Relationship between health-related quality of life and work productivity in patients with ulcerative colitis in the tofacitinib OCTAVE Phase 3 induction and maintenance studies

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Introduction

- Tofacitinib is an oral small molecule Janus kinase inhibitor for the treatment of UC
- > Tofacitinib induction treatment has been shown to improve work productivity in patients with UC. However, the relationship between HRQoL and work productivity in the tofacitinib OCTAVE clinical program has not been described

Objective

> To evaluate the relationship between the IBDQ and WPAI-UC score among patients with UC in the Phase 3 studies evaluating tofacitinib as induction or maintenance therapy for UC (OCTAVE Induction 1 and 2 [NCT01465763, NCT01458951] and OCTAVE Sustain [NCT01458574])



Endpoints

> The 32-item IBDQ¹ was used to measure disease-related quality of life; higher scores indicate better HRQoL (Table 1)

Table 1. Breakdown of IBDQ total score						
IBDQ total score (32–224 points)						
Bowel domain (10–70 points)	Emotional domain (12–84 points)	Social domain (5–35 points)	Systemic domain (5–35 points)			

- > The WPAI-UC² is a self-administered six-item survey that generates four components: absenteeism (work time missed), presenteeism (impairment while working), work productivity loss (overall work impairment from both absenteeism and presenteeism), and activity impairment (non-work activity impairment)
- WPAI component scores are expressed as percentages, with higher percentages indicating greater impairment and less productivity
- Work productivity loss encapsulates both absenteeism and presenteeism and is thus the most comprehensive WPAI-UC component representing overall work impairment

Statistical analysis

- > Relationships between the IBDQ (total and domain scores) and WPAI-UC components were estimated using a repeated-measures longitudinal model in which IBDQ domain score was a continuous anchor and WPAI-UC was the outcome (ie, a linear relationship was imposed between the outcome and anchor)
- In sensitivity analyses, IBDQ domain score was used as a categorical anchor to assess the linearity assumption (which did not impose any functional relationship between outcome and anchor)
- > Analyses used all available pooled data from patients receiving tofacitinib or PBO



- also robust; the relationship with absenteeism was weak (Figures 2b-e)
- as measured by the IBDQ total score (32-224) is shown in Table 2



	WPAI-UC component (percentage points)				
	Absenteeism	Presenteeism	Work productivity loss	Activity impairment	
IBDQ total score	0.22	0.50	0.50	0.55	
1 point	(0.20, 0.24)	(0.48, 0.52)	(0.47, 0.52)	(0.53, 0.56)	
IBDQ total score	3.49	8.06	7.93	8.75	
16 points ^a	(3.17, 3.81)	(7.75, 8.36)	(7.50, 8.35)	(8.53, 8.97)	

^aA 16-point change equals the minimal clinically important difference³

Abbreviations

BID, twice daily; CI, confidence interval; HRQoL, health-related quality of life; IBDQ, Inflammatory Bowel Disease onnaire; PBO, placebo; N, number of patients; UC, ulcerative colitis; WPAI-UC, Work Productivity and Activity Impairment-Ulcerative Colitis.

References

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These data included 614 patients from OCTAVE Induction 1 (PBO, N=122; tofacitinib 10 mg BID, N=476; tofacitinib 15 mg BID, N=16), 547 patients from OCTAVE Induction 2 (PBO, N=112; tofacitinib 10 mg BID, N=429; tofacitinib 15 mg BID, N=6), and 593 patients from OCTAVE Sustain who were clinical responders in the induction studies and were re-randomized (PBO, N=198; tofacitinib 5 mg BID, N=198; tofacitinib 10 mg BID, N=197)

Limitations

- > These post hoc clinical trial data may not be fully generalizable to clinical practice
- WPAI-UC questionnaire responses are a patient's reflection of how they feel their UC has impacted them and there are limitations on what can be interpreted from a single question response. In addition, the data had a skewed distribution for some variables
- > In some analyses, using the anchor as a continuous variable resulted in predicted (estimated) values below 0% and above 100% for WPAI-UC components at the extreme values of the anchor
- This was due to the small number of available observations at the extremes of the range and imposing a linear relationship. When the anchor was used as a categorical variable, as expected, there were no such occurrences



- > In patients with UC in the induction and maintenance studies, generally linear relationships between IBDQ (total score and domains) and presenteeism, overall work productivity loss, and non-work activity impairment were observed; increases in HRQoL corresponded with a decrease in both work and non-work activity impairment
- > These robust relationships suggest that patients' work productivity and non-work activities are strongly associated with HRQoL
- > The weak relationship with absenteeism suggests that patients attend work regardless of their poor HRQoL
- > Characterizing and guantifying these relationships will help inform healthcare providers on the impact of UC on patients' work and non-work activities

Reference to other presentations

The inter-relationships among treatment, Mayo index components, or IBDQ domains,

Disclosures

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