Psoriasis: Targets and Therapy

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ORIGINAL RESEARCH

# Effectiveness and Safety of Adalimumab Biosimilars in Pediatric Psoriasis: A Multi-Center International Experience

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**Background:** Many adalimumab biosimilars have been approved for the same indications as their originator (Humira ®). However, data on their efficacy and safety in children with psoriasis are scarce.

**Objective:** To assess the effectiveness and safety of adalimumab biosimilars in a group of adalimumab-naïve patients and another group of patients who switched from originator adalimumab to biosimilars. The co-primary endpoints were the PASI absolute mean, PASI 75, and PASI 90 at 16, 24 and 52 weeks.

**Methods:** In this 52-week, multi-center, non-interventional, observational, retrospective study, patients starting biosimilars in routine practice after January 2022 were enrolled at 10 sites across Italy, Portugal, and France. Disease activity scores such as the Psoriasis Area Severity Index (PASI) and safety data were captured during 12 months following adalimumab biosimilar initiation.

**Results:** A total of 102 pediatric patients with psoriasis receiving adalimumab biosimilar therapy either as naïve (n = 72) or switching from originator adalimumab (n = 30) were enrolled. Median absolute PASI remained low at weeks 16, 24, and 52 in both groups (naïve 5.4, 4.3, 2.8; switching 2.6; 2.0; 1.4 respectively). PASI 75 response at weeks 16, 24, and 52 was observed in 41.7, 55.0, and 77.8% of patients in the naive group and 82.8%, 86.2%, and 92.6% of patients in the switch group. PASI 90 response at weeks 16, 24, and 52 was achieved by 23.3%, 26.7%, and 46.3% of patients in the naïve group and 58.6%, 65.5%, and 55.6% of patients in the switch group. Three patients discontinued biosimilars after the switch due to loss of efficacy. No emergency room visits or hospitalizations were observed during the study period and none of the patients experienced serious adverse effects.

**Conclusion:** Adalimumab biosimilars showed a favorable effectiveness/safety profile in childhood psoriasis. Switching from reference adalimumab to biosimilars did not impact effectiveness and safety. A likelihood of discontinuation was noted in patients who switched from Humira to biosimilars.

**Keywords:** treatment, psoriasis, children, effectiveness, safety, biologics, TNF-alpha

## Key Points/Highlights

Why was the study undertaken? To evaluate the effectiveness and safety of adalimumab biosimilars in pediatric psoriasis, focusing on adalimumab-naïve patients and those who switched from the originator drug (Humira®). The study addresses the gap in data regarding biosimilar use in children with psoriasis.

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What does this study add? Demonstrates a favorable effectiveness and safety profile of adalimumab biosimilars over 52 weeks in children with psoriasis. Provides evidence that switching from originator adalimumab to biosimilars does not compromise effectiveness or safety. Highlights the durability of treatment responses, with PASI 75 and PASI 90 rates increasing over time in both groups.

What are the implications of this study for disease understanding and/or clinical care? Supports the use of adalimumab biosimilars as an effective and safe treatment for pediatric psoriasis. Reinforces the clinical viability of switching from originator adalimumab to biosimilars without compromising outcomes. Suggests a need for monitoring patients post-switch, as some may experience loss of efficacy requiring treatment adjustment.

## Introduction

Psoriasis is a T-lymphocyte-mediated, chronic inflammatory systemic disease with a relapsing-remitting course. It is linked to numerous comorbid conditions and is associated with a significant physical and psychological burden.[1] Psoriasis can develop at any age, but onset in childhood is observed in almost one-third of patients.[2] In Europe, the prevalence range reported in the pediatric age is between 0.17% and 1.5%, with a linear increase steadily with age up to eighteen years.[3,4]

The availability of biologics in children has changed the treatment paradigm for moderate to severe pediatric psoriasis.[5,6] Specific recommendations for the management and treatment of severe psoriasis in children have emphasized how all five European Medicine Agency (EMA)-approved biologics are supported by clinical trials in children and adolescents. Therefore, they are recommended as first-line therapy in children and adolescents with moderate to severe psoriasis.[6] In addition, biologics represent an attractive option given their dosing schedules, safety profiles, and need for less frequent laboratory monitoring, when compared with traditional systemic therapies.[7] Among available biological agents approved for the treatment of psoriasis in children, adalimumab is a fully human anti-tumor necrosis factor (TNF)-alpha monoclonal antibody. It is licensed to treat moderate to severe plaque psoriasis in adults and children aged 4 years and above. Patent expiration has allowed the introduction of many adalimumab biosimilars, providing opportunities for cost reduction to the reference product.

