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Validation of Electronic Data Capture of the Irritable Bowel Syndrome—Quality of Life Measure, the Work Productivity and Activity Impairment Questionnaire for Irritable Bowel Syndrome and the EuroQol

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ABSTRACT

Objectives: To assess the comparability, 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) instruments.

Methods: Comparability of EDC and paper questionnaires was evaluated in 72 subjects with 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. 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 internal consistency and test–retest reliability, and have greater patient acceptability.

Keywords: electronic data capture, EQ-5D, EuroQoL, IBS-QOL, irritable bowel syndrome, quality of life, work productivity, WPAI:IBS.

Background

Patient-reported outcomes in clinical studies have generally been obtained by self-administered paper questionnaires. Electronic data capture (EDC) with hand-held or desktop computers is an alternative mode of data collection that offers many potential benefits over paper questionnaires, including customization of questions depending on a prior response, automatic date and time stamping, and immediate data entry that eliminates the possibility of subsequent entry errors. Several recent studies have found that patient-reported outcome data collected with EDC are psychometrically comparable to data collected by the standard paper mode, in terms of validity and reliability, and that EDC has high acceptance, and is generally preferred over the paper mode by the majority of subjects [1–6].

The validity and acceptability of EDC in studies of patients with irritable bowel syndrome (IBS) have not been investigated. Questionnaires useful for assessing outcomes in IBS studies include validated disease-specific quality of life and work productivity questionnaires, as well as general health questionnaires or utility measures for valuing IBS decrements relative to other diseases. The IBS Quality of Life Questionnaire (IBS-QOL) is an IBS-specific measure with established internal consistency, test–retest reliability and validity [7,8]. The Work Productivity and Activity Impairment Questionnaire has been validated for IBS (WPAI:IBS) [9], as well as for other diseases, such as allergies [10], gastroesophageal reflux disease [11], and chronic hand dermatitis [12]. The validity and reliability of the EuroQol (EQ-5D) [13], a general health measure, has been established in several diseases, including inflammatory bowel disease [14], rheumatoid arthritis [15],

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AIDS [16], and IBS [17]. The objectives of this study were to test the equivalence of the EDC versions of the IBS-QOL, WPAI:IBS and EQ-5D with the paper versions of these questionnaires in IBS patients, and to assess respondent acceptability of the EDC format to determine whether EDC would be a valid and appropriate methodology for obtaining patient-reported outcomes in IBS studies.

Methods

Subject Enrollment and Study Design

This was a randomized crossover study designed to test the effect of mode of questionnaire administration (paper vs. EDC) on patient-reported outcomes. The study was conducted between May and July 2004, at two US sites (Seattle, Washington and Rockford, Illinois) with recruitment through general advertisement. Patients aged 18 years or above who met Rome II diagnostic criteria for IBS [18] and signed informed consent were eligible to participate. Patients were randomized in equal numbers to the two sequences of questionnaire administration; efforts were made to recruit patients who were diverse as to sex and type of IBS (constipation predominant, diarrhea predominant, and alternating). The study consisted of the completion of a baseline questionnaire (paper or EDC), a crossover questionnaire within 24 hours, and a retest of the crossover questionnaire 7 days later, that is, a sequence of either paper-EDC-EDC or EDC-paper-paper (see Fig. 1).

A hand-held electronic device with entry by stylus was used for EDC. One question was displayed per screen and once a response was entered the next item automatically appeared. Subjects were not allowed to skip questions, and there was an option to return to review or change a previous question. There were minor formatting differences between the paper questionnaire and EDC, for example, in fonts and bolding, but the questions themselves were identical in both presentations. All paper questionnaires and EDC were completed at the study site (research facility in Seattle and clinical setting in Rockford).

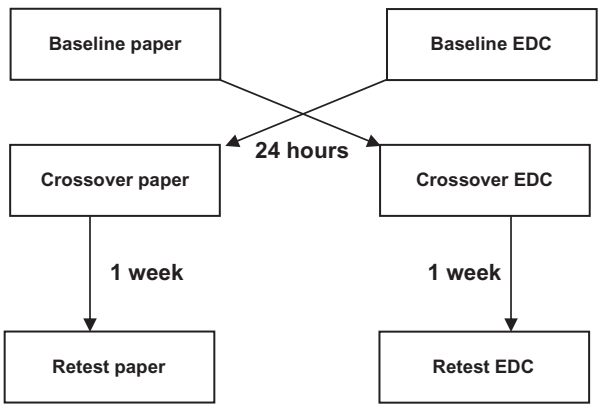

Figure 1 Study design. EDC, electronic data capture.

