Original Paper

Dermatology

Dermatology 2016;232:640–647
DOI: 10.1159/000452740

Received: March 7, 2016
Accepted after revision: October 3, 2016
Published online: January 12, 2017

Efficacy and Survival of Systemic Psoriasis Treatments: An Analysis of the Swiss Registry SDNTT

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Keywords
Psoriasis · Swiss psoriasis registry · Conventional systemic treatment · Biologics

Abstract
Background: The Swiss psoriasis registry SDNTT (Swiss Dermatology Network for Targeted Therapies) records the long-term safety and effectiveness of systemic treatment regimens for psoriasis. ***Patients and Methods:*** Patients with moderate to severe psoriasis are included in the SDNTT when treatment with a conventional systemic agent or biologic is initiated that was not previously used by the respective patient. Patients are followed over a 5-year period. Clinical data are obtained every 3–6 months using standardized case report forms. Here, baseline data and follow-up data for 1 year of patients included from October 2011 until December 2014 were analyzed. ***Results:*** Within 39 months, 323 patients from 7 tertiary dermatology centers in Switzerland were recruited in the SDNTT; 165 patients received biologics and 158 conventional systemic therapies. Patients treated with biologics had a significantly higher severity (PASI 11.3 vs. 9.2, BSA 15.6 vs.11.9, psoriatic arthritis 36.4 vs. 10.8%; $p \leq 0.005$, $p \leq 0.013$, $p \leq 0.001$) and a longer duration of illness (19.2 vs. 14.4 years, $p \leq 0.003$) compared to patients starting a conventional systemic treatment. PASI reduction was satisfying in both treatment groups, with 60.6% of patients treated with biologics achieving PASI75 after 1 year compared to 54.2% of patients receiving conventional systemic

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drugs (nonsignificant). On average, the drug survival in patients receiving a biologic therapy was significantly longer than those receiving conventional systemic treatments (30.5 vs. 19.2 months, $p \leq 0.001$). ***Conclusions:*** In the real-world setting of a prospective national therapy registry, the application of current therapeutic guidelines for patients with moderate to severe psoriasis resulted in a PASI reduction of approximately 70% within the first year of treatment, but current therapeutic targets of PASI75 and PASI90 were reached in only 58 and 36% of patients, respectively, at 1 year, highlighting a gap in efficacy between selective clinical trials and the real-world setting.

Introduction

Patient registries are systematic, prospective, protocol-driven collections of patient data. They generate knowledge on the safety and efficacy of drugs under routine conditions and on their mechanisms of action [1]. In contrast to randomized clinical trials, registries usually have less stringent inclusion criteria. Furthermore, they allow long-term study of disease and therapy [1, 2]. In addition to the analysis of effectiveness under day-to-day conditions, another asset of patient registries is the recording of drug safety data (pharmacovigilance) even in patient groups that are generally excluded from randomized controlled trials because of comorbidities, co-medications or other criteria [3].

The Swiss Dermatology Network for Targeted Therapies (SDNTT) of the Swiss Society of Dermatology and Venereology (SGDV) was established in 2010 to study the efficacy and safety of approved systemic therapies available for psoriasis in Switzerland.

The SDNTT is a noninterventional observational registry which is based on an electronic case report form provided by the Centre of Excellence for Health Services Research in Dermatology (CVderm, Competenzzentrum Versorgungsforschung in der Dermatologie) at the University Medical Center Hamburg-Eppendorf, Germany.

Documentation is managed using a patient-based database as a registry. Since October 2011, adult patients with moderate to severe psoriasis newly treated with a systemic therapy not previously used by the respective patient were included prospectively into the registry upon provision of informed consent. The patients were included in the registry for a period of 5 years regardless of subsequent treatment changes. The SDNTT aims to collect data of at least 500 patients during an observation period of 5 years.

The participating centers are the University Hospitals of Basel, Lausanne, Bern, Zurich, and Geneva as well as the Cantonal Hospitals of St. Gallen and Aarau.

