



Tocilizumab treatment in giant cell arteritis in real world clinical practice: Observational, monocenter study of 34 patients.

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Background: GiACTA study showed that tocilizumab (TCZ) is more effective than placebo plus blinded prednisone taper for inducing sustained remission at 52 weeks in giant-cell arteritis (GCA). Assessing real-life efficacy and safety of TCZ in GCA is thus warranted.

Aim: To compare the rate of disease remission, accrual of comorbidity and glucocorticoid (GC) toxicity as well as GCA outcome in patients treated with GC monotherapy compared to combination of GC with TCZ.

Methods: Observational, retrospective, monocenter study of 34 consecutive patients of GCA patients. The following outcome variables were compared from the time of diagnosis to the last encounter from January 2013 to October 2020: cardiovascular comorbidity (stroke, IHD, HTN, PVD, and/or CHF), diabetes mellitus (DM assessed by HbA1c), severe infection, osteoporotic fracture, cataract, blindness, and glaucoma. We also determined the rate of GC-free remission (≥ 6 months), GC and TCZ treatment duration as well as GCA relapse rate.

Results: Our cohort comprised of 22 (64.71 %) females and 12 males (35.29%), with a mean age of 71.06 ± 8.49 years. Temporal artery biopsy-proven diagnosis was found in 29 out of 30 biopsied patients (96.66%), and extra-cranial GCA was found in 10 patients (29.41%). The mean disease duration from diagnosis to initiation of TCZ treatment was 6.67 ± 6.67 months. The mean GC treatment duration was significantly shorter in the TCZ plus GC group (13.62 ± 7.47 months) compared to the GC alone group (30.24 ± 16.53 months), $p < 0.0054$. TCZ treatment was significantly associated with higher rate of GC discontinuation (HR 8.602, 95% CI 3.224 - 22.954, $p < .0001$), and lower rate of relapse (HR 0.145, 95% CI 0.033 - 0.633, $p = 0.0102$). GC-free remission ≥ 6 months was found in 24 patients (70.59%): 16 patients (66.67%) in the TCZ plus GC group and 8 patients (33.3%) in the GC alone group ($p = 0.451$). Mean Hb1c at last encounter was significantly lower in the TCZ+GC group ($5.61 \pm 0.6\%$) vs. the GC alone group ($6.31 \pm 0.84\%$), $p < 0.0321$. The rate of accrual of other comorbidities did not statistically differ between the treatment groups, probably due to the

small sample size of our cohort. Cardiovascular comorbidity $P < 0.168$, GC toxicity $P < 0.728$, Malignancy $P < 1$. Of note, 3 patients have died, all in the GC alone group ($p = 0.048$). We did not find significant adverse effects, including severe infections, in the TCZ plus GC group compared to GC alone group.

Conclusions: Our real-world study data are in accordance with the GiACTA study. Adding TCZ to GC therapy significantly shortens GC treatment duration and reduces the risk for disease relapse, as well as reduces the HBA1C level.