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REVIEW

Anti-tumor necrosis factor agents in psoriasis: addressing key challenges using biosimilars

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ABSTRACT

Introduction: Anti-tumor necrosis factor agents are key treatment options in moderate–severe psoriasis. The advent of multiple biosimilars of these drugs provides a major opportunity to address this particular factor by helping to reduce costs. Reduced cost can help improve undertreatment, which is one of the challenges in treating moderate-severe psoriasis. There is now a wealth of real-world evidence demonstrating that patients with psoriasis can be initiated on – or transitioned to – an anti-TNF biosimilar without detrimental effects on overall safety and efficacy. Furthermore, recent results suggest that patients can be switched between different biosimilar versions of the same anti-TNF agent without any compromise in outcomes.

Areas covered: In this review, we summarized the role of anti-TNFs in psoriasis, health economic aspects of anti-TNF biosimilars, and their real-world data in clinical practice and registries.

Expert opinion: The introduction and competition of anti-TNF biosimilars reduced the cost of biologics and accumulated real-world data support efficacy and safety of anti-TNF biosimilars for psoriasis treatment. Although IL-17 and IL-23 inhibitors show better efficacy in psoriasis patients, long-term efficacy and safety data of anti-TNF and cost-effectiveness of anti-TNF biosimilars may play an important role to increase patient access to biologics through greater adoption of biosimilars.

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Adalimumab; anti-TNF; biosimilar; etanercept; infliximab; psoriasis

1. Introduction

Anti-tumor necrosis factor (anti-TNF) drugs are recommended mainstay treatments for psoriasis. In 2018, three anti-TNFs – adalimumab, etanercept, and infliximab – accounted for almost 50% of all biologic drug use for psoriasis across seven major developed countries (USA, Japan, France, Germany, Italy, Spain, UK) [1].

A key factor underlying this usage is our deep understanding of the long-term safety, efficacy, and manageability of these molecules, derived from many years of clinical experience [2,3]. International management guidelines all recommend anti-TNF agents as options in the treatment of moderate–severe psoriasis [4,5]. According to Amin M et al., due to their broad indications for use, anti-TNF agents are recommended first-line biologic options in patients with associated comorbid diseases, such as psoriatic arthritis (PsA) and infliximab and adalimumab for inflammatory bowel disease [6].

Nonetheless, there remain important challenges around the use of anti-TNF drugs in psoriasis. One of these relates to the definition of moderate–severe disease, and the disconnection between physicians and patients in their understanding and perception of severity. In a survey of more than 3000 individuals with psoriasis, 65% of those with ≤3% body surface area coverage – who would typically be considered medically to have 'mild' disease – perceived their own disease to be moderate or severe (Figure 1) [7]. This indicates that many patients currently ineligible for biologic therapy perceive a substantial disease burden that impacts their lives.

A second key challenge relates to under-treatment. In an analysis of treatment patterns in 2011, 23.6% of patients with moderate disease and 9.4% of those with severe disease received no therapy [8]. Furthermore, even among patients receiving treatment, around a quarter of those with moderate–severe psoriasis were prescribed only topical agents [8].

Underlying these challenges is the reality that originator biologic medicines are typically expensive, which limits their use. Biosimilar versions of these medicines have the potential to reduce the associated costs, and hence increase accessibility [9]. One of the reasons to include biosimilars in our clinical practice is to reduce the cost of biologic treatment; thus, allowing the introduction of innovator biologics in the market, to allow the treatment of refractory patients. Thus, with biosimilars of anti-TNF agents now becoming more widely available, there is a real opportunity to overcome some of the current challenges in psoriasis. This concise review aims to discuss the development of biosimilars and their potential to improve access to anti-TNF therapy in psoriasis.

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Article highlights

- A biosimilar has demonstrated biosimilarity to the originator without meaningful clinical differences compared to the originator
- Accumulated real-world data of anti-TNF biosimilars in psoriasis treatment increase confidence toward prescribing biosimilars
- Newly generated biosimilar to biosimilar switch data reduce concerns about efficacy and safety of biosimilar to biosimilar switch

This box summarizes the key points contained in the article.

