Table 1. Adverse Events During the 12-Month Post-Index Period, Stratified by OGC Daily Dose

	Dose Q1 ≥ 1.00 to < 13.75 mg N = 184	Dose Q2 ≥ 13.75 to < 25.00 mg N = 184	Dose Q3 ≥ 25.00 to < 40.00 mg N = 198	Dose Q4 ≥ 40 mg N = 161
Patients without type 2 diabetes and without HbA1c ≥ 7.5 in the pre-index period, n	120	136	130	110
With type 2 diabetes diagnosis or HbA1c ≥ 7.5 in the post-index period, n (%)	9 (7.5)	16 (11.8)	16 (12.3)	27 (24.5)
Maximum HbA1c value across HbA1c lab results during post-index, mean (SD)	7.75 (2.46)	8.30 (2.86)	8.25 (2.42)	8.61 (3.09)
Patients with diabetes diagnosis in the pre-index period but without HbA1c ≥ 7.5 in the post-index period, n	31	18	40	15
With worsening diabetes with HbA1c ≥ 7.5 in the post-index period, n (%)	10 (32.3)	6 (33.3)	20 (50.0)	4 (26.7)
Patients without blood glucose level ≥ 200mg/dL in the pre-index period, n	173	169	179	147
With blood glucose level ≥ 200mg/dL in the post-index period, n (%)	13 (7.5)	15 (8.9)	24 (13.4)	22 (15.0)
Adverse events in the post-index period, n (%)				
Serious infection requiring hospitalization for infection and/or IV antibiotics	31 (16.8)	39 (21.2)	44 (22.2)	40 (24.8)
Serious infection requiring IV antibiotics	29 (15.8)	33 (17.9)	42 (21.2)	35 (21.7)
Serious infection requiring hospitalization for infection	6 (3.3)	12 (6.5)	12 (6.1)	8 (5.0)
Cataracts	22 (12.0)	27 (14.7)	34 (17.2)	35 (21.7)
Gastrointestinal bleeding or ulcer	11 (6.0)	11 (6.0)	13 (6.6)	19 (11.8)
Patients with BMI in pre- and post-index, n	171	162	181	141
Increase in BMI by 5, n (%)	7 (4.1)	5 (3.1)	9 (5.0)	9 (6.4)

BMI, body mass index; HbA1c, hemoglobin A1c; IV, intravenous; Q, quantile.

FRI0273 SURVEYING PATIENTS WITH TAKAYASU ARTERITIS WITH A DELAYED DIAGNOSIS

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Background: Takayasu arteritis (TA) is a well known, but rarely identified variety of large vessel vasculitis. Frequency of initial misdiagnosing in TA patients has been reported to reach 80%. Up to 80% of TA cases are correctly diagnosed only 2 to 11 years after the symptoms presentation. Objectives: to study possible reasons for misdiagnosing in TA patients with a delayed diagnosis.

Methods: cross-sectional survey included 30 TA patients. All subjects met ACR criteria for TA and more than 12 months since the onset of the clinical manifestations delayed diagnosis. The subjects were asked to recall if vessels auscultation (VA), measurement of both arms and legs blood pressure (BP), assessment of BP and pulse asymmetry (PA) were performed during their first physician visit following the symptoms onset.

Results: 19 (67%) patients reported no VA during the initial examination, only 3 (10%) subjects confirmed the test performed, 5 (17%) were not sure and 3 (10%) did not apply for medical aid during the first year of the symptoms occurrence. Arms BP asymmetry was not assessed in 13 (43%) patients, in 6 (20%) subjects correct BP tests were performed, 8 (27%) responders were not sure and 3 (10%) had not consulted any physician timely. PA was assessed in 7 (23%) cases, PA was not tested in 12 (40%) patients, and 8 (27%) subjects were not sure. Arms and legs BP was not assessed in 26 (87%) patients during their initial examination.

Conclusion: the data obtained confirm paramount importance of proper physical examination during initial physician's consultation for timely and correct Takayasu arteritis diagnosis.

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FRI0274 ULTRASOUND CUT-OFF VALUE FOR INTIMA-MEDIA THICKNESS OF THE AXILLARY ARTERIES IN PATIENTS WITH CHRONIC LARGE-VESSEL GIANT CELL ARTERITIS

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Background: The European League Against Rheumatism (EULAR) recently recommended the use of ultrasound for the detection of inflamed

artery walls in giant cell arteritis (GCA) for diagnostic purposes. Intima media thickness (IMT) values, defining the "halo" sign in acute GCA patients, have also recently been proposed. In patients with chronic GCA, already receiving a treatment, the ultrasound appearance of inflamed artery walls changes and becomes difficult to detect.(1-4)

IMT measurement may help to identify patients with chronic large-vessel GCA (LV-GCA) by assessing the axillary arteries; however, a cut-off for distinguishing between chronically affected arteries and unaffected ones is not yet available.

Objectives: To determine an ultrasound IMT cut-off value for axillary arteries in patients with chronic LV-GCA.

Methods: Ultrasound of temporal and axillary arteries was performed in 127 GCA patients at the time of diagnosis and at one or two follow-up visits. Axillary arteries of GCA patients with sonographic signs of inflammation at the time of diagnosis were compared to unaffected axillary arteries of GCA patients and to axillary arteries of healthy controls. Receiver operating curves (ROC) were calculated using follow-up data to identify the optimal IMT cut-off.

Results: 148 axillary arteries of GCA patients showed signs of ultrasound inflammation at baseline (=LV-GCA group). The control group consisted of 162 axillary arteries, including 82 (50.6%) axillary arteries of GCA patients without signs of ultrasound inflammation at baseline or follow-up exam and 80 (49.4%) axillary arteries of 40 healthy controls. The mean age and gender distribution of the two groups at follow-up were 71 years (S. D. 7.9) with 69.9% females, respectively in the chronic LV-GCA group and 74 years (S.D. 6.9) with 59.8% females, respectively in the control group. The mean IMT values in the LV-GCA group were 1.14 (S.D. 0.38, n=78) for the right and 1.18 (S.D. 0.47, n=70) for the left axillary arteries as compared to 0.60 (S.D. 0.11, n=77) for the right and 0.62 (S. D. 0.11, n=85) for the left axillary arteries in the control group. Intervals from diagnosis to follow-up were 0.5-3 years, 3-6 years and >6years, with a distribution of 96 (65%), 32 (22%) and 20 (13%) exams in the LV-GCA group and 29 (35%), 41 (50%) and 12 (15%) exams in the control group (excluding healthy controls), respectively.

The optimal IMT cut-off value for the axillary arteries in patients with chronic LV-GCA was 0.87 mm with 75.0% sensitivity and 99.4% specificity (see figure 1). Sensitivity analysis (comparing patients with and without an involvement of the temporal artery at the time of diagnosis) validated this cut-off value.

Conclusion: An ultrasound IMT cut-off value for the axillary arteries can distinguish between patients with chronic LV-GCA and patients without chronic large vessel involvement.

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ROC curve for axillary artery cut-off

Figure. 1. Receiver operating curve for the axillary artery cut-off in chronic large-vessel giant cell arteritis.

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