Universitätsklinikum Hamburg-Eppendorf

IVDP Institut für Versorgungsforschung in der Dermatologie und bei Pflegeberufen

CVderm Competenzzentrum Versorgungsforschung in der Dermatologie

PsoBest: Drug safety in systemic treatments for Psoriasis and Psoriatic Arthritis

Spehr C, Reich K, Mrowietz U, Radtke MA, Thaci D, Rustenbach SJ, Augustin M

For participating registry sites and scientific advisory board of PsoBest

Objectives

The nationwide non-interventional Psoriasis registry PsoBest observes patients with moderate to severe psoriasis starting a biologic or conventional systemic treatment for 10 years in routine care. 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 with respect to psoriasis (Pso) vs. psoriatic arthritis (PsA) with special focus on serious adverse events (SAE).

Methods

About 650 registry sites are participating (clinics and resident dermatologists) and report adverse events by regular visits. Events in association with hospitalization, life threating situation, malignancies, birth defect or death are reported as SAE on special forms. Events are classified into MedDRA preferred terms and assigned to treatment in terms of time including a 90 day risk window. Standardized patient rates per 100 patient years (PY) are calculated using MedDRA system organ classes (SOC) for males and females classified by treatments. Safety data of all patients registered until June 2014 with at least one follow-up information on treatment was analyzed. A pilot tested algorithm is used for the determination of PsA at each assessment: Criteria are a) a physician's diagnosis of Psoriatic arthritis or b) a probable diagnosis of PsA at the time of assessment accompanied by enthesitis or dactylitis.

Results

Until June 2014 3,322 patients were registered in PsoBest (40.5% female, mean age 47 years). Both men and women showed high skin impairment (mean PASI 14.4, BSA 23.6) when starting a new systemic treatment. Nearly every fifth patient suffer from PsA at baseline, whereby women are affected more often and distinct (21.9% vs. 17.0%, PsA pain 5.3 vs. 4.5, VAS 0-10). In most aspects patients with psoriatic arthritis showed a higher burden of disease (see table 1) and comorbidity at baseline (see table 2).

In total 2,704 PY with biologic treatment have been observed, 3,787 PY on conventional systemic treatment. There were no significant differences in SAE rates regarding gender. Patients receiving biologic treatment show a higher risk for general disorders and surgical procedures (1.61 vs. 0.03 pat/100PY and 2.4 vs. 1.11 pat/100PY, p≤0.05), while risk for endocrine disorders is decreased (0.04 vs. 1.5 pat/100PY, p≤0.05). Rates of SAE are not different with respect of diagnosis for conventional systemic treatment. Patients with PsA show higher rates for surgical procedures and gastrointestinal disorders when they receive a biologic treatment (3.29 vs. 1.53 pat/100PY and 0.75 vs. 0.0 pat/100PY, p≤0.05). Other rates, e.g. Immune system events or vascular disorders showed similar rates in both groups. Neoplasms were observed with 0.86 pat/100PY for biologic and 0.7 pat/100PY in conventional systemic treatment (p>0.05), all cause death almost identically distributed with 0.48 pat/100PY vs. 0.51 pat/100PY.

Table 1. Baseline characteristics by gender and diagnosis; * VAS 0-10

	Pso			PsA		
	♂	♀	total	♂	♀	total
n	1641	1050	2691	337	294	631
patients [%]	61.0	39.0	100.0	53.4	46.6	100.0
age [y]	46.5	47.3	46.8	48.6	51.2	49.8
weight [kg]	90.5	76.2	84.9	91.8	80.7	86.6
BMI (kg/m2)	28.4	27.7	28.1	28.8	29.5	29.1
Obesity (BMI>30)[%]	26.7	28.1	27.2	33.5	36.7	35.0
PASI	15.2	13.6	14.6	14.9	12.8	14.0
BSA	24.3	23.2	23.9	24.3	20.3	22.4
DLQI	10.4	11.9	11.0	10.6	12.3	11.4
PsA pain *	.	.	.	4.5	5.3	4.9
duration of illness [y]	16.3	17.8	16.9	20.0	23.0	21.4
nail involvement [%]	58.1	37.3	50.0	68.8	53.4	61.6

Notes. y=years, BMI=Body Mass Index, PASI=Psoriasis Area and Severity Index (0-72=maximum severity), BSA=Body surface area (%), DLQI= Dermatology Life Quality Index (0-30= highest impairment)