The real-life effectiveness and safety of adalimumab biosimilars in pediatric patients with plaque psoriasis have not been investigated. In addition, no studies have analyzed outcomes in pediatric patients following the transition in routine practice from reference adalimumab to EMA-approved biosimilars. Therefore, we aimed to study adalimumab biosimilars' real-life effectiveness and safety in pediatric patients with moderate to severe chronic plaque psoriasis.

## Methods

A multicenter, non-interventional, observational, retrospective study enrolled all consecutive pediatric patients with moderate to severe psoriasis receiving adalimumab biosimilars in 10 sites across Italy (n = 7), Portugal (n = 2), and France (n = 1). Patients under the age of 18 years with psoriasis who started adalimumab biosimilars in routine practice at the standard posology after January 2022 were considered eligible if they had completed at least 52 weeks of treatment. Selecting a single biosimilar product was infeasible due to the many biosimilars in the participating centers. Therefore, the different biosimilar products were considered as a single group. Patient demographics including sex, age, body mass index (BMI), diagnosis of psoriatic arthritis (PsA), age at first diagnosis of psoriasis, comorbidities, and severity of psoriasis, measured with the Psoriasis Area and Severity Index (PASI) were collected.

Patients were classified into two groups: group 1 included those naïve to adalimumab who started a biosimilar (n = 72) (naïve); group 2 those who switched from adalimumab originator to one biosimilar (n = 30) (switchers) for non-medical reasons (other than effectiveness, side effects, or adherence) and shared decision making. All patients belonging to group 2 had been in clinical remission for at least 3 months before switching (PASI score < 3). No concomitant systemic therapies were allowed.

The co-primary endpoints considered were the PASI absolute in both groups and the relative PASI response. PASI absolute was recorded at baseline, 16, 24, and 52 weeks. In addition, the proportion of patients with a decrease of ≥75% and of ≥90% in the PASI from baseline (PASI 75 and PASI 90) at the same time points were registered. The secondary

endpoint was safety data assessed by reporting any adverse events registered during the observational period of 12 months following adalimumab biosimilar initiation.

This study was performed following the Helsinki Declaration of 1964 and its later amendments. This study adhered to established clinical standards with data captured retrospectively using patient charts. Approval from the institutional review board was not required. All data access was conducted in compliance with relevant data protection and privacy laws.

## Statistical Analysis

Statistical analysis was performed using STATA® software version 17 (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC). Descriptive statistics were presented for baseline demographic clinical characteristics for the entire patient. Continuous variables were presented as mean, standard deviation (SD), minimum (min), and maximum (max) and compared between subgroups using Unpaired Student's *t*-test; analysis of variance (ANOVA) was used to evaluate the differences of the parameters under examination for variables with three or more categories. We performed a post hoc test using Tukey-Kramer's method for pairwise comparison of subgroups, while categorical variables were presented as frequency (N, percentage [%]) and compared using Pearson's chi-squared test. A p-value <0.05 was considered significant.

# Results

One-hundred-two patients with psoriasis treated with adalimumab biosimilars and clinical follow-up available were included in the analysis. Patients were stratified into two groups: group 1 included subjects naive to the originator who started one of the EMA-approved adalimumab biosimilar (n = 72) (naïve); group 2 included patients who switched from the adalimumab originator to one of its biosimilar (n = 30) (switchers). Table 1 shows the baseline characteristics of the patients at the time of starting adalimumab biosimilars or switching from reference adalimumab. Median age was 12.4 ± 3.2 years, without significant differences between the two groups (p = 0.204). Forty-five patients (44.1%) were male, 57

