Clinical Characteristics of Flares of Giant Cell Arteritis: Two-Year Outcomes From the SELECT-GCA Phase 3 Trial

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OBJECTIVE

- To characterize flares among patients in the phase 3 SELECT-GCA trial with giant cell arteritis who achieved sustained remission from weeks 28 to 52 in period 1 (double-blind treatment period) with upadacitinib 15 mg and who experienced a flare after either continuing with upadacitinib or switching to placebo in period 2 (52-week re-randomized blinded extension)

INTRODUCTION

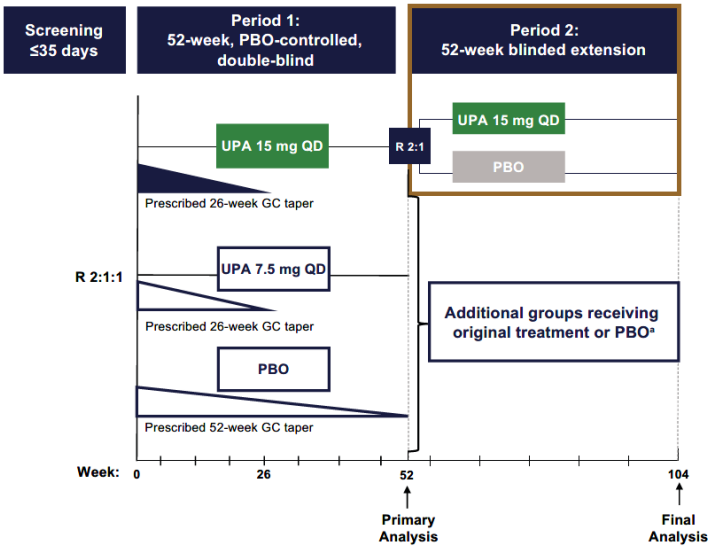
- Giant cell arteritis (GCA) is a vasculitis that most commonly affects the medium-to-large blood vessels of the head and neck among patients aged >50 years[1-3]
- Symptoms of GCA are variable and can include headache, vision loss (permanent or temporary), jaw or limb claudication, scalp tenderness, fever, polymyalgia rheumatica (PMR), and fatigue[1-3]
- Despite treatment with glucocorticoids (GCs), the occurrence of GCA flares after a period of remission is common[1]
- Upadacitinib (UPA) is an oral, selective Janus kinase inhibitor that is approved for the treatment of GCA[4,5]
- In the phase 3 SELECT-GCA trial (NCT03725202), treatment with UPA 15 mg for 52 weeks with a GC taper for 26 weeks showed superior efficacy compared with placebo (PBO) with a 52-week GC taper in outcomes related to remission, flare timing and number, and cumulative GC exposure[6]

METHODS

STUDY DESIGN AND PARTICIPANTS

- SELECT-GCA was a 2-period, multicenter, phase 3, randomized, double-blind, PBO-controlled trial **(Figure 1)**
  - Patients were aged ≥50 years and had active new-onset or relapsing GCA
  - Patients had received ≥40 mg/day prednisone before baseline and ≥20 mg/day at baseline
  - Period 1: patients were randomized 2:1:1 to UPA 15 mg or 7.5 mg daily plus a 26-week GC taper, or PBO plus a 52-week GC taper
  - Period 2: patients who achieved sustained remission for ≥24 consecutive weeks (weeks 28-52) with UPA in period 1 were re-randomized 2:1 to continue treatment with the same dose of UPA or switch to PBO; those treated with PBO who achieved sustained remission continued PBO
- Patients were not receiving GC treatment when entering period 2
- Sustained remission was defined as the absence of signs and symptoms of GCA and adherence to the GC taper regimen from weeks 28 to 52 in period 1
- This analysis focused on patients who received treatment with UPA 15 mg in period 1 and who experienced a flare in period 2

FIGURE 1. STUDY DESIGN



GC, glucocorticoid; PBO, placebo; R, randomization; UPA, upadacitinib.
[a]Not included in this analysis

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METHODS (continued)

ASSESSMENTS AND ANALYSIS

- The presence of flares and associated characteristics were monitored throughout period 2
- Patients were considered to have a flare during period 2 if they met the criteria listed in **Box 1**

