BioReg: Long term prospective observational register for the treatment of inflammatory rheumatic diseases with biologic agents

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The Austrian *BioReg* registry (*http://www.bioreg.at*) was initiated in 2009. Patients with a chronic inflammatory rheumatic disease and ongoing biologic therapy (bDMARDs) as well as biologic-naïve patients starting biologic therapy treated with a biologic approved in Austria can be included. The inclusion criteria have been extended and also patients treated with targeted conventional DMARDs (so called “small molecules”) may be documented as well as patients treated out of label. Further documentation is recommended about every six months. Until August 201 (figure 1), 1877 patients (rheumatoid arthritis (RA) n=1046, ankylosing spondylitis (SpA) n= 446, psoriatic arthritis (PsA) n=322) have been documented (1).

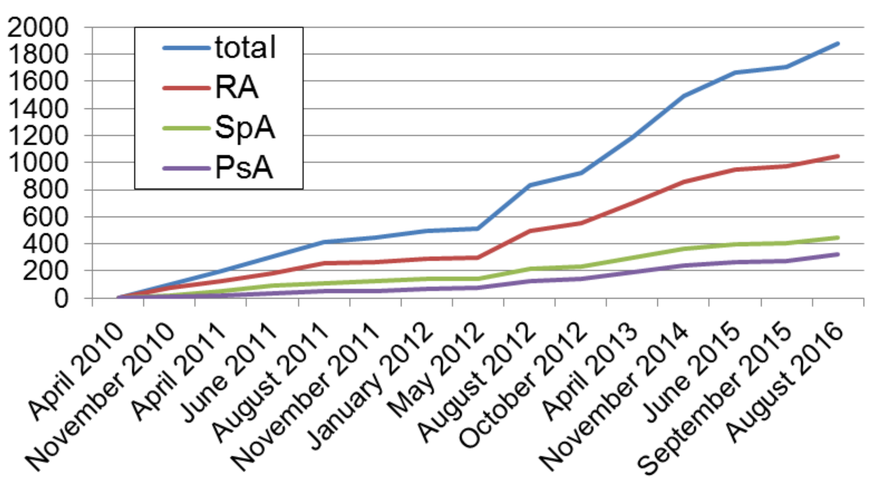

Figure 1: Patients included in BioReg until 08/2016

In comparison to the German registry RABBIT the distribution of biologics prescribed in Austria is similar.
Most biologics are approved and recommended for treatment of RA only in combination with methotrexate (MTX). Nevertheless in Austria more then one third of RA patients are treated with biologic monotherapy (figure 2). At baseline 39.7% of patients received a biologic as monotherapy and the percentage of RA patients (40.1; 38.2; 43.9%) on biologic monotherapy seems to increase with time of treatment (2). These data are in agreement with observations from other registries (3).
Data extracted from *BioReg* indicates successful RA treatment with bDMARDs in Austria at reasonable tolerability (figure 3). After one year of treatment there were no differences with respect to disease activity in patients with RA on established biological DMARDs before inclusion into the register and beginners at the time point of inclusion (4).

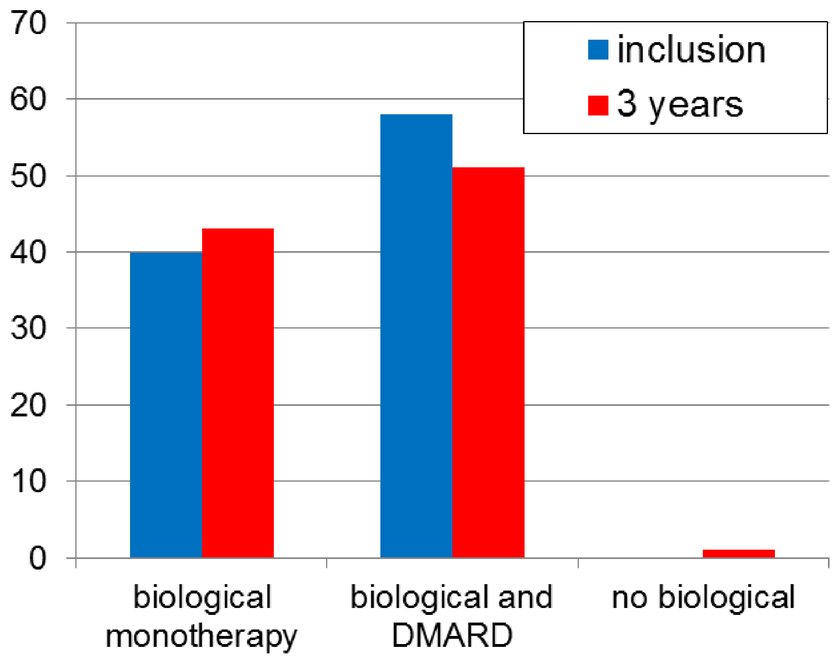

Figure 2: Patients under biologic monotherapy

The national biologic registry *BioReg* is in Austria the biggest data collection of patients with chronic inflammatory rheumatic diseases. The data confirm the high efficiency of biologic therapies with keeping most patients in remission or low disease activity. Biologics are well tolerated, severe side effect are rare. With increasing data a more detailed evaluation on specific question may be expected..

Table 3: Percentages of remission at baseline and one-year follow-up and percentages of concomitant csDMARD and GC therapy in EST and NEW patients

	EST n=284		NEW n=62	
	baseline	after 1 year follow up	baseline	after 1 year follow up
DAS28 remission %	47.2	51.1	1.6	53.2
RADAI-5 remission %	31.3	36.3	1.6	27.4
BC remisson %	21.1	26.1	1.6	21.0
GC%	25.0	27.8	66.1	48.4
csDMARD %	56.0	51.8	83.9	67.7
bDMARD %	100.0	94.0	na	87.1

Abbreviations: BC Boolean criteria; bDMARD biologic DMARD; csDMARD conventional synthetic DMARD; DAS28 Disease Activity Score using ESR out of 28 joints; ESR Erythrocyte sedimentation rate; EST pts with established bDMARD treatment before inclusion in BIOREG of whom a full data set as described is viable; GC glucocorticoid; na not applicable; NEW pts included in BIOREG with start of biologic treatment ± 30 days; pts patients; RADAI-5 Rheumatoid Arthritis Disease Activity Index-5;

Figure 3: Percentages of remission at baseline and one-year follow-up and percentages of concomitant csDMARD and GC therapy in EST and NEW patients

References: 1. Herold M. Jatros Rheumatologie 2016;ii:76-76
2. Herold M et al. EULAR 2016, abstract FRI0172
3. Zhang J et al. Arthritis Care Res 2014 doi: 10.1002/acr.22510
4. Rintelen B et al. BMC Musculoskelet Disord 2016 in press

Disclosures: *BioReg* is a non-profit association for the application of bDMARDs and newly tsDMARDs in inflammatory rheumatic diseases supported by companies of the pharmaceutical industry.