Aims

The purpose of this prospective analysis, focusing on a period of 1 full year of systemic therapy, was to characterize changes in disease severity in patients with psoriasis and/or psoriatic arthritis subsequent to beginning a new systemic therapy with a biologic (including adalimumab, etanercept, infliximab, or ustekinumab) or a conventional systemic therapy (including methotrexate, fumaric acid esters, cyclosporine, acitretin, or systemic PUVA). Furthermore, the duration of treatment with the same systemic drug (drug survival) was analyzed.

Patients and Methods

For further details, see the supplementary materials (for all online suppl. material, see www.karger.com/doi/10.1159/000452740) [4, 5] (Fig. 1, 2).

Results

A total of 323 patients were included in the SDNTT registry between October 2011 and December 2014. Table 1 shows the distribution of different treatments at inclusion and the number of visits within the first year of observation. Overall, 165 patients on biologics and 158 patients on conventional systemic treatment were included into the SDNTT. Adalimumab was the most frequently used biologic, and among the conventional systemic drugs, methotrexate was most often prescribed. More than half of the patients had received phototherapy before being included in the registry (70.3% in the biologic arm, 56.3% in the conventional systemic treatment arm). As to the sequence of systemic treatments, we observed that 39.2% of patients starting a conventional systemic treatment had switched from another prior conventional treatment, whereas only 8.9% switched from a prior biologic to a conventional systemic treatment, and nearly half of the patients switched from a prior biologic at inclusion (47.9%) to another biologic drug.

Patients treated with biologics had a significantly higher disease activity at inclusion than patients treated with conventional systemic agents: PASI (Psoriasis Area and

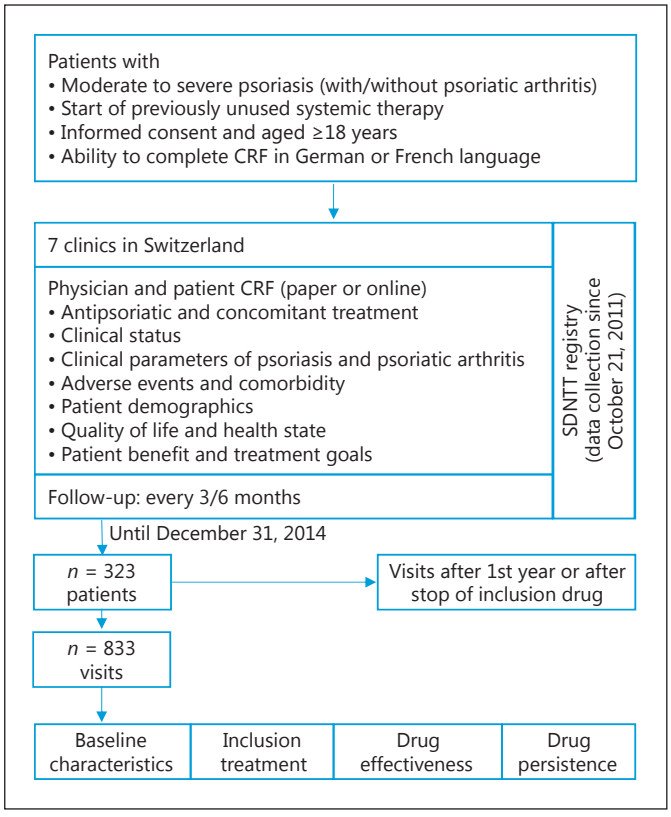

Fig. 1. Flowchart of Patients and Methods. CRF, case report form.

Table 1. Visits by inclusion therapy: biologics and conventional systemics

	Visit 1 0 mo	Visit 2 3 mo	Visit 3 6 mo	Visit 4 12 mo
Biologics				
Adalimumab	69	53	48	27
Etanercept	33	25	18	11
Infliximab	6	4	4	4
Ustekinumab	56	41	40	24
Golimumab	1	0	0	0
Total	*165*	*123*	*110*	*66*
Conventional systemics				
Cyclosporine A	6	3	2	0
Fumaric acid esters	27	14	12	7
Methotrexate	119	81	56	29
Retinoid	6	3	3	1
Total	*158*	*101*	*73*	*37*
Total	*323*	*224*	*183*	*103*

Numbers of patients are shown. mo, months.

