Validation of electronic data capture versions of Irritable Bowel Syndrome Quality Of Life, EuroQoL and Work Productivity and Activity Impairment questionnaires

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ABSTRACT

Objective: To assess the validity, reliability and subject acceptability of electronic data capture (EDC) versions of irritable bowel syndrome quality of life (IBS-QOL), EuroQoL (EQ-5D) and work productivity and activity impairment (WPAI:IBS) questionnaires.

Methods: Comparability of EDC and paper questionnaires was evaluated in 72 subjects with irritable bowel syndrome (IBS) who completed a baseline EDC or paper questionnaire, a crossover questionnaire 24 hours later and a retest of the crossover version at 1 week. The EDC version was presented on a hand-held device. Comparability was assessed using paired *t*-test statistics, intraclass correlation coefficients (ICC) and tests for internal consistency (Cronbach's alpha).

Results: No significant differences were found between scores obtained by paper questionnaire and EDC at the baseline and crossover assessments. ICCs between baseline and crossover assessments ranged from 0.83 to 0.96 for the IBS-QOL scores, 0.82 to 0.96 for the WPAI:IBS scores and 0.77 to 0.82 for the EQ-5D. Internal consistency was comparable for the two data collection methods for the IBS-QOL overall score (0.96) and subscales and the EQ-5D Index (0.70 vs 0.74). Retest statistics (ICC) were generally comparable between the EDC and paper versions for all scores, as was the relationship between scores and levels of IBS symptom severity. Ease of use was comparable for the two modes of administration, but more patients preferred EDC (47.2%) than the paper questionnaire (23.6%).

Conclusions: EDC versions of the IBS-QOL, EQ-5D, and WPAI:IBS are comparable to paper questionnaires in terms of internal consistency, test-retest reliability, and have greater patient acceptability.

BACKGROUND

- Recent studies have found that patient-reported outcome data collected with electronic data capture (EDC) are psychometrically comparable to data collected by the standard paper mode, in terms of validity and reliability[1,2]
- The validity, reliability and acceptability of EDC in studies of patients with irritable bowel syndrome (IBS) have not been investigated

OBJECTIVE

- The objective of this study was to assess comparability of EDC and paper questionnaires of the Irritable Bowel Syndrome-Quality of Life measure (IBS-QOL), EuroQoL (EQ-5D) and the Work Productivity and Activity Impairment Questionnaire for Irritable Bowel Syndrome (WPAI:IBS) and the acceptability of EDC among IBS patients

METHODS

- Seventy-two subjects with IBS were randomized to complete a baseline EDC or paper questionnaire, a crossover questionnaire 24 hours later and a retest of the crossover questionnaire 7 days later (Figure 1)

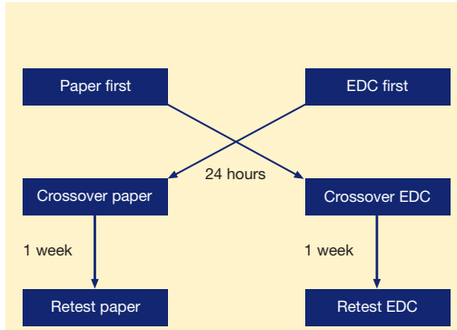

Figure 1. Study design.

- Comparability was assessed using paired *t*-test statistics, intraclass correlation coefficients (ICCs) and tests for internal consistency (Cronbach's alpha). The retest analysis was restricted to subjects reporting no change in health
- Concurrent validity was assessed relative to symptom severity with analysis of variance (ANOVA). Severity was assessed with a 0–10 numerical scale recorded on paper
- Respondent acceptability of and preference for the two modes of administration was assessed with questions regarding ease of use

RESULTS

- Table 1 shows the characteristics of the population by initial mode of questionnaire administration
- No significant differences were found between scores obtained by paper questionnaire and EDC at the baseline and crossover assessments in either administration group, paper first or EDC first
- ICCs between baseline and crossover assessments were above the recommended 0.70[3] for each IBS-QOL, EQ-5D and WPAI:IBS measure, and ranged from 0.83 to 0.96 for the IBS-QOL scores, 0.82 to 0.96 for the WPAI:IBS scores and 0.77 to 0.82 for the EQ-5D

RESULTS (cont'd)

Table 1. Patient demographics.

