Treatment Patterns in Large Vessel Arteritis (Giant Cell Arteritis and Temporal Arteritis): Findings from a Large Contemporaneous Real-World Cohort in the US

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Background

Giant cell arteritis (GCA) is the most common form of primary systemic vasculitis with annual incidence as high as 27 per 100,000 in persons over the age of 50 years. Key issues in management after a diagnosis of GCA include prompt initiation of therapy, prevention and treatment of adverse effects related to treatment, and close monitoring for disease flares. Glucocorticoids are the mainstay of therapy and are used for induction and maintenance of remission. However, there is little consensus on the optimal treatment strategies for GCA. We present treatment patterns in a large real-world population of patients with GCA managed by rheumatologists across the US.

Methods

The OM1 platform collects, links, and leverages, structured and unstructured data from electronic medical records (EMR) and other sources in an ongoing and continuously updating manner to create a next generation registry-a novel approach to real world evidence. The OM1 GCA Cohort includes data who met our definition of at least two GCA related diagnosis codes [ICD-10: M31.6, M31.5, M31.4; ICD-9:446.7, 446.5] within a 1 year period, treated by rheumatologists.

Patients characteristics, including demographics, comorbidities and medication exposures are based on all data after GCA diagnosis dates. Baseline diagnosis test is the first available test after GCA diagnosis date. The changes in diagnosis tests are the differences between the first two test results that are at least 30 days apart during the study period.

Results

The cohort included 1,567 patients with a mean age of 73±10 years, three quarters were Caucasian (78%) and female (76%). Median follow up time was 24 months with a median of 7 rheumatology ambulatory encounters [Table 1]. Nearly a third of the cohort had a concomitant diagnosis of polymyalgia rheumatica (33%) and 60% had rheumatoid arthritis. Only 6% of patients had a documented temporal artery biopsy [Figure 1]. About half of the patients had at least one erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) measurement. Median ESR at baseline was 21mm/hr (Q1, Q3: 8, 48) and median (Q1, Q3) CRP was 1mg/L (0.3, 4.0). The majority of patients received glucocorticoids (85%), 22% were treated with methotrexate, 8% with hydroxychloroquine, 5% with aspirin, 5% with tocilizumab and 3.5% with azathioprine [Figure 2]; 14% were treated with more than one drug concurrently. Patient reported pain scores were available in 26% of the patients with a median duration of 6 months between first and last assessment. Changes in ESR, CRP, pain and global scores are not statistically different (P>0.05) among patients treated with the 3 most common medications [Figure 3].