Additional information was obtained by paper questionnaire throughout the course of the study. Before randomization, all qualified patients completed questions about demographics, IBS characteristics and other health information. Following administration of the baseline and crossover questionnaires patients completed questions about the acceptability of the administration mode just completed, and at the crossover assessment, questions about preferences for the mode of administration. At baseline, symptom severity was rated and at the retest visit, patients completed a question assessing the global rating of change in overall quality of life. All patients enrolled completed the study. Patients were compensated for their participation.

Outcomes Questionnaires

The IBS-QOL is a 34-item condition-specific instrument that assesses overall quality of life and eight domains (dysphoria, interference with activity, body image, health worry, food avoidance, social reactions, relationships, and sexual). Each item has a five-point Likert response scale that assesses how much the item describes the respondent during the past month (not at all, slightly, moderately, quite a bit, and extremely or a great deal). Items scores are summed to derive the overall score and eight subscales; scores are transformed to a 0- to 100-scale ranging from 0 (poor quality of life) to 100 (maximum quality of life).

The WPAI:IBS asks questions about the effect of IBS symptoms, for example, abdominal discomfort, abdominal pain, bloating, constipation, and diarrhea on ability to work and perform regular daily activities during the past 7 days. It consists of six items: employment status; hours missed resulting from IBS; hours missed for other reasons; hours worked; lost work productivity and daily activity impairment resulting from IBS. Four scores are calculated: absenteeism (work time missed), presenteeism (impairment while at work), overall work productivity loss (absenteeism + presenteeism), and daily activity impairment. Scores are expressed as percentages, with higher scores indicating more productivity loss.

The EQ-5D consists of a five-item descriptive system and the EQ Visual Analog Scale (VAS). The descriptive system records the level of self-reported problems on each of the dimensions of the classification (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) on the day the questionnaire is completed. Health states defined by the descriptive system can be converted into a weighted health state index by applying scores elicited from general population samples. Respondents describe their own health

status that day using a 20-cm VAS, ranging from 0, worst imaginable health state, to 100, best imaginable health state.

Additional Measures

The Short Form 36-Item Health Survey (SF-36) [19] is a generic measure of functional status and well-being. It contains 36 questions that measure health across eight dimensions and two summary measures: the physical component (PCS) and the mental component (MCS). Scores within a dimension are reported on a scale from 0 to 100, where higher scores indicate "good health" and 0 indicates "poor health." Items with a recall period refer to the last 4 weeks.

Respondent acceptability of the two modes of administration was assessed with questions regarding ease of reading, ease in changing response and difficulty using the two formats. Responses were scored on 10-cm VAS, from 0, not at all easy (difficult) to 100, extremely easy (difficult). Preference for administration mode was assessed by asking which method was easier to use and which method was preferred. Severity of IBS symptoms during the past 7 days was assessed using a 0- to 10-point numerical scale ranging from no symptoms (0) to very severe symptoms (10). At the final retest visit, patients rated the global change in their overall quality of life as "A lot better," "Somewhat better," "About the same," "Somewhat worse," or "A lot worse."

Statistical Methods

Comparability of the two modes of administration was evaluated by testing differences in scores between the baseline and 24-hour crossover assessments with Student's *t*-test and the intraclass correlation coefficient (ICC). The ICC is the preferred measure of strength of association for determining stability of scores over time because it corrects for lack of independence between measurement intervals [20]. The ICC ranges between 0.00 and 1.00, and the minimal acceptable level is 0.70 [21].

Cronbach's alpha was used to determine whether the items within the scaled questionnaires had the same degree of association in the two modes of administration at the baseline assessment. A minimum correlation of 0.70 is necessary to support internal consistency and alpha values between 0.85 and 0.95 are preferred [22]. An alpha value of 0.95 has been previously reported for the IBS-QOL total score [7]. Internal reliability does not apply to the WPAI:IBS or EQ-5D because these scores are single items.

Test–retest reliability was assessed using the ICC to compare the relationship between the crossover assessment and the retest assessment for the two modes of administration. The test–retest analysis was restricted to subjects rating their overall quality of life "about the same" on the global rating of change item at the retest visit. Previously reported ICC values for the IBS-QOL total score was 0.86 [7].