2. Biosimilar anti-TNF agents in psoriasis: helping to address key challenges

A biosimilar may be defined as a biologic product that is highly similar to the originator (reference) medicine; has no clinically meaningful differences compared to the originator; has limited variability, kept within strict limits; and is approved according to the same strict standards of quality, safety, and efficacy as the originator [10].

When biosimilar versions of a biologic drug come onto the market, competition is increased, and this typically drives down the price of the originator. The resulting cost savings represent a potential innovation for patients with psoriasis via a number of potential advantages. The high price of drugs and restricted health-care budget are barriers to easy access to biologics [11]. Economic advantages transfer the cost savings of biosimilar to patients, which could improve access, adherence to treatment [12], and improvements in patient care via reallocation of budgets [13].

Biosimilars have been part of the broader (non-psoriasis) treatment landscape for almost 15 years. The European Medicines Agency (EMA) introduced an approval pathway for biosimilar medicines in 2005, and the first approval was granted in 2006; by the end of 2018, the EMA had granted 48 biosimilar authorizations [14]. Although the US Food and Drug Administration (FDA) was initially more cautious, it authorized 12 biosimilars between 2015 and 2018 [14].

In psoriasis, the first biosimilar anti-TNF drug (infliximab) was approved by the EMA in 2013. As of December 2019, there are now 10 biosimilar versions of TNF-inhibitors approved in Europe for use in psoriasis: five adalimumab; two etanercept; and three infliximab.

When using biosimilars, it is essential that prescribers understand the development and approval processes of these drugs, and in some countries, physicians need to explain the differences to their patients. The European Commission and EMA have developed literature to support this process [10,15].

With regard to regulatory approval of a new biosimilar product, if it is considered to be highly similar to the originator medicine and has comparable safety and efficacy in one therapeutic indication, extrapolation of indications is often possible – as long as this can be scientifically justified [10,16]. In such a scenario, other indications of the originator may be granted to the biosimilar without needing to go through separate, large-scale clinical study programs, but most clinicians would not accept extrapolation to use a new product in clinical practice. For example, when the first biosimilar infliximab was approved by the EMA in psoriasis in 2013, clinical data demonstrating similarity with the originator came from studies in ankylosing spondylitis and rheumatoid arthritis [17–19]. In addition, psoriasis indication was added based on extrapolation and real-world data in psoriasis showed that biosimilar is effective and safe in psoriasis as well. For example, the NOR-SWITCH phase 4 trial randomized a group of patients treated with originator infliximab – including many with psoriasis or PsA – to either continue with the originator or switch

