Results: A 60 year old man presented to the surgeons with an itchy, non-tender lump over his left temple and lethargy. PV was normal. Doppler ultrasound revealed a thrombosed temporal artery. Biopsy confirmed GCA.

Three months after stopping two years of prednisolone he represented with weights, weight loss and an itchy right temple, again without headache. CRP and PV were raised and repeat biopsy showed active GCA. Restarting prednisolone led to resolution of symptoms and inflammatory indices.

An 89 year old lady presented to dermatology with an area of scalp necrosis. Biopsy showed inflamed squamous epithelium and granulation. Bloods showed raised PV and anaemia. A history of tongue pain on eating and a non-pulsatile temporal artery were elicited. After starting prednisolone the skin lesion healed and PV normalised.

A 68 year old lady presented to the physicians with dizziness, malaise and forearm pain. Examination revealed unrecordable blood pressure, absent radial and brachial pulses. Bloods showed raised PV, CRP, ALP and anaemia. CT angiography showed left vertebral, bilateral subclavian and axillary artery occlusion with collateral vessel formation. MR angiography showed left vertebral, bilateral subclavian and right renal artery. Temporal artery biopsy confirmed GCA. Prednisolone led to dramatic clinical improvement and normalisation of inflammatory indices.

Conclusion: Rheumatologists need to ensure other clinicians are aware of atypical presentations of GCA to avoid unnecessary investigation and delays in diagnosis.

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PP13. PHASE II STUDY OF THE SAFETY AND EFFICACY OF INFlixIMAB IN GIANT CELL ARTERITIS (GCA): 22 WEEK INTERIM ANALYSIS

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Background: Although GCA is responsive to glucocorticoids (GCS), therapy causes significant toxicity and often fails to induce sustained remission. Purpose: Assess safety and efficacy of infliximab (IFX) in patients (pts) with new onset GCA in a randomized, double-blind, placebo-controlled, multi-center, Phase II study.

Methods: Eligibility: diagnosis of GCA (ACR criteria); GCA of ≤4 weeks (wks) duration; resolution of GCA features and normal ESR following treatment with 40–60 mg prednisone or prednisolone/day; remission for 1 wk prior to randomization. Exclusions: absence of infection, malignancies within 5 yrs, congestive heart failure and advanced disease of critical organs. Treatment randomization: 1:2 ratio, to receive infusions of placebo or IFX 5 mg/kg, respectively, at wks 0, 2, 6, 14, 22, 30, 38, 46. All pts received GCS on a specified tapering schedule with starting dose of GCS.

Secondary endpoints included: (i) proportion of relapse-free patients through wk 22 and safety (frequency and types of adverse events). Relapse definition: rise in ESR, normal to ≥40 mm; and one of following (i) 1 or more specified features of GCA; and (ii) any other features of GCA not attributable to any other cause and a concomitant increase in dose of GCS.

Results: 44 pts were randomized (placebo, n = 16, IFX, n = 28) at 22 centers in 5 countries. Mean age in both groups (gps) was 71.0 yrs (range: 50–93). Baseline features between gps were comparable except for gender (placebo 31.3% males vs. IFX 43.3% males); fever (placebo 50.0% vs. IFX 17.9%) and visual impairment (placebo 31.3% vs. IFX 7.1%). More IFX-treated pts had positive temporal artery biopsies (66.7% placebo vs. IFX 92.3%). Efficacy was evaluated using cumulative data from 22 wks follow up. There were no differences between gps in regard to: (1) proportion of pts remaining relapse-free (50% placebo vs. 43% IFX, p = 0.651), (2) cumulative doses of GCS therapy (placebo mean ± SD = 3117 ± 971 mg vs. IFX = 3051 ± 770 mg, p = NS) and (3) among pts who had 1st relapse, days to 1st relapse (placebo median = 84.5, IFX median = 96.5, p = NS). There was 1 case of heart failure in an IFX-treated pt. Infections were infrequent and limited to upper respiratory tract (12.5% placebo vs. 14.3% IFX).

Conclusions: In this elderly population of pts with newly diagnosed GCA, IFX 5 mg/kg every 8 weeks, was well-tolerated, but during 22 weeks of treatment did not reduce number of 1st relapses or cumulative GCS dosage.

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