**This is the end of the SAMPLE FDDQL scoring instructions.
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**QUALITY OF LIFE QUESTIONNAIRE FOR
FUNCTIONAL DIGESTIVE DISORDERS**

This questionnaire is strictly anonymous and confidential.

Investigator's stamp:

Registration number: _____

_____ (OFFICE USE ONLY)

ACTIVITIES

Over the last 14 days, because of your digestive problems,

1. have you had any difficulties carrying out your daily activities?

₁ Not at all ₂ A little bit ₃ Moderately ₄ Quite a bit ₅ Extremely

2. have you had to disrupt your daily activities?

₁ Never ₂ Rarely ₃ Sometimes ₄ Often ₅ Always

3. have you had any difficulties carrying out your leisure activities (DIY, gardening, walks in the country...)?

₁ Not at all ₂ A little bit ₃ Moderately ₄ Quite a bit ₅ Extremely

4. have you had any difficulties concentrating, especially when reading or listening to music?

₁ Never ₂ Rarely ₃ Sometimes ₄ Often ₅ Always

5. have you felt restricted in performing strenuous physical activities like running, lifting heavy objects, pushing a table...?

₁ Not at all ₂ A little bit ₃ Moderately ₄ Quite a bit ₅ Extremely ₆ Not applicable

**This is the end of the SAMPLE FDDQL questionnaire.
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