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ORIGINAL ARTICLE

Treatment patterns with etanercept and adalimumab for psoriatic diseases in a real-world setting

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Background: **This study examined real-world etanercept and adalimumab treatment patterns in patients with psoriasis, psoriatic arthritis, or both.** ***Methods:*** **This retrospective analysis utilized data from patients with psoriasis, psoriatic arthritis, or both from a large, US claims database. Outcome measures included persistence on index therapy; pauses (7–59 days) and gaps (≥60 days) in therapy; and rates of discontinuing, switching and restarting index therapy in nonpersistent patients.** ***Results*****: Of 4,453 patients, 2,534 initiated etanercept and 1,919 initiated adalimumab. In psoriasis patients (*n* = 2,775), 46.4% and 56.8% on etanercept and adalimumab, respectively, were persistent for ≥12 months, 49.0% and 56.3% discontinued, 23.8% and 22.4% restarted and 14.9% and 11.3% switched index therapy within 12 months. In psoriatic arthritis patients (*n* = 1,197), 60.7% and 63.3% on etanercept and adalimumab, respectively, were persistent for ≥12 months, 48.3% and 51.6% discontinued, 25.8% and 20.0% restarted and 16.5% and 17.9% switched index therapy. In patients with both (*n* = 481), 58.1% and 59.6% on etanercept and adalimumab, respectively, were persistent for ≥12 months, 42.7% and 63.2% discontinued, 24.3% and 12.6% restarted and 21.4% and 15.8% switched index therapy.** ***Conclusions*****: Treatment modifications were common in patients with psoriasis, psoriatic arthritis, or both within 12 months of initiating etanercept or adalimumab.**

Key words: TNF-inhibitors, psoriasis, psoriatic arthritis, switch, restart, discontinue

Introduction

Psoriasis is a systemic, chronic, autoimmune disease of the skin that affects approximately 2% of the population of the United States (1,2). Plaque psoriasis (psoriasis vulgaris) is the most common form of the disease, occurring in 85%–90% of patients with psoriasis (2). Plaque psoriasis is characterized by raised, well-demarcated, erythematous lesions with adherent silvery scales that appear primarily on the elbows, knees, scalp, back and abdomen (1,2). Psoriatic arthritis is a chronic, immune-mediated inflammatory disease that can affect both the peripheral joints and spine (3). Psoriatic arthritis is estimated to affect 0.3%–1% of the US population, including up to 42% of patients with psoriasis (4). Psoriatic arthritis typically occurs following long-standing psoriasis, but has been reported to precede a psoriasis diagnosis in 6%–18% of cases (3). Originally believed to be a form of rheumatoid arthritis, psoriatic arthritis is now classified as a distinct entity based primarily on the clinical feature of enthesitis, inflammation of the sites where tendons or ligaments attach to bone (5,6). These psoriatic diseases share some epidemiological, genetic and clinical features (e.g., comorbidities and response to therapy), suggesting that psoriasis and psoriatic arthritis share at least some pathogenic mechanisms (7,8). Because these psoriatic diseases frequently occur together, both rheumatologists and dermatologists diagnose and treat these skin and joint diseases.

The inflammatory cytokine tumor necrosis factor (TNF) plays a key role in the pathogenesis of the psoriatic diseases. Several TNF-inhibitor medications are now available for the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis (9–11). Efficacy of TNF-inhibitor medications in psoriatic diseases is likely due to blockade of inflammatory pathways and the interleukin (IL)-17-mediated pathways in skin (12,13). Etanercept and adalimumab are the most frequently prescribed TNF-inhibitors for the treatment of psoriasis and psoriatic arthritis. Etanercept was approved by the US Food and Drug Administration (FDA) for the treatment of active psoriatic arthritis in 2002 and for moderate to severe plaque psoriasis in 2004. Adalimumab was approved for the treatment of active psoriatic arthritis in 2005 and for moderate to severe plaque psoriasis in 2008.

