ORIGINAL REPORT

Real-world Drug Survival of Biosimilar SB5 vs GP2017 Following a Mandatory Non-medical Switch from Adalimumab Originator for Psoriasis: A Nationwide Cohort Study

Johan SIEBORG[1], Julia-Tatjana MAUL[2,3], Jashin J. WU[4], Nikolai Nguyen LOFT[5], Lone SKOV[5,6,7], Lars Erik BRYLD[6,8], Mads Kirchheiner RASMUSSEN[6,9], Tomas Norman DAM[6,10], Trine BERTELSEN[6,9], Kawa Khaled AJGEIY[11], Simon Francis THOMSEN[1], Jacob P. THYSSEN[1], Alexander EGEBERG[1,6,7] and David THEIN[1]

[1]Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark, [2]Department of Dermatology, University Hospital of Zürich, Zürich, Switzerland, [3]Faculty of Medicine, University of Zürich, Zürich, Switzerland, [4]Department of Dermatology, University of Miami Miller School of Medicine, Miami, USA, [5]Department of Dermatology and Allergy, Copenhagen University Hospital – Herlev and Gentofte, Copenhagen, Denmark, [6]DERMBIO registry, [7]Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark, [8]Department of Dermatology, Zealand University Hospital, Roskilde, Denmark, [9]Department of Dermatology, Aarhus University Hospital, Aarhus, Denmark, [10]Dermatology Clinic, Nykøbing Falster, Denmark, and [11]Department of Dermatology, Odense University Hospital, Odense, Denmark

Biosimilars are designed to be analogous to the biologic originators. However, comprehensive comparisons between biosimilars are limited and lacking for patients with psoriasis. This study's objective was to compare 1-year drug survival of the 2 adalimumab biosimilars, GP2017 with SB5, following a non-medical mandatory switch from the adalimumab originator. Based on the national clinical database DERMBIO, this nationwide cohort study included all patients with psoriasis treated with the adalimumab originator who underwent a non-medical mandatory switch to GP2017 or SB5. The study included 525 patients switching from adalimumab originator to 1 of 2 biosimilars: GP2017 (*n*=267 patients) or SB5 (*n*=258 patients). When comparing the drug survival of the biosimilars, the hazard ratio was 1.11 (95% confidence interval, 0.58–2.12) for SB5 with GP2017 as reference. In the sensitivity analysis investigating changes in PASI, no differences were found when comparing the GP2017 group and the SB5 group at 120 days of follow-up (1.9% vs 1.6% improved, 1.9% vs 2.0% worsened, and 43.1% vs 40.9% remained unchanged). When comparing GP2017 and SB5, no discernible differences were found in drug survival or effectiveness based on PASI. Determining drug survival and effectiveness could benefit patients and clinicians in treatment decisions.

Key words: psoriasis; biologics; biosimilar; GP2017; SB5; drug switching.

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Corr: Johan Sieborg, Master of Science, Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Denmark. E-mail: Johan.sieborg@regionh.dk

SIGNIFICANCE

Biological treatment is used to treat moderate to severe plaque psoriasis often following failure of conventional systemic treatment. Highly similar biologics, named biosimilars, have been approved by regulatory authorities. This Danish study examined the drug survival and effectiveness between 2 biosimilars, GP2017 and SB5, in 525 psoriasis patients. Our results showed no discernible difference in drug effectiveness between GP2017 and SB5. In sum, this study offers relevant insight into treatment of psoriasis patients with the biosimilars GP2017 and SB5 and may help benefit patients and clinicians in treatment decisions.

Psoriasis is a chronic inflammatory skin disease that affects around 5% of the Danish population and approximately 3% of Western Europe (1). The treatment of psoriasis follows a stepwise approach depending on the severity of the disease (2). For moderate to severe plaque psoriasis, biological treatment may be used following the failure of conventional systemic treatment or if these therapies are contraindicated (3–5).

As biological originators have lost exclusivity, highly similar biosimilars have been approved by regulatory authorities (6). To ensure that biosimilars are safe and similar, they must demonstrate no meaningful differences when compared with the originator drug (e.g., structure, biological activity, effectiveness, safety, and immunogenicity profile) (7–10). While biosimilars may be clinically similar to the originator, often within an equivalence margin of ±15%, few studies have compared biosimilars from the same originator (11, 12). As such, one biosimilar might be slightly better while another might be slightly worse, ultimately resulting in one outperforming the other. Hence it remains to be investigated whether these similarities persist when comparing biosimilars from the same originator.