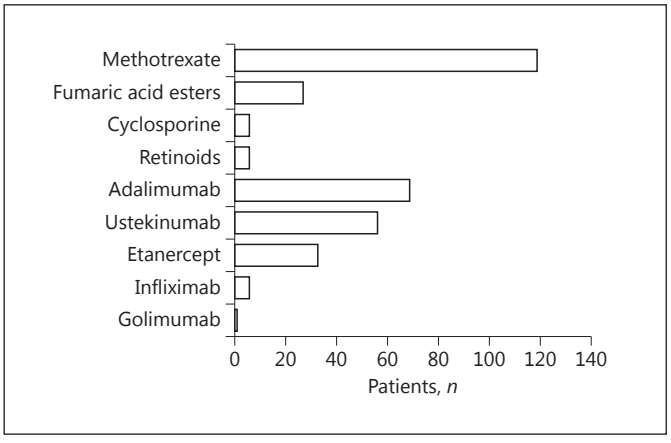

Fig. 2. Number of patients with conventional systemic and biologic treatment at inclusion in SDNTT.

Severity Index) 11.3 vs. 9.2, $p \leq 0.005$; BSA (body surface area) 15.6 vs. 11.9, $p \leq 0.013$. A subanalysis within the treatment groups revealed that the mean PASI in biologic treatment starters ranged from 10.2 for ustekinumab ($n = 55$, SD 5.9) to 12.3 for etanercept ($n = 33$, SD 7.5). For patients starting a conventional systemic treatment upon inclusion the average PASI ranged from 7.8 in fumaric acid esters ($n = 27$, SD 5.4) to 9.0 in methotrexate ($n = 119$, SD 5.8). Within the very small subgroups (each $n = 6$) of infliximab, cyclosporine A, and retinoid, patients had a relatively high PASI with an average of 13.0 ($n = 18$, SD 8.3) at inclusion.

Both groups had comparable rates of nail involvement: biologic therapy 62.4%, conventional systemic therapy 58.2% (nonsignificant) and impairment of quality of life: biologic therapy 11.8 (SD 7.8), conventional systemic therapy 10.7 (SD 6.6, nonsignificant). Patients starting a biologic treatment had suffered from psoriasis for a significantly longer period of time compared to patients who received a conventional systemic treatment (biologic therapy 19.2 years, conventional systemic therapy 14.4 years, $p \leq 0.003$). Patients in the biologic treatment group were significantly more frequently affected with psoriasis arthritis (biologic therapy 36.4%, conventional systemic therapy 10.8%, $p \leq 0.001$) (Table 2).

Effect of Systemic Therapy on Disease Activity

Table 3 and Figure 3 show the evolution of mean PASI scores during the first treatment year for all treatment subgroups that contained at least 10 patients. After 3

Table 2. Sociodemographic and clinical parameters by inclusion treatment group

	Biologic treatment					Conventional systemic treatment				
	n	mean	min	max	SD	*n*	mean	min	max	SD
Female, %	165	32.7				158	31.6			
Nail involvement, %	165	62.4				158	58.2			
Psoriatic arthritis, %***	165	36.4				158	10.8			
Duration of illness, years**	145	19.2	0.0	63.0	13.9	146	14.4	0.0	59.0	13.0
Age, years	165	47.1	20.0	79.0	14.2	158	47.1	18.0	82.0	16.0
Weight, kg	164	48.0	165.0	84.1	22.3	158	43.0	148.0	81.9	19.8
PASI**	164	11.3	0.0	50.4	7.5	158	9.2	0.0	32.4	6.1
BSA*	164	15.6	0.0	98.0	14.4	158	11.9	0.0	60.0	12.0
DLQI	149	11.8	0.0	30.0	7.8	151	10.7	0.0	27.0	6.6

Significant differences: * $p \leq 0.05$, ** $p \leq 0.01$, *** $p \leq 0.001$.