BOX 1. Flare Definition

1. An event determined by the investigator to represent recurrence of signs or symptoms of GCA **OR** an ESR measurement >30 mm/hour attributable to GCA by investigator discretion
   AND
2. Associated with an increased dose of GC

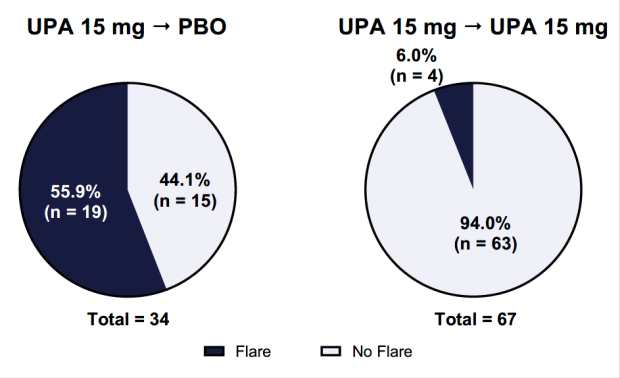
- Severe flares were defined as the presence of ≥1 of the following:
  - Initial GC dose used to treat the flare: >20 mg prednisone equivalent
  - Signs or symptoms of visual abnormalities
  - New or worsened extremity claudication
  - Jaw claudication
- These analyses were not powered for inferential statistics due to the small number of patients; results are descriptive only

RESULTS

PATIENTS

- During period 2, 4/67 patients (6.0%) experienced a flare when continuing treatment with UPA 15 mg, compared with 19/34 patients (55.9%) who switched to PBO **(Figure 2)**
- Demographics and clinical characteristics at the beginning of period 1 for those experiencing any flares in period 2 are reported in **Table 1**

Figure 2. Proportion of Patients Entering Period 2 Who Experienced a Flare of GCA



GCA, giant cell arteritis; PBO, placebo; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.

FLARE CHARACTERISTICS

- A majority of patients with flares in period 2 experienced both recurrence of signs and symptoms of GCA and ESR elevation (>30 mm/hr; **Figure 3**)
- None of the patients who were continuing treatment with UPA 15 mg had >1 flare during period 2, while 3 of the patients who switched to PBO had multiple flares **(Figure 4)**
- The proportion of severe flares was lower among patients who continued treatment with UPA 15 mg than for patients who switched to PBO **(Figure 4)**

Table 1. Baseline (Period 1 Entry) Demographics and Disease Characteristics of Patients Who Achieved Remission of GCA During Period 1 and Experienced a Flare in Period 2

Characteristic	UPA 15 mg + 26-week GC taper → PBO (n=19)	UPA 15 mg + 26-week GC taper → UPA 15 mg (n=4)
Age (years)		
Mean (SD)	70.7 (8.2)	76.3 (3.9)
Median (min, max)	73.0 (56.0, 82.0)	76.5 (72.0, 80.0)
Female, n (%)	14 (73.7)	2 (50.0)
BMI (kg/m^2)		
Mean (SD)	24.0 (3.7)	26.5 (6.1)
Median (min, max)	23.8 (18.1, 30.6)	25.1 (20.8, 34.8)
Prior use of IL-6 inhibitor, n (%)	4 (21.1)	0
Baseline disease status, n (%)		
New onset	11 (57.9)	3 (75.0)
Relapsing	8 (42.1)	1 (25.0)
Baseline GC dose (mg)		
Mean (SD)	31.6 (14.3)	37.5 (17.1)
Median (min, max)	30.0 (20.0, 60.0)	35.0 (20.0, 60.0)
Disease duration since diagnosis (years)		
Mean (SD)	1.2 (1.9)	1.6 (3.0)
Median (min, max)	0.1 (0.1, 7.3)	0.1 (0.1, 6.0)
CRP (mg/dL)		
Mean (SD)	0.3 (0.4)	0.2 (0.2)
Median (min, max)	0.2 (0.02, 1.6)	0.1 (0.1, 0.5)
ESR (mm/hr)		
Mean (SD)	16.1 (11.0)	13.8 (9.2)
Median (min, max)	15.0 (2.0, 40.0)	14.0 (3.0, 24.0)
Ischemia-related vision loss, n (%)	1 (5.3)	0
History of PMR, n (%)	9 (47.4)	2 (50.0)
History of cranial symptoms, n (%)	18 (94.7)	4 (100)
History of TAB revealing features of GCA, n (%)	10 (52.6)	2 (50.0)
Evidence of vasculitis by imaging, n (%)	15 (78.9)	2 (50.0)