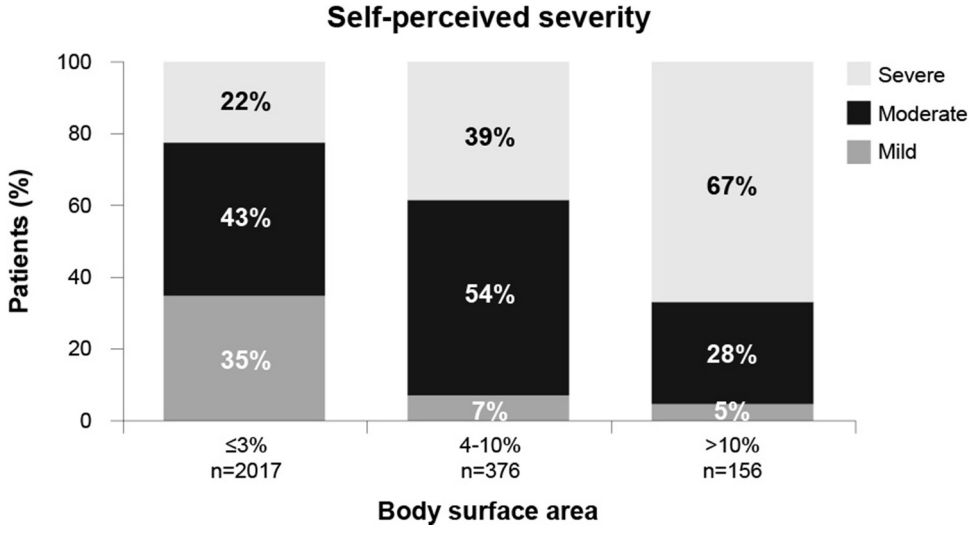

Figure 1. Patients' self-perceived disease severity according to affected BSA from large, multinational, population-based survey of psoriasis and/or psoriatic arthritis patients in North America and Europe. Self-perceived severity generally correlated with the body surface area (BSA) affected based on palm counts in 2,549 patients with psoriasis.

BSA, body surface area. Reproduced with permission from Lebwohl et al. 2014 [7].

to the biosimilar and found that the biosimilar was non-inferior to the originator [20]. An important consequence of this approval mechanism is that it can reduce the cost of biosimilar development relative to the originator, thus helping to support a lower price without reducing efficacy and safety.

Although the same levels of rigorous quality control are required when manufacturing a biosimilar as with the originator, the process does not have to be identical. As long as the resulting molecules are similar in quality, small manufacturing differences can be tolerated [10]. Indeed, variations are normal even within the lifespan of individual originator biologic products. For example, the manufacturing processes of the most commonly used originator biologic medicines have changed in various ways since their approval, which may have resulted in minor differences relative to the molecules that were used in clinical trials [10]. Regulatory authorities now have sufficient experience to conclude that these do not affect the quality, safety, or efficacy of the product [10].

3. Biosimilar anti-TNF agents in psoriasis: real-world insights

Since biosimilars were first introduced, many studies have assessed the safety and efficacy of switching from originators. Indeed, a recent systematic review identified a total of 90 such studies, enrolling more than 14,000 participants [21]. Of these, five were in psoriasis, including 983 patients. Overall, the data suggested that safety and efficacy were typically unchanged after switching from an originator biologic to a biosimilar [21].

A wealth of recent real-world data has been published on switching from an originator to a biosimilar anti-TNF agent in psoriasis [22–30]. For example, two recently published studies demonstrated positive clinical experiences with an etanercept biosimilar (SB4) in patients with psoriasis [24,25]. The first included 44 patients with moderate–severe psoriasis and/or PsA, who were either etanercept-naive (n = 12) or transitioned to SB4 from the originator (n = 32) [24]. In the switch cohort, there was no statistically significant difference in mean disease activity score in 28 joints (DAS 28) before and after switching, and Psoriasis Area and Severity Index (PASI) actually improved significantly ($p< 0.001$); in the naive cohort, improvements in PASI score of >50% were observed as early as week 12 in 67% of participants, with further amelioration by week 24 (PASI 75 was achieved in 75% of patients) [24]. A second single-center study included 40 patients initiating SB4: 14 with plaque-type psoriasis and 26 with PsA [25]. By week 24, mean PASI score had improved significantly in both groups ($p< 0.001$), and no serious adverse events were observed. This study also included a cost assessment, which found that the use of the biosimilar instead of the originator resulted in cost savings of >60%, whether using 25-mg or 50-mg vials [25].

Similarly, two Italian studies assessed the use in normal clinical practice of an infliximab biosimilar (CT-P13) [22,23]. The first, which included 30 patients with moderate–severe plaque psoriasis switching from originator to biosimilar infliximab, observed no changes in either PASI or arthritis pain scores (visual analog scale) [22]. The second, which enrolled 22 patients switched from the originator, also observed no significant change in efficacy based on cutaneous symptoms, and there were no new safety signals [23].