Figure 1. % of patients with comorbid conditions

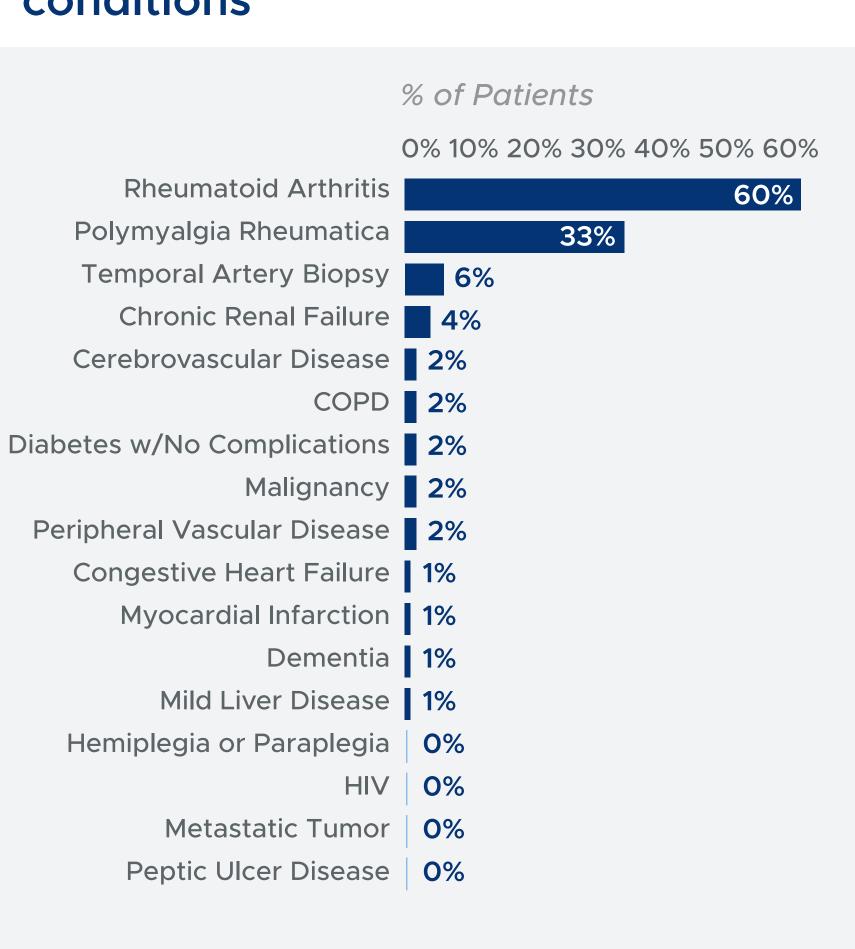


Figure 2. Treatment exposure for GCA