The FDA-recommended doses for etanercept are 50 mg weekly administered subcutaneously (SC) for patients with psoriatic arthritis and 50 mg twice weekly for 3 months followed by 50 mg once weekly for patients with psoriasis (14). The FDA labeling for etanercept also notes that starting doses of 25 mg or 50 mg weekly have been shown to be efficacious for patients with psoriasis. The recommended doses for adalimumab are 40 mg every other week (EOW) SC for patients with psoriatic arthritis and 80 mg for an initial dose followed by 40 mg EOW starting one week after initial dose for patients with psoriasis (15). To our knowledge, treatment and dosing patterns of etanercept and adalimumab in patients with psoriatic diseases have not been well characterized.

The objective of this study was to examine etanercept and adalimumab treatment patterns in patients with psoriasis, psoriatic arthritis and both. Persistence, pauses of 7–59 days in therapy, gaps of ≥60 days in therapy, discontinuations, switches, restarts and time on therapy were evaluated using data from a US claims database in a real-world setting.

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Patients and methods

Data sources

This was a retrospective analysis of data from the Truven Health Analytics MarketScan® Commercial Claims and Encounters (Commercial) and Medicare Supplemental and Coordination of Benefits (COB) Research Databases. The Commercial database includes data from a variety of fee-for-service and managed-care health plans, including exclusive provider organizations, preferred provider organizations, point of service plans, indemnity plans, health maintenance organizations and most recently consumer-driven health plans. The Medicare database includes data from both Medicare-covered and employer-covered payments. These databases include enrollment data from approximately 150 large employers and health plans across the US, which provide private healthcare coverage. More than 60 million employees, dependents and retirees have been included in these databases in the last 3 years.

Patients

Adult (≥18 years of age) patients with psoriasis, psoriatic arthritis or both, who initiated therapy with etanercept or adalimumab and who had medical and pharmacy benefit eligibility ≥6 months prior and ≥12 months following initiation of treatment, were included in the analysis. Their first claim for either etanercept or adalimumab was their index claim, and this defined their index agent. The study period was between July 1, 2005, and September 30, 2010. Only patients with psoriasis or both psoriasis and psoriatic arthritis, who had initiated treatment after February 1, 2008, and patients with psoriatic arthritis only who had initiated treatment after January 1, 2006, were included because these dates represented the times when etanercept and adalimumab were both FDA-approved for these indications. Patients were biologic-naïve (did not have a claim for a biologic approved for either psoriasis or psoriatic arthritis; e.g., adalimumab, alefacept, efalizumab, etanercept, golimumab, infliximab or ustekinumab) for 6 months prior to their index claim. Patients with cancer or with another indication for which etanercept or adalimumab could be prescribed (rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, Crohn's disease or ulcerative colitis) were excluded. Patients were followed for 12 months after their index date.

Study measures

Outcome variables included the initial weekly dose, persistence with index medication, pauses in therapy from 7 to 59 days, gaps in therapy of ≥60 days and total treatment days. Patients were classified into one of four mutually exclusive hierarchical groups: restarting index biologic therapy, switching to a different biologic, discontinuation and other (e.g., patients who were not on therapy at day 365 and who could not be classified as discontinuing because they did not have a gap after the end of days supply of their last prescription of at least 45 days). Time to restarting index medication was also analyzed for patients with treatment gaps of ≥60 days.

The initial dose was the average weekly dose of the index prescription fill. Gaps in therapy were identified as the time between the run-out of a fill until the date of the next fill. Persistence to index medication was measured as the number of days from the index date to either the date of a switch to another TNF-blocker or a gap in therapy ≥45 days over the run out of the fill (fill date plus days supply), whichever came first. Patients with a ≥60-day gap who did not have a subsequent claim for any biologic approved for either psoriasis or psoriatic arthritis (abatacept, adalimumab, alefacept, efalizumab, etanercept, golimumab, infliximab, or ustekinumab) during the 12-month follow-up period were considered to have discontinued index medication. Time to restarting or switching to another biologic was calculated as the total number of days from the index date until the time that a patient restarted or switched therapy; patients who did not switch therapies or have a ≥60-day gap in therapy were considered persistent on therapy for the entire study period.

To test for differences between treatments within each indication, chi-square tests were used for categorical variables, and t-tests were used for continuous variables.