Registries enrolling psoriasis patients treated with various biosimilar anti-TNF agents have revealed similar results to single-center studies. For example, in the Danish DERMBIO registry of patients with moderate–severe plaque psoriasis treated with biologics, there were no significant differences in the risk of discontinuation between originator and biosimilar anti-TNF agents (SB4 and CT-P13), and safety profiles were comparable. Also, they found no significant differences in drug survival for biosimilars compared with originators [26]. The Italian Psobiosimilars registry was set up to assess the long-term effectiveness and safety of biosimilars in patients with psoriasis [27,28]. It collects data on biosimilar treatment and also on PASI scores, comorbidities, age at diagnosis, and the number of previous systemic treatments received. Almost 800 patients have now been enrolled. Published data from the registry included 204 individuals treated with an infliximab biosimilar: at 6 months, a PASI 75 response was achieved by 80% of previously infliximab-naive patients; PASI scores remained unchanged in those who were switched from the originator ($p= 0.3$) [27]. Similarly, among 197 patients treated with an etanercept biosimilar (SB4), PASI scores among etanercept-naive individuals were significantly reduced from baseline to 6 months (from 12.5 ± 6.2 to 6.7 ± 2.2; $p= 0.03$) and were unchanged in those who transitioned from originator etanercept (Figure 2) [28]. Data from a prospective registry in the UK and Ireland have also been recently published [31]. Among 189 patients initiated on an etanercept biosimilar (SB4), most of whom were previously anti-TNF-naive, disease activity scores were improved overall and discontinuation rates were in line with the originator [31].

Although most switch data to date have been based on patients transitioning from the originator to a biosimilar anti-TNF agent, data are now beginning to emerge for switching from biosimilar to biosimilar. For example, 96 patients with chronic plaque psoriasis (25 of whom also had PsA) who cross-switched from one infliximab biosimilar (CT-P13) to another (SB2) [32]. At 6 months, there was no significant change in mean PASI score (0.9 ± 2 at the time of switch; 0.7 ± 1.1 at 6 months) and there were no additional adverse events [32]. Confirmatory data from greater patient numbers and longer follow-up are still required but these early results are reassuring – particularly given that biosimilar-to-biosimilar switching is likely to become increasingly common as price becomes a key driver of anti-TNF drug choice.

Finally, in Europe, most of the biosimilar anti-TNF switching experience has involved infliximab and etanercept. However, the recent patent expiry of originator adalimumab offers an important new opportunity. Adalimumab remains one of the most cost-effective biologics available [33], and this is likely to be further improved by price competition among different versions of adalimumab (including biosimilars). Indeed, given that adalimumab biosimilar has better efficacy than etanercept biosimilar and is more convenient in administration method than infliximab biosimilar, it will be more frequently used in moderate–severe psoriasis than etanercept or infliximab biosimilars [9].

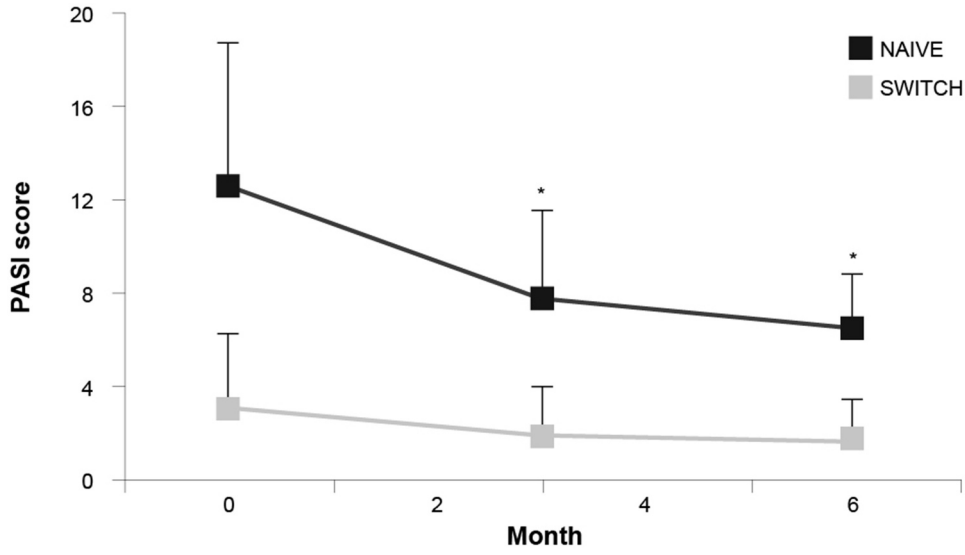

Figure 2. Severity scores in psoriasis patients treated with the etanercept biosimilar SB4 in the Psobiosimilars registry. Effectiveness of etanercept SB4 was evaluated by measuring the PASI changes between baseline and month 6.