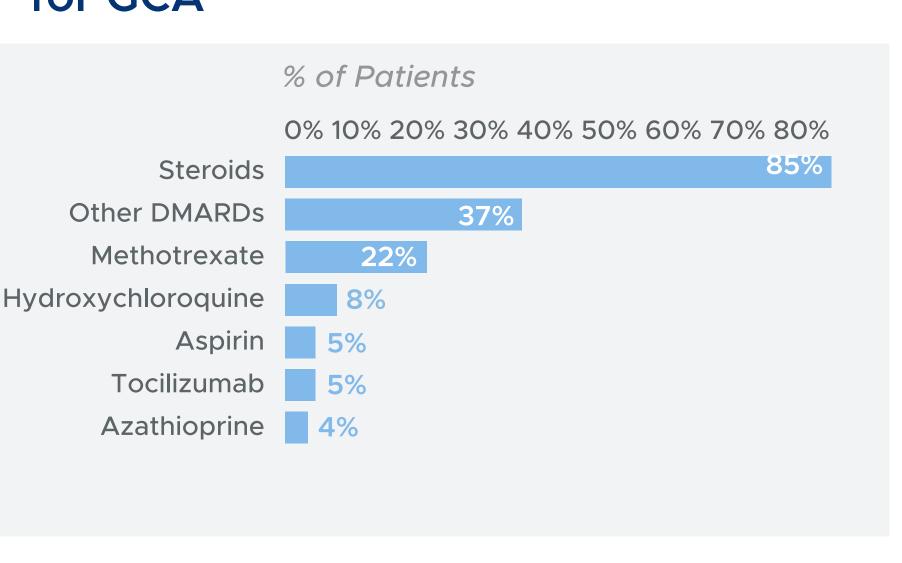


Table 1. Patient Characteristics

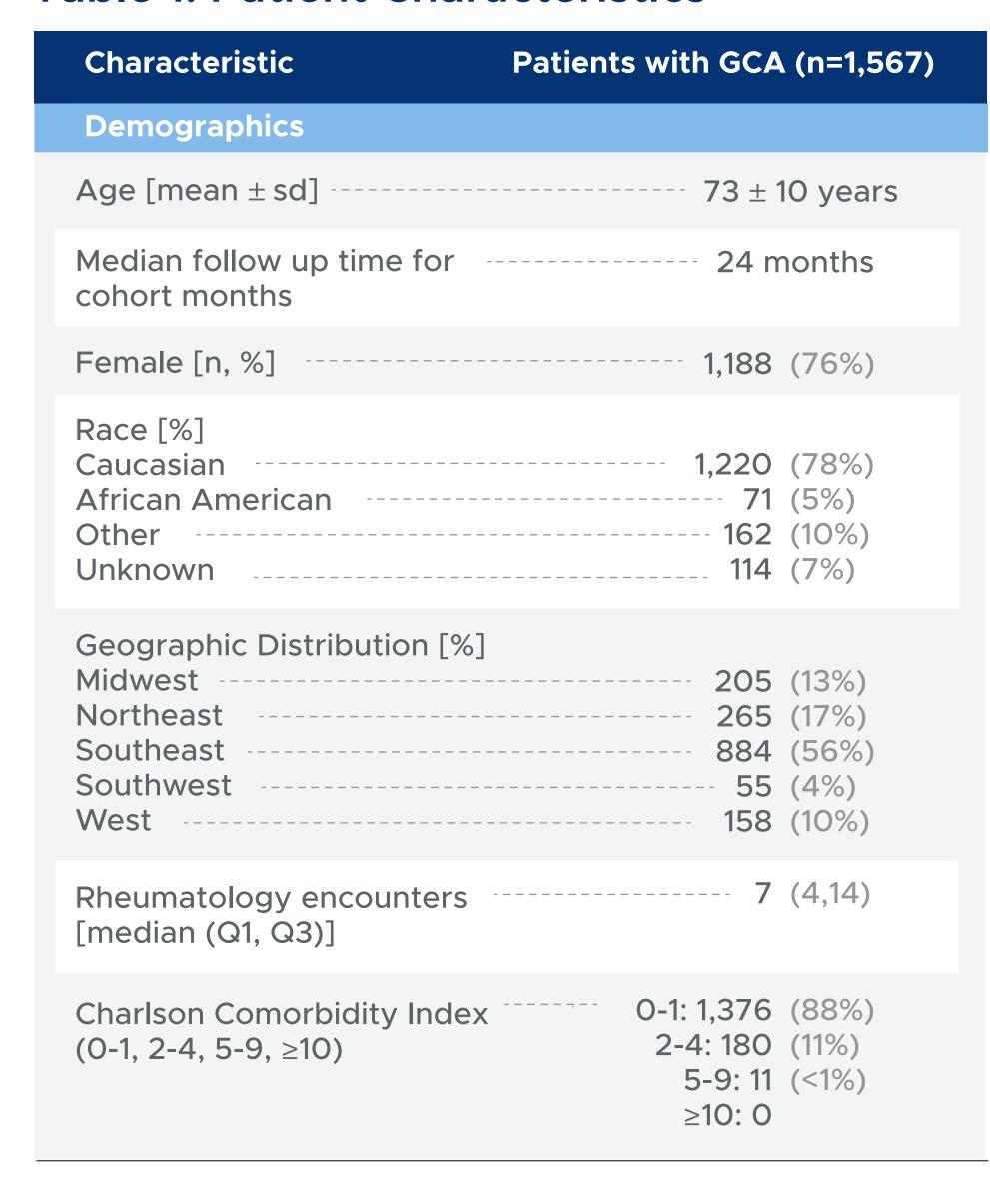
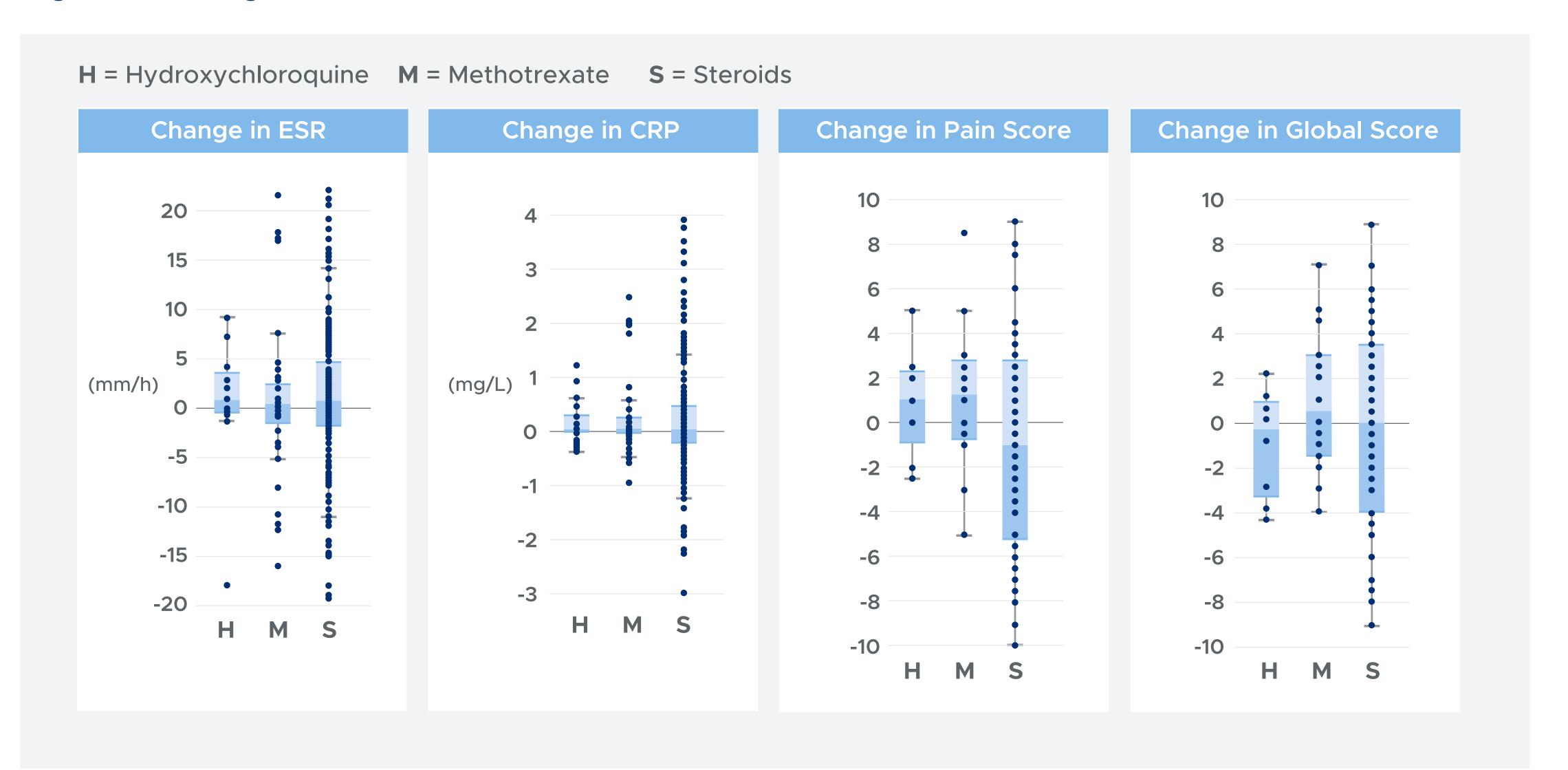


