PsoBest: drug safety in systemic treatment for psoriasis

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INTRODUCTION & OBJECTIVES

The national non-interventional Psoriasis registry PsoBest observes patients with moderate to severe psoriasis starting a biologic, biosimilar, small molecule or conventional systemic treatment for 10 years in routine care since 2008. Long term data collection does not depend on further treatment. PsoBest aims to evaluate long term safety and effectiveness of systemic treatment in Germany. Actual analyses were conducted to characterize safety profile of treatment with respect indication and gender.

PATIENTS AND METHODS

About 700 registry sites are participating, clinics as well as resident dermatologists, and report adverse events by regular visits. Events in association with hospitalization, life threating situations, malignancies, birth defects or death are reported as SAE on special forms and independently from regular visits. All events reported were coded as MedDRA preferred terms and assigned to treatment if the date of an event falls between treatment start and end (plus a 90 day risk window). Standardized patient rates per 100 patient years (PY) are calculated using MedDRA system organ classes (SOC) for male and female patients classified by biologic (adalimumab, etanercept, efalizumab, golimumab, ustekinumab or sekucinumab) or conventional systemic treatment (cyclosporine, fumaric acid esters, methotrexate, retinoids, Leflunomid or systemic PUVA). Safety data of all patients registered until December 2015 with at least one follow-up information on treatment was analyzed. Presented here are safety data by SOC, gender and biologic vs. conventional systemic treatment.

RESULTS

Baseline

Until 31.12.2015, data of 4,048 patients (40.3% female, mean age 47.2 years, see table 1) was captured. Overall, nearly every third patient was suffered from psoriatic arthritis (47.7% in biologics and 27.1% in conventional systemics).
Most patients (76.4%) received conventional systemic treatment, when starting the registry. Patients starting biologics were more often male (61.9% vs. 58.5%, p≤0.034, see table 1) and showed a higher burden of disease (Psoriasis Area and Severity Index 13.7 vs. 15.4, Body Surface Area 22.1 vs. 25.3, Dermatology Life Quality Index 10.8 vs. 12.0, p≤0.001).

Table 1. Mean patient characteristics at baseline by registration treatment.

	N	mean	median	range
Biologics-cohort, n=1427				
Age [y]	1426	47.3	47.0	18-87
Duration of illness [y]	1328	20.5	18.0	0-63
PASI	1399	15.4	13.4	0-66.6
BSA	1402	25.3	18.0	0-100
DLQI	1365	12.0	11.0	0-30
Systemics-cohort, n=3094				
Age [y]	3094	47.3	47.0	18-92
Duration of illness [y]	2853	16.6	14.0	0-74
PASI	3015	14.1	12.2	0-66.6
BSA	3023	23.0	15.0	0-100
DLQI	2961	11.0	10.0	0-30

