

Tubo Digestivo

EP-064 - CORRELATION BETWEEN PHYSICIAN AND PATIENT DISEASE ASSESSMENTS IN ULCERATIVE COLITIS: BASELINE DATA FROM THE ICONIC STUDY OF 1816 PATIENTS IN 33 COUNTRIES

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Background

ICONIC is the largest prospective multi-country (n=33) observational study, assessing burden in adult ulcerative colitis (UC) patients (pts) under routine care. Both pt & physician assessments of disease severity, activity & life impact will be captured at 6 month intervals through 2 yrs. This analysis will evaluate baseline (BL) demographics, clinical characteristics & the extent of agreement between pts & physicians in measures of disease activity.

Methods

Adult pts with early UC (diagnosed ≤ 36 months) were enrolled irrespective of disease severity or treatment. Pt self-assessments include: disease severity, Pictorial Representation of Illness & Self-Measure (PRISM, [a tool assessing perception of disease-associated suffering]), Patient Health Questionnaire-9 (PHQ-9), Short Inflammatory Bowel Disease Questionnaire (SIBDQ) & pt-modified Simple Clinical Colitis Activity Index (P-SCCAI). Physician assessments include: clinical parameters, PRISM, & SCCAI. Correlation between PRISM & SIBDQ, PHQ-9, & SCCAI were evaluated. BL characteristics were obtained from observed data by calculating means. Mean differences between pt & physician measures were calculated using a one-sample t-test. Correlation analyses were performed by kappa statistics & Pearson correlation.

Table 1. Baseline clinical & demographic characteristics of UC patients in ICONIC*

Characteristic	All patients N=1816
Sex, n (%)	
Female	833 (45.9)
Age, years	
Mean \pm SD	38.5 \pm 14.6
Current smoker, n (%)	212 (11.7)
Time since UC diagnosis, days	
Median (25% 0, 75% Q)	171 (59, 317)
Disease Duration, n (%)	
0 - 6 months	873 (48.1)

6 months - 1 year	584 (32.2)
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1-3 years	278 (15.3)
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Duration of symptoms prior to UC diagnosis, n (%)

< 1 year	
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1-3 years	1296 (71.4)
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> 3 years	380 (20.9)
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	134 (7.4)
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Disease severity since diagnosis, n (%)

Improved	1278 (70.4)
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Worsened (flare)	157 (8.6)
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Remains similar	330 (18.2)
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Endoscopic finding, n (%)

Normal/Inactive	93 (5.1)
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Mild	390 (21.5)
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Moderate	550 (30.3)
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Severe	209 (11.5)
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Physician assessment of UC severity, n%

Mild	672 (37.0)
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Moderate	668 (36.8)
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Severe	234 (12.9)
In remission	230 (12.7)
SI BDQ	
Mean \pm SD	48.4 \pm 13.2
PHQ-9	
Mean \pm SD	6.3 \pm 5.4
PHQ-9 depression severity, n (%)	
None-minimal	822 (45.3)
Mild	556 (30.6)
Moderate	256 (14.1)
Moderately severe	109 (6.0)
Severe	51 (2.8)
ELMs, n (%)	186 (10.2)
Any treatment since UC diagnosis, n (%)	1724 (94.9)
Response to current UC treatment, n (%)	
Not applicable/no current treatment	63 (3.5)
Too early to assess	187 (10.3)
Complete response	757 (41.7)
Partial response	712 (39.2)

No response

70 (3.9)

*** Only available observed data are shown.**

Results

BL demographic & clinical characteristics of 1816 UC pts enrolled in ICONIC are summarized in Table 1. At BL, pt/physician PRISM was moderately correlated with SIBDQ, PHQ-9, P-SCCAI, or SCCAI (Table 2). For 1796 pts with self & physician assessments, most showed agreement on disease severity (concordant pairs: mild 60.3%, moderate 60.6%, severe 56.0%) ($\kappa=0.43$, 95% CI 0.40–0.47, $P<0.0001$). Although P-SCCAI & physician SCCAI mean values \pm SD differed (4.2 ± 3.6 & 3.0 ± 3.0 [$P<0.0001$]), the measures were highly correlated (Table 2). For pt/physician PRISM assessments, mean scores (4.0 ± 2.5 & 4.3 ± 2.4 , respectively) differed ($P<0.0001$) & were moderately correlated (Table 2).

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