**Table 1** Baseline Characteristics of the Patients at the Time of Starting Adalimumab Biosimilar (Group 1) or Switching From Reference Adalimumab (Group 2)

| | **Total, 102** | **Group 1 Biosimilar naïve** | **Group 2 Adalimumab Switch from Originator to Biosimilar** | **p-value** |
|---|---|---|---|---|
| | | **n=72 (70.6)** | **n=30 (29.4)** | |
| Age at biosimilar administration, mean ±SD (range) | 12.4 ±3.2(4–17) | 12.7 ±3.0(7–17) | 11.8 ±3.7(4–17) | 0.204 |
| Gender<br>F<br>M | <br>57 (55.9)<br>45 (44.1) | <br>40 (55.6)<br>32 (44.4) | <br>17 (56.7)<br>13 (43.3) | 0.918 |
| Weight (Kg), mean ±SD (range) | 47.9 ±16.3(23–104) | 50.0 ±16.6(23–104) | 42.7 ±14.3(25–77) | 0.036 |
| Height (1, XX), mean ±SD (range) | 1.5 ±0.1(1.1–1.8) | 1.5 ±0.1(1.2–1.8) | 1.4 ±0.2(1.1–1.8) | 0.019 |
| BMI, mean ±SD (range) | 20.8 ±4.0(9.4–32.1) | 21.1 ±4.4(9.3–32.1) | 20.2 ±2.7(14.7–25) | 0.300 |
| Disease onset (age of onset), mean ±SD (range) | 7.7 ±3.3(1–16) | 7.9 ±3.3(1–16) | 7.0 ±3.0(2–14) | 0.200 |
| Psoriatic arthritis<br>Yes | <br>3 (2.9) | <br>2 (2.8) | <br>1 (3.3) | 0.880 |
| Comorbidities<br>Yes | <br>17 (17.6) | <br>14 (19.4) | <br>3 (13.3) | 0.461 |
| PASI before any treatment, mean ±SD (range) | 15.0 ±5.5(5–38) | 14.7 ±4.1(5–31.3) | 15.8 ±6.2(6–38) | 0.359 |
| Duration Humira treatment, mean ±SD (range) | | | 21.5 ±15.7(4–85) | |


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females (55.9%); gender distribution was similar across groups (p = 0.918). The mean weight was lower in the switch group (42.7 kg) compared to the biosimilar-naive group (50.0 kg) (p = 0.036). The mean height was also lower in the switch group (1.4 m) versus the biosimilar-naive group (1.5 m) (p = 0.019). The mean body mass index in the whole group was 20.8 ± 4.0 without a significant difference between the two groups (p = 0.300). The mean age of disease onset was 7.7± 3.3 years and was similar across the two groups (p = 0.200). Median disease onset was 7.7± 3.3 years. Three patients (2.9%) had psoriatic arthritis. Seventeen patients (14 in biosimilar naïve group, 3 in switch group) had comorbidities which included endocrine disorders (hypoadrenalism, growth impairment, Hashimoto's thyroiditis, precocious puberty, type 1 diabetes), atopic dermatitis, allergic rhino-conjunctivitis (2 patients), interstitial lung disease, asthma, pulmonary dysplasia and trunk ectasia, Down syndrome, obesity (2 patients), reflux esophagitis, thalassemic trait (2 patients) and juvenile myoclonic epilepsy. The mean duration of treatments with adalimumab originator before switching in group 2 was 21.5 ±15.7 months. At the beginning of the treatment with the originator or biosimilars, median PASI was similar between groups (Group 1: 14.7; Group 2: 15.8; p = 0.359), while at the time of the switch mean PASI in Group 2 was 2.5 (p < 0.001).

Biosimilars utilized were five products: ABP 501 (Amgevita®), GP2017 (Hyrimoz®), MSB11022 (Idacio®), SB 5 (Imraldi®), and CT-P17 (Yuflyma®) in group 1, and ABP 501 (Amgevita®), GP2017 (Hyrimoz®), SB 5 (Imraldi®) in group 2.

## Absolute PASI Reduction

In group 1 (naïve) mean PASI score decreased progressively over time, reaching 5.4 at week 16, 4.3 at week 24, and 2.8 at week 52. These numbers correspond to a PASI reduction, respectively, of −64.4%, −69.5%, and −80.1% (see Table 2). In group 2 (switchers) median PASI score remained stable at week 16 (2.6), decreasing slightly at week 24 (2.0), and further to week 52 (1.4). Considering the PASI baseline at the beginning of adalimumab originator, PASI reduction was, respectively, −87.2%, −64.4%, and −89.3%. The PASI reduction at 52 weeks was not statistically significant across the two groups (p = 0.127). These results can be observed graphically in Figure 1.

