FRI0261

RISK FACTORS FOR TREATMENT FAILURE IN PATIENTS WITH GIANT CELL ARTERITIS TREATED WITH TOCILIZUMAB PLUS PREDNISONE VERSUS PREDNISONE ALONE

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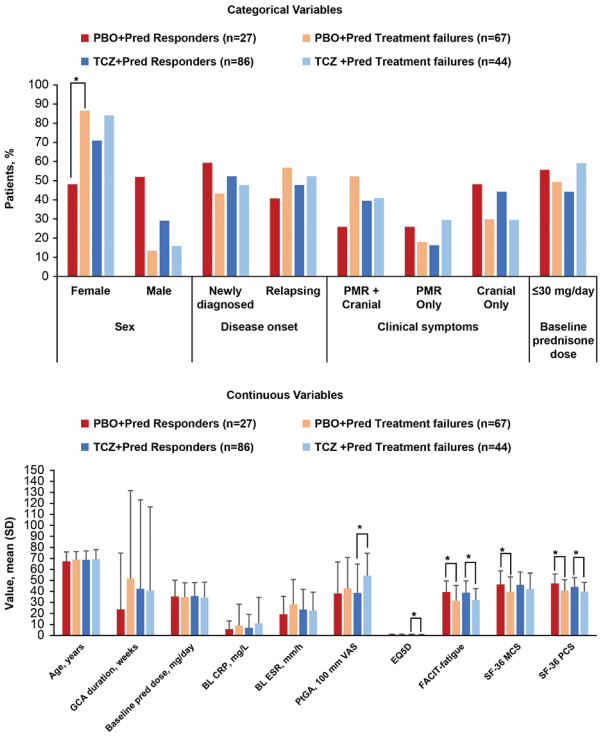
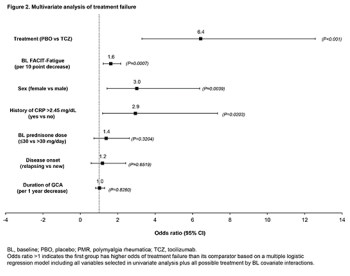
Background: Risk factors for treatment failure in patients with giant cell arteritis (GCA) are poorly understood.
Objectives: To identify predictors of treatment failure in GCA patients receiving tocilizumab (TCZ) or placebo (PBO) in combination with prednisone in a randomized controlled trial.[1]
Methods: Two hundred fifty GCA patients received weekly or every-other-week TCZ plus a 26-week prednisone taper (TCZ+pred) or PBO plus a 26- or 52-week prednisone taper (PBO+pred). Patients who achieved and maintained clinical remission (CR) from week 12 to week 52 while adhering to the protocol prednisone taper were classified as responders. CR, adjudicated by investigators, was defined as the absence of disease flare (GCA signs or symptoms, and/or ESR elevation attributable to GCA that required further treatment [eg, rescue prednisone]) regardless of CRP level. Treatment failure was defined as failure to achieve CR by week 12 or occurrence of flare between weeks 12 and 52. Both TCZ groups and both PBO groups were combined for this analysis. Potential predictors investigated included baseline demographics, disease- and treatment-related factors, and health-related quality of life (HRQOL) measures. Univariate and multivariate analyses were performed.
Results: Overall, 45% (113/250) of patients were responders: 27% (27/101) in the PBO+pred groups and 58% (86/149) in the TCZ+pred groups. In contrast, 44% (111/250) of patients experienced treatment failure: 66% (67/101) in the PBO+pred group and 30% (44/149) in the TCZ +pred group. The other 10% (26/250) of patients were nonresponders for reasons other than treatment failure: 7 in the PBO+pred group and 19 in the TCZ+pred group. In univariate analysis, female sex and lower baseline SF-36 Physical Component Summary (PCS), Mental Component Summary, and FACIT-Fatigue scores were associated with treatment failure among PBO+pred–treated patients, whereas higher patient global assessment of disease activity scores and lower SF-36 PCS, FACIT-Fatigue, and EQ-5D scores were associated with treatment failure among TCZ +pred–treated patients (Figure 1). Among TCZ+pred–treated patients, no treatment response difference according to sex was observed. Age, previous relapse, starting prednisone dose, and GCA clinical features (cranial or polymyalgia rheumatica symptoms) were not associated with treatment failure in either group based on univariate analysis. Multivariate logistic regression demonstrated that PBO+pred treatment, female sex, worse FACIT-Fatigue scores at baseline, and historical CRP >2.5 mg/dL all independently increased the risk for treatment failure (Figure 2).
Conclusion: Female GCA patients responded particularly poorly if treated with prednisone alone according to univariate analysis. Female sex, impaired HRQOL at baseline, history of elevated CRP, and treatment with prednisone alone are independent risk factors for treatment failure in GCA. These factors may be considered when determining which treatment would be best for a particular patient.

Figure 1. Univariate analysis of treatment failure



BL, baseline; CRP, C-reactive protein; EQ-5D, Euro-Qol 5D; ESR, erythrocyte sedimentation rate; GCA, giant cell arteritis; MCS, Mental Component Summary; PBO, placebo; PCS, Physical Component Summary; PMR, polymyalgia rheumatica; Pred, prednisone; PtGA, patient global assessment; SF-36, Short Form 36; TCZ, tocilizumab; VAS, visual analog scale.
14 patients in the PBO+prednisone group and 23 patients in the TCZ+prednisone group were nonresponders for reasons other than treatment failure. Percentages are based on number of responders/treatment failures (n).
*p<0.05 treatment failures vs responders (based on χ^2 test for categorical variables and *t* test for continuous variables).



BL, baseline; PBO, placebo; PMR, polymyalgia rheumatica; TCZ, tocilizumab.
Odds ratio >1 indicates the first group has higher odds of treatment failure than its comparator based on a multiple logistic regression model including all variables selected in univariate analysis plus all possible treatment by BL covariate interactions.

REFERENCES:
[1] Stone JH, et al. N Engl J Med. 2017;377:317-328.

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