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Comparative Risk of Infection and Prevalence of Combination Targeted Therapy in Psoriatic Arthritis

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IMPORTANCE Achieving good disease control in psoriatic arthritis (PsA) remains a major challenge. Combining multiple systemic immunomodulatory therapies has been shown to be beneficial in other immune-mediated diseases with reasonable safety profiles, but data on the current use and safety of combination targeted therapy among individuals with PsA are limited.

OBJECTIVE To evaluate the use and safety of combination targeted therapies among adults with PsA.

DESIGN, SETTING, AND PARTICIPANTS Data from the IBM MarketScan Commercial Claims Database from January 2015 to December 2024 were used to describe use patterns and perform safety analyses. Data were analyzed from April 2024 to June 2025. A validated claims algorithm was used to identify adults with PsA, who were separated into a standard therapy control cohort that was matched 2:1 with the combination targeted therapy cohort.

MAIN OUTCOMES AND MEASURES Descriptive analysis of the use of combination targeted therapies. The safety analysis included a comparison of frequencies of *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* codes for serious or opportunistic infections requiring an inpatient level of care. Relative risks (RRs) were calculated before and after propensity score matching.

RESULTS Among 82 399 individuals identified with PsA, 542 individuals (median [IQR] age, 52.5 [44.0-59.0] years; 341 female individuals [62.9%]) were receiving combination targeted therapy for 3 consecutive months and 200 (median [IQR] age, 55.0 [45.0-61.0] years; 114 female individuals [57.0%]) were receiving combination therapy for 6 consecutive months. The 2 most common combinations used were a tumor necrosis factor inhibitor with apremilast (34%-37%) and an interleukin 17 inhibitor with apremilast (27%-29%). The serious infection incidence rate among patients receiving combination targeted therapy ranged from 7.38 to 15.00 events per 1000 patients; the opportunistic infection incidence rate ranged from 0 to 1.85 events per 1000 patients. Patients receiving combination targeted therapy did not have a significantly increased risk of serious infection (propensity score–matched 3-month and 6-month RRs, 0.53 [95% CI, 0.17-1.63] and 1.50 [95% CI, 0.34-6.65], respectively) or opportunistic infection (adjusted 3-month and 6-month RRs, 1.00 [95% CI, 0.09-11.02] and not applicable, respectively) across all analyses.

CONCLUSIONS AND RELEVANCE The results of this cohort study suggest that among commercially insured adults with PsA, around 1% of individuals were receiving combination targeted therapy. The most common combinations used different biologics with apremilast. This study found no significant difference between the incidence of serious bacterial and opportunistic infections requiring hospitalization compared with standard therapy, suggesting that combination targeted therapy may not be associated with significantly increased infection risk, but further larger studies are needed.

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Supplemental content

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Psoriatic arthritis (PsA) is a chronic, complex inflammatory disease characterized by a wide range of clinical features and manifestations.[1,2] However, despite the variety and different mechanisms of therapies available, up to half of individuals with PsA do not achieve remission with an initial or subsequent monotherapy.[1-3]

To address this gap in treatment efficacy, combining 2 or more agents with different mechanisms in treating PsA has been suggested.[2,4] In other autoinflammatory diseases, particularly rheumatoid arthritis, combination targeted therapy (CTT) not only showed little, if at all, improved efficacy, but also significantly increased risks of serious infection, resulting in a reluctance to combine 2 targeted therapies.[5,6] However, recent studies using this approach have demonstrated promising results in other immune-mediated conditions, such as inflammatory bowel disease, with comparable safety profiles, sparking a renewed interest in combined biologic or biologic and targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs) therapy for PsA.[7]

Although the use of CTT in PsA has previously been described in the literature, to our knowledge, limited data exist regarding the clinical use.[8,9] While reports have anecdotally demonstrated improved results compared with monotherapy, some have suggested a higher rate of infectious complications, requiring a need for larger cohorts to investigate safety risk.[8-10] Thus, we aimed to characterize the prevalence of CTT and risk of infections in patients with PsA treated with CTT.

Key Points

Question In patients with psoriatic arthritis (PsA), what is the prevalence and infection risk associated with combination targeted therapy (CTT)?

Findings In this retrospective cohort study that included 542 CTT patients among 82 399 individuals identified with PsA, the most common CTT was a tumor necrosis factor–α inhibitor and apremilast. There was no significant difference in the risk of serious or opportunistic infection in patients receiving CTT compared with standard therapy.

