The infliximab biosimilar in the treatment of moderate to severe plaque psoriasis

Paolo Dapavo, MD,[a] Igor Vujic, MD,[b,c] Maria Teresa Fierro, MD,[a]
Pietro Quaglino, MD,[a] and Martina Sanlorenzo, MD[a]
Turin, Italy, and Vienna, Austria

Background: The infliximab originator's patent recently expired, leading to the production of biosimilar versions of the drug. The biosimilars' efficacy was not tested on patients with psoriasis but most regulatory authorities approved their use in psoriasis because of an extrapolation of data from studies conducted in other diseases.

Objective: We sought to describe the use of the infliximab biosimilar (Remsima; CT-P13) in patients with psoriasis.

Methods: Objective (Psoriasis Area and Severity Index) and subjective (visual analog pain scale) measurements of disease activity were collected in 2 cohorts of patients with moderate to severe plaque psoriasis: cohort 1 patients switched from the infliximab originator to the infliximab biosimilar; and cohort 2 patients were infliximab-naïve and started on the infliximab biosimilar.

Results: We observed no changes of Psoriasis Area and Severity Index and visual analog pain scale scores in 30 patients who switched from the infliximab originator to the biosimilar. Four of 5 infliximab-naïve patients who started infliximab biosimilar treatment achieved 75% improvement or better from baseline Psoriasis Area and Severity Index score at the end of the induction phase.

Limitations: Number of patients and length of follow-up was limited.

Conclusions: Patients with psoriasis taking infliximab originator treatment can switch to the infliximab biosimilar without experiencing a significant change in clinical response or additional adverse events. The use of the infliximab biosimilar could reduce the growing pressure on health care budgets. (J Am Acad Dermatol 2016;75:736-9.)

Key words: biosimilar; CT-P13; infliximab; psoriasis; Remicade; Remsima.

The infliximab originator (Remicade, Janssen Biotech, Inc, Horsham, PA), an anti–tumor necrosis factor-alfa monoclonal antibody, has shown its efficacy in treating psoriasis but is relatively expensive.[1,2] Cheaper biosimilars (drugs designed to have the same pharmacodynamic and pharmacokinetic properties as their previously licensed reference drugs) are available, but were not tested in patients with psoriasis.[3,4] Most regulatory agencies have approved the use of infliximab biosimilars for the treatment of psoriasis by extrapolating efficacy from studies in other diseases.[5-8] Here, we describe our experience in the use of the infliximab biosimilar Remsima (CT-P13, Celltrion, Korea) in the treatment of patients affected by moderate to severe plaque psoriasis.

From the Department of Medical Sciences, Section of Dermatology, University of Turin[a]; Department of Dermatology, Rudolfstiftung Hospital, Academic Teaching Hospital, Medical University Vienna[b]; and School of Medicine, Sigmund Freud University, Vienna.[c]
Drs Dapavo and Vujic contributed equally to this article.
Funding sources: None.
Conflicts of interest: None declared.
Accepted for publication April 25, 2016.

Reprint requests: Martina Sanlorenzo, MD, Department of Medical Sciences, Section of Dermatology, University of Turin, Via Cherasco 23, 10126 Torino, Italy. E-mail: martina.sanlorenzo@hotmail.it.
Published online July 27, 2016.
0190-9622/$36.00

http://dx.doi.org/10.1016/j.jaad.2016.04.068

METHODS

The study was approved by the local ethical committee. All patients included in this study had a diagnosis of moderate to severe plaque psoriasis, signed the participation consent forms, and were treated at the University of Turin (Italy) in the period from July 1, 2015, to January 20, 2016. The following data were collected: age, gender, previous treatments, presence of psoriatic arthritis, Psoriasis Area and Severity Index (PASI) and visual analog scale for arthritic pain scores at baseline and at each visit, along with any adverse events. Statistical analyses were performed using software (Stata 12.0, Stata Corp, College Station, TX). Follow-up time was calculated as the time from the first cycle of biosimilar use until the end of the study. Comparisons between correlated groups were performed using McNemar exact test. A P value less than .05 was considered significant. For the analysis we divided the patients into 2 cohorts: cohort 1 patients took infliximab originator at the beginning of the study period and were later switched to the infliximab biosimilar; and cohort 2 patients were infliximab-naïve and started on the infliximab biosimilar at the beginning of the study period.

CAPSULE SUMMARY

- Infliximab biosimilars have shown efficacy in other diseases but testing in psoriasis has been limited.
- In our study, patients with psoriasis who switched from the infliximab originator to the infliximab biosimilar maintained their clinical response and experienced no additional adverse events.
- The infliximab biosimilar may be a viable treatment option for patients with psoriasis.

RESULTS

Cohort 1: Patients with psoriasis who switched from the infliximab originator to the infliximab biosimilar

Thirty patients with psoriasis had ongoing infliximab originator treatment at study initiation (July 1, 2015). The mean PASI score before infliximab treatment was 29.2. Ten patients also had a diagnosis of psoriatic arthritis. The median time on infliximab originator was 237 weeks (range 14-576 weeks) (Table I). After switching to the infliximab biosimilar, treatment was continued on the same schedule and dosage. The median follow-up on the biosimilar was 23 weeks (range 13-33 weeks), with a median number of cycles of 4 (range 2-7). PASI and visual analog scale scores were not significantly different (McNemar exact test; $P > .05$) before the switch to the biosimilar and at the end of the observation period (January 20, 2016).

These results are similar to those published for other diseases such as rheumatoid arthritis and ankylosing spondylitis, where the infliximab biosimilar proved its efficacy.[9,10]

About 50% of patients with psoriasis who start infliximab have to discontinue treatment within the first year because of loss of efficacy attributed to anti-infliximab antibodies and a faster drug clearance.[11-13] Cohort 1 patients had a long-lasting response to the infliximab originator before the switch, with most patients receiving the drug for more than 12 months (Table I). This makes occurrences of adverse events and the development of immunogenicity in these patients unlikely. During follow-up, 1 patient developed herpes zoster and his symptoms resolved completely after a 7-day course of systemic valacyclovir hydrochloride and paracetamol. No other adverse events were observed.

Our study shows that patients with psoriasis and a long-lasting response to the infliximab originator can be switched to the infliximab biosimilar without experiencing a significant change in clinical response or additional adverse events.

Cohort 2: Infliximab-naïve patients who started treatment with an infliximab biosimilar

Cohort 2 consisted of 5 patients with moderate to severe plaque psoriasis for whom at least 1 systemic treatment failed and who did not receive infliximab before the beginning of the study (Table II). The mean PASI score at the beginning of the treatment was 27.3. All cohort 2 patients received the infliximab biosimilar starting with an induction phase (week 0, 2, 6). Four of 5 patients reached 75% improvement from baseline PASI score at week 10. Although only 5 patients were treated, we hypothesize that the PASI reduction by the infliximab biosimilar is in line with that reported for the infliximab originator.[2]

DISCUSSION

Despite the limitations of our study (low sample size, limited follow-up time) we conclude that the infliximab biosimilar is an appealing treatment choice for patients affected by plaque psoriasis. Considering possible price differences between the