Results

Patients

The final sample comprised 4,453 patients, including 2,534 patients initiating etanercept and 1,919 patients initiating adalimumab. Of these, 2,775 patients had psoriasis, 1,197 patients had psoriatic arthritis and 481 patients were listed as having both. Demographic characteristics at baseline of patients receiving etanercept or adalimumab were similar for each indication (Table I). The most prevalent comorbid conditions were hypertensive disease and diabetes among patients with psoriasis, psoriatic arthritis, or both. Fewer patients with psoriasis (12%) were receiving methotrexate during the 6-month pre-index period than patients with psoriatic arthritis (41%) or both psoriasis and psoriatic arthritis (34%).

Treatment patterns

Most patients initiated index therapy at the FDA-recommended dose (Table II). The majority of patients with psoriasis taking etanercept (56.3%) initiated therapy at 100 mg weekly and an additional 25.9% initiated therapy at 50 mg weekly. For patients initiating adalimumab, 61.3% of those with psoriasis had an initial prescription at 40 mg per week, which likely corresponds to the recommended initial dose of 80 mg followed by 40 mg EOW starting the next week. The vast majority of patients with psoriatic arthritis taking either etanercept (88.1%) or adalimumab (90.3%) initiated treatment at the recommended dose. Over 90% of patients with both psoriasis and psoriatic arthritis initiated treatment at the recommended dose for one of those conditions. Across psoriatic diseases, patients had an average of 2 pauses in therapy of 7–59 days during the 12-month follow-up period.

Among patients with psoriasis, 46.4% of patients on etanercept and 56.8% on adalimumab were persistent on index medication for 12 months ($p < 0.001$). Approximately half (53.6%) of patients with psoriasis receiving etanercept had a ≥60-day gap in therapy compared with 43.2% of patients with psoriasis initiating adalimumab ($p < 0.001$) (Table II). Of patients with psoriasis who had a ≥60-day gap in therapy, 49.0% of patients receiving etanercept and 56.3% of patients on adalimumab discontinued index medication ($p = 0.249$); 14.9% of patients on etanercept and 11.3% of patients on adalimumab switched therapy ($p = 0.001$); 23.8% of patients on etanercept and 22.4% of patients on adalimumab restarted index therapy ($p = 0.013$); and 12.3% of patients on etanercept and 9.9% of patients on adalimumab had other changes in therapy ($p = 0.009$). The mean time to switch was significantly longer in psoriasis patients receiving etanercept than in patients receiving adalimumab ($p = 0.029$) (Table II). Mean total time of treatment on index therapy was longer for patients on adalimumab than for patients on etanercept ($p < 0.001$) (Table II).

Among patients with psoriatic arthritis, 60.7% of patients on etanercept and 63.3% on adalimumab were persistent on index medication for 12 months ($p = 0.132$). In the psoriatic arthritis cohort, more than one-third of patients receiving etanercept

Table I. Patient demographics and disease characteristics of PsO, PsA and PsO/PsA patients who initiated etanercept or adalimumab at baseline.