For each mode of administration, the relationship between IBS-QOL, EQ-5D, and WPAI:IBS component scores and the physical and mental summary scores of the SF-36 was assessed using Pearson correlation coefficients, and the magnitude of the coefficients was compared across mode of administration. Discriminant validity of the scores from the two modes of administration (pooled from baseline and crossover for paper and for EDC) was compared relative to IBS symptom severity. An examination of responses to the symptom severity question indicated that they could be categorized as low (0–5), middle (6–7) or high (8–10) to permit a sufficient sample size in each category. Differences in mean scores between severity categories were tested with analysis of variance (ANOVA).

Acceptability of the two modes of administration was evaluated with descriptive statistics. Differences in the ease of using the two modes, as reported by the participants, were assessed with Student's paired *t*-test.

Results for work productivity scores apply only to employed patients and are limited by the small sample size. All analyses were conducted using SPSS [23]. A *P*-value <0.05 was required for significance using two-sided hypothesis tests; no *P*-value adjustments were made for the analysis of multiple endpoints.

Results

Table 1 shows the characteristics of the population by initial mode of questionnaire administration. Patients had a mean age of 46.2 years and were predominately female (86.1%); 69.4% were currently employed. All IBS types were represented: 25% of patients had IBS with constipation, 33.3% had IBS with diarrhea, and 41.7% had alternating IBS. Compared with patients randomized to the paper-first group, the EDC-first group tended to be younger (42.4 vs. 48.5 years), female (91.4% vs. 81.1%), and less likely to have a college degree (18.9% vs. 34.3%). The EDC-first group was more likely to have IBS with diarrhea (40% vs. 27%) and have a shorter IBS duration (13.0 vs. 16.9 years). Employment rates were comparable.

Table 2 shows the mean scores for the baseline and crossover assessments by mode of initial questionnaire administration. There were no significant differences between the baseline and crossover scores for subjects in either administration group. ICC statistics were above 0.70 for each IBS-QOL, EQ-5D, and WPAI measure for both sequences of administration.

Table 3 shows the results of the internal consistency evaluation of the IBS-QOL and the EQ-5D Index at baseline and test–retest reliability of these two measures and the EQ-5D VAS and WPAI:IBS. Internal consistency was comparable for both modes of administration of the IBS-QOL and the EQ-5D; both

Table 1 Characteristics of the population by mode of initial administration

Characteristic	Mean (±SD) or percentage initial administration		
	EDC (n = 37)	Paper (n = 35)	Total (n = 72)
Age (years)	42.4 (13.7)	48.5 (14.2)	46.2 (13.5)
[range]	[21.–72]	[21–83]	[21–83]
	$F = 1.931$ ($P = 0.16909$)		
Sex (female, %)	81.1	91.4	86.1
	$\chi^2 = 1.610$ ($P = 0.20446$)		
Highest level of school (%)			
High school graduate or less	21.6	28.6	25.0
Some college/2-year degree	59.5	37.1	48.6
4-year college graduate	18.9	34.3	26.4
	$\chi^2 = 3.435$ ($P = 0.32933$)		
Length of time with IBS symptoms (years)	13.0 (9.5)	16.9 (15.2)	14.8 (12.6)
	$F = 1.799$ ($P = 0.18423$)		
Type of IBS (%)			
Constipation	20.0	29.7	25.0
Diarrhea	40.0	27.0	33.3
Alternating	40.0	43.2	41.7
	$\chi^2 = 1.635$ ($P = 0.44162$)		
Currently employed (%)	70.3	68.6	69.4
	$\chi^2 = 0.008$ ($P = 0.92725$)		

EDC, electronic data capture; IBS, irritable bowel syndrome.

Table 2 IBS-QOL, EQ-5D and WPAI:IBS scores for baseline and crossover questionnaires by first administration