**Table 2** PASI Absolute in the Whole Patient Population Before Any Treatment, After Starting Adalimumab Originator (Group 1) and Switching From Reference Adalimumab (Group 2) (Baseline, weeks 16, 24, and 52). Report of the Adverse Events During the Follow up

| | **Total, 102** | **Group 1 Biosimilar naïve** | **Group 2 Adalimumab Switch from Originator to Biosimilar** | **p-value** |
|---|---|---|---|---|
| | | **n=72 (70.6)** | **n=30 (29.4)** | |
| PASI baseline, mean ±SD (range) | 11.1 ±7.3(0–31.3) | 14.7 ±5.1(5–31.3) | 2.5 ±3.8(0–16) | <0.001 |
| PASI 16 w, mean ± SD (range) | 4.6 ±4.6(0–20.2) | 5.4 ±4.7(0–20.2) | 2.6 ±3.8(0–15) | 0.04 |
| PASI 24 w, mean ± SD (range) | 3.5 ±3.9(0–18.6) | 4.3 ±4.2(0–18.6) | 2.0 ±2.9(0–14.3) | 0.011 |
| PASI 52 w, mean ± SD (range) | 2.3 ±3.2(0–20.7) | 2.8 ±3.7(0–20.7) | 1.4 ±1.3(0–4) | 0.070 |
| Adverse events<br>0<br>Pso worsening<br>Fatigue<br>Local reaction<br>Mild Covid | <br>96 (94.1)<br>3 (2.9)<br>1 (0.9)<br>1 (0.9)<br>1 (0.9) | <br>69 (95.8)<br>0 (0.0)<br>1 (1.4)<br>1 (1.4)<br>1 (1.4) | <br>27 (90.0)<br>3 (10.0)<br>0 (0.0)<br>0 (0.0)<br>0 (0.0) | 0.074 |
| PASI before any treatment, mean ±SD (range) | 15.0 ±5.5(5–38) | 14.7 ±4.1(5–31.3) | 15.8 ±6.2(6–38) | 0.359 |

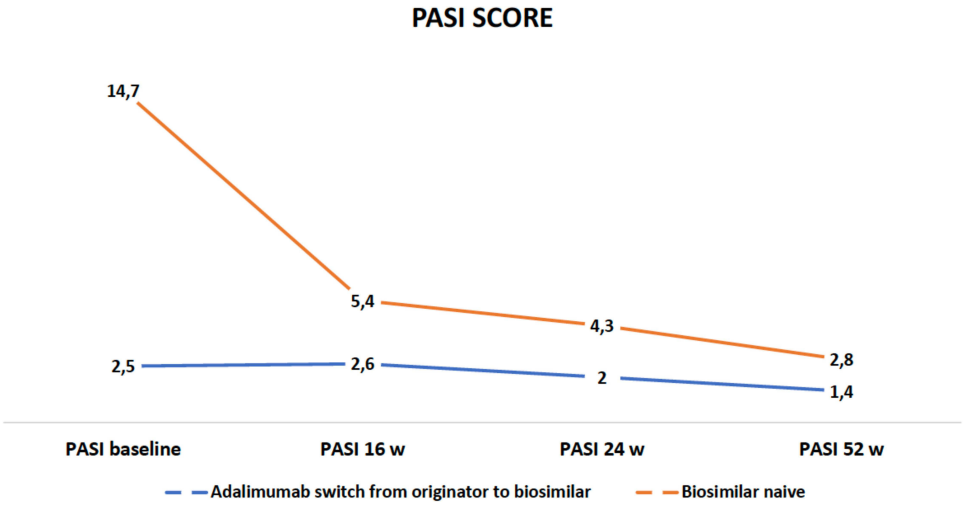


**Figure 1** The trend of mean PASI score median values during the 12 months of observation: comparison between switch and naïve Groups. Orange line: naïve patients; blue line: switchers from Adalimumab to a biosimilar. PASI scores were plotted at four time-points: at initiation of treatment with adalimumab biosimilar and at 16, 24, and 52 weeks after this switch. Overall, both groups experienced a reduction in PASI scores over time, with the switch group maintaining consistently lower PASI scores throughout the study.