To investigate the similarity of 2 biosimilars, GP2017 and SB5, we compared drug survival following a non-medical mandatory switch from the adalimumab originator to GP2017 or SB5, with a follow-up time of 1 year. The drugs were provided on a regional basis, allowing for a pseudorandomized observational study design emulating cluster randomization. This study is a continuation of our previous study of drug survival of biosimilars as a whole vs adalimumab originator (3).

METHODS

Data sources

DERMBIO is a Danish national registry that contains information on all patients diagnosed with plaque psoriasis and treated with either biologics or novel immunomodulators (e.g., apremilast) outside clinical trials. Data are available from 2007 to November 2019, and data registration is mandatory for all dermatologists who prescribe or manage biologics. The registry includes information on prescription drugs, date of prescription and discontinuation, age at prescription, number of treatment series with biologics, psoriatic arthritis status, and Psoriasis Area and Severity Index (PASI).

Setting, study population, follow-up, and outcome

In November 2018, a non-medical mandatory switch from adalimumab originator to the biosimilars GP2017 or SB5 was dictated for all adults older than 18 years of age. In Eastern Denmark (the Capital Region and Region Zealand), the transition was made to GP2017, while in Western Denmark (Region North, Middle, and South), the switch was made to SB5.

The study encompassed all patients with psoriasis who underwent the compulsory switch from the adalimumab originator to either biosimilar, GP2017 or SB5. The inclusion period spanned from 1 November 2018, to 30 April 2019. Patients were excluded if they continued treatment with the adalimumab originator or switched to a biosimilar outside the inclusion period.

To enter the originator comparator group used in the sensitivity analysis, patients must have used the adalimumab originator for at least 1.5 years prior to inclusion, so as to minimize the risk of selection bias.

The follow-up was limited to 1 year, starting from the date of the switch. The primary endpoint was drug discontinuation within the first year, irrespective of the cause of discontinuation. Patients were censored after 1 year of active treatment with the biosimilar they initially switched to.

Danish healthcare system and biologic treatment of psoriasis

The Danish healthcare system is tax-financed, and biologic treatment is managed at and provided by specialized medical centres without co-pay. Guidelines for biological therapy in psoriasis are issued by the National Council RADS (until 2017) and the Danish Medicines Council (from 2017 onwards). The mandatory non-medical switch was stipulated by the Danish Medicines Council and the national institution Amgros, and it was applied to the majority of patients, except for children or in cases of medical contraindications.

Statistics

Baseline characteristics were presented using frequencies with percentages for categorical variables and median with interquartile range (IQR) for continuous variables. In the primary analysis, the drug survival of GP2017 or SB5 was illustrated using Kaplan–Meier plots and compared using a Cox proportional hazard regression model. For the Cox proportional hazard regression model, the hazard rates were adjusted for patient age (per 10 years), sex, number of biologics, and prior drug duration (per 5 years). All variables were chosen *a priori*, and GP2017 was used as reference.

In a sensitivity analysis, the drug survival of the 2 biosimilars was compared with the adalimumab originator. Patients in the adalimumab originator group were sampled using propensity score matching (1-to-1 without replacement). Patients were matched on sex, PsA status, treatment series, and age. A Cox proportional hazard regression model was used to compare the biosimilars to the originator.

An additional sensitivity analysis compared the mean PASI during 180 days before and 120 days after switching from the originator to a biosimilar, considering the 3 outcomes of the disease as improving, worsening, or remaining unchanged. The disease improved if PASI decreased by more than or equal to 3 points, worsened if PASI increased by more than or equal to 3 points, and remained unchanged if PASI had an absolute difference of less than 3 points. The results were compared using a χ^2 test. Furthermore, the results were likewise provided at 365 days of follow-up.

All statistical analyses were completed using R statistical software version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria) and Python 3.7.4 (Python Software Foundation, https://www.python.org/).