	Patients initiating etanercept (n = 2,534)			Patients initiating adalimumab (n = 1,919)		
	PsO (n = 1,609)	PsA (n = 679)	PsO/PsA (n = 246)	PsO (n = 1,166)	PsA (n = 518)	PsO/PsA (n = 235)
Age, mean years (SD)	45.5 (12.7)	48.2 (11.0)	47.9 (12.3)	45.8 (12.1)	47.6 (10.8)	47.6 (11.8)
Sex, n women (%)	690 (42.9)	302 (44.5)	103 (41.9)	525 (45.0)	248 (47.9)	120 (51.1)
Geographic region, n (%)						
Northeast	161 (10.0)	92 (13.5)	32 (13.0)	73 (6.3)	77 (14.9)	20 (8.5)
North Central	456 (28.3)	147 (21.6)	60 (24.4)	324 (27.8)	111 (21.4)	58 (24.7)
South	708 (44.0)	291 (42.9)	100 (40.7)	582 (49.9)	241 (46.5)	126 (53.6)
West	277 (17.2)	148 (21.8)	51 (20.7)	185 (15.9)	89 (17.2)	30 (12.8)
Unknown	7 (0.4)	1 (0.1)	3 (1.2)	2 (0.2)	0	1 (0.4)
Provider Specialty						
Rheumatologist	16 (1.0)	396 (58.3)	86 (35.0)	15 (1.3)	301 (58.1)	86 (36.6)
Dermatologist	1262 (78.4)	15 (2.2)	70 (28.5)	927 (79.5)	14 (2.7)	59 (25.1)
Other	291 (18.1)	247 (36.4)	80 (32.5)	202 (17.3)	192 (37.1)	74 (31.5)
Missing	40 (2.5)	21 (3.1)	10 (4.1)	22 (1.9)	11 (2.1)	16 (6.8)
Charlson-Deyo Comorbidity Index, mean score (SD)	0.20 (0.57)	0.26 (0.73)	0.22 (0.53)	0.19 (0.60)	0.19 (0.55)	0.24 (0.62)
Comorbid conditions, n (%)						
Hypertensive disease	244 (15.2)	117 (17.2)	46 (18.7)	191 (16.4)	77 (14.9)	41 (17.4)
Ischaemic heart disease*	55 (3.4)	28 (4.1)	38 (15.4)	16 (1.4)	5 (1.0)	26 (11.1)
Conduction & rhythm disorders	26 (1.6)	28 (4.1)	5 (2.0)	32 (2.7)	12 (2.3)	10 (4.3)
Heart failure	7 (0.4)	5 (0.7)	1 (0.4)	7 (0.6)	5 (1.0)	1 (0.4)
Other heart disease	28 (1.7)	12 (1.8)	7 (2.8)	26 (2.2)	10 (1.9)	6 (2.6)
Cerebrovascular disease	15 (0.9)	8 (1.2)	0	10 (0.9)	5 (1.0)	3 (1.3)
Peripheral arterial disease	13 (0.8)	7 (1.0)	0	7 (0.6)	5 (1.0)	3 (1.3)
Venous disease	35 (2.2)	13 (1.9)	7 (2.8)	24 (2.1)	9 (1.7)	8 (3.4)
Other CV (non-heart) disease	13 (0.8)	9 (1.3)	4 (1.6)	13 (1.1)	6 (1.2)	2 (0.9)
Diabetes	155 (9.6)	62 (9.1)	26 (10.6)	106 (9.1)	47 (9.1)	24 (10.2)
Emphysema	0	0	1 (0.4)	4 (0.3)	0	0
Methotrexate use at baseline, n (%)	167 (10.4)	250 (36.8)	77 (31.3)	168 (14.4)	240 (46.3)	85 (36.2)

*Coronary arterial disease.
PsO = Psoriasis; PsA = Psoriatic arthritis; PsO/PsA = Both psoriasis and psoriatic arthritis; CV = Cardiovascular.

(39.3%) and adalimumab (36.7%) had a 60-day gap in index therapy (p = 0.351) (Table II). Of those patients with a 60-day gap, a similar proportion of patients on etanercept (48.3%) and adalimumab (51.6%) discontinued index medication (p = 0.972); switched therapy (16.5% etanercept, 17.9% adalimumab; p = 0.954), restarted their index medication (25.8% etanercept, 20.0%

Table II. Treatment patterns in PsO, PsA and PsO/PsA patients.

