professional (HCP) contact following BA-fatigue, with dose adjustment in 8 and discontinuation in 5 patients. Basic demographics and characteristics that differ significantly between patients reporting BA-fatigue and patients not reporting BA-fatigue are summarized in table 1. No significant difference was found for other biologics, IMiDs, combination therapy and comorbidities. BA-fatigue was reported by 27% of rituximab users (n=33), 27% of vedolizumab users (n=26), 16% of tocilizumab users (n=50), 14% of infliximab users (n=159) and 3% of etanercept users (n=418). Although 29 patients in the BA-fatigue population had RA and 29 patients had Crohn's disease (CD), 571 patients in our overall study population had RA and 194 patients had CD, suggesting BA-fatigue was reported by CD patients more often. The mean burden of BA-fatigue was higher than the mean burden of other ADRs ($p < 0.001$).

Table 1. Characteristics of patients with BA-fatigue compared to patients with other ADRs and without ADRs

	n	Patients with BA-fatigue n (%)	Patients with other ADRs n (%)	Patients without ADRs n (%)
		100 (100%)	596 (100%)	673 (100%)
Basic demographics	Age (years) (mean $\pm$ SD)	50.0 $\pm$ 14.6	53.4 $\pm$ 13.6 *	55.7 $\pm$ 14.2 ***
	Gender (Female)	59 (59%)	398 (67%) ^{ns}	342 (51%) ^{ns}
	Smoking n (%)	25 (25%)	97 (16%) *	100 (15%) *
	BMI (kg/m ²) (mean $\pm$ SD)	25.7 $\pm$ 4.4	25.9 $\pm$ 4.7 ^{ns}	26.6 $\pm$ 5.5 ^{ns}
Biologic	Infliximab	22 (22%)	53 (9%) ***	84 (12%) *
	Etanercept	13 (13%)	177 (30%) ***	228 (34%) ***
	Rituximab	9 (9%)	18 (3%) **	6 (1%) ***
	Tocilizumab	8 (8%)	29 (5%) ^{ns}	13 (2%) **
	Vedolizumab	7 (7%)	12 (2%) *	7 (1%) ***
IMiD	Rheumatoid arthritis	29 (29%)	270 (45%) **	272 (40%) *
	Crohn's disease	29 (29%)	77 (13%) ***	88 (13%) ***
Combination therapy	Other indication	16 (16%)	53 (9%) *	39 (6%) ***
	Methotrexate	23 (23%)	167 (28%) ^{ns}	227 (34%) *
Comorbidity	Psychiatric disorder	11 (11%)	49 (8%) ^{ns}	31 (5%) *
	Other comorbidity	30 (30%)	124 (21%) *	102 (15%) ***
	Mean burden of ADR $\pm$ SD	2.9 $\pm$ 0.9	2.4 $\pm$ 1.1 ***	

Mann Whitney U, independent t-test and Fisher's exact as appropriate

ns: not significant * $p \leq 0.05$ ** $p \leq 0.01$ *** $p \leq 0.001$

Conclusion: HCPs should be aware that fatigue may be associated with biologic therapy and has a significant burden on patients. Evaluating the course of the symptoms might be helpful in recognizing BA-fatigue.

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OP0209

INTERVAL PROLONGATION IN ETANERCEPT-TREATED PATIENTS WITH RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS OR PSORIATIC ARTHRITIS: AN OPEN-LABEL, RANDOMISED CONTROLLED TRIAL

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Background: The majority of patients with a rheumatic disease treated with etanercept may be overexposed. Data regarding etanercept tapering is scarce, particularly in psoriatic arthritis (PsA) and ankylosing spondylitis (AS). Dose reductions can potentially reduce blood drug levels too much, resulting in loss of effect.

Objectives: We compared extending the dose interval to continuation of the standard dose and studied the success rate of etanercept discontinuation. Etanercept concentrations were measured throughout the study.

Methods: 160 consecutive patients with rheumatoid arthritis (RA), PsA or AS with sustained minimal disease activity (MDA) were enrolled in this 18-month, open-label, randomised controlled trial. The intervention group doubled the dosing-interval at baseline and discontinued etanercept 6 months later. The control group continued the standard dose up to 6 months, after which the dosing-interval was doubled. Primary outcome was the proportion of patients maintaining MDA after 6 months follow-up.

Results: At 6 months, MDA status was maintained in 47 (63%) patients in the intervention group and 56 (74%) in the control group ($p=0.15$), with comparable results in all rheumatic diseases. Median etanercept concentrations decreased from 1.50 $\mu\text{g/mL}$ (25-75th percentile 1.06-2.65) to 0.46 $\mu\text{g/mL}$ (0.28-0.92) after 6 months of interval prolongation (figure 1). In total, 40% discontinued etanercept successfully with maintained MDA for at least 6 months.

Figure 1. Median (with Q1 to Q3 boxplots) etanercept concentrations (per protocol) during the first 6 months of follow-up in the intervention group (prolongation; gray boxplots) and the control group (continuation; white boxplots), separated by disease (RA, PsA, AS). Bars represent 10-90 percentile and outliers are shown separately (dots).

Conclusion: As observed in RA, etanercept tapering can be safely attempted in PsA and AS patients in sustained MDA. A substantial proportion of patients could stop etanercept for at least 6 months. In many patients low drug concentrations proved sufficient to control disease activity. However, the risk of minor and major flares is substantial, even in patients continuing standard dosing.

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