Meaning The study results suggest that CTT has a risk of infection similar to standard therapy in adult patients with PsA, but these findings should be further confirmed by larger studies.

Methods

Cohort Selection

We used IBM MarketScan data from January 1, 2015, to December 31, 2024. The University of Texas Southwestern institutional review board approved this study. Patient consent was waived due to the use of deidentified data. This study followed Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines. We used a validated claims algorithm to identify patients older than 18 years with PsA (eFigure in Supplement 1).[11] We excluded patients who had other indications for biologic or tsDMARDs therapy or insurance discontinuation longer than 90 days. We then identified a CTT cohort, defined as patients that had 3, 4, or 6 consecutive months of overlapping medication fill data for 2 or more different classes of biologic or tsDMARDs (apremilast, deucravacitinib, and Janus kinase inhibitors), and a standard therapy cohort, defined as patients that had at least 3, 4, or 6 consecutive months of medication fill data for any PsA-related drug classes and excluding any individual in the CTT cohort. The standard therapy cohort included those receiving other combination therapy besides CTT (ie, a conventional synthetic DMARD, such as methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide with a biologic or tsDMARD).

Outcomes

Follow-up started the day of initiating consecutive months of either standard therapy or CTT, and patients were censored at the date of death, disenrollment, end of data stream, or 365 days after cohort entry, whichever came first. All events of serious bacterial infection or opportunistic infection that led to hospital admission were recorded as end points (eMethods in Supplement 1).

Statistical Analysis

To assess the association between therapy and the risk of opportunistic and serious infections, odds ratios and 95% CIs were estimated using logistic regression models, adjusting for baseline patient characteristics. Propensity score (PS) matching via logistic regression (2-to-1 nearest-neighbor without replacement) was used to balance cohorts, achieving standardized mean differences less than 0.1. Analyses were repeated for each cohort and were conducted using R (version 4.1.3; R Foundation).

Results

We identified 82 399 individuals who met the criteria for PsA (eFigure in Supplement 1). Among these, 53 025 (64.4%) had at least 3 consecutive months of medication fill data for any PsA medication, with 542 individuals (1.0%) having at least 3 consecutive months of fill data for 2 or more different targeted therapy classes (**Table 1**). The 6-month standard therapy and CTT cohort contained 39 101 patients and 200 patients, respectively. The most common class combinations were a tumor necrosis factor (TNF)-α inhibitor and apremilast (34.8%-37.3%) and an interleukin (IL)-17 inhibitor and apremilast (27.1%-28.8%) (**Table 2**). The most common dual biologic therapy was an IL-17 inhibitor and TNF-α inhibitor (0.5%-2.8%).

The risk of serious infection among individuals receiving 3, 4, and 6 months of CTT therapy was 7.38, 7.92, and 15.00 per 1000 patients, respectively (**Table 3**). Comparison of patients receiving CTT with patients receiving standard therapy found no significant differences in serious infection risk after adjusting for age, sex, therapy duration, and CCI score (3-month adjusted relative risk [RR], 0.44; 95% CI, 0.17-1.17; 4-month adjusted RR, 0.51; 95% CI, 0.17-1.58; 6-month adjusted RR, 1.02; 95% CI, 0.33-3.11). After 2-to-1 PS matching, there remained no significant differences in serious infection rates between CTT and standard therapy (3-month

Table 1. Baseline Patient Characteristics Before and After Propensity Score (PS) Matching