	Patients initiating etanercept (n = 2,534)			Patients initiating adalimumab (n = 1,919)		
	PsO (n = 1,609)	PsA (n = 679)	PsO/PsA (n = 246)	PsO (n = 1,166)	PsA (n = 518)	PsO/PsA (n = 235)
Initial dose of index therapy, n (%)						
<50 mg weekly	33 (2.1)	24 (3.5)	7 (2.8)			
50 mg weekly	417 (25.9)	598 (88.1)	162 (65.9)			
51–99 mg weekly	253 (15.7)	16 (2.4)	16 (6.5)			
100 mg weekly	906 (56.3)	41 (6.0)	61 (24.8)			
40 mg EOW				311 (26.7)	468 (90.3)	157 (66.8)
>40 mg EOW to <40 mg weekly				103 (8.8)	7 (1.4)	7 (3.0)
40 mg weekly*				715 (61.3)	40 (7.7)	68 (28.9)
>40 mg weekly				37 (3.2)	3 (0.6)	3 (1.3)
Pauses per patient†, mean no. (SD)	2.1 (1.7)¶	2.0 (1.7)	2.1 (1.8)	1.9 (1.5)	1.8 (1.7)	1.9 (1.7)
Length of pause, mean days (SD)	19.3 (28.5)¶	15.4 (22.9)	15.8 (21.8)	14.9 (24.2)	14.0 (21.5)	13.3 (20.5)
Longest pause, mean days (SD)	43.2 (43.7)¶	34.2 (35.6)	34.2 (33.3)	34.7 (39.0)	30.4 (34.0)	29.0 (33.2)
Patients persistent on index medication for 12 months, n (%)	746 (46.4)	412 (60.7)	143 (58.1)	662 (56.8)¶	328 (63.3)	140 (59.6)
Patients with 60-day gap‡, n (%)	863 (53.6)¶	267 (39.3)	103 (41.9)	504 (43.2)	190 (36.7)	95 (40.4)
Time to switch, mean days (SD)	199.9 (78.4)‖	191.6 (79.4)§	189.7 (73.3)	193.2 (81.2)	178.9 (80.8)	179.3 (77.3)
Total time on treatment on index medication, mean days (SD)	305.0 (107.0)	325.2 (99.8)	321.4 (104.1)	318.2 (105.2)¶	323.6 (104.0)	311.4 (110.3)
Total treatment on switch medication, mean days (SD)	321.0 (97.8)	337.5 (91.5)	339.3 (92.7)	327.7 (99.3)	338.7 (92.1)	322.5 (104.1)

*May be 80 mg loading dose followed by 40 mg every other week.
†Pause in therapy of 7–59 days.
‡Gap ≥60 days in index therapy.
¶$p < 0.001$.
§$p < 0.01$.
‖$p < 0.05$.
PsO = Psoriasis; PsA = Psoriatic arthritis; PsO/PsA = Both psoriasis and psoriatic arthritis.

adalimumab; $p = 0.09$) and had other treatment changes (9.4% etanercept, 10.5% adalimumab; $p = 0.872$). The mean time for switching therapy was significantly longer in patients receiving etanercept than patients receiving adalimumab ($p = 0.006$) (Table II). Mean total time of treatment on index therapy was similar for etanercept and adalimumab (Table II).

Among patients with both psoriasis and psoriatic arthritis, 58.1% of patients on etanercept and 59.6% on adalimumab were persistent on index medication for 12 months ($p = 0.943$). The proportion of patients with both psoriasis and psoriatic arthritis with a 60-day gap was similar in patients initiating etanercept and adalimumab (41.9% etanercept, 40.4% adalimumab; $p = 0.748$) (Table II). Of patients with both psoriasis and psoriatic arthritis with a 60-day gap in therapy, fewer patients on etanercept than on adalimumab discontinued index medication (42.7% etanercept, 63.2% adalimumab; $p = 0.042$). A similar proportion of patients on etanercept and adalimumab switched therapy (21.4% etanercept, 15.8% adalimumab; $p = 0.292$), or had other treatment changes (11.7% on etanercept and 8.4% on adalimumab; $p = 0.418$). More patients who had been taking etanercept (24.3%) than adalimumab (12.6%) restarted their index therapy ($p = 0.038$). The mean time to switching index therapy was similar in patients receiving etanercept and patients receiving adalimumab ($p = 0.13$) (Table II). Mean total time of treatment on index therapy was similar for etanercept and adalimumab (Table II).

Discussion

In this retrospective analysis of claims data, patients with psoriasis, psoriatic arthritis and both psoriasis and psoriatic arthritis initiating therapy with the TNF-blockers etanercept and adalimumab, treatment modifications were common. Gaps in treatment of ≥60 days occurred in 43%–54% of patients with psoriasis, 37%–39% of patients with psoriatic arthritis and 40%–42% of patients with both psoriasis and psoriatic arthritis. Of patients with ≥60-day gap, 11%–21% switched from their index medication, 13%–26% restarted their index medication and 43%–63% discontinued their index medication. These results are consistent with the variability in psoriasis and psoriatic arthritis course of disease; patients with psoriasis and psoriatic arthritis suffer flares, and psoriasis severity can be affected by external factors such as weather and stress. The frequent gaps in therapy may therefore reflect periods of reduced disease activity. Among patients with psoriasis or psoriasis plus psoriatic arthritis who had a gap in therapy, more patients on etanercept restarted their index medication than patients on adalimumab. Of patients who switched from their index medication to another TNF-blocker, the time to switch was significantly longer for patients with psoriasis and patients with psoriatic arthritis receiving etanercept than for patients receiving adalimumab.