Table 3. Mean PASI within the first treatment year

	Visit 1 (0 mo)		Visit 2 (3 mo)		Visit 3 (6 mo)		Visit 4 (12 mo)	
	PASI	*n*	PASI	*n*	PASI	*n*	PASI	*n*
Adalimumab	11.4	69	3.6	53	2.5	48	2.8	27
Etanercept	12.3	33	6.2	25	4.9	18	3.8	11
Ustekinumab	10.2	55	2.9	40	3.1	40	2.8	24
Pooled biologics	*11.3*	*164*	*4.0*	*122*	*3.3*	*110*	*3.3*	*66*
Fumaric acid esters	7.8	27	4.9	14	3.8	12	2.4	7
Methotrexate	9.0	119	3.3	80	2.2	55	2.2	28
Pooled conventional systemics	*9.2*	*158*	*3.5*	*100*	*2.6*	*72*	*2.2*	*36*

Only treatment subgroups with at least 10 patients at inclusion visit are shown. mo, months.

months of continuous biologic treatment 43.1% of patients had experienced an improvement in PASI of at least 75% compared to baseline value, and nearly every fifth patient reached PASI90 (18.7%). These response rates further increased to 60.6% for PASI75 and 33.3% for PASI90 after 1 year of continuous treatment. At this point, the mean PASI reduction was 70.8%. The mean absolute PASI score for patients on biologic treatment was 4.0 after 3 months and 3.3 after 12 months.

After 3 months of conventional systemic treatment 35.6% of patients had achieved a PASI reduction of at least 75%, further improving to 54.1% at 12 months. The percentages of patients achieving PASI90 were 13.9% at 3 months and 40.5% at 12 months. The mean PASI reduction was 76.1%. Patients on conventional systemic treatment had a mean absolute PASI score of 3.5 after 3 months and 2.2 after 12 months.

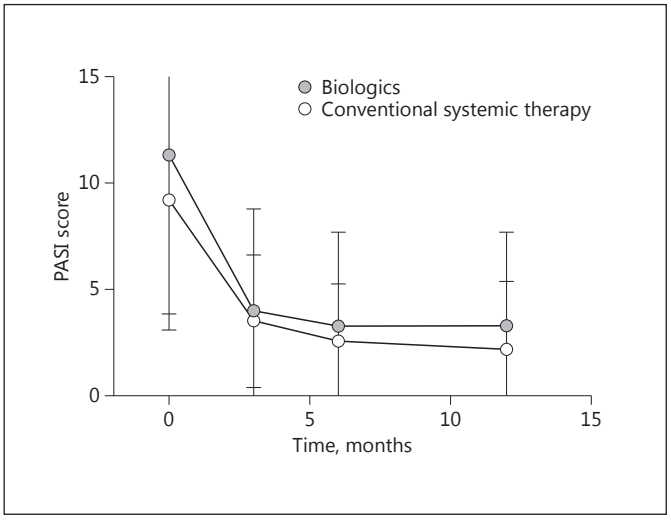

Fig. 3. PASI reduction within the first treatment year.

Table 4. PASI75 and PASI90 within the first treatment year; no significant differences were seen

	PASI75			PASI90		
	visit 2 (3 mo)	visit 3 (6 mo)	visit 4 (12 mo)	visit 2 (3 mo)	visit 3 (6 mo)	visit 4 (12 mo)
Adalimumab	53 (41.5%)	48 (60.4%)	27 (66.7%)	53 (18.9%)	48 (39.6%)	27 (44.4%)
Etanercept	25 (24.0%)	18 (33.3%)	11 (27.3%)	25 (4.0%)	18 (16.7%)	11 (18.2%)
Ustekinumab	41 (53.7%)	40 (70.0%)	24 (75.0%)	41 (26.8%)	40 (37.5%)	24 (33.3%)
Biologics	*123 (43.1%)*	*110 (58.2%)*	*66 (60.6%)*	*123 (18.7%)*	*110 (34.5%)*	*66 (33.3%)*
Fumaric acid esters	14 (14.3%)	12 (25.0%)	7 (28.6%)	14 (7.1%)	12 (0.0%)	7 (14.3%)
Methotrexate	81 (37.0%)	56 (53.6%)	29 (58.6%)	81 (13.6%)	56 (28.6%)	29 (44.8%)
Conventional systemics	*101 (35.6%)*	*73 (47.9%)*	*37 (54.1%)*	*101 (13.9%)*	*73 (23.3%)*	*37 (40.5%)*

Only treatment subgroups with at least 10 patients at inclusion visit are shown. mo, months.

