An Evaluation of Real-World Use of Biologics in Rare Systemic Vasculitides During Routine Clinical Care in the US

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Background

The treatment for vasculitis has typically been corticosteroids and other cytotoxic and immunosuppressive medications to achieve and maintain remission. Novel treatments for giant cell arteritis and some forms of polyangiitis have recently become available, however unmet need remains.

Objective

The purpose of this study is to explore the real-world use of biologic agents with different mechanisms of action in patients with Behçet's Disease (BD), Takayasu Arteritis (TA), and other rare systemic vasculitides, despite a paucity of regulatory-approved options.

Methods

The OM1 Real World Data Cloud (OM1, Boston, MA) including over 250M US patients was used to identify patients with rare vasculitides using certain DMARDs from 2013 to 2020 and who did not also have an FDA-approved indication for use (e.g., rheumatoid arthritis, psoriasis)

Results

- For patients with BD, anti-TNFs were the most commonly used (4.4%) followed by rituximab. Anti-TNF and anti-IL-6 use was noted in 4.0% and 1.8% of TA patients, respectively; rituximab use was less common (Table 1). Other bDMARDs evaluated were rare.
- In BD, a higher proportion of patients treated with TNFa inhibitors were younger (age <45, 65% vs. 44%) and male (34% vs. 25%) and were more likely to also have been treated with glucocorticoids, azathioprine, cyclosporine and cyclophosphamide (data on file).
- In GPA/EGPA patients treated with biologics (rituximab and/or mepolizumab), a higher proportion of patients were < 65 years old compared to those not treated with biologics (70% versus 60%, respectively). Glomerulonephritis was more often recorded In patients treated with biologics (25% vs.19%) (data on file).

Conclusion

Use of bDMARDs (including off-label use) is common in some rare vasculitides, with rituximab, mepolizumab and anti-TNF alpha medications being used most often. Older patients appear less likely to be treated with a bDMARD. Harnessing these real world experiences may help inform clinical practice, including decisions to switch therapies, and clinical trial design.

Table 1. Distribution of Select Treatments in Rare Vasculitides

	GPA N= 24,839	BD N= 11,976	PAN N= 6297	MC N= 4195	TA N= 3465	MPA N= 3433	EGPA N= 3402
Age (years), n							
<18	421	681	320	10	305	122	27
≥ 18 to < 45	4,816	5,862	1,265	402	1,224	419	653
≥ 45 to < 65	10,102	4,242	2,540	2,035	1,282	1,167	1,544
≥ 65	9,500	1,191	2,172	1,748	654	1,725	1,178
% Female	**55.2%**	**75.1%**	**61.1%**	**58.9%**	**81.3%**	**65.6%**	**59.2%**
Treatment, n (%)							
Rituximab	4,958* (20.0%)	97 (0.8%)	775 (12.3%)	449 (10.7%)	38 (1.1%)	1,072 (31.2%)*	308 (9.1%)
Mepolizumab	25 (0.1%)	4	5	3	0	3	365* (10.7%)
Anti-TNF	47 (0.2%)	532 (4.4%)	29 (0.5%)	6 (0.01%)	140 (4.0%)	5 (0.1%)	3
Anti-IL-6	3	9	6	0	64 (1.8%)	3	0
Anti-IL-17	2	0	0	0	0	0	0
Anti-IL-12/23	4	8	0	1	0	0	0
Abatacept	5	3	3	0	0	0	0

Note: Values without percentages are < 0.1%.

Abbreviations: granulomatosis with polyangiitis (GPA), Behcets disease (BD), polyarteritis nodosa (PAN), mixed cryoglobulinemia (MC), Takayasu arteritis (TA), microscopic polyangiitis (MPA), eosinophilic granulomatosis with polyangiitis (EGPA)

*At the time of this analysis, rituximab was indicated for adult patients with MPA and GPA forms of vasculitis only and mepolizumab was indicated for adult patients with EGPA

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