

Discriminant validity of the Work Productivity and Activity Impairment questionnaire in patients with Crohn's disease

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Background

- Crohn's disease (CD) is a chronic inflammatory disease of the gastrointestinal tract characterised by debilitating symptoms, including abdominal pain, weight loss, anaemia and persistent diarrhoea. It emerges in early adulthood and has no known cure. Patients with CD experience an ongoing cycle of remissions and unpredictable exacerbations, leading to a considerable degree of uncertainty in their lives.
- The efficacy and safety of certolizumab pegol, a PEGylated Fab' fragment of a humanised anti-TNF monoclonal antibody that neutralises tumour necrosis factor (TNF), has been demonstrated in the PRECiSE programme. PRECiSE 1¹ and PRECiSE 2² were large randomised controlled Phase III trials including over 1300 patients with moderate to severe CD, representing the largest and most comprehensive development programme for an anti-TNF in the treatment of CD.

Introduction

- The huge economic burden of CD is driven by hospitalisations and drug therapies, but more importantly by indirect costs: more than 70% of the total cost to society of CD is due to absences from work and losses of productivity.³
- The Work Productivity and Activity Impairment questionnaire⁴ (WPAI) is used to collect data on the impairment due to a health problem during the previous 7 days. Results are summarised into four impairment scores expressed in percentages (%):
 - Absenteeism: hours missed from work
 - Presenteeism: impairment while working
 - Overall work impairment: combination of Absenteeism and Presenteeism
 - Daily activities impairment: eg shopping, exercising, childcare, etc.
- The validity of the WPAI questionnaire in the measurement of health related productivity was demonstrated in several diseases, including hepatitis C⁵ and the digestive pathologies irritable bowel syndrome⁶ and gastro-oesophageal reflux disease.⁷
- The CD-specific WPAI (WPAI:CD) was administered for the first time in the PRECiSE 1 and PRECiSE 2 studies, the baseline results of which already confirmed the reduced productivity of patients with active CD at work and in daily activities.⁸

Objectives

- The objective was to compare the WPAI:CD scores of patients categorised by baseline disease severity and health-related quality of life (HRQoL) level, with the a priori assumption that more severe health conditions are associated with higher impairments in work productivity and daily activities.

Methods

- The 1330 randomised patients were divided into 'best' and 'worst' subgroups determined by the CD Activity Index (CDAI), Medical Outcomes Short-Form (36-item) Health Survey (SF-36) and EuroQoL 5-Dimensional (EQ-5D) instruments.
- 'Best' health was identified by CDAI scores less than or equal to the median, SF-36 Physical and Mental Component Summary scores (PCS and MCS) greater than the median (Table 1) and modality '1' responses to the EQ-5D (Table 2).
- The baseline WPAI:CD scores (Table 3) were then calculated by subgroups and compared using a nonparametric Wilcoxon test.

Table 1. Thresholds used in the analysis for CDAI, SF-36 PCS and MCS (PRECiSE 1 and 2, baseline, all subjects)

| Instrument | n | Median score |
|---|------|--------------|
| CDAI ^a | 1322 | 288.1 |
| SF-36 Physical Component Summary ^b | 1304 | 37.5 |
| SF-36 Mental Component Summary ^b | 1304 | 37.4 |

^aLower is better. ^bHigher is better.

Table 2. Proportion of patients without problems, as defined by the EQ-5D for each dimension (PRECiSE 1 and 2, baseline, all subjects)

| EQ-5D dimension | n | Proportion of patients with 'No problems' ^a at baseline (%) |
|--------------------|------|--|
| Mobility | 1324 | 62.7 |
| Self-care | 1324 | 93.1 |
| Usual activities | 1323 | 26.0 |
| Pain/discomfort | 1324 | 4.3 |
| Anxiety/depression | 1325 | 30.2 |

^ai.e. selecting modality '1'.

Table 3. WPAI:CD results (PRECiSE 1 and 2, baseline, all subjects)

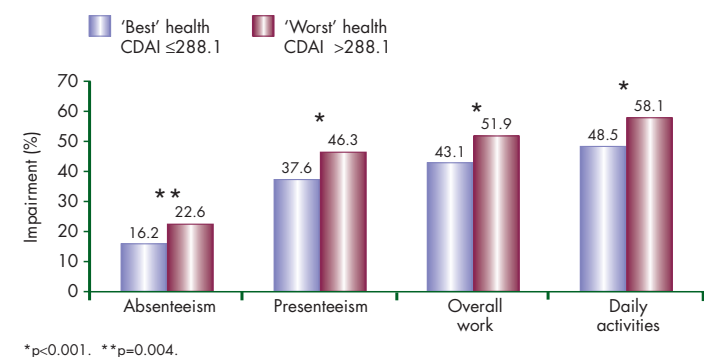
| WPAI:CD dimension | n | Mean (SD) impairment (%) ^a |
|-------------------|------|---------------------------------------|
| Absenteeism | 706 | 19.5 (29.2) |
| Presenteeism | 715 | 42.0 (24.8) |
| Overall work | 656 | 47.5 (26.4) |
| Daily activities | 1289 | 53.3 (24.9) |

^aLower is better. SD = standard deviation.

