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NO EVIDENCE THAT CONCOMITANT GLUCOCORTICOID THERAPY AFFECTS EFFICACY AND SAFETY OF TOCILIZUMAB MONOTHERAPY IN RHEUMATOID ARTHRITIS CLINICAL TRIALS

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Background: For rheumatoid arthritis (RA) patients included in clinical trials, background treatment with glucocorticoids (GCs) is quite common (40–60%), but their potential contribution to efficacy and safety of the disease modifying anti-rheumatic drug (DMARD) tested in that trial has rarely been evaluated.

Objectives: To establish whether a stable GC dose at baseline and during the study contributed to the efficacy and safety of TCZ monotherapy initiated in RA patients in 4 TCZ RCTs. In addition, to investigate the same issue in the comparator arms of these trials, in which adalimumab (ADA) or methotrexate (MTX) was initiated.

Methods: Data from 4 randomized controlled double-blind trials (AMBITION, ACT-RAY, ADACTA and FUNCTION) with TCZ monotherapy arms was analysed in this post hoc analysis [1–4]. Study participants were MTX-naïve, intolerant or had an inadequate response to conventional synthetic DMARDs (csDMARD-IR). Because of differences between the studies in region, and baseline RA duration and disease severity, analyses were done separately for each study. Stable GC dose at baseline was allowed and was to be continued unchanged during the first 24 weeks. Analyses of covariance (ANCOVA) of change from baseline to Week 24 in CDAI and DAS28 and logistic regression analyses at Week 24 for CDAI remission and ACR50 were performed. Repeated measures analyses using all visits up to week 24 were also done. Incidence rates of serious adverse events (SAEs) were assessed by GC use.

Table 1 Disease Activities at week 24 of GC Users versus non-GC Users per Treatment per Study

	AMBITION				ACT-RAY			
	T12 Users		M73 Users		T12 Users		M73 Users	
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)
Median	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0
Range	0–15	0–15	0–15	0–15	0–15	0–15	0–15	0–15
Mean (SD)	10.2 (3.2)	10.2 (3.2)	10.2 (3.2)	10.2 (3.				