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Miscellaneous

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Safety Of Targeted Therapies In A Cohort Of Paraguayan Patients: Data From Biobadaguay

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Background/Objectives: BIOBADAGUAY is the Paraguayan/Uruguayan registry of adverse events (AE) in patients with inflammatory rheumatic conditions under Targeted Therapies (TT). The objective of this study is to determine the frequency and severity of AE in patients under TT in Paraguayan patients in the BIOBADAGUAY registry.

Methods: Prospective, observational study to verify the efficacy, safety, and survival of the TT. The methodology applied is available at <https://biobadaguay.ser.es>. For the present study epidemiological and clinical variables, TT, type, and severity of AE were analyzed. The incidence rate (IR) was calculated as the total number of adverse events per 1000 patients/year and the incidence rate ratio (IRR) was analyzed using the Poisson regression model. (Significance value 0,05).

Results: 696 patients with TT were analyzed. 1047 AE were observed, 928 (88.6%) no severe, 110 (10.5%) severe and 9 (0.9%) mortals. Infection was the most frequent AE, 579 (55.3% of total AE), The IR global of AE was 323.8 (304.5-344.0), no serious 287.0 (268.8-306.1), severe 34.0 (27.0-41.0) and mortal 2.8 (1.3-5.2). The global IR of infections was 179.1 (164.8-194.3) and 19.5 (15.0-24.0) in severe and mortal infections. When IR was analyzed according to severity, the second and subsequent cycles of TT were significantly associated with a higher IR of global AE (IRR=1.9 [95% CI, 1.4-2.8] p=0.00001), no serious AE (IRR=1.9 [95% CI, 1.4-2.6] p=0.00001) and mortals (IRR=4.5 [95% CI 95%(1.2-16.8)] p=0.02) compared to the first cycle of TT. Treatment with anti-TNF was significantly associated with lower IR of global AE (IRR= 0.6 [95% CI, 0.5-0.8] p=0.0003), no serious (IRR=0.6 [95% CI, 0.5-0.9] p=0.003), serious (IRR=0.5 [95% CI, 0.3-0.8] p=0.001) and mortal AE (IRR= 0.1 [95% CI, 0.0-0.5] p=0.004) compared to non-anti-TNF. RA was associated with a higher IR of global AE (IRR=1.4 [95% CI,1.1-1.8] p=0.01), no serious (IRR=1.3 [95% CI,1.0-1.8] p=0.04) and serious/mortals (IRR=2.1 [95% CI,1.3-3.4] p=0.003) compared to others diagnoses. Psoriatic arthritis (PsA) was associated with lower IR of global AE, (IRR=0.6 [95% CI,0.3-1.0] p=0.007). Juvenile idiopathic arthritis (JIA) was associated with lower IR of serious/mortals AE (IRR=0.5 [95% CI,0.2-1.0] p=0.04).

Conclusion: AE were no serious in general and infections were the most frequent. RA presented a higher IRR of global AE, whereas PsA and JIA lower IRR of AE. Second and Subsequent cycles of TT presented a higher IRR of global an AE.