Characteristic	3-mo Criteria		4-mo Criteria		6-mo Criteria	
	Combination targeted therapy	Standard therapy	Combination targeted therapy	Standard therapy	Combination targeted therapy	Standard therapy
Before PS matching						
Patients, No.	542	52 483	379	47 016	200	38 901
Age, median (IQR), y	52.5 (44.0-59.0)	51.0 (43.0-58.0)	53.0 (44.0-59.0)	52.0 (43.0-58.0)	55.0 (45.0-61.0)	52.0 (43.0-59.0)
Female, No. (%)	341 (62.9)	29 155 (55.6)	234 (61.7)	25 938 (55.2)	114 (57.0)	21 269 (54.7)
Male, No. (%)	201 (37.1)	23 328 (44.4)	145 (38.3)	21 078 (44.8)	86 (43.0)	17 632 (45.3)
CCI score, median (IQR)	2.0 (1.0-4.0)	1.0 (0-2.0)	2.0 (1.0-4.0)	1.0 (0-2.0)	2.0 (1.0-4.0)	1.0 (0-3.0)
Total duration of consecutive months of therapy, median (IQR)	9.0 (6.0-15.0)	6.0 (4.0-11.0)	10.0 (7.0-18.0)	8.0 (5.0-12.0)	13.0 (9.5-21.0)	10.0 (7.0-15.0)
Serious infection events, No. (%)	4 (0.7)	685 (1.3)	3 (0.8)	564 (1.2)	3 (1.5)	460 (1.2)
Opportunistic infection events, No. (%)	1 (0.2)	79 (0.2)	0 (0)	65 (0.1)	0 (0)	48 (0.1)
After 2:1 PS matching						
Patients, No.	542	1083	379	758	200	400
Age, median (IQR), y	52.5 (44.0-59.0)	53.0 (44.0-59.0)	53.0 (44.0-59.0)	53.0 (45.0-59.0)	55.0 (45.0-61.0)	55.0 (45.0-60.0)
Female, No. (%)	341 (62.9)	683 (63.1)	234 (61.7)	473 (62.4)	114 (57.0)	228 (57.0)
Male, No. (%)	201 (37.1)	400 (36.9)	145 (38.3)	285 (37.6)	86 (43.0)	172 (43.0)
CCI score, median (IQR)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-4.0)
Total duration of consecutive months of therapy, median (IQR)	9.0 (6.0-15.0)	9.0 (6.0-15.0)	10.0 (7.0-18.0)	10.0 (7.0-18.0)	13.0 (9.5-21.0)	13.0 (9.0-21.0)
Serious infection events, No. (%)	4 (0.7)	15 (1.4)	3 (0.8)	8 (1.1)	3 (1.5)	4 (1.0)
Opportunistic infection events, No. (%)	1 (0.2)	2 (0.2)	0	0	0	0

Abbreviation: CCI, Charlson Comorbidity Index.

Table 2. Most Common Drug Classes Used in Combination Targeted Therapies

Medication class	No. (%)		
	3-mo Criteria	4-mo Criteria	6-mo Criteria
No. of unique patients	542	379	200
Total occurrences	598 (100)	414 (100)	212 (100)
TNFi and apremilast	209 (34.8)	150 (35.9)	79 (37.3)
IL-17i and apremilast	163 (27.1)	118 (28.2)	61 (28.8)
IL-23i and apremilast	88 (14.6)	73 (17.5)	39 (18.4)
JAKi and apremilast	35 (5.8)	26 (6.2)	16 (7.5)
IL-12/23i and apremilast	27 (4.5)	21 (5.0)	8 (3.8)
IL-17i and TNFi	17 (2.8)	4 (1.0)	1 (0.5)
Abatacept and apremilast	15 (2.5)	11 (2.6)	6 (2.8)
IL-17i and IL-12/23i	8 (1.3)	1 (0.2)	1 (0.5)
IL-23i and TNFi	8 (1.3)	2 (0.5)	0
IL-23i and JAKi	7 (1.2)	6 (1.4)	0
IL-17i and IL-23i	5 (0.8)	0	0
IL-12/23i and TNFi	5 (0.8)	0	0
TNFi and deucravacitinib	4 (0.7)	2 (0.5)	1 (0.5)
JAKi and TNFi	3 (0.5)	0	0
Abatacept and IL-23i	1 (0.2)	0	0
IL-17i and JAKi	1 (0.2)	0	0
Deucravacitinib and JAKi	1 (0.2)	0	0
Deucravacitinib and apremilast	1 (0.2)	0	0

Abbreviations: i, inhibitor; IL, interleukin; JAKi, JAK inhibitor; TNFi, tumor necrosis factor α inhibitor.

PS-matched RR, 0.53; 95% CI, 0.17-1.63; 4-month PS-matched RR, 0.75; 95% CI, 0.20-2.81; 6-month PS-matched RR, 1.50; 95% CI, 0.34-6.65).

The risk of opportunistic infection among patients receiving 3, 4, and 6 months of combination targeted therapy was 1.85, 0, and 0 per 1000 patients (Table 3). There were no significant differences in opportunistic infection risk after adjusting for age, sex, therapy duration, and CCI score (3-month adjusted RR, 1.02; 95% CI, 0.14-7.29; 4-month adjusted RR, not applicable; 6-month adjusted RR, not appli-

Table 3. Relative Risk of Serious and Opportunistic Infection in Patients Receiving Nonconventional Combination Therapy