	Mean (±SD)		*P*-value*	Intraclass correlation coefficient
	Paper	EDC		
Baseline paper questionnaire and 24-hour crossover electronic data capture (EDC) (n = 35)				
IBS-QOL				
Overall	69.3 (18.4)	73.8 (17.6)	0.29	0.96
Dysphoria	71.0 (21.7)	76.9 (20.4)	0.24	0.91
Interference with activity	58.9 (24.9)	63.9 (24.4)	0.39	0.95
Body image	62.4 (22.0)	68.1 (19.9)	0.25	0.96
Health worry	71.2 (22.5)	76.0 (20.6)	0.34	0.83
Food avoidance	62.7 (24.3)	63.5 (23.1)	0.88	0.91
Social reactions	75.3 (21.9)	79.7 (19.7)	0.38	0.91
Sexual	81.9 (20.3)	84.9 (18.0)	0.51	0.93
Relationships	76.2 (21.7)	81.0 (21.5)	0.34	0.93
EQ-5D				
VAS	75.8 (15.4)	75.1 (16.4)	0.85	0.77
Index	0.72 (0.25)	0.72 (0.24)	0.91	0.80
WPAI:IBS				
Absenteeism (n = 23)	4.0 (9.3)	3.7 (7.7)	0.52	0.96
Presenteeism (n = 23)	27.4 (23.0)	22.6 (20.9)	0.15	0.84
Work productivity loss (n = 23)	31.4 (28.0)	26.3 (20.9)	0.56	0.90
Daily activity impairment (n = 35)	33.7 (25.0)	29.7 (24.0)	0.18	0.87
Baseline electronic data capture (EDC) and 24-hour crossover paper questionnaire (n = 37)				
IBS-QOL				
Overall	66.1 (20.5)	63.5 (21.0)	0.60	0.96
Dysphoria	66.7 (25.3)	62.9 (26.6)	0.54	0.95
Interference with activity	60.4 (29.2)	56.4 (30.2)	0.57	0.91
Body image	63.8 (22.0)	60.6 (21.3)	0.53	0.93
Health worry	67.0 (25.9)	68.1 (25.9)	0.87	0.91
Food avoidance	58.5 (29.1)	54.9 (29.4)	0.60	0.94
Social reactions	69.3 (26.1)	69.3 (24.1)	1.00	0.91
Sexual	72.5 (22.8)	72.7 (23.5)	0.97	0.93
Relationships	75.0 (22.8)	71.8 (22.5)	0.55	0.90
EQ-5D				
VAS	70.8 (21.0)	64.0 (24.5)	0.21	0.82
Index	0.71 (0.23)	0.63 (0.28)	0.16	0.77
WPAI:IBS				
Absenteeism (n = 25)	3.3 (6.4)	3.4 (7.5)	0.78	0.94
Presenteeism (n = 25)	30.4 (21.5)	33.6 (23.6)	0.34	0.85
Work productivity loss (n = 25)	33.7 (24.7)	37.0 (28.2)	0.32	0.90
Daily activity impairment (n = 25)	40.5 (25.7)	42.0 (23.9)	0.67	0.82

*Student's *t*-test.

IBS-QOL, Irritable Bowel Syndrome—Quality of Life; VAS, Visual Analog Scale; WPAI:IBS, Work Productivity and Activity Impairment questionnaire—Irritable Bowel Syndrome version.

Table 3 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 (vs. paper) (n = 20)	EDC (vs. 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 intraclass correlation coefficient using the crossover and retest assessment at 1 week. Includes only those patients reporting no change on the global rating of change at the 1-week retest.

EDC, electronic data capture; NA, not applicable; VAS, Visual Analog Scale; WPAI:IBS, Work Productivity and Activity Impairment questionnaire—Irritable Bowel Syndrome version.

questionnaires and modes of administration demonstrated internal consistency with alpha values all above 0.70, with the exception of the Relationship domain of the IBS-QOL EDC which was 0.69. Among stable subjects, retest statistics (ICC) were comparable between the EDC and paper versions of the IBS-QOL, with all correlations above 0.88, and for the EDC and paper versions of the EQ-5D, with all correlations above 0.73. The analysis of the reliability of the WPAI:IBS was limited by the small sample of stable employed patients in the paper and EDC groups (n = 15 and 13, respectively). Nevertheless, all correlations were above 0.75, except for absenteeism, which was 0.68.

