E42. PATTERNS OF TOCILIZUMAB USE AND SAFETY IN PATIENTS WITH RHEUMATOID ARTHRITIS: INTERIM RESULTS FROM ACT-UP: A MULTINATIONAL OBSERVATIONAL STUDY

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Background: Tocilizumab (TCZ) is indicated for RA patients with inadequate responses to DMARDs, either as monotherapy (Mono) or in combination with DMARDs (Combo). ACT-UP pools data from several international, observational, post-marketing studies of i.v. TCZ. Interim observations of patterns of TCZ-use in RA patients, adherence to label recommendations and safety are reported.

Methods: Adult patients with moderate-to-severe RA who started TCZ in routine practice were observed in clinical practice for 6 months. There were no specified dosing regimens (concomitant RA treatments permitted) and no interventional procedures, clinic visits, or laboratory analyses outside routine practice.

Results: Data are reported for 961 patients receiving TCZ [352 (37%) initiated as Mono and 609 (63%) as Combo]. 94% and 95% of Mono and Combo patients, respectively, started TCZ at 8 mg/kg, and 93% and 94% of patients, respectively, taking TCZ at 6 months received 8 mg/kg. TCZ dose changes occurred in 34 (10%) Mono patients (7 increased, 11 decreased, 16 increased and decreased) and 68 (11%) Combo patients (13 increased, 20 decreased, 35 increased and decreased). Reasons for dose changes were: adverse events (AEs; 4% Mono; 5% Combo) and lack of efficacy (2% Mono; 1% Combo). Median MTX dose for Combo patients was 15.0 mg/week. 63 patients changed MTX dose (median dose change 5.0 mg/week). 28 (8%) of TCZ mono patients added a DMARD during the study. Corticosteroids were used by 57% of Mono and 70% of Combo patients (median prednisone-equivalent dose (at baseline) 7.5 and 5.0 mg/day, respectively). At 6 months, 72% of Mono and 84% of Combo patients were still receiving TCZ. 100 (10%) patients discontinued TCZ in the first 3 months; 94 (10%) in the next 3 months (reasons: lack of efficacy (11% Mono; 27% Combo), AEs (27% Mono; 29% Combo), other reasons (62% Mono; 44% Combo). AEs occurred in 53% of patients (Table 1). Infections were less common in Mono patients. No gastrointestinal perforations were reported.

Conclusion: In clinical practice, 37% of patients started TCZ as monotherapy and most patients continued with TCZ treatment (Mono and Combo) 6 months after initiation. TCZ was well tolerated in both groups.

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E42 TABLE 1. Safety data from ACT-UP (6 months)

	TCZ Mono ($n=352$)	TCZ Combo ($n=609$)	All patients ($n=961$)
AEs, *n* (%)	185 (52.6)	324 (53.2)	509 (53.0)
Rate per 100 py	193	205	201
AEs by SOC[a]			
Infections and infestations	56 (15.9)	132 (21.7)	188 (19.6)
Investigations	38 (10.8)	71 (11.7)	109 (11.3)
Musculoskeletal and connective tissue disorders	33 (9.4)	52 (8.5)	85 (8.8)
Gastrointestinal disorders	29 (8.2)	49 (8.0)	78 (8.1)
Skin and s.c. tissue disorders	28 (8.0)	44 (7.2)	72 (7.5)
General disorders and administration site conditions	22 (6.3)	34 (5.6)	56 (5.8)
Blood and lymphatic system disorders	20 (5.7)	44 (7.2)	64 (6.7)
Nervous system disorders	18 (5.1)	32 (5.3)	50 (5.2)
Metabolism and nutrition disorders	18 (5.1)	23 (3.8)	41 (4.3)
SAEs, *n* (%)	34 (9.7)	49 (8.0)	83 (8.6)
Rate per 100 py	23	19	21
Infection SAEs, *n* (%)	6 (1.7)	15 (2.5)	21 (2.2)
Total AEs leading to withdrawal, *n* (%)	32 (9.1)	42 (6.9)	74 (7.7)
Rate per 100 py)	21	14	16
AEs leading to withdrawal by SOC[b]			
Skin and s.c. tissue disorders, *n* (%)	6 (1.7)	5 (0.8)	11 (1.1)
Infections and infestations, *n* (%)	5 (1.4)	6 (1.0)	11 (1.1)
Gastrointestinal disorders, *n* (%)	4 (1.1)	1 (0.2)	5 (0.5)
Cardiac disorders, *n* (%)	4 (1.1)	—	4 (0.4)
Blood and lymphatic system disorders, *n* (%)	3 (0.9)	7 (1.1)	10 (1.0)

Rate per 100 py is based on total number of events during TCZ exposure, determined for each patient as date of last TCZ dose − date of first TCZ dose + 28 days. [a]Reported in ≥5% of patients in a treatment group. [b]Reported in ≥1% of patients in a treatment group. Combo: in combination with DMARDs; Mono: monotherapy; py: patient-years; SAEs: serious AEs; SOC: system organ class; TCZ: tocilizumab.