

Patients and Methods

The SDNTT registry contains data of psoriasis patients ≥ 18 years receiving a systemic therapy. All patients from the participating centers (University Hospitals of Basel, Lausanne, Bern, Zürich, and Geneva as well as the Cantonal Hospitals of St. Gallen and Aarau) suffering from psoriasis vulgaris (with or without psoriatic arthritis) and requiring systemic therapy are offered participation in the SDNTT, regardless of comorbidities or co-medications. Hence, the patients of the registry largely correspond to those in routine care and reflect real-life data. The observation period is five years. Prerequisites for inclusion are the ability to complete a questionnaire in German or French. Inclusion occurs at the time of initiation of therapy with a conventional systemic therapeutic agent or biologic that the patient has not previously been treated with.

Before the start of the study, ethical approval for all participating centers was obtained. The psoriasis treatment was performed according to the European consensus paper on therapy targets in psoriasis [4] and the S3 guidelines for the treatment of psoriasis [5]. The registry inclusion formalities were performed by the treating dermatologists in hospital-based practices. The standardized physician and patient questionnaires were to be completed a total of twelve times in the physician's office within the five-years observation period (every 3 months for the first 6 months and every 6 months thereafter).

This analysis focused on the baseline data and the first year of follow-up (until visit 4) of all patients included over a period of 39 months from October 21, 2011 to December 31, 2014. As patients start in the registry at different time points, not all of them reached a one-year follow-up at the time of analysis. Nevertheless, data on all visits available were included. All therapies flagged for inclusion in the registry were prescribed at least in one patient included in the registry: methotrexate, fumaric acid esters, cyclosporine A, acitretin, systemic PUVA, adalimumab, etanercept, infliximab, and ustekinumab (Fig. 2).

Data were recorded in the SDNTT using standardized forms (case report forms (CRF)). The documentation was recorded either as paper CRF, (the filled-in forms were faxed to the study center) or a web-based online case report form. The data acquisition was done according to the harmonized PsoNet study protocol, the international standards of epidemiological studies ("best epidemiological practice"), requests of pharmacovigilance, and the German AWMF guidelines concerning the collection of life-quality data in dermatology [5]. CVderm data management independently monitored and approved the data of all patient visits until December 31, 2014. For the purpose of this analysis, visits 1-4, corresponding to the first year of treatment for each patient, were analyzed.

Patient and physician questionnaires as well as subgroup analyses were performed on a periodic basis to generate safety reports for the pharmaceutical companies and the responsible agencies. Patients were assigned to treatment groups according to their newly initiated therapy at inclusion in the registry. Biologics combined with any conventional systemic drug were referred to as biologic treatment. Patient parameters recorded to detect differences in treatment groups were PASI (Psoriasis Area and Severity Index, range 0=no psoriasis, ≥ 10 =moderate-to-severe, 72=highest severity), affected body surface area (BSA, percentage, $\geq 10\%$ =moderate-to-severe) and disease-specific quality of life (DLQI: range 0 = no, >10 = severe, 30 = highest impairment) at baseline and upon regular follow-up visits, as well as extra cutaneous involvement such as psoriatic arthritis or nail involvement.

To evaluate drug effectiveness, the change in PASI score was analyzed within the first year of treatment, and two patient groups were created, namely, a biologics group and a conventional systemic therapy group. Only visits with data from patients on treatment with the same drug as that started upon inclusion in the registry were considered. PASI75 and PASI90 rates were calculated for all selected patients, where PASI75 means a reduction in PASI of at least 75% in relation to baseline value.

For statistics, descriptive analyses were performed using standard parameters (absolute and relative frequencies, means, SD). For comparison of two groups a 2-sided t test (unpaired) or Chi-squared-test was used. Treatment duration and differences regarding treatment were analyzed using the Kaplan-Meier method. This allowed analysis of all treatment courses regardless of the time of initiation. Patients with an observation period of <1 year were handled as right-censored for analysis.