RESULTS

From the initial study population of 568 patients, 43 were excluded. Among the remaining 525 patients who switched from the adalimumab originator, 268 switched to GP2017, and 257 switched to SB5 (**Fig. 1**). In the SB5

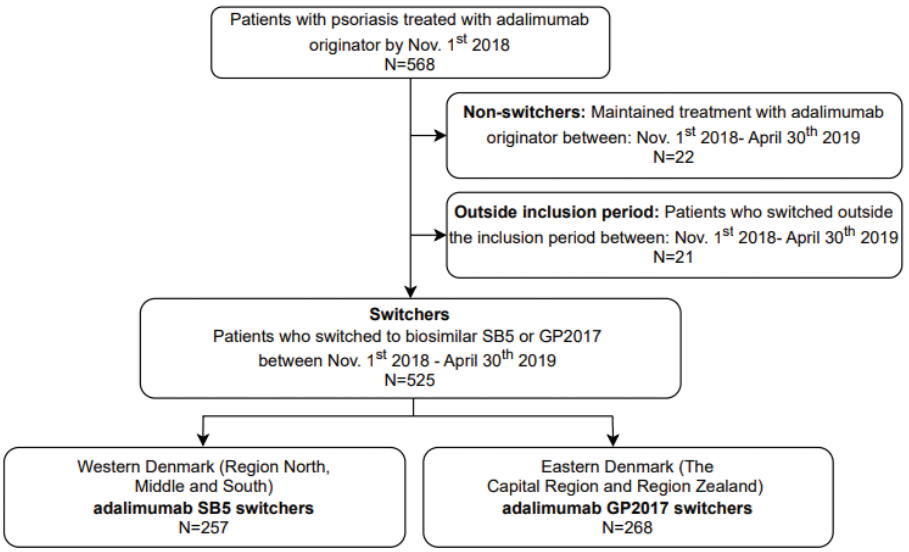

Fig. 1. Consort diagram over the study population.

Table I. Baseline characteristics for patients who switched from originator to GP2017/SB5

Factor	Adalimumab SB5	Adalimumab GP2017	*p*-value (%)
Total number of unique patients	257	268	
Women, *n* (%)	71 (27.6)	79 (29.5)	0.99
Prior treatment duration, years, median (IQR)]	7.2 (5.2, 9.8)	6.80 (4.9, 10.0)	0.71
Age at prescription, year, median (IQR)	52.0 (42.0, 62.0)	51.0 (41.0, 61.0)	0.73
Prior methotrexate, *n* (%)	229 (89.1)	208 (77.6)	0.32
Prior phototherapy (PUVA, UVB), *n* (%)	202 (78.6)	190 (70.9)	0.60
Prior acitretin, *n* (%)	57 (22.2)	43 (16.0)	0.50
Prior cyclosporine, *n* (%)	46 (17.9)	39 (14.6)	0.84
Psoriatic arthritis, *n* (%)	58 (22.6)	65 (24.3)	1.00
Biologic treatment series no. 1 (bio-naive) (%)	129 (50.2)	173 (64.6)	0.60
Biologic treatment series no. 2 (%)	87 (33.9)	58 (21.6)	0.09
Biologic treatment series ≥3 (%)	41 (16.0)	37 (13.8)	0.94

PUVA: photochemotherapy; UVB: ultraviolet light therapy; IQR: interquartile range.

group, the median age was 52.0 years (IQR: 42.0–62.0 years), the median treatment duration with the adalimumab originator before the switch was 7.2 years (IQR: 5.2–9.8 years), 27.6% were women, and 22.2% had PsA (**Table I**). For GP2017, the median age was 51.0 years (IQR: 41.0–61.0 years), the mean treatment duration with the adalimumab originator before the switch was 6.8 years (IQR: 4.9–10.0 years), 27.3% were women, and 24.3% had PsA **(**Table I**).**

Comparing GP2017 and SB5

During a total follow-up of 503 person-years, 7.1% of patients treated with biosimilar GP2017 discontinued treatment compared with 7.4% among patients treated with SB5 (hazard ratio [HR] (95% confidence interval [CI]) 1.11 [0.58–2.12]) (**Figs 2** and **3**). The most common cause of discontinuation was lack of effect, which occurred in 20 (52.6%) patients (13 [34.2%] GP2017 vs 7 [18.4%] SB5). Adverse events led to discontinuation for 12 (31.6%) patients (3 [7.9%] GP2017 vs 9 [23.7%] SB5). For 6 (15.8%) patients, the cause of discontinuation was not related to lack of effect or adverse events (3 [7.9%] GP2017 vs 3 [7.9%] SB5). A sub-analysis was performed using patients with less than 2 years of prior treatment with the adalimumab originator. Similar to the main result, the sub-analysis found no difference in drug survival between the GP2017 and SB5 (Fig. S1 and Table SI).