## PASI 75 and PASI 90 Response

PASI 75 score was reached at week 16 by 41.7%, at week 24 by 55.0% and at 52 weeks by 77.8% of patients in the naive group (see Table 3). The proportion of patients achieving PASI 75 is shown in Figure 2.

PASI 90 score was achieved at week 16 by 23.3% of patients, at week 24 by 26.7% in the naïve group, at week 52 by 46.3% of patients in the naive group. The proportion of patients who achieved PASI 90 is illustrated in Figure 3.

## Safety

Adverse events, as detailed in Table 1, were infrequent. No treatment-emergent serious adverse effects were reported. However, there was a trend toward a higher incidence of adverse events in the switch group (p = 0.074), consisting of psoriasis worsening in 3 patients (10%). Due to loss of response, adalimumab biosimilar treatment was discontinued in one patient 16 weeks after the switch and in two patients 24 weeks after the switch.

**Table 3** PASI 75 and PASI 90 Response Rates in the Whole Patient Population, in Patients Biosimilar Naïve (Group 1) and in Patients Switching From Reference Adalimumab (Group 2) (Baseline, 16, 24, and 52 weeks)

| | **Total, 102** | **Group 1 Biosimilar naïve** | **Group 2 Adalimumab Switch from Originator to Biosimilar** | **p-value** |
|---|---|---|---|---|
| | | **n=72 (70.6)** | **n=30 (29.4)** | |
| Reduction PASI 16w %, mean ±SD (range) | −71.8 ±27.1(−100 to 0) | −64.4 ±28.4(−100 to 0) | −87.2 ±15.9(−100 to −43.8) | <0.001 |
| Reduction PASI 24w %, mean ±SD (range) | −75.3 ±30.9(−100 to 120.3) | −69.5 ±34.7(−100 to 120.3) | −87.3 ±15.9(−100 to −34.7) | 0.010 |
| Reduction PASI 52w %, mean ±SD (range) | −83.2 ±25.6(−100 to 83.2) | −80.1 ±30.1(−100 to 83.2) | −89.3 ±10.3(−100 to −60) | 0.127 |
| Pasi 75 at 16 w: n (%) | 49 (55.1) | 25 (41.7) | 24 (82.8) | <0.001 |
| Pasi 75 at 24 w: n (%) | 48 (65.2) | 33 (55.0) | 25 (86.2) | 0.004 |
| Pasi 75 at 52 w: n (%) | 67 (82.7) | 42 (77.8) | 25 (92.6) | 0.096 |
| Pasi 90 at 16 w: n (%) | 31 (34.8) | 14 (23.3) | 17 (58.6) | 0.001 |
| Pasi 90 at 24 w: n (%) | 35 (39.3) | 16 (26.7) | 19 (65.5) | <0.001 |
| Pasi 90 at 52 w: n (%) | 40 (49.4) | 25 (46.3) | 15 (55.6) | 0.432 |


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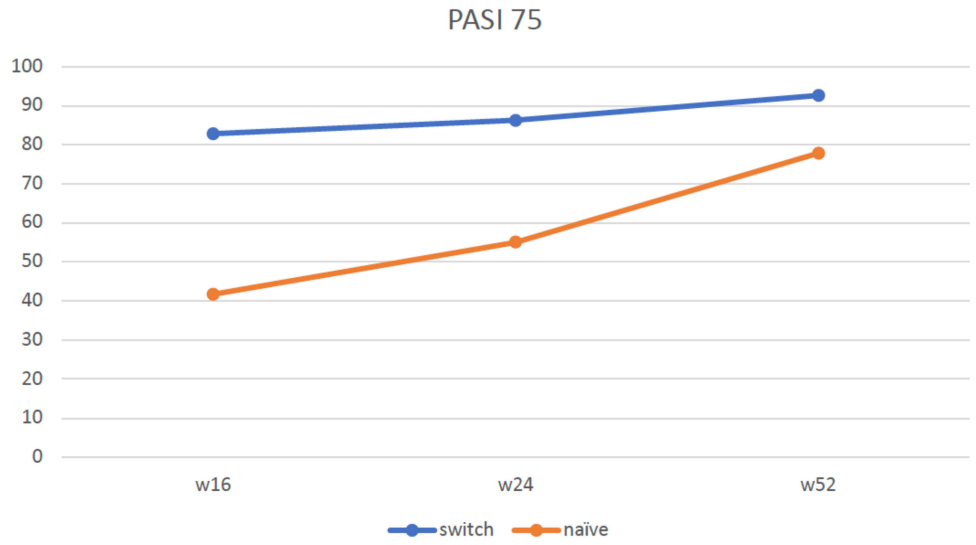


**Figure 2** The proportion of patients achieving PASI 75 Over Time: PASI 75 response rates continued to improve through week 24 in the biosimilar-naïve group, while remaining stable in the switch group.