Table 2. Disease Activity Markers

Characteristic	Patients with GCA (n=1,567)
Disease Activity	
ESR (mm/h): % of patients with 1 measurement2+ measurements	
ESR at baseline median(Q1-Q3)	21 (8, 48)
Change in ESR (mm/h): Median(Q1-C	Q3) 0.5 (-1.4, 3.7)
Median (Q1-Q3) time in days between ESR labs 50 (30, 91)	
CRP (mg/L): % of patients with 1 measurement 2+ measurements	629 (40%) 548 (35%)
CRP at baseline median (Q1-Q3) (mg	g/L) 1 (0.3, 4)
Change in CRP (mg/L): Median (Q1-0	Q3) ····· 0 (-0.1, 0.2)
Median (Q1-Q3) time in days between	en CRP labs 49 (30, 91)
% of patients with a least one Patier Global Score	nt Reported 407 (26%)
Baseline Global Score: Median (Q1-G	23) 3 (1, 6)
Change in Global Score: Median (Q1	-Q3) 0 (-1.5, 1.5)
% of patients with a least one Patier Pain Score	nt Reported 400 (26%)
Baseline Pain Score: Median (Q1-Q3)	3 (0.5, 6)
Change in Pain Score: Median (Q1-Q	3) 0 (-1.0, 1.0)

Figure 3. Changes in ESR, CRP, Pain Score, and Global Score



Conclusions

We present findings from a large, representative, cohort of real-world patients seen in routine clinical practice.

There are wide variations in patient profile and treatment practices and glucocorticoids remain the most common treatment with a minority of patients receiving steroid sparing agents. This may reflect the lack of clarity around value of additional steroid-sparing agents to avoid the common glucocorticoid adverse effects and to reduce time to remission.

Disease activity measures were not routinely performed and only half of the patients had at least one inflammatory marker measurement and less than a quarter had an assessment of pain. Given the potential side effects of commonly used medications, functional assessments of symptom improvement may be a useful and critical tool to evaluate effectiveness of therapy and guide clinical decision-making.