PSORIASIS

PHARMAKOVIGILANCE OF SYSTEMIC ANTIPSORIATIC TREATMENT: RESULTS FROM MORE THAN 11,000 PATIENT YEARS IN THE GERMAN PSORIASIS REGISTRY PSOBEST

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Introduction: The spectrum of antipsoriatic systemic therapies is constantly changing. The German Psoriasis Registry PsoBest aims to gain long-term evidence of safety and effectiveness in routine care.

Objectives: We present updated interim data of long-term safety of biological and non-biological treatment of psoriasis.

Materials & Methods: The non-interventional German Psoriasis Registry PsoBest observes adult patients with moderate to severe psoriasis. Patients are registered at naïve systemic treatment start and are observed in routine care. Data is collected in dermatological practices and walk-in clinics. We present classified and standardised patient rates. The update comprises patients and reports of adverse events until December 2017.

Results: We observed 7,184 patient years (py) on non-biologic treatments in 4,482 patients and 5,253 patient years (py) on biologic treatment (2370 patients). Non-serious adverse events were most frequent in gastrointestinal disorders in non-biologics (11.3 patients/100 py) and due to general disorders and administration site conditions in biologic treatment (9.1 patients/100 py). Differences between treatments were found in well-known side effects, i.e. higher rates of non-serious infections in biologics (6.8 vs. 4.8) and more frequent gastrointestinal complaints in non-biologics (2.5 vs. 11.3). Patient rates in serious adverse events were highest regarding surgical and medical procedures (3.8 and 2.8 patients/100 py in biologics and non-biologics). Most system organ classes showed patient rates less than 1 patient/100 py without differenced in treatment cohorts. We observed 0.5 and 0.6 cases of all-cause death per 100 py in biologics and non-biologics. The rate of new malignancies was 0.9 and 1.0/100 py, both without significant differences.

Conclusions: In general, there is no increased risk of biological or non-biological treatments.

For robust data on recently authorised therapeutics, more observation time is needed, especially with a constantly changing spectrum of treatments.