Adalimumab originator compared with GP2017 and SB5 using propensity matching

In a sensitivity analysis, 450 patients were sampled from the adalimumab originator group using propensity matching (52.5% from Western Denmark and 47.3% from Eastern Denmark). Patient characteristics are listed in Table SII. When comparing the originator and the biosimilars using Kaplan–Meier survival curves and a Cox proportional hazard regression model, there was no evidence against the null hypothesis, i.e., that there was no difference in drug survival (GP2017: HR 1.01 [95% CI 0.53–1.92]; SB5: HR 1.25 [95% CI 0.68–2.29]) (Fig. S2).

PASI before and after switching to a biosimilar

No significant change was detected in the mean PASI before and after the switching, and PASI remained mostly unchanged during the first 120 days (40.9% for SB5 and 43.1% for GP2017) (**Table II** and Table SIII). Following the switch, an improvement in PASI was found for 1.6% of SB5 switchers and 1.9% of GP2017 switchers, while

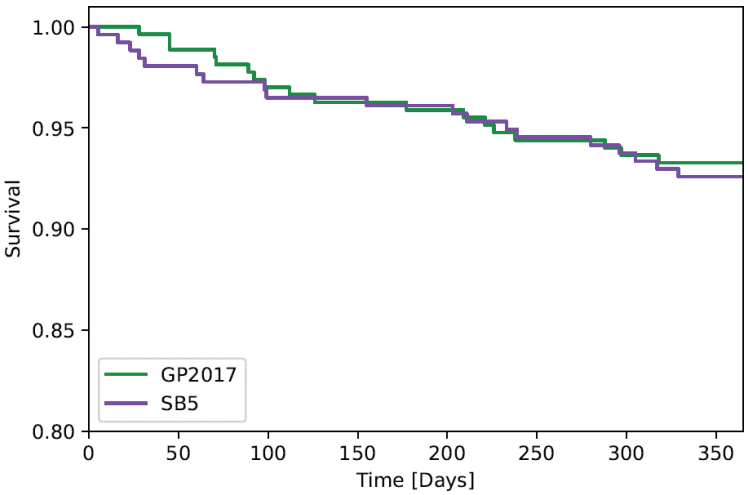

Fig. 2. Kaplan–Meier curves illustrating drug survival for the two biosimilar biologics GP2017 and SB5.

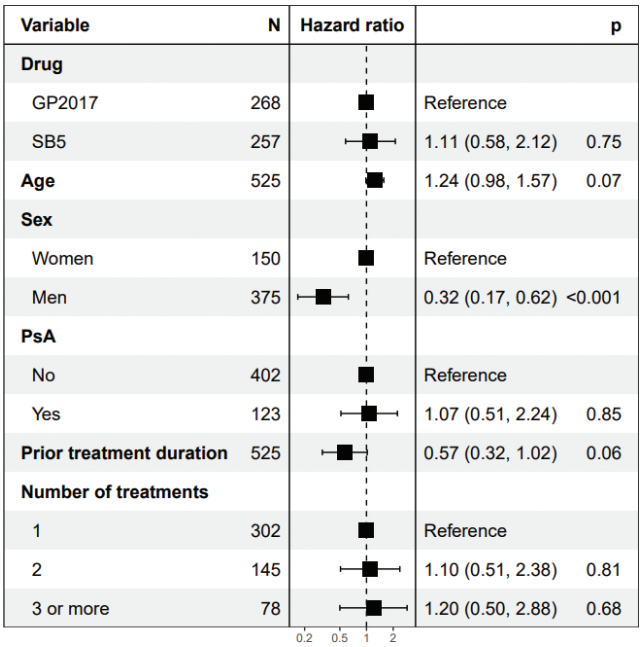

Fig. 3. Forest plot for the hazard ratios of the Cox proportional hazard regression model comparing GP2017 and SB5. PsA: psoriatic arthritis.