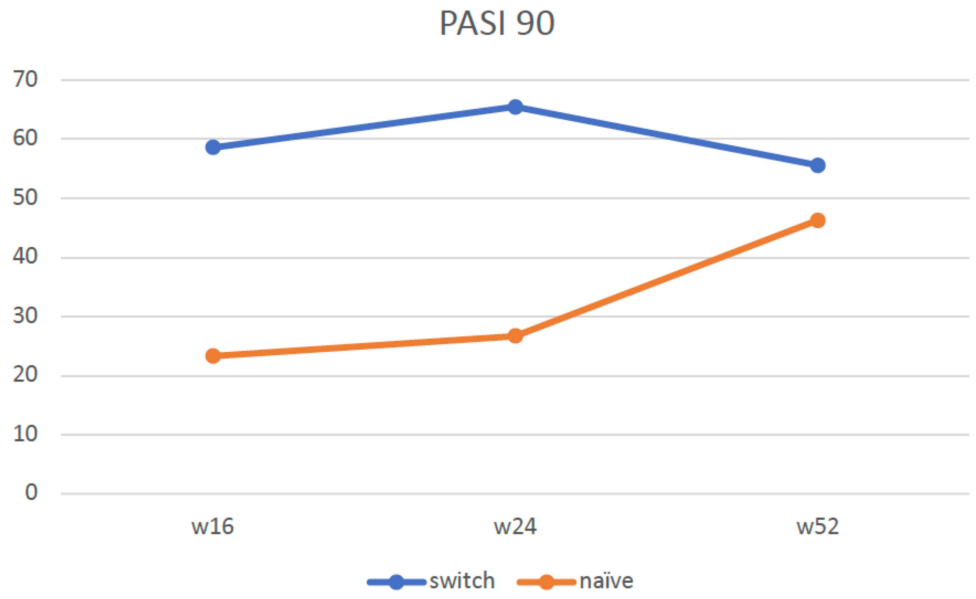


**Figure 3** The proportion of patients achieving PASI 90 Over Time: PASI 90 response rates continued to improve through week 24 in the biosimilar-naïve group. In the switch group, after an initial improvement, the percentage of patients who achieved PASI90 slightly decreased by week 52.

## Discussion

The use of biological drugs has changed the management of moderate to severe psoriasis in adults as well as in children, inducing long-term disease remission and improving patient outcomes, also in difficult clinical scenarios. The recent introduction of biosimilars with a good cost-effectiveness ratio may help to reduce costs and promote broader use of biologics.

In European countries, substitution of a reference drug with a biosimilar product is often encouraged for treatment-naïve patients. However, switching patients from a reference product to a biosimilar product has also become a common practice under the pressure of healthcare payors. Consequently, an expanding amount of data on biosimilar products is becoming available not only by randomized clinical trials[8–10] and meta-analysis,[11] but also by real-life studies[12–14] in adult psoriatic patients, while limited data is available in children.[15]

Adalimumab is the most frequently prescribed biologic treatment for moderate to severe psoriasis of childhood.[16] This is the first study conducted under clinical practice conditions analyzing the effectiveness and safety of adalimumab biosimilars for pediatric psoriasis, either in naïve patients or after switching from adalimumab originator.