Table 5. Mean treatment duration in months

	n	Mean	Min	Max	SD
Adalimumab	69	11.5	0.0	36.8	9.7
Etanercept	33	9.5	0.0	29.1	8.3
Ustekinumab	56	10.2	0.0	32.9	8.4
Biologics	*165*	*10.7*	*0.0*	*36.8*	*8.8*
Fumaric acid esters	27	9.3	0.0	31.4	9.3
Methotrexate	119	7.7	0.0	36.0	7.2
Conventional systemics	*158*	*7.9*	*0.0*	*36.0*	*7.5*

Duration due to termination of treatment or observation. Only treatment subgroups with at least 10 patients at inclusion visit are shown.

A comparison of response rates between patients treated with biologics and patients treated with conventional systemic therapy did not reveal significant differences in PASI75 or PASI90 at 3 and 12 months. The PASI75, for example, was 43.1% for patients treated with biologics versus 35.6% for patients receiving conventional systemic therapy at 3 months (nonsignificant), and 60.6 versus 54.1%, respectively, at 12 months (nonsignificant) (Table 4).

Treatment Survival

Since the inclusion of the first patient in October 2011, a total observation time on systemic treatment of 303.96 patient-years has been registered in the SDNTT. The mean observation time of the 323 included patients was 11.3 months (range 0–37, SD 9.4), and no significant difference was observed between the treatment groups (biologics 11.7 months, conventional systemic therapy 10.8 months, nonsignificant).

Table 5 depicts the drug survival, or the mean time period for which a patient remained on the treatment initiated at inclusion before the treatment was switched to another medication or stopped. The cause of discontinuation was available for 50 discontinuations of biologic treatment and 115 of conventional systemics. Most treatments were stopped due to lack or loss of efficacy (52.0% in the biologics group, 29.6% in the conventional treatment group). Side effects were reported in 22.0 and 32.2%, respectively. Other reasons for discontinuation were complete disease control (13.0% in the conventional systemic treatment group, 0% in the biologics group) and patient's wish (6.1% in the conventional systemic treatment group, 14.0% in the biologics group). There were 2 discontinuations of undisclosed motivation in the biologics group and 4 in the conventional systemic treatment group.

Analysis of treatment survival revealed that patients remained on the initial treatment longer if it was a biologic. Patients starting on biologics had a mean treatment duration with the same biologic of 30.5 months (95% CI 27.8–33.2), which was significantly longer than that observed for patients treated with conventional systemic therapy (19.2 months, 95% CI 16.0–22.5, $p \leq 0.001$) (Table 5; Fig. 4).

Adverse events between biologic and conventional systemic treatment occurred at equal rates except for gastrointestinal disorders (4.6 patients/100 patient-years in biologics vs. 16.8 patients/100 patient-years in conventional systemic treatment; 95% CI 11.9–23.0 vs. 2.4–8.0, $p \leq 0.05$).

After 18 months, 50% of the patients in the systemic treatment group had stopped their therapy due to situations representing a contraindication (i.e., methotrexate stop due to planned pregnancy), adverse reactions, or

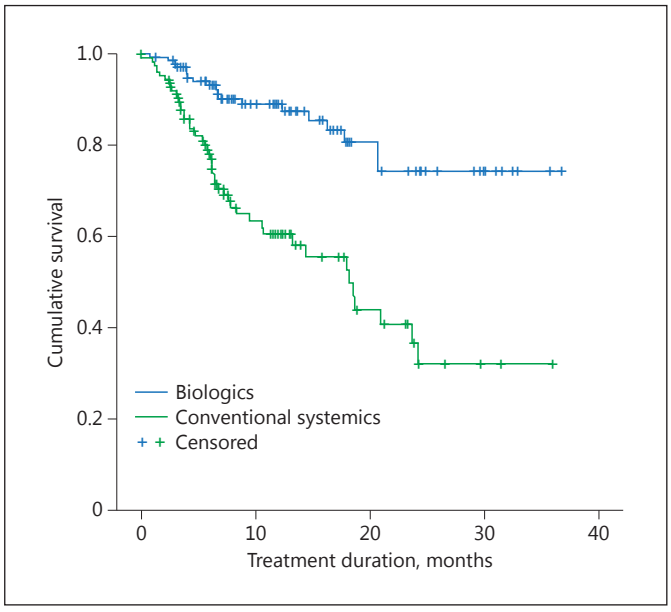

Fig. 4. Drug survival: treatment duration of biologic and conventional systemic treatment; censoring due to observation period.

treatment success. In the biologic treatment group, the survival function decreased to 75% after approximately 40 months (Fig. 4).

