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EFFICACY AND SAFETY OF TOCILIZUMAB IN GIANT CELL ARTERITIS INDEPENDENTLY OF THE INICIAL PREDNISONE DOSE

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Background: Tocilizumab (TCZ) has been approved for the treatment of Giant Cell Arteritis (GCA). It showed to be effective to induce remission, prevent relapses and decrease the cumulative prednisone dose. However, the glucocorticoids are the mainstay in the acute treatment of GCA.

Objectives: Our aim was to compare the efficacy and safety of the initial dose of prednisone at the onset of TCZ treatment.

Methods: Retrospective, multicenter study on 134 patients with GCA in treatment with TCZ. We compared two subgroups of patients according to the initial dose of prednisone at TCZ onset. Clinical efficacy, analytical improvement and safety was studied.

Results: We studied 134 patients (101 w/33 m) and made a comparative study between 2 groups: a) TCZ and ≤ 15 mg of prednisone; 68 (50.7%) cases, and b) TCZ and > 15 mg of prednisone, 66 (49,3%) patients. It is summarized in **TABLE 1**. It was no statistical significance according to age, sex and evolution time of disease. In the group receiving > 15 mg of prednisone, the patients presented more visual involvement (p<0.001) at TCZ onset. In terms of prolonged remission and relapses no significant difference was seen between both groups. The risk of presenting adverse effects (11.8% vs 36.4%) and severe infections (4.4% vs 19.7%) was related with the prednisone dose, being more frequent in the group with > 15 mg of prednisone (p=0.001 and p=0.006, respectively). **TABLE 2** summarizes the infections of our patients.

Conclusion: According with our results, we can conclude that TCZ is equally effective; in terms of prolonged remission and relapses, with doses ≤ 15 mg of prednisone at treatment onset. Being the most important data, the higher risk to develop adverse effects, as well as infections with higher doses of prednisone.

TABLE 1

	PREDNISONE ≤ 15 mg (n=68)	PREDNISONE > 15 mg (n=66)	p
ACUTE PHASE REACTANTS			
ESR, mm/1st hour, mean (SD)	38.6 ± 30.5	34.5 ± 32.2	0.500
CRP, mg/dL mean (SD)	3.3 ± 6.8	2.6 ± 3.2	0.603
Hemoglobin, g/dL, mean (SD)	11.5 ± 0.64	13.2 ± 1.5	0.104
CORTICOSTEROIDS AT TCZ ONSET			
Prednisone dose, mg/d mean (SD)	9.8 ± 3.7	34.8 ± 14.3	**<0.001**
EFFICACY AND SAFETY AFTER TCZ			
Prolonged remission n (%)			
Month 6	37 (69.8)	21 (44.7)	**0.018**
Month 12	27 (73)	19 (59.4)	0.232
Month 24	19 (82.6)	8 (47.1)	0.018
Relapses n (%)			
Month 1	3 (4.5)	1 (1.6)	0.620
Month3	3 (4.9)	4 (6.6)	1.000
Month 6	2 (3.8)	3 (6.4)	0.664
Month 12	3 (8.1)	6 (18.8)	0.285
Month 24	2 (8.7)	5 (29.4)	0.113
SIDE EFFECTS, n (%)			
Relevant adverse events	8 (11.8)	24 (36.4)	**0.001**
Serious infections	3 (4.4)	13 (19.7)	**0.006**

TABLE 2

	PREDNISONE ≤ 15 mg (n=68)	PREDNISONE > 15 mg (n=66)
SERIOUS INFECTIONS, n (%)		
Cytomegalovirus (bilateral pneumonia)	-	1 (1.5)
Endocarditis	-	1 (1.5)
Facial Herpes Zoster Infection †	-	2 (3.0)
Bacterial Infective Bursitis †	-	1 (1.5)
Severe Infectious Cellulitis †	-	1 (1.5)
Infectious Meningitis	-	1 (1.5)
Infected ulcer †	-	1 (1.5)
Infected Necrotizing ulcer	-	1 (1.5)
Pneumonia	2 (2.9)	1 (1.5)
Recurrent urinary infection and sepsis †		2 (3.0)
Urinary sepsis	1 (1.5)	1 (1.5)
Anal abscess ‡		1 (1.5)

REFERENCES

[1] Proven A. Glucocorticoid therapy in giant cell arteritis: duration and adverse outcomes. Arthritis Rheum. 2003; 49:703-8.

[2] Calderón-Goercke M. Tocilizumab in giant cell arteritis. Observational, open-label multicenter study of 134 patients in clinical practice. Semin Arthritis Rheum. 2019 Jan 5. pii: S0049-0172(18)30571-7. doi: 10.1016/j.semarthrit.2019.01.003. [Epub ahead of print]

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