A previous retrospective database study of patients with psoriasis or psoriatic arthritis by Thayer et al. examined etanercept treatment patterns but did not include patients receiving adalimumab (16). Similar percentages of patients in that study and the current study initiated etanercept therapy at 50 mg weekly for patients with psoriasis (23.5% vs 25.9%, respectively), psoriatic arthritis (91.5% vs 88.1%) and both psoriasis and psoriatic arthritis (53.7% vs 65.9%). More patients in the Thayer study than the current study initiated etanercept at 100 mg weekly for patients with psoriasis (75.8% vs 56.3%, respectively) or both psoriasis and psoriatic arthritis (46.0% vs 24.8%), although rates were similar in patients with psoriatic arthritis (7.5% vs 6.0%). Rates of pauses, gaps, discontinuation, switching, or restarting were not reported in Thayer et al.

In other studies of TNF-blocker treatment patterns in US health plans, 40%–42% of patients with psoriasis (17) and 45%–50% of patients with psoriatic arthritis (18) were persistent on either etanercept or adalimumab for 1 year. In those studies, 36.6%–45.2% of patients with psoriasis and 24.8%–35.1% of patients with psoriatic arthritis discontinued their index medication. Of those who discontinued, 37.0%–39.2% of patients with psoriasis and 41.5%–46.4% of patients with psoriatic arthritis restarted their index medication, and 14.9%–19.6% of patients with psoriasis and 19.2%–20.0% of patients with psoriatic arthritis switched to another biologic. Collectively, these studies support the results of our study to show that treatment gaps and modifications are common in patients with psoriatic diseases on TNF-blockers.

A study of patients with psoriatic arthritis from the British Society of Rheumatology Biologics Register (BSRBR) reported 1-year persistence rates of 86% for patients receiving etanercept and 91% for patients receiving adalimumab (19), somewhat higher than the rates observed in the current US study (i.e., patients without a >60-day gap) of 60.7% of patients initiating etanercept and 63.3% of patients initiating adalimumab. The rates were likely higher in the BSRBR study because gaps up to 90 days were allowed.

The results of the current study may be generalizable to other patients with psoriatic diseases in US managed-care populations but may not be representative of the entire US population, Medicare patients or underinsured or uninsured patients. Limitations of this analysis are related to the nature of claims data: these databases do not accurately capture individual medical histories and comorbidities that may affect treatment decisions and do not provide reasons for discontinuation or switching. Clinical measures for assessing treatment response are not captured in claims databases. Strengths of the study included the utilization of data from real-world prescribing practices and the relatively large number of patients in the psoriasis, psoriatic arthritis and psoriasis plus psoriatic arthritis cohorts.

In summary, many patients with psoriatic diseases in a large, US managed-care system initiating etanercept and adalimumab had treatment modifications within the first year of initiating a biologic therapy, and many of them restarted or switched biologics. Treatment pattern differences were most notable in psoriasis; rates of 60-day gaps, switching and restarting index therapy were higher, and time to switch was longer for etanercept than adalimumab. Etanercept and adalimumab treatment patterns were similar for patients with psoriatic arthritis. For patients with both psoriasis and psoriatic arthritis, rates of restarting were higher and time to switching was longer for etanercept than adalimumab, and more patients on adalimumab were persistent on index medication than patients on etanercept. Time to switch was longer for etanercept than adalimumab in psoriasis and psoriatic arthritis. Further studies of treatment patterns in these patients should allow payers and formulary managers to manage biologic inventories and perform cost analyses of biologics used to treat psoriatic diseases.

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a consultant for Amgen, Inc. Crystal Watson is a former employee and holds shares in Amgen, Inc. Shravanthi R. Gandra is an employee and shareholder of Amgen, Inc.

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