Table 4 shows the correlation coefficients between the IBS-QOL, EQ-5D, and WPAI:IBS component scores and the SF-36 physical and mental summary scores. The correlation coefficients were generally comparable for the two modes of administration. Table 5 shows the mean IBS-QOL, WPAI:IBS, and EQ-5D scores for the two modes of administration (pooled baseline and crossover) by level of disease severity. For the paper version, there were significant differences for

Table 4 Correlation between IBS-QOL, EQ-5D, and WPAI:IBS and SF-36 summary scores by mode of administration

	SF-36 physical component summary		SF-36 mental component summary	
	Paper (n = 72)	EDC (n = 72)	Paper (n = 72)	EDC (n = 72)
IBS-QOL				
Overall	0.40 (0.00058)	0.36 (0.00207)	0.47 (0.00003)	0.46 (0.00005)
Dysphoria	0.49 (0.00002)	0.45 (0.00008)	0.51 (0.00000)	0.50 (0.00000)
Interference with activity	0.36 (0.00225)	0.30 (0.01039)	0.37 (0.00133)	0.40 (0.00054)
Body image	0.21 (0.07984)	0.23 (0.05312)	0.32 (0.00594)	0.34 (0.00306)
Health worry	0.32 (0.00646)	0.35 (0.00234)	0.43 (0.00016)	0.44 (0.00012)
Food avoidance	0.33 (0.00455)	0.24 (0.04316)	0.34 (0.00387)	0.34 (0.00370)
Social reaction	0.19 (0.10465)	0.17 (0.16435)	0.29 (0.01219)	0.33 (0.00482)
Sexual	0.22 (0.06297)	0.19 (0.10924)	0.32 (0.00709)	0.24 (0.04495)
Relationships	0.22 (0.06948)	0.26 (0.02916)	0.31 (0.00914)	0.27 (0.02193)
EQ-5D				
VAS	0.55 (0.00000)	0.60 (0.00000)	0.54 (0.00000)	0.45 (0.00007)
Index	0.63 (0.00000)	0.60 (0.00000)	0.32 (0.00582)	0.47 (0.00004)
WPAI:IBS				
Absenteeism†	0.04 (0.79057)	0.07 (0.64161)	–0.33 (0.02246)	–0.41 (0.00374)
Presenteeism‡	–0.33 (0.01954)	–0.22 (0.13021)	–0.35 (0.01425)	–0.46 (0.00113)
Work productivity loss†	–0.24 (0.09970)	–0.17 (0.25854)	–0.39 (0.00614)	–0.49 (0.00035)
Daily activity impairment	–0.60 (0.00000)	–0.43 (0.00015)	–0.34 (0.00351)	–0.40 (0.00049)

†n = 49 paper, n = 48 EDC.

‡n = 50 paper, n = 48 EDC.

EDC, electronic data capture; IBS-QOL, Irritable Bowel Syndrome—Quality of Life; VAS, Visual Analog Scale; WPAI:IBS, Work Productivity and Activity Impairment questionnaire—Irritable Bowel Syndrome version.

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

IBS symptom severity	Overall IBS-QOL	EQ-5D VAS	Overall work productivity loss	Activity Impairment
Paper administration (pooled baseline and crossover)				
Low (0–5)				
Mean	77.0	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-value	$P = 0.00096$	$P = 0.00590$	$P = 0.02533$	$P = 0.00015$
EDC administration (pooled baseline and crossover)				
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-value	$P = 0.00156$	$P = 0.28841$	$P = 0.10140$	$P = 0.00026$

EDC, electronic data capture; IBS-QOL, Irritable Bowel Syndrome—Quality of Life; VAS, Visual Analog Scale; WPAI:IBS, Work Productivity and Activity Impairment questionnaire—Irritable Bowel Syndrome version.

all measures by severity category (*P*-values 0.03 to <0.0001), with higher severity scores associated with higher impairment. Each of the summary scores were markedly different at each level of symptom severity, with the exception of the EQ-5D Index which had comparable scores for the low and middle severity groups (0.78 and 0.75). For EDC, there were significant differences by level of severity for the IBS-QOL overall score ($P < 0.002$) and the WPAI:IBS activity impairment score ($P < 0.0001$). Again, the EQ-5D Index scores did not differentiate the low and middle symptom severity groups (0.70 for both). Although the trend for the WPAI:IBS overall work productivity loss score indicated that higher symptom severity was associated with higher impairment (21.2%, 37.2%, and 40.5% for the low, middle, and high severity groups, respectively), the differences were not significant.

Table 6 shows ease of use for the two modes of administration by initial mode of administration. 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. Patients reported it was significantly easier to go back and change answers on the EDC version than in the paper version, regardless of whether paper or EDC was administered first (*P*-values 0.004 and 0.001), but there were no significant differences in difficulty using the two administration modes.