PASI worsened for 1.9% of GP2017 switchers and 2.0% of SB5 switchers.

DISCUSSION

This nationwide study found no significant differences in drug survival or negative impacts on PASI between GP2017 and SB5 for the 525 patients who underwent a mandatory non-medical switch from the adalimumab originator. Moreover, similar drug survivals were observed in a sensitivity analysis comparing the biosimilars with a propensity matched adalimumab originator group.

While studies have frequently compared biosimilars with the originator and demonstrated comparable results, direct comparisons between biosimilars remain limited. A prior Danish study suggested better drug survival of GP2017 in patients with inflammatory rheumatic disease (HR: 0.6 [95% CI: 0.4–0.9]) when compared with SB5 (12). However, our study did not confirm this finding for patients with psoriasis.

The present study demonstrated better drug survival when compared with previous studies on adalimumab (13–15). This can probably be contributed to the study design, as patients underwent a mandatory treatment switch rather than therapy failure. In most cases, patients were probably well controlled on the adalimumab originator prior to switching. To investigate this potential bias, a sub-analysis was performed using patients with less than 2 years of prior treatment with the adalimumab originator. Similar to the primary result, the sub-analysis found no difference in drug survival between GP2017 and SB5 (Fig. S1 and Table SI).

While numerous European nations have adopted biosimilars, other countries have exhibited hesitancy, primarily due to concerns regarding their effectiveness and safety (16). Although the results of this study indicated no differences in drug survival between biosimilars (GP2017 and SB5), drug survival may not directly measure effectiveness alone. In the sensitivity analysis, we examined the pre- and post-switching PASI. All results indicated similar effectiveness for the 2 biosimilars as well as stable PASI before and after the switch. These findings are in accordance with other studies conducted on biosimilar biologics different from the adalimumab originator (3, 17–19).

Although highly speculative, the presented results, together with previous studies, could suggest that switching between biosimilars is unlikely to negatively impact disease control. This hypothesis may find further support in the phase III clinical trial for patients with psoriasis, wherein multiple switches between the adalimumab originator and the biosimilar GP2017 demonstrated no discernible effects on efficacy, safety, or immunogenicity (17). Further research is required to investigate this hypothesis.

Strengths and limitations

Strengths of this study included the nationwide Danish databases and the use of geography as an instrumental variable fostering a pseudo-randomization that mimics the design of a randomized clinical trial. The latter allows this study to investigate how patients respond to a non-medical switch in an observational study design. Among the study's main limitations are: (*i*) potential unresolved bias, such as prior treatment experience or living conditions, which could vary between Western Denmark and Eastern Denmark; (*ii*) the use of conventional drug survival as measured by discontinuation alone, thus omitting relative treatment failures (13); (*iii*) data are not always missing completely at random, which could potentially have influenced our results; (*iv*) variability in

Table II. Assessment of Psoriasis Area and Severity Index (PASI) score before and after switching from the originator to a biosimilar, with a change of < |3| defined as unchanged

Factor	SB5 after 120 days	SB5 after 365 days	GP2017 after 120 days	GP2017 after 365 days
PASI improved, *n* (%)	4 (1.6)	5 (2.0)	5 (1.9)	8 (3.0)
PASI worsened, *n* (%)	5 (2.0)	6 (2.3)	5 (1.9)	6 (2.3)
PASI remained unchanged, *n* (%)	105 (40.9)	166 (64.6)	115 (43.1)	177 (66.3)
PASI missing, *n* (%)	143 (55.6)	80 (31.1)	142 (53.2)	76 (28.5)

PASI: Psoriasis Area and Severity Index

the time intervals between medical appointments. Such variability could lead to missing data points in the assessment of PASI. However, it is reasonable to anticipate that patients encountering a loss of disease control would proactively seek medical attention, resulting in a reassessment of their PASI and biasing the results towards lower effectiveness. Hence, this limitation is expected to have minimal impact based on the presented results.

Conclusion

Based on this nationwide study emulating cluster randomization, our study found no discernible differences in drug survival or changes in PASI when comparing GP2017 and SB5, or when comparing the biosimilars twith a matched group of patients treated with the adalimumab originator. These outcomes are consistent with previous findings and results from other studies and clinical trials.

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Data availability: Research data are not shared.

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