PS matching	3-mo Criteria		4-mo Criteria		6-mo Criteria	
	Combination targeted therapy	Standard therapy	Combination targeted therapy	Standard therapy	Combination targeted therapy	Standard therapy
Before PS matching						
Patients, No.	542	52 483	379	47 016	200	38 901
Serious infection events, No.	4	685	3	564	3	460
Serious infection risk per 1000 patients	7.38	13.05	7.92	12.00	15.00	11.82
Risk ratio for serious infection, unadjusted (95% CI)	0.57 (0.21-1.51)	1 [Reference]	0.66 (0.21-2.04)	1 [Reference]	1.27 (0.41-3.91)	1 [Reference]
Risk ratio for serious infection, adjusted (95% CI)[a]	0.44 (0.17-1.17)	1 [Reference]	0.51 (0.17-1.58)	1 [Reference]	1.02 (0.33-3.11)	1 [Reference]
Opportunistic infection events, No.	1	79	0	65	0	48
Opportunistic infection risk per 1000 patients	1.85	1.51	0	1.38	0	1.23
Risk ratio for opportunistic infection, unadjusted (95% CI)	1.23 (0.17-8.79)	1 [Reference]	NA[b]	1 [Reference]	NA[b]	1 [Reference]
Risk ratio for opportunistic infection, adjusted (95% CI)[a]	1.02 (0.14-7.29)	1 [Reference]	NA[b]	1 [Reference]	NA[b]	1 [Reference]
After PS matching						
Patients, No.	542	1083	379	758	200	400
Serious infection events, No.	4	15	3	8	3	4
Serious infection risk per 1000 patients	7.38	13.85	7.92	10.55	15	10
Risk ratio for serious infection after PS matching (95% CI)	0.53 (0.17-1.63)	1 [Reference]	0.75 (0.20-2.81)	1 [Reference]	1.50 (0.34-6.65)	1 [Reference]
Opportunistic infection events, No.	1	2	0	0	0	0
Opportunistic infection risk per 1000 patients	1.85	1.85	0	0	0	0
Risk ratio for opportunistic infection after PS matching (95% CI)	1.00 (0.09-11.02)	1 [Reference]	NA[b]	1 [Reference]	NA[b]	1 [Reference]

Abbreviation: PS, propensity score.

[a] Adjusted for age, sex, therapy duration, and Charlson Comorbidity Index score.

[b] Model does not converge.

cable). After 2-to-1 PS matching, there remained no significant differences in opportunistic infection risk between CTT and standard therapy (3-month PS-matched RR, 1.00; 95% CI, 0.09-11.02; 4-month PS-matched RR, not applicable; 6-month PS-matched RR, not applicable).

Discussion

In this cohort study among commercially insured adults with a diagnosis of PsA, a small proportion of patients receiving treatment were treated with CTT, and even fewer individuals received dual biologic therapy. Most combinations used different classes of biologics with apremilast, with the frequency of biologic use following market prevalence.

Fewer patients were receiving 2 or more targeted agents for longer periods. This may be associated with physician hesitancy in combining 2 or more targeted therapies for extended periods, that payers are reluctant to allow continued CTT, or that there may have been possible increased adverse effects. Alternatively, disease activity may have declined with the use of an additional immunosuppressive agent, which was discontinued once better control was achieved.

This study demonstrated no significantly increased risk of serious or opportunistic infection in adults treated with CTT compared with standard therapy. Our findings on safety corroborated those of other reports and trials studying apremilast use in combination with other biologics in psoriasis or PsA.[12-14] Overall rates of serious and opportunistic infections were low in both cohorts. Clinical evidence establishing the use and safety of these therapy combinations is crucial and clinically relevant, particularly in the context of increasing use, including the AFFINITY study (combination guselkumab [IL-23 inhibitor]) and golimumab (TNF inhibitor) therapy in PsA (NCT05071664).[15] Our study examined 542 patients, to our knowledge the largest sample to date, and adds to the current use and safety knowledge of CTT.

Limitations

Our study had several limitations. While our sample size was larger than that of similar studies, the CTT cohort sizes were still small, and the number of adverse events were low. Most of the CTT included apremilast; thus, the findings are most relevant for combinations that include apremilast. Additionally, we did not assess combination therapy with other immunosuppressive agents, such as corticosteroids. Confounding by indication and challenging bias may have influenced our findings. MarketScan also contains limited clinical information, and medications not covered or purchased without insurance may not be captured.

Conclusions

This population-based, PS-adjusted cohort study represents a descriptive and comparative safety evaluation of CTT in adult patients with PsA. CTT most commonly included a biologic therapy and apremilast and had a similar infection risk as standard therapy. Further studies are needed to confirm our findings in larger populations and more diverse therapy combinations.

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