*p= 0.03 versus baseline. n = 158 switched from etanercept originator; n = 39 etanercept-naïve. PASI, Psoriasis Area and Severity Index. Reproduced with permission from Gisondi et al. 2019 [28].

4. Conclusions

Anti-TNF agents are a key component of the treatment armamentarium in moderate–severe psoriasis. However, even in developed countries, access to these drugs remains suboptimal. The advent of biosimilars provides a major opportunity to address the health economic aspects of this issue. There is now a wealth of data from both clinical trials and real-life clinical practice to show that patients can be initiated on – or switched to – a biosimilar without any compromise in safety or efficacy. As such, biosimilar versions of the anti-TNF agents will likely continue to redefine the standard of care in psoriasis.

5. Expert opinion

Anti-TNF biosimilars are commonly used to treat moderate-to-severe psoriasis patients. CT-P13, the first anti-TNF biosimilar, was introduced in the European Union (EU) market in early 2015. However, unmet needs in psoriasis patients with severe disease due to low accessibility still exist. The introduction and competition of anti-TNF biosimilars are expected to reduce cost, not only biosimilars but also originators. These savings could be used to increase patients' access to biological treatment. Change in the price and quantity changes for a prescription of infliximab, etanercept, and adalimumab in Denmark were examined by using Danish database [34,35]. The cost reduction by switching from originators (infliximab, etanercept, and adalimumab) to biosimilars saved approximately two-thirds of monthly total cost of infliximab and 80% monthly total cost of adalimumab and increased quantity consumption of three anti-TNFs in Denmark.

Advances in technological innovations and biomanufacturing are key to a reduction in the cost and time to develop biosimilars. Biosimilarity is demonstrated based on the totality of evidence. Without directly studied in a comparative clinical trial with the biosimilars, efficacy and safety data can be extrapolated to another indication. For example, CT-P13 (infliximab biosimilar) and SB4 (etanercept biosimilar) approved for plaque psoriasis have been granted approval for all indication based on evidence that included comparable efficacy and safety in patients with rheumatoid arthritis, as this population is considered a sensitive model to establish equivalent efficacy between originator and biosimilars [18,36]. Accumulated real-world data indicate that biosimilars also demonstrate comparable efficacy and safety in psoriasis patients. Real-world data of biosimilar to biosimilar switching in psoriasis patients are useful to reassure physician and patients of the safety and efficacy of biosimilars. In the coming years, we expect more and more real-world data on biosimilar to biosimilar switch.

The more novel biologics such as IL-17 and IL-23 inhibitors have shown better efficacy profiles based on FIXTURE (PASI 75 response rate at week 12 were 77.1% with 300 mg of secukinumab, 67.0% with 150 mg of secukinumab, and 44.0% with etanercept [37]) and VOYAGE 1 (PASI 75 response rate at week 16 were 91.2% with guselkumab and 73.1% with adalimumab [38]) in patients with psoriasis. However, due to their high costs, patient access is limited in certain parts of the world. Anti-TNF biosimilars may therefore play important roles and accumulated clinical data as well as robust pharmacovigilance of biosimilars will support physicians to prescribe anti-TNF biosimilars with confidence.

Accumulated long-term data and cost-effectiveness may be helpful for increasing the confidence of physicians in the use of biosimilars in psoriasis treatment as a first-line treatment option [39]. However, to our knowledge, no published studies regarding the cost-effectiveness of anti-TNF biosimilars for psoriasis compared to other biologics have been published yet but these studies are certainly needed.

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