

TOCILIZUMAB IMPROVES HEALTH-RELATED QUALITY OF LIFE IN RA PATIENTS WITH INADEQUATE RESPONSE TO PRIOR DMARDs: OPTION/TOWARD POOLED ANALYSIS

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Rheumatoid arthritis (RA) is a debilitating disease that impairs patient (pt) quality of life (QoL) through progressive joint destruction and systemic inflammation, resulting in pain, physical dysfunction, and systemic manifestations such as fatigue. The effect of tocilizumab (TCZ), an IL-6 receptor inhibitor, on health-related QoL in pts with inadequate response to MTX or other conventional DMARDs was evaluated in the double-blind, randomized, controlled, phase 3 studies OPTION and TOWARD.

Methodology

This was a post hoc analysis of adult pts with moderate to severe active RA who received TCZ 8 mg/kg and DMARDs or placebo and DMARDs (control) every 4 wks for 24 wks in OPTION and TOWARD. QoL outcomes (SF-36, FACIT-fatigue, HAQ-DI) were assessed up to wk 24 and pooled for this analysis.

Results

A total of 1625 pts were included in the ITT population. Pts in the TCZ group had significant improvements in SF-36 physical component score (PCS), SF-36 mental component score (MCS), all SF-36 domain scores, FACIT-fatigue score, and HAQ-DI at wk 24 vs pts in the control group (Table). Proportions of pts who achieved clinically meaningful improvement in physical function (change in HAQ-DI ≥ -0.25) were significantly higher in the TCZ vs control group as early as wk 2 (41% vs 28%; $p < 0.0001$) and wk 24 (68% vs 50%; $p < 0.0001$). Pts in the TCZ group achieved the minimal clinically relevant improvement in fatigue (≥ 4) after wk 4 ($p < 0.0001$ vs control); pts in the control group reached it after wk 16. Change from baseline in PCS and MCS were significant as early as wk 8 for pts in the TCZ vs control group (PCS, 6.4 vs 3.4; MCS, 4.9 vs 2.3; $p < 0.0001$, both), and the proportions of pts who achieved clinically relevant changes (SF-36 PCS or SF-36 MCS ≥ 2.5) at wk 8 were greater in the TCZ vs control group (PCS, 54% vs 37%; MCS, 45% vs 34%).

Conclusion: TCZ in combination with DMARDs provides rapid and clinically meaningful improvements in health-related QoL measures for pts with prior inadequate response to DMARDs.

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Mean Change From Baseline to wk 24 ^a	TCZ 8 mg/kg + DMARDs n=617	Placebo + DMARDs n=1008	Difference (95% CI)	p
SF-36 PCS	9.2	4.7	4.5 (3.5, 5.4)	<0.0001
SF-36 MCS	6.4	3.0	3.4 (2.2, 4.5)	<0.0001
SF-36 domain scores				
Bodily pain	11.7	6.1	5.6 (4.6, 6.6)	<0.0001
Physical health	6.1	3.4	2.7 (1.8, 3.6)	<0.0001
Mental health	6.3	3.1	3.1 (2.1, 4.2)	<0.0001
Physical functioning	7.7	3.5	4.2 (3.1, 5.2)	<0.0001
Role emotional	7.9	3.6	4.3 (2.8, 5.8)	<0.0001
Role physical	9.3	4.4	4.9 (3.6, 6.1)	<0.0001
Social functioning	7.9	3.8	4.1 (3.0, 5.2)	<0.0001

Vitality	8.3	3.9	4.4 (3.3, 5.5)	<0.0001
FACIT-fatigue score	8.4	3.9	4.5 (3.5, 5.6)	<0.0001
HAQ-DI	-0.51	-0.25	-0.26 (-0.32, -0.20)	<0.0001

^aAdjusted for baseline values and site.