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Baricitinib-Related Adverse Events in Alopecia Areata and Rheumatoid Arthritis: A Comparative Study

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INTRODUCTION

In 2021, the United States Food and Drug Administration (FDA) updated the boxed warnings for three JAK inhibitors (JAKi) following results from a post-marketing safety study of tofacitinib rheumatoid arthritis (RA) patients, which revealed increased risks of adverse events of special interest (AESIs) such as major adverse cardiovascular events (MACE) and malignancies.[1,2] Baricitinib, one of the JAKis subject to the revised warning, was approved in 2022 for the treatment of alopecia areata (AA), a condition that typically affects a younger and healthier population. Given that the revised warnings were based on data from an RA cohort, there is a need for a comparative study discerning risks for AESIs between the two groups.[3]

MATERIALS AND METHODS

This retrospective cohort study utilized TriNetX, a global health research network of de-identified electronic health record data, to identify patients with a diagnosis of AA (ICD-10 L63) or RA (ICD-10 M05.9, M06) who were prescribed baricitinib between March 2006 and March 2025. Demographic and clinical characteristics were first evaluated in unmatched cohorts, then age-sex-race matching was performed to assess differences in AESI outcomes.

RESULTS

The RA cohort was older (mean age 60 vs 37.9 years), had a higher proportion of females (75.7% vs 65.4%), and exhibited a greater prevalence of comorbidities, including hypertension,

TABLE 1.

Clinical Characteristics of Alopecia Areata (AA) and Rheumatoid Arthritis (RA) Patients on Baricitinib

Characteristics	RA n=3073	AA n=1565	*P*-value*
Age, mean (SD)	60.15 +/- 14.2	37.79 +/- 16.7	<0.0001
Sex, no (%)			
Female	2327 (75.7)	1024 (65.4)	<0.0001
Male	709 (23.1)	527 (33.7)	<0.0001
Unknown	37 (1.2)	14 (0.9)	0.360
Race, no (%)			
White	1759 (57.2)	893 (57.1)	0.907
Black or African American	238 (7.8)	213 (13.6)	<0.0001
Asian	201 (6.5)	129 (8.2)	0.037
Other/unknown race	90 (2.9)	100 (6.4)	<0.0001
Comorbidities, no (%)			
Essential hypertension	1344 (43.7)	197 (12.6)	<0.0001
Overweight and obesity	773 (25.2)	178 (11.4)	<0.0001
Type 2 diabetes mellitus	625 (20.3)	64 (4.1)	<0.0001
Tobacco use	128 (4.2)	20 (1.3)	<0.0001
Nicotine dependence	422 (13.7)	77 (4.9)	<0.0001
Concomitant immunomodulating medications, no (%)			
Prednisone	1432 (46.6)	479 (30.6)	<0.0001
Methotrexate	1153 (37.5)	194 (12.4)	<0.0001
Hydroxychloroquine	921 (30)	95 (6.1)	<0.0001
Other (Cyclosporine, Azathioprine, Mycophenolate Mofetil)	389 (12.7)	134 (8.6)	<0.0001
Rituximab	256 (8.3)	10[A] (0.64)[A]	<0.0001

AA, Alopecia areata; RA, Rheumatoid arthritis; SD, Standard Deviation [A]The value is between 1 and 10, listed as 10 for patient privacy.
*: *P*-values were adjusted for multiple comparisons using the Benjamini-Hochberg False Discovery Rate (FDR) correction.

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TABLE 2.

Adverse Events of Special Interest (AESI) Following Baricitinib Initiation in Patients with Alopecia Areata (AA) and Rheumatoid Arthritis (RA) Cohorts Matched by Age, Sex, and Race With *P*-values

Adverse event of special interest (AESI)[D]	RA, no (%)	AA, no (%)	Odds Ratio (RA/AA)	*P*-value*
Infections				
Infections (general)	136 (28.6)	60 (10.9)	3.29	<0.0001
Urinary tract infection	64 (8.3)	10 (1.2)[C]	7.41	<0.0001
Rare opportunistic infection[A]	59 (7.8)	17 (2.1)	3.94	<0.0001
Upper respiratory tract infection	58 (7.5)	17 (2.2)	3.67	<0.0001
Cardiovascular				
Hypertension	89 (15.1)	19 (2.6)	6.74	<0.0001
Other cardiovascular disorders[B]	87 (12.8)	16 (2.0)	7.07	<0.0001
Acute myocardial infarction	13 (1.5)	10 (1.1)[C]	1.34	0.541
Cerebral infarction	18 (2.0)	10 (1.1)[C]	1.85	0.142
Thromboembolic events	23 (2.7)	10 (1.1)[C]	2.43	0.027
Malignancies				
Non-lymphoma/non-hematologic	86 (12.4)	50 (8.7)	1.5	0.043
Lymphomas/hematologic	10 (1.1)[C]	10 (1.1)[C]	1.01	0.986

RA, Rheumatoid arthritis
[A]Candidiasis, CMV, HSV, Pneumocystosis, TB, Zoster, Histoplasmosis, Cryptococcosis. [B]Includes rheumatic heart diseases, non-myocardial infarction ischemic heart diseases, pulmonary heart disease, diseases of arteries/arterioles/capillaries, other and unspecified disorders of the circulatory system. [C]The value is between 1 and 10, listed as 10 for patient privacy. [D]Patients that were diagnosed with these outcomes prior to the initiation of baricitinib were excluded from the analysis. *: *P*-values were adjusted for multiple comparisons using the Benjamini-Hochberg False Discovery Rate (FDR) correction.

obesity, and type 2 diabetes mellitus, compared to the AA cohort. They were also more likely to have received concomitant immunosuppressive therapies prior to baricitinib initiation (Table 1). The AA cohort included higher proportions of Black (13.6% vs 7.8%) and Asian patients (8.2% vs 6.5%).

Matched outcome analysis showed no statistically significant differences in rates of cerebral infarction, acute myocardial infarction, or lymphomas/hematologic malignancies. However, RA patients showed significantly higher odds of urinary tract infections (OR=7.41), other cardiovascular disorders (OR=7.07), hypertension (OR=6.74), rare opportunistic infections (OR=3.94), upper respiratory tract infections (OR=3.67), general infections (OR=3.29), thromboembolic events (OR=2.43), and non-lymphoma/non-hematologic malignancies (OR=1.5) (Table 2).

DISCUSSION

These findings indicate that while baricitinib is associated with higher AESI risk in RA patients, AA patients may have a more favorable safety profile due to fewer baseline comorbidities and less concomitant immunosuppression.[4,5] Nevertheless, the boxed warning remains relevant for both populations, as certain AESIs, including infections, thromboembolic events, and malignancies, though less frequent in AA, were still observed. Given the expanding use of JAKis in dermatology, ongoing pharmacovigilance and tailored risk-benefit assessments are essential, particularly in younger AA patients where long-term safety data are limited. Study limitations include a short follow-up duration, a relatively small sample size limiting multivariate adjustments, and potential dosing variability (2 mg for RA, 2–4 mg for AA). Larger, longer-term studies are needed to validate these findings and improve patient management.

DISCLOSURES

The authors have no conflict of interest to declare.

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