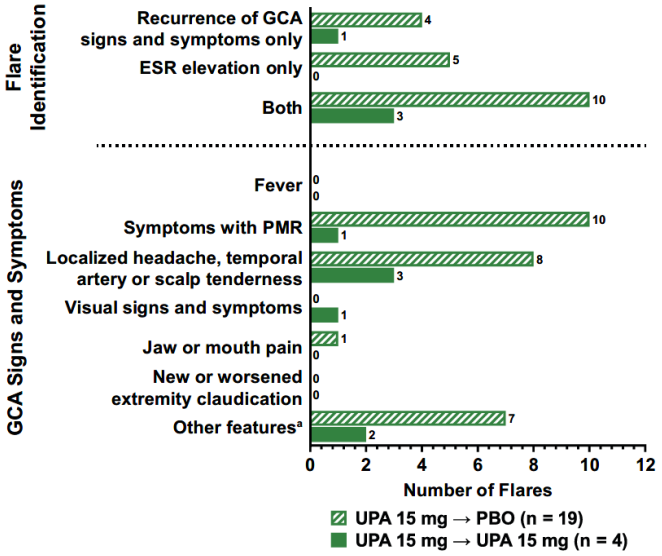
BMI, body mass index; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; GC, glucocorticoid; GCA, giant cell arteritis; IL-6, interleukin 6; PBO, placebo; PMR, polymyalgia rheumatica; TAB, temporal artery biopsy; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.

RESULTS (continued)

FLARE CHARACTERISTICS (continued)

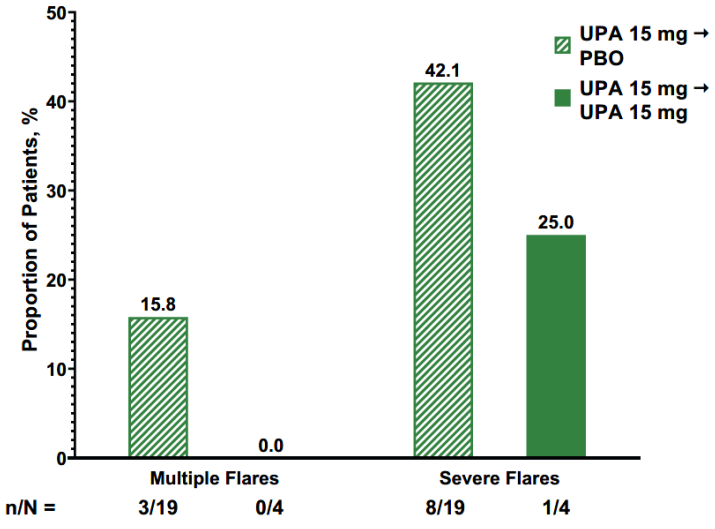
- The initial dose of GC used to treat the first flare was lower for patients who continued treatment with UPA 15 mg than for patients who switched to PBO **(Figure 5)**
- From period 2 entry until the first flare, levels of CRP and ESR increased for both treatment groups **(Figure 6)**

Figure 3. Characteristics of Flares Among Patients Who Achieved Remission of GCA During Period 1 and Experienced a Flare in Period 2



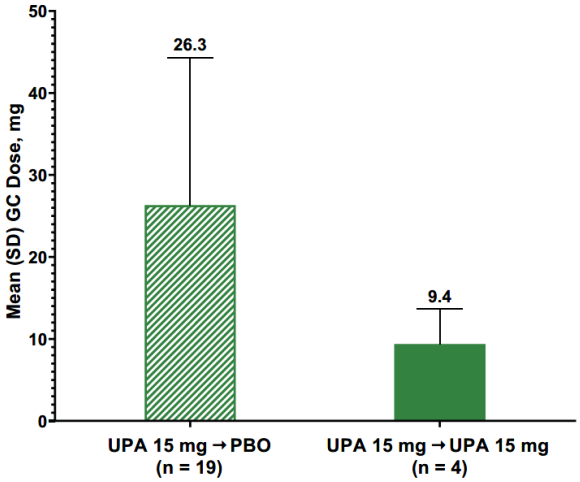
ESR, erythrocyte sedimentation rate; GCA, giant cell arteritis; PBO, placebo; PMR, polymyalgia rheumatica; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.
[a]Other features were determined by the investigator and included elevated markers of inflammation, characteristic imaging findings, and nonspecific.