Table 7 shows the preference for the two modes of administration. 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

Table 6 Ease of using the paper questionnaire and electronic data capture (EDC) by mode of first administration

	Paper first mean (±SD) [Range] n = 35		EDC first mean (±SD) [Range] n = 37	
	Paper	EDC	Paper	EDC
How easy was the diary to read *Not at all easy (0) to extremely easy (100)*	90.7 (8.1) [72–100]	87.9 (17.1) [26–100]	91.8 (11.8) [47–100]	91.2 (11.3) [47–100]
How easy was it to go back and change answers? *Not at all easy (0) to extremely easy (100)*	77.9 (26.6)* [10–100]	92.3 (9.1) [64–100]	73.1 (35.8)* [0–100]	93.5 (14.8) [9–100]
How difficult was it to use this diary? *Not at all difficult (0) to extremely difficult (100)*	10.1 (19.5) [0–82]	9.1 (18.2) [0–94]	13.5 (26.2) [0–100]	5.9 (10.4) [0–47]

*$P \leq 0.004$ by Student's paired *t*-test.

Table 7 Preference for mode of administration by mode of first administration

	Paper first n = 35	EDC first n = 37	Total
Method easier to use			
Paper and pencil	5 (14.3%)	12 (32.4%)	17 (23.6%)
Computer	19 (54.3%)	15 (40.5%)	34 (47.2%)
No difference	11 (31.4%)	10 (27.0%)	21 (29.2%)
Preferred method in future study			
Paper and pencil	5 (14.3%)	5 (13.5%)	10 (13.9%)
Computer	18 (51.4%)	18 (48.6%)	36 (50.0%)
No difference	12 (34.3%)	14 (37.8%)	26 (36.1%)

EDC, electronic data capture.

another study, half would prefer EDC, 13.9% would prefer paper questionnaires, and 36.1% would have no preference. No missing data were found in either mode of administration.

Discussion

Electronic data capture is increasingly being used to collect patient-reported outcomes data in clinical studies. We tested three previously validated questionnaires (IBS-QOL, WPAI:IBS, EQ-5D) to determine whether the EDC versions of these questionnaires were comparable to the paper versions and acceptable to subjects, and therefore suitable for use in IBS studies.

We found no significant differences between the scores obtained by paper questionnaire and EDC and no pattern of results emerged that would suggest that one mode of administration was better than the other in terms of its psychometric properties. Scores from both modes of administration had comparable correlations with SF-36 measures of physical and mental well-being. Scores obtained by both paper questionnaire and EDC demonstrated internal consistency, test–retest reliability, and validity, as measured by the relationship of scores to symptom severity. The one exception was the EQ-5D VAS that did not differentiate the low and middle symptom severity groups in either mode of administration. This is not surprising considering that this is a general health measure for a single day and the criterion for discriminant validity was IBS symptom severity for the past 7 days. Acceptability of both modes of administration was high, but patients reported the EDC mode was significantly easier for going back and changing a response, and more patients preferred EDC over the paper questionnaire.

Our subjects were selected to be representative of IBS patients in terms of sex and type of IBS, but our results are limited by the small sample size, particularly among the employed (n = 49) in the investigation of WPAI:IBS work productivity measures. Consequently, although we failed to demonstrate statistically significant differences between the two modes of administration, there may be differences that we were unable to detect. For example, we note that impairment as measured by the IBS-QOL and WPAI:IBS domain scores uniformly decreased from baseline to the 24-hour crossover assessment, regardless of mode of administration, whereas the EQ-5D scores were generally higher when obtained by paper questionnaire, regardless of whether paper was administered first or second. Investigation of these differences was outside the scope of the planned analysis and warrant additional investigation.

Another limitation of our findings is that they may not reflect the application of the two modes of administration in the typical clinical setting, in terms of missing information. Because subjects could not skip an entry in EDC and the site coordinators rigorously reviewed completed paper questionnaires and retrieved missing information from subjects, missing information was not found in either mode of administration. In other settings, paper questionnaires have had higher rates of missing information relative to EDC [24–26], so the advantage of EDC in this study may be understated.

Despite the study's limitations, the findings of comparability between the two modes of administration are consistent with a growing body of research in a variety of diseases, populations, and settings that has shown EDC to be comparable to paper questionnaires.

Conclusion

Electronic Data Capture versions of the IBS-QOL, EQ-5D, and WPAI:IBS are generally comparable to paper questionnaires and demonstrate internal consistency, test–retest reliability, and subject acceptability; discriminant validity of the questionnaires by the two modes of administration is comparable.

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