Discussion

One of the aims of the SDNTT is to increase our insight into drug safety and efficacy in a real-life setting in order to optimize the management of patients suffering from psoriasis and psoriatic arthritis. During the period analyzed by our study, more than 2/3 of the included patients in the SDNTT registry suffered from moderate to severe psoriasis: DLQI (Dermatology Life Quality Index) >10 or BSA >10 or PASI >10.

The average PASI improvement reached 70.8% in the biologic treatment group and 76.1% in the conventional treatment group after 1 year of treatment (nonsignificant). No significant differences in PASI improvement was observed after 3 months or after 1 year of follow-up in patients receiving conventional systemic treatment (PASI75 54.1%) compared to treatment with a biologic (PASI75 60.6%). Our data suggests, however, that in the specific patient population studied, patients treated with biologics when analyzed as a pooled group had a trend to more rapid improvement in their PASI score than the group of patients treated with conventional systemic treatments (biologics PASI75 43.1, 58.2, and 60.6% vs. conventional systemic treatments 35.6, 47.9, and 54.1% after 3, 6, and 12 months, respectively, nonsignificant).

The rates of response to biologics in the SDNTT differed somewhat from those of published randomized controlled trials. In our registry, 66.7% of patients treated with adalimumab reached a PASI75 response after 1 year. In a trial on adalimumab 40 mg every 2 weeks, 53% of the patients treated with the regular doses of adalimumab showed a PASI75 response after 52 weeks of treatment [6]. In the CHAMPION randomized controlled trial, adalimumab was compared to methotrexate and placebo in psoriasis patients. After 16 weeks, 79.6% of adalimumab-treated patients achieved PASI75 compared to 35.5% of methotrexate-treated patients ($p < 0.001$ methotrexate vs. adalimumab) and 18.9% of patients receiving placebo ($p < 0.001$ placebo vs. adalimumab) [7]. In the real-world setting of our registry, only 41.5% of adalimumab and 37% of methotrexate patients reached the PASI75 at 12 weeks. However, the results cannot be directly compared, as the data from our registry were taken at week 12 (compared to week 16), the numbers of patients within the different treatment groups in our registry were uneven, and the groups were nonhomogeneous. It should be noted that the mean baseline PASI was relatively low compared to those reported in clinical trials, and comparable PASI reduction rates were therefore harder to achieve. Nevertheless, satisfying absolute PASI scores were achieved in the real-world setting of this prospective national therapy registry (3.3 at week 52 in biologics and 2.2 in conventional systemic treatment).

A randomized phase III trial with 618 patients on etanercept 50 mg twice weekly showed that 47% of patients achieved PASI75 at week 12 [8]. In our registry, only 23% of etanercept-treated patients achieved PASI75 at 3 months.

A multicenter, phase III, double-blind, placebo-controlled study (PHOENIX 2) with moderate to severe plaque psoriasis patients found that more patients treated with ustekinumab (45 or 90 mg) achieved PASI75 at week 12 than those treated with placebo (67 and 76%, respectively, vs. 4%) [9]. In our real-life setting, we observed that ustekinumab showed a lower response rate of 53.7% achieving PASI75 at week 12.

It has been observed that, in general, biologic therapies can lose effectiveness over time [10]. The drug survival of biologics in our Swiss registry was similar to other national registries. The British registry [11] demonstrated that ustekinumab had the highest drug survival in biologic-naive patients, followed by adalimumab. A multicenter

Dutch study of 213 patients found a 1-year survival rate of 85% for ustekinumab, 74% for adalimumab, and 68% for etanercept, concluding that ustekinumab had a significantly higher drug survival than etanercept [12]. In the SDNTT, significant differences in drug survival were only detectable between biologics and conventional systemic therapy, because both the duration of follow-up and the number of patients on different drugs were still too small for a subgroup analysis of each drug. There are few studies on factors associated with drug survival of conventional systemic treatment. It has been shown that comorbidities are a predictor for discontinuation of treatment and that lack of folic acid supplementation in patients treated with methotrexate is associated with treatment dropout [13].