Figure 4. Multiple Flares and Severe Flares in Period 2 Among Patients Who Achieved Remission of GCA During Period 1 and Experienced a Flare in Period 2



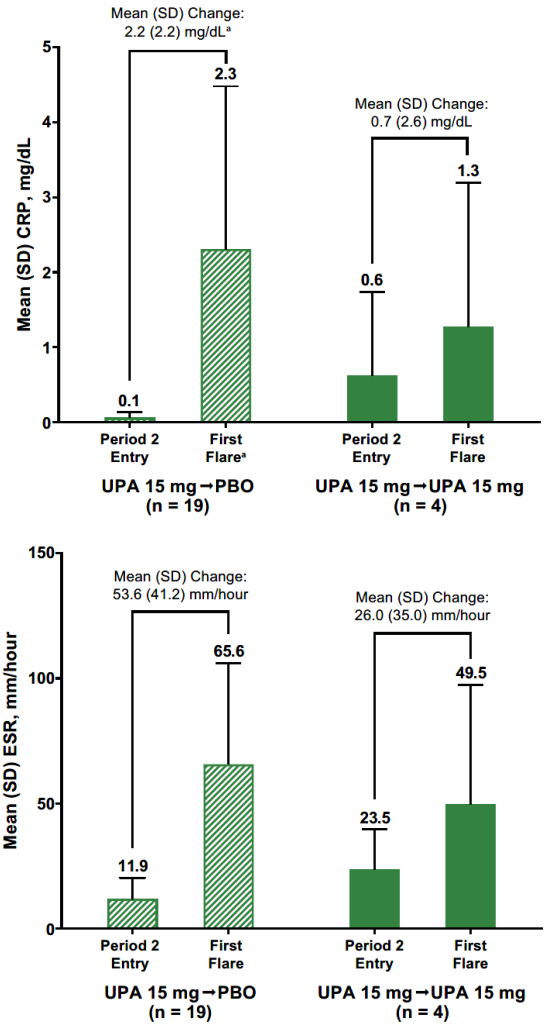
GCA, giant cell arteritis; PBO, placebo; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.

Figure 5. Initial GC Dose Used to Treat Flares in Period 2 Among Patients Who Achieved Remission of GCA During Period 1 and Experienced a Flare in Period 2



GC, glucocorticoid; GCA, giant cell arteritis; PBO, placebo; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.

Figure 6. Change in CRP and ESR Levels From the Period 2 Entry to First Flare Among Patients Who Achieved Remission of GCA During Period 1 and Experienced a Flare in Period 2



CRP, C-reative protein; ESR, erythrocyte sedimentation rate; GCA, giant cell arteritis; PBO, placebo; UPA, upadacitinib; UPA 15 mg → PBO, randomized to UPA 15 mg in study period 1 and switched to PBO in period 2; UPA 15 mg → UPA 15 mg, randomized to UPA 15 mg in study period 1 and continued UPA 15 mg in period 2.
[a]n=14

LIMITATIONS

- The number of participants experiencing flares in period 2 was small, particularly for patients continuing treatment with UPA, resulting in the potential for bias and limiting the generalizability of the results

CONCLUSIONS

- Patients with giant cell arteritis who continued treatment with upadacitinib 15 mg for up to 2 years had fewer flares than those who switched from upadacitinib to placebo after 1 year
- Of patients who experienced a flare in period 2, those who continued treatment with upadacitinib had fewer subsequent flares, fewer severe flares, and required lower initial glucocorticoid doses to treat flares compared with those who switched to placebo
  - A majority of flares in both groups were identified by recurrence of signs and symptoms of giant cell arteritis and elevation of erythrocyte sedimentation rate
- Erythrocyte sedimentation rate and C-reactive protein levels increased in both groups at the time of flare, although there was a smaller difference between biomarker levels from the entry of period 2 to the first flare among patients who continued treatment with upadacitinib vs those who switched to placebo
- Upadacitinib 15 mg demonstrated long-term benefits for reducing the incidence and severity of flares in patients with giant cell arteritis

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