Results

- CD patients with the 'worst' disease severity showed higher impairment in overall work (+8.9%) and activities (+9.6%) versus patients with 'best' health (Figure 1).

Figure 1. WPAI:CD scores by health state severity, as defined by CDAI baseline score (PRECiSE 1 and 2, all subjects).



- Patients with 'worst' HRQoL showed higher impairments in overall work (+20.0% by PCS; +18.5% by MCS) and activities (+22.2% by PCS; +15.5% by MCS) versus 'best' HRQoL (Figures 2 and 3).

Figure 2. WPAI:CD scores by health state severity, as defined by the SF-36 Physical Component Summary score (PRECiSE 1 and 2, all subjects).

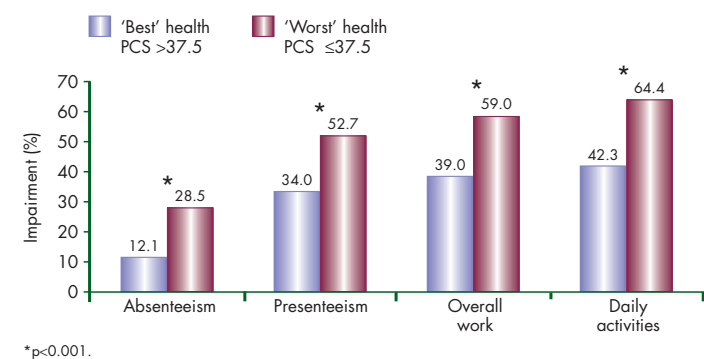
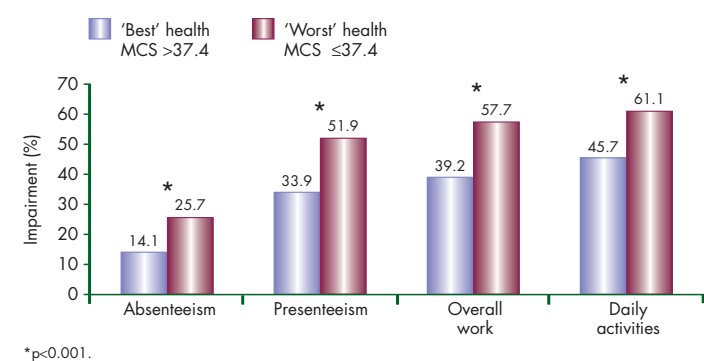
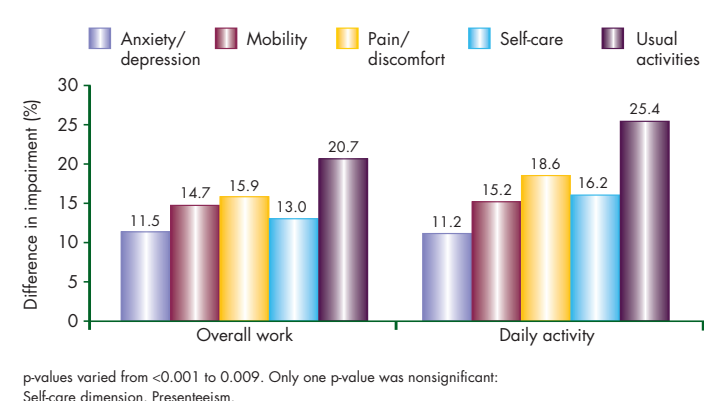


Figure 3. WPAI:CD scores by health state severity, as defined by the SF-36 Mental Component Summary score (PRECiSE 1 and 2, all subjects).



- Patients with the 'worst' EQ-5D states reported more impairment in overall work (+15.2% averaged over the five dimensions) and activities (+17.3%) versus patients with the 'best' states (Figure 4).

Figure 4. Differences in impairment between 'worst' and 'best' health states defined by the EQ-5D answers, Overall work and Daily activities dimensions (PRECiSE 1 and 2, all subjects).



Conclusion

- The measurement of expected differences in work and activity impairment by disease severity and HRQoL levels supports the discriminant validity of the WPAI:CD.
- The WPAI:CD is a valid tool for assessing the indirect costs of CD.

References

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