Characteristic	Mean (± S.D.) or percentage		
	EDC (n=37)	Paper (n=35)	Total (n=72)
Age (years)	42.4 (13.7)	48.5 (14.2)	46.2 (13.5)
Gender (female %)	81.1	91.4	86.1
Length of time with IBS symptoms (years)	13.0 (9.5)	16.9 (15.2)	14.8 (12.6)
Currently employed (%)	70.3	68.6	69.4

S.D. = Standard Deviation

Table 2. Internal consistency and test-retest reliability of the questionnaires by mode of administration.

	Internal consistency*		Test-retest reliability†	
	Paper (n=35)	EDC (n=37)	Paper (n=20)	EDC (n=20)
IBS-QOL				
Overall	0.96	0.96	0.99	0.95
Dysphoria	0.94	0.95	0.99	0.93
Interference with activity	0.82	0.89	0.93	0.96
Body image	0.79	0.72	0.93	0.95
Health worry	0.74	0.79	0.94	0.88
Food avoidance	0.83	0.88	0.95	0.90
Social reactions	0.84	0.80	0.91	0.90
Sexual	0.75	0.77	0.92	0.94
Relationships	0.77	0.69	0.94	0.92
EQ-5D Index	0.74	0.70	0.77	0.75
EQ-5D VAS	NA	NA	0.82	0.73
WPAI:IBS‡				
Absenteeism	NA	NA	0.68 (n=15)	0.93 (n=13)
Presenteeism	NA	NA	0.75 (n=15)	0.97 (n=13)
Work productivity loss	NA	NA	0.84 (n=15)	0.98 (n=13)
Daily activity impairment	NA	NA	0.90 (n=20)	0.83 (n=20)

*As measured by Cronbach's alpha using baseline administration
†As measured by the ICC using the crossover and re-test assessment at 1 week. Includes only those patients reporting no change on the global rating of change at the 1 week retest
‡Work impairment measures apply only to the employed
NA = Not applicable

Table 3. IBS-QOL, EQ-5D and WPAI:IBS summary scores by symptom severity and mode of questionnaire administration.

		Paper questionnaire			
IBS symptom severity		Overall IBS-QOL	EQ-5D VAS	Overall work productivity loss	Activity impairment
Low (0–5)	Mean	77	0.78	19.9	21.7
	n	24	24	18	24
Middle (6–7)	Mean	67.3	0.75	39.6	40.9
	n	32	32	21	32
High (8–10)	Mean	54.5	0.55	41.5	53.1
	n	16	16	10	16
Total	Mean	67.7	0.72	32.7	37.2
	n	72	72	49	72
		p=0.001*	p=0.006*	p=0.03*	p<0.0001*
		Electronic data capture (EDC)			
IBS symptom severity		Overall IBS-QOL	EQ-5D VAS	Overall work productivity loss	Activity impairment
Low (0–5)	Mean	78.5	0.70	21.2	21.7
	n	24	24	18	24
Middle (6–7)	Mean	67.5	0.70	37.2	38.8
	n	32	32	20	32
High (8–10)	Mean	56.3	0.58	40.5	51.9
	n	16	16	10	16
Total	Mean	68.7	0.67	31.9	36.0
	n	72	72	48	72
		p=0.002*	p=0.29*	p=0.10*	p<0.0001*

*As measured by ANOVA

RESULTS (cont'd)

- Internal consistency was comparable for both modes of administration of the IBS-QOL and the EQ-5D, with alpha values all above 0.70 except for the 'relationship' domain of the IBS-QOL EDC, which was 0.69 (Table 2)
- Retest statistics (ICCs) were comparable between the EDC and paper versions. WPAI:IBS results were inconclusive due to the small sample of employed patients (Table 2)
- Relationships between IBS-QOL, EQ-5D and WPAI:IBS scores and symptom severity were comparable for the two modes of administration (Table 3)
- Both versions were rated easy to read, regardless of which mode was administered first, with mean scores ranging from 87.9 to 91.8 out of a possible high score of 100
- Overall, 47.2% of the patients thought the EDC version was easier to use; 23.6% thought the paper questionnaire was easier to use and 29.2% thought there was no difference between methods
- If the patients were to participate in another study, 50% would prefer EDC, 13.9% would prefer paper questionnaires and 36.1% would have no preference

CONCLUSIONS

- The EDC version of self-reported health status measures in IBS is comparable to the paper version in validity, internal consistency and test-retest reliability, and has greater patient acceptability
- These results support the use of EDC for data collection in clinical practice and research

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This research was funded by Novartis Pharma AG, Basel, Switzerland. Poster presented at ISPOR 2005.