

DEVELOPMENT AND VALIDATION OF A SHORTENED VERSION OF THE SPANISH QUALITY OF LIFE QUESTIONNAIRE FOR INFLAMMATORY BOWEL DISEASE

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Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/1588>

EU PAS number

EUPAS1587

Study ID

1588

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Questionnaires for measuring quality of life in patients with inflammatory bowel disease usually include a large number of items and are time-consuming for both administration and interpretation. Our aim was to elaborate and validate a short quality-of-life questionnaire with the most representative items from the Spanish version of the 36-item Inflammatory Bowel Disease Questionnaire (IBDQ-36) using the Rasch analysis. The responses to 311 IBDQ-36 questionnaires from 167 patients with ulcerative colitis (UC) and 144 with Crohn's disease (CD) were analyzed. IBDQ-36 was shortened with successive Rasch analyses until all the remaining items showed acceptable separation and goodness-of-fit properties. Validation of the short questionnaire was studied in a new group of 125 patients by determining its validity and reliability. A 9-item short questionnaire was obtained (IBDQ-9). Its correlation with IBDQ-36 was excellent ($r = 0.91$). Correlation between IBDQ-9 and clinical indices of activity was statistically significant in UC ($r = 0.70$) and CD ($r = 0.70$). IBDQ-9 score discriminates adequately between patients in clinical remission or relapse ($P < 0.01$). Sensitivity to change was determined in 14 patients who improved clinically, showing significant IBDQ-9 changes between both determinations ($P < 0.01$), with an effect size of -2.67 in UC and -5.29 in CD. IBDQ-9 was also homogeneous, with a Cronbach's alpha of 0.95 in UC and 0.91 in CD. In 35-clinically stable patients, test-retest reliability was good, with a statistically-significant correlation between both questionnaires ($r = 0.76$ in UC and 0.86 in CD, $P < 0.01$) and an intraclass correlation coefficient of 0.82 in UC and 0.84 in CD. In conclusion, a short and valid questionnaire to measure quality of life in patients with inflammatory bowel disease was obtained using a new measurement model. Its use should facilitate comprehension of the impact of inflammatory bowel disease.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Vall d'Hebron (HUVH)

☐ Spain

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Institution

Educational Institution

Hospital/Clinic/Other health care facility

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/10/2002

Study start date

Actual: 02/12/2002

Date of final study report

Actual: 11/11/2003

Sources of funding

- Other

More details on funding

Ministry of Science & Technology, Vall d'Hebron Hospital

Study protocol

[Tesis Maria Jose Alcala.pdf](#)(398.19 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Development of a questionnaire for health related quality of life assessment

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To elaborate and validate a short quality-of-life questionnaire with the most representative items from the Spanish version of the 36-item Inflammatory Bowel Disease Questionnaire (IBDQ-36) using the Rasch analysis

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Crohn's disease

Inflammatory bowel disease

Population studied

Short description of the study population

Patients with ulcerative colitis and Crohn's disease

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Ulcerative colitis and Crohn's disease patients

Estimated number of subjects

311

Study design details

Data analysis plan

The responses to 311 IBDQ-36 questionnaires from 167 patients with ulcerative colitis (UC) and 144 with Crohn's disease (CD) were analyzed. IBDQ-36 was shortened with successive Rasch analyses until all the remaining items showed acceptable separation and goodness-of-fit properties. Validation of the short questionnaire was studied in a new group of 125 patients by determining its validity and reliability.

Documents

Study publications

Alcalá MJ, Casellas F, Fontanet G, Prieto L, Malagelada JR. Shortened
questionn...

Casellas F, Alcalá MJ, Prieto L, Miró JR, Malagelada JR. Assessment of the infl...

Data management

Data sources

Data sources (types)

[Disease registry](#)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No