

How Dermatologists Can Evaluate Systemic Psoriasis Treatments

MARCUS SCHMITT-EGENOLF ON BEHALF OF ALL CONTRIBUTING DERMATOLOGISTS AND THE PsoREG STEERING BOARD

Department of Public Health and Clinical Medicine, Dermatology and Venereology, Umeå University, SE-901 85 Umeå, Sweden. E-mail: marcus.schmitt-egenolf@dermven.umu.se. URL: www.derma.org



Dr Marcus Schmitt-Egenolf from the Department of Public Health and Clinical Medicine at Umeå University, held a lecture on Systemic Follow-up of Conventional and Biologic Psoriasis Treatment: The Swedish Registry PsoReg at the Nordic Congress of Dermato-Venereology in Reykjavik. This article summarizes the status quo of PsoReg.

The selection of the best and safest medicine for individual patients from the numerous options available in today's pharmacopeia requires substantial knowledge. A profession-based registry is a tool to improve this knowledge by systematic analyses of the experiences of all participating physicians. Because registries are generally designed and managed by healthcare professionals, the entire process of creating, analysing and finally applying the collective knowledge to the individual patient is carried out within the profession and by design sheltered from commercial influences (1) (Fig. 1).

The advanced epidemiological infrastructure and competence in Sweden provides the possibility of establishing quality-registries for optimizing treatment and enhancing patient safety. The success of the Swedish quality-registries may be explained by the fact that they are in a positive spiral, in which the oldest registries, which were established in the 1970s and centre on arthroplasties, have provided a solid basis for the development of subsequent registries.

PsoReg provides a systematic but real-life picture of the diseased population

We established PsoReg as the first national quality-registry in Swedish dermato-venereology and, after Italy, as the second nationwide psoriasis treatment registry in the world (2). PsoReg is dedicated to enhancing patient safety by long-term evaluation of effectiveness and safety profiles of non-biological versus biological psoriasis treatments (3). The broad collective experience of PsoReg with the large number of wide-spectrum patients might even allow the identification of both target phenotypes for different treatments and safety concerns in patient subpopulations. Visualize how much better a drug could perform if we could calculate *a priori* which patients are likely to respond optimally, and which patients have an elevated risk of adverse drug reactions (ADRs). Furthermore, we can analyse the impact on the quality of life and cost-effectiveness across different treatments. Even reliable cost-utility calculations can be performed. In the future those data

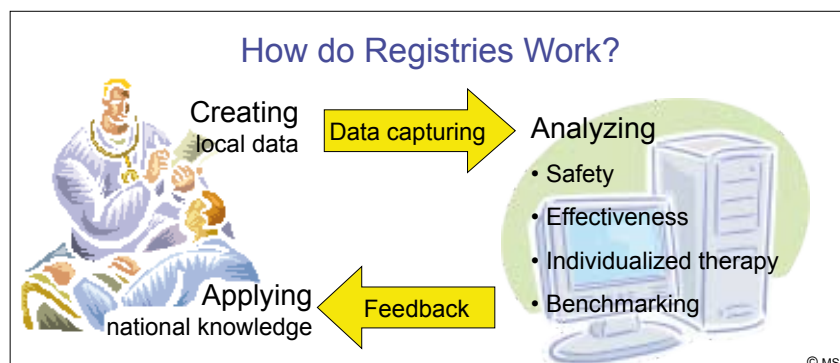


Fig. 1. In profession-based treatment registries, the entire process of creating, analysing, and finally applying the collective knowledge is, by design, sheltered from commercial influence.

may help to ensure that sufficient resources are allocated to psoriasis treatment, allowing psoriasis patients to have access to the best therapies available.

Randomized clinical trials (RCTs) are today the dominant method in treatment evaluation, and meta-analyses of RCTs are the backbone of evidence-based medicine. Despite the recognized power of this approach, it has the major structural drawback that such studies are typically not conducted in conditions representative of real life (4), and one may be not be able to generalize from RCTs to clinical practice. In contrast to RCTs, registries for collecting observational data can provide a systematic but real-life picture of the diseased population in actual practice (5). However, we must bear in mind the potential for bias and confounding in interpreting associations identified using data from observational studies. In this way the two approaches, RCTs and registries, complement each other.

Design

PsoReg has a web-based design to ensure easy accessibility and to assist clinicians in their day-to-day patient management by providing useful tools. PsoReg enables participating physicians to evaluate their treatment results continuously, in dialogue with the patient, emphasizing the role of the patient as a partner in the disease management process. In addition, the patient is actively involved in data generation, as the development of the disease burden as experienced by the patient according to a visual analogue scale (VAS) is plotted alongside

the Psoriasis Activity and Severity Index (PASI) to illustrate the different treatments employed over time (Fig. 2).

PsoReg not only employs features to monitor and improve effectiveness, but also includes a module for the spontaneous reporting of ADRs. With the push of a button an ADR report can be directly sent to the Medical Product Agency, Sweden’s national drug regulatory authority. This usability incentive helps to integrate PsoReg into everyday care. Furthermore, this tool facilitates the rapid identification of ADRs. We can even calculate the incidence rate of ADRs, because we know the number of affected individuals (the numerator) as well as the person-time at risk (the denominator). Moreover, we can use this information to evaluate whether ADRs are associated with particular patient characteristics. If we are able to identify populations at particular risk and avoid prescribing certain drugs to them, we can improve the benefit-risk profile of marketed products.

PsoReg will allow us to evaluate the effectiveness and safety profiles of non-biological versus biological psoriasis treatments

Less than 2 years after its inception, PsoReg is used in almost all Swedish hospital-based dermatology departments and in several private practices. In February 2009 PsoReg included 1176 patients. The therapy these patients received at entry to the register is shown in Fig. 3. Thanks to the combined effort of Swedish dermatologists we will soon have accumulated a sufficient amount of observational data to perform the proposed analyses.