We found that adalimumab biosimilars were effective in naïve patients with 41.7% and 77.8% of patients achieving PASI 75 at 16 and 52 weeks, while 23.3% and 46.7% achieved PASI 90 at 16 and 52 weeks. PASI 75 and 90 responses at week 16 were achieved by a greater proportion of children and adolescents in the randomized clinical trial by Papp et al, with 58% of patients achieving PASI 75 and 22% achieving PASI 90.[17,18] However, our results do not differ significantly from efficacy outcomes at week 52 in the long-term extension study which showed that 72.2 and 44.4% of the adalimumab-treated patients maintained, respectively, a PASI 75 and PASI 90 clinical response.[19] Real-life experiences with adalimumab originator in children have shown better responses in terms of PASI 75 and PASI 90 at week 16 (achieved by 55% and 29.6% of patients). However, similar results were observed at week 52 (PASI 75 achieved by 61% and PASI 90 by 55.5%).[20]

In our group of patients, the switch to biosimilars did not produce any significant difference compared to the outcomes achieved with the reference product. Patients undergoing to switch maintained stable disease activity throughout the 52-week follow-up showing that switching between adalimumab originator and biosimilars was effective and safe. Three patients (10%) who switched adalimumab originator to biosimilars discontinued biosimilars within the first year of treatment due to loss of efficacy. Premature discontinuation could be ascribed to extended drug exposure with possible immunogenicity. However, we were not able to measure antidrug antibodies in these cases. Anyway, the majority of patients in group 2 maintained PASI values or achieved even lower PASI values after switch.

By the end of 52 weeks, no significant differences in PASI responses were observed between the groups, despite the two groups had started biosimilars with different initial conditions—one group already being on stable treatment. Overall, both groups exhibited comparable PASI responses, underscoring the similar long-term effectiveness of treatment regardless of prior exposure to adalimumab originator. Patients who had previously responded to the adalimumab originator did not experience adverse events following non-medical switching to a biosimilar.

These results support the efficacy studies of biosimilar drugs and allow for a safe and effective transition between treatments, providing evidence of encouraging outcomes after switching from reference adalimumab to its biosimilars.

Ultimately, this approach will enable more people to access the treatment due to the economic balance to which healthcare systems and payors are exposed.

Our study has some limitations, which include its open and retrospective design, the gathering of different biosimilars in a single group, the relatively small sample size, and the limited period of observation. These factors may have influenced the demonstrated efficacy of biosimilars when considered as a single group, potentially masking variability between the individual agents or affecting the interpretation of their comparable long-term effectiveness.

Additionally, potential selection bias and the absence of immunogenicity assessments represent further limitations, which may have influenced the interpretation of treatment response and should be explored in future prospective studies. Large-scale and long-term data are warranted to provide a more robust assessment of the long-term effectiveness, safety, and economic impact of non-medical switching to biosimilars and to further validate the encouraging results observed in this study.

## Ethical Approval

This was a retrospective analysis of records stored in databases and official approval was received based on the Guidelines for Clinical Research issued by the Ministry of Health of Italy. All procedures complied with the declaration of Helsinki. Patients give consent to the retention of medical records, either as identifiable data or in anonymised form.

## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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There is no funding to report.

## Disclosure

L. Stingeni has been principal investigator in clinical trials sponsored by or has received personal fees for participation in advisory boards from AbbVie, Amgen, BMS, LEO Pharma, Lilly, Novartis, and Sanofi, outside the submitted work.

K. Hansel received personal fees for participation in advisory boards from AbbVie, Amgen, BMS, LEO Pharma, Novartis, Sanofi, and UCB outside the submitted work.

M. Ortoncelli has served as advisory board member and/or consultant and has received fees and speaker's honoraria or has participated for clinical studies for AbbVie, Almirall, Lilly, Leo Pharma, Novartis, Pfizer and Sanofi Genzyme outside the submitted work.

ML Musumeci has served as a consultant/investigator for AbbVie, Lilly, Janssen, Novartis, Biogen, UCB, Sandoz, Almirall, Leopharma outside the submitted work.

C. Gerbino has served as sub-investigator for Galderma and UCB.

E. Mahé has undertaken activities as a paid consultant, adviser or speaker for AbbVie, Almirall, Amgen, Biolane, Janssen-Cilag, Leo Pharma, Lilly, Novartis, Sanofi, and UCB outside the submitted work.

V. Di Lernia has served as member of advisory boards and/or received speaker honoraria from Abbvie, Amgen, Eli Lilly outside the submitted work; has participated as Principal Investigator for clinical studies for Almirall, Sanofi, Jansen, Lilly, Novartis.

The authors report no other conflicts of interest in this work.

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