Table 2. Baseline comorbidity by diagnosis

[% (0.95-CI)]	Pso	PsA
asthma	3.5 (0.0-10.4)	4.3 (0.0-20.1)
chronic bronchitis	2.0 (0.0-7.4)	3.5 (0.0-17.8)
depression	6.5 (0.0-15.9)	11.7 (0.0-36.8)
arterial hypertension	27.2 (10.4-44.1)	32.0 (0.0-68.4)
CHD	3.9 (0.0-11.2)	5.1 (0.0-22.2)
myocardial infarction	0.3 (0.0-2.2)	0.3 (0.0-4.2)
cerebrovascular disease	1.0 (0.0-4.8)	0.8 (0.0-7.7)
M. Crohn	0.3 (0.0-2.4)	0.5 (0.0-5.8)
colitis ulcerosa	0.1 (0.0-1.6)	0.5 (0.0-5.8)
smoking	45.0 (26.2-63.8)	36.8 (0.0-74.4)
former smoking	30.5 (13.1-47.9)	33.1 (0.0-69.8)
alcohol abuse	4.2 (0.0-11.7)	4.8 (0.0-21.4)
hyperlipidaemia	9.3 (0.0-20.2)	10.1 (0.0-33.7)
diabetes mellitus, type II	8.5 (0.0-19.1)	10.6 (0.0-34.7)

Conclusion

PsA patients showed a higher burden of disease(s) at baseline. For treatment safety, no relevant signals were observed. The small differences in safety profiles detected have to be analyzed in more detail by adjusting for burden of disease, comorbidity and comedications. In sum, the results show the safety of systemic and biological treatment of Pso and PsA in Germany, which is in line with results from recent publications of psoriasis registries of different countries [1,2].

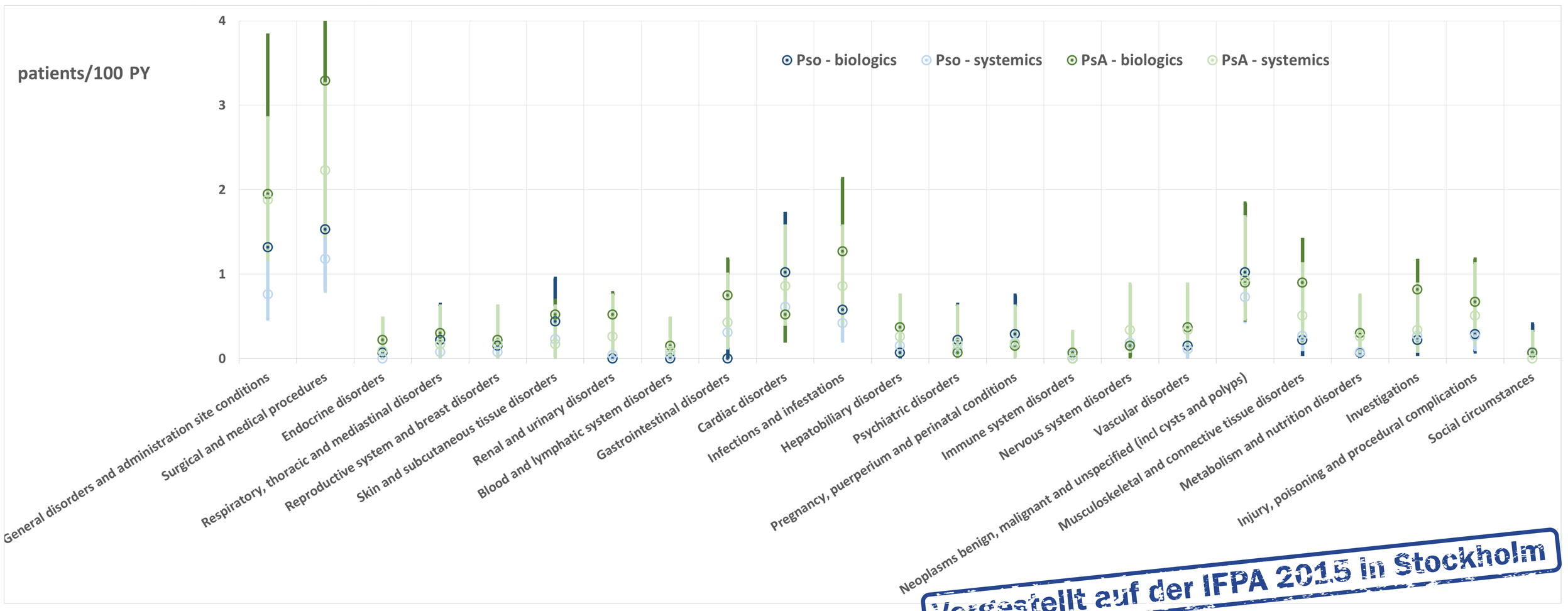

Figure 1. Standardized SAE patient rates by treatment and diagnosis

Vorgestellt auf der IFPA 2015 in Stockholm

References: 1 Ahlehoff O et al (2014) Cardiovascular outcomes and systemic anti-inflammatory drugs in patients with severe psoriasis: 5-year follow-up of a Danish nationwide cohort. J Eur Acad Dermatol Venereol. Doi: 10.1111/jdv.12768 [Epub ahead of print]; 2 Carretero G et al (2015) Risk of adverse events in psoriasis patients receiving classic systemic drugs and biologics in a 5-year observational study of clinical practice: 2008-2013 results of the Biobadaderm registry. J Eur Acad Dermatol Venereol 29(1):156–163

Thanks to all participating registry sites and patients.

Contact: Christina Spehr, Dipl. BioMath CVderm, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, c.spehr@uke.de