Reported gastrointestinal symptoms and/or side effects were significantly more frequent in the conventional systemic treatment group (16.8 patients/100 patient-years in conventional systemic treatment vs. 4.6 patients/100 patient-years in biologic treatment, $p \leq 0.05$). Correspondingly, gastrointestinal adverse events are known to lead to a discontinuation of treatment, especially in patients treated with fumaric acid esters [14], and nausea is frequent in methotrexate treatment as well.

As a whole, adverse events were evenly distributed in both treatment groups. Comparable to this study, a meta-analysis of 25 randomized clinical trials evaluating the efficacy and safety of systemic long-term treatments in patients with moderate to severe psoriasis showed no relevant differences in safety concerning rates of adverse events and serious adverse events between conventional and biologic systemic therapy [15]. A more detailed analysis of reasons for treatment termination and differences in duration of treatment is planned for the future when there are enough patients in each treatment group to do subgroup analysis for each drug. Recently, a Spanish registry inception cohort analyzed the risk of serious adverse events associated with biologic and nonbiologic psoriasis systemic therapy in randomized controlled trials and in a real-world setting. It was shown that the risks of adverse events are different between randomized clinical trials and real-world registries [16].

Strengths and Limitations

The SDNTT registry has its strength in the prospective real-world study design and the high quality of patient data that were systematically collected, independently analyzed, and monitored by multiple centers in Switzerland. A further strength is the relatively long follow-up data available for individual patients despite the young age of the registry and extensively collected data points allowing numerous covariates to be analyzed in the future.

This study has limited statistical power due to the currently relatively small number of cases with long-term follow-up in this rather young registry. Therefore, only the results of patients with adalimumab, etanercept, ustekinumab, fumaric acid esters, and methotrexate were used for direct comparisons. The limited power also precluded determining a potential difference of efficacy between conventional drugs and biologics, even though there was a trend towards higher efficacy of biologics. Another limitation is that the mean PASI at the time of inclusion and start of treatment was higher in the group of patients subsequently treated with biologics. Further analyses, including subgroup analyses of patients as well as medium-term safety analysis will be performed once the number of included patients allows sufficient statistical power.

Conclusion

The SDNTT registry was established as a noninterventional observational registry in 2010 to study the efficacy and safety of approved systemic therapies available for psoriasis in Switzerland as a first step towards nationwide long-term research of systemic psoriasis therapy integrating patient benefit, efficacy, and safety under real-life conditions.

At 1 year of follow up, our data indicate no difference in efficacy between biologics and conventional systemic therapy as yet. However, the duration of treatment in patients receiving a biologic therapy was significantly longer than those receiving conventional systemic treatment. Due to currently limited statistical power, analyses such as the reasons for discontinuation are planned for a later time point.

In the SDNTT, an overall PASI reduction of approximately 70% within the first year of treatment was seen, but the current therapeutic target of PASI75 was reached in only 61 and 54% of patients on biologics and conventional systemic drugs, respectively, after 1 year. These results demonstrate a gap in efficacy between randomized placebo-controlled clinical trials including only selected patient cohorts and the real-world setting of patients with moderate to severe psoriasis as documented by our registry.

Acknowledgments

We thank the participating dermatologists and patients who made this study possible and the entire SDNTT staff for data management and support.

The SDNTT is financially supported by AbbVie, Janssen, Pfizer, and Novartis. The study sponsors had no role in the study design or in data collection, analysis or interpretation of the data, writing of the manuscript, or the decision to submit it for publication. The publication of this article was not upon approval by supporters.

Statement of Ethics

Ethics approval for the collection of patient data was given by the Ethics Commission for Clinical Research from the Ethic Commission of Canton Aargau, Basel (leading committee: Ethics Committee Northwest/Central Switzerland – EKNZ), Bern, Geneva, St. Gallen, and Vaud. Patient consent was obtained.

Disclosure Statement

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria, employment, stock ownership or other equity interest, expert testimony, or patent-licensing arrangements) in the subject matter or materials discussed in this manuscript.

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