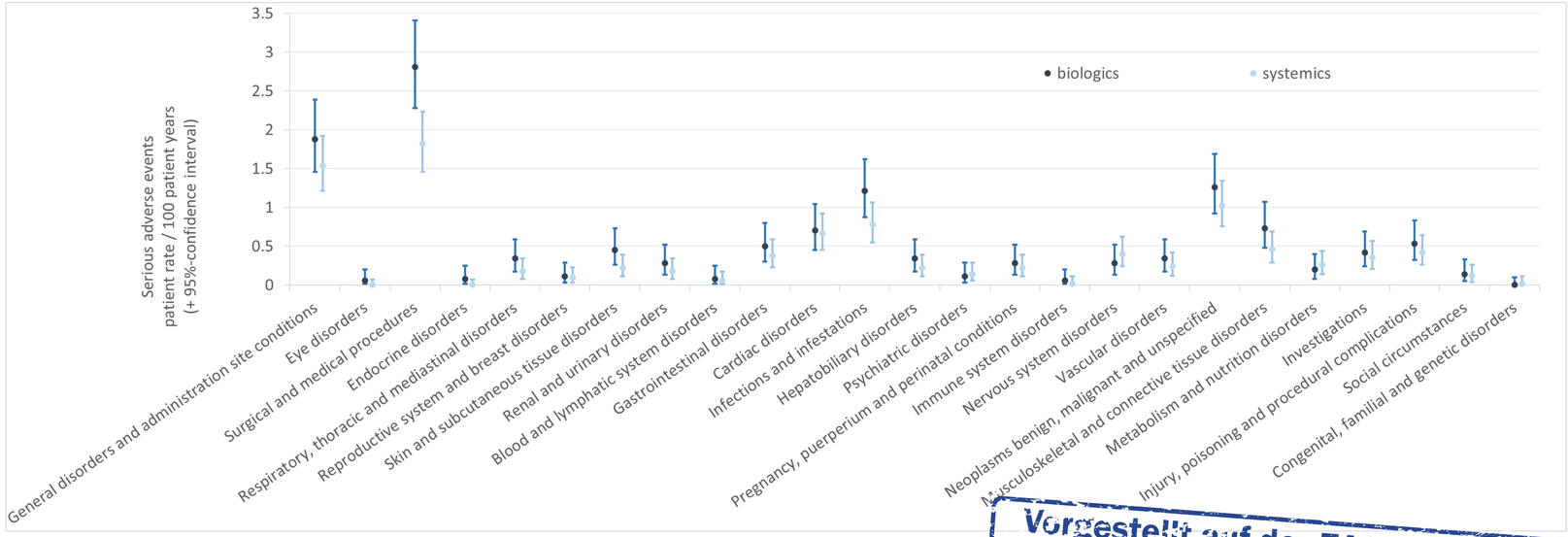

Figure 1. Serious adverse events observed, patient rate/100 PY

Adverse events

In total 2,565 PY with biologic treatment have been observed, 5013 PY on conventional systemic treatment. Non-serious adverse events from SOC Skin, Blood and Lymphatic system as well as gastrointestinal disorders and nervous system disorders were observed more often in patients on conventional systemic treatment (2.1 vs. 5.8; 0.4 vs. 2.2; 2.4 vs. 11.5; 1.2 vs. 2.5 patients per 100 PY, p≤0.05). Patients with joint affection showed higher rates on musculoskeletal and respiratory disorders. Women were suffered more often from renal and urinary disorders than men on conventional systemic treatment (1.2 vs. 0.4 patients per 100 PY, p≤0.05), but not on biologic treatment. Most often reported adverse event in both treatment arms was drug ineffective (see table 2).

Table 2. Most reported adverse events by treatment group (non-serious)

MedDRA PT	events	% patients	Patients /100 PY (95% CI)
Biologics-cohort, n=1427			
Drug ineffective	289	16.3	6.54 (5.72-7.43)
Nasopharyngitis	196	11.0	4.40 (3.74-5.15)
Condition aggravated	59	3.7	1.49 (1.11-1.94)
Fatigue	43	2.7	1.07 (0.75-1.46)
Hypertension	38	2.6	1.04 (0.73-1.43)
Systemics-cohort, n=3094			
Drug ineffective	419	10.9	6.70 (6.00-7.46)
Diarrhoea	328	9.1	5.63 (4.99-6.32)
Erythema	203	5.2	3.23 (2.75-3.77)
Nausea	187	5.0	3.11 (2.64-3.64)
Nasopharyngitis	133	3.6	2.19 (1.80-2.64)

Serious adverse events

For serious adverse events (SAEs), slight differences regarding treatment cohorts were observed, e.g. 1.21 vs. 0.14 patients with infections per 100 PY on biologic and conventional systemic treatment, respectively, without showing significance (see figure 1). Events regarding surgical and medical procedures were expectably reported more often for (older and more comorbid) patients on biologic treatment (2.8 vs. 1.8 /100 PY, p≤0.05).
Most often reported event regarding general disorders was condition aggravated: 1.1/100 PY in biologic treatment, 1.5/100 PY in systemics. For serious infections pneumonia was the most often reported event with 0.1/100PY in patients on systemic treatment and 0.3/100 PY on biologics.
Rates of all cause death and malignancies did not show any significant differences regarding treatment or gender. There were 1.0 malignancies/100 PY in biologics (53 events in 39 patients) and 0.8/100 PY in conventional systemic treatment (61 events in 46 patients).

CONCLUSION

Up to the end of 2015, no potential safety signal was observed in the registry.. The small differences in safety profiles observed have to be analyzed in more detail by adjusting for potential cohort inequalities, such as burden of disease, comorbidity and comedications. In sum, the results show the safety of systemic and biological treatment of psoriasis in Germany.

Values and ranges
PASI… Psoriasis Area and Severity Index (0-72=highest severity); BSA… Body Surface Area (0-100=maximum impairment); DLQI… Dermatological Life Quality Index (0-30= highest impairment); EQ-5D Visual Analogue scale 0-100=best health state

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