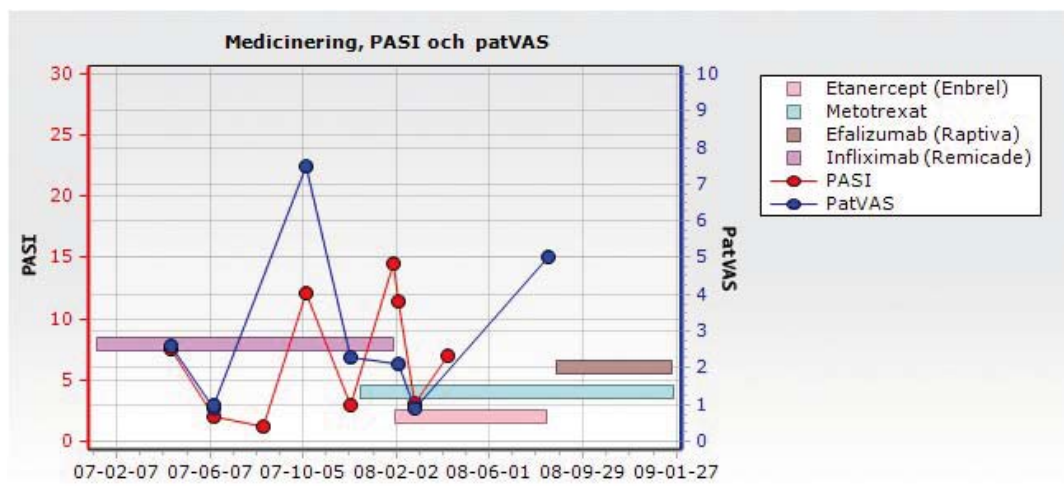


Fig. 2. Development of two disease parameters over time, one objective, the Psoriasis Area and Severity Index (PASI) and one subjective, the patient’s experienced disease burden (PatVAS), along the different therapies employed (hypothetical data).

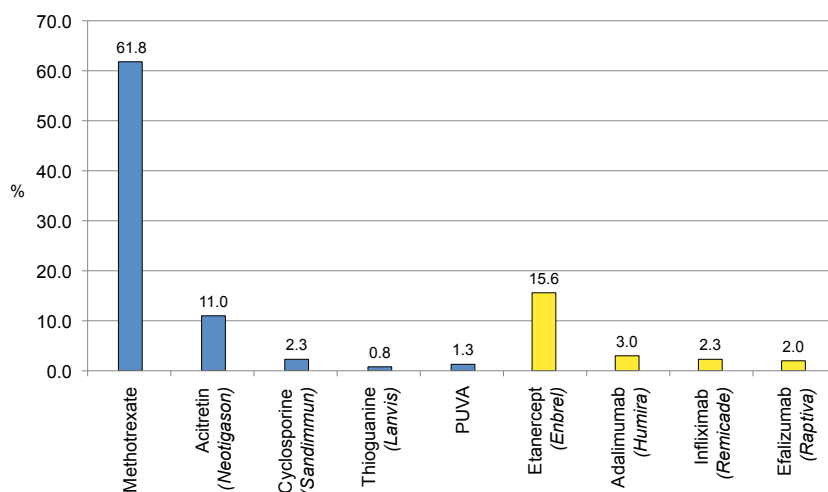


Fig. 3. Distribution of the different therapies at entry into the register of 1176 patients. 907 (77%) patients received non-biological drugs (blue columns) while 269 (33%) received biologicals (yellow columns).

Acknowledgements

The author wishes to thank all those who helped to create and use PsoReg. To mention a few: my Swedish colleagues from the PsoReg steering board – *Ing-Marie Bergbrant* and *Ingela Flytström*, Göteborg; *Ove Bäck*, Lund; *Kari Dunér*, Karlskrona; *Berndt Stenberg*, Umeå; *Mona Ståhle*, Stockholm; *Birgitta Wilson Claréus*, Farsta Läkarhus. *Magnus Bruze*, President of the SSDV and *Ronny Lestander*, the County of Västerbotten. Thanks are also extended to *Gunilla Sjölin-Forsberg* from the Swedish Medical Products Agency and *Ulf Persson* from the Swedish Institute for Health Economics.

PsoReg received grants from public authorities: the Swedish Board of Health and Welfare and the Swedish Association of Local Authorities and Regions. Without the financial support of our industry sponsors in Sweden: Abbott, Janssen-Cilag,

Leo Pharma, Schering-Plough, and Wyeth, we would not have been able to establish PsoReg.

References

1. DeAngelis CD, Fontanarosa PB. Impugning the integrity of medical science: the adverse effects of industry influence. *JAMA* 2008; 299: 1833–1835.
2. Lecluse LL, Naldi L, Stern RS, Spuls PI. National Registries of Systemic Treatment for Psoriasis and the European “Psonet” Initiative. *Dermatology* 2008; Dec [E-pub ahead of print].
3. Schmitt-Egenolf M. PsoReg – the Swedish Registry for Systemic Psoriasis Treatment. *Dermatology* 2007; 214: 112–117.
4. Sokka T, Pincus T. Most patients receiving routine care for rheumatoid arthritis in 2001 did not meet inclusion criteria for most recent clinical trials or American College of Rheumatology criteria for remission. *J Rheumatol* 2003; 30: 1138–1146.
5. Schmitt-Egenolf M. Psoriasis therapy in real life: the need for registries. *Dermatology* 2006; 213: 327–330.