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BIOBADABRASIL: SAFETY PROFILE OF THE FIRST BIOLOGICAL AGENT OR JAK INHIBITOR FOR THE TREATMENT OF RA

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BACKGROUND

After failure of conventional synthetic disease modifying antirheumatic drugs (csDMARDs) in the therapy of rheumatoid arthritis (RA), treatment may be escalated to a biological DMARDs (bDMARDs) or JAK inhibitors (JAKi). However, the use of bDMARDs, especially anti-TNF agents, has been associated with higher risk of serious infections in comparison to csDMARDs. Recently, other anti-TNF agents have been introduced in the market, and non-anti-TNF-biologics/JAKi can also be used as first-line advanced therapy in RA. So, our aim in the present study is to evaluate the safety profile of the first biologic/JAKi used in the therapy of RA in our setting.

MATERIALS AND METHODS

BiobadaBrasil is a multicentric prospective cohort study of patients with rheumatic diseases starting their first bDMARD/JAKi or a csDMARD. The present analysis includes RA patients recruited from January 2009 to November 2019, followed-up over the first course of treatment with a bDMARD/JAKi until censoring (latest date, November 19, 2019) or occurrence of the outcome of interest. The primary outcome was the incidence of serious AE (SAE) of any kind. Secondary outcomes were serious infectious. Multivariate Cox proportional hazards models were used to estimate hazard ratios (HR) and 95% confidence intervals (CIs).

RESULTS

In total, 1351 patients (4180 patient-years [PY]) were enrolled. The overall incidence of SAEs was 6.1/100 PY. Adalimumab was the most frequently prescribed agent, followed by infliximab (n = 362). The hazard of SAE and serious infections comparing with infliximab is described in Table 1.

CONCLUSION

In our study, infliximab presented a higher hazard of SAE comparing with most other anti-TNF agents and tofacitinib.

Table 1. Hazard of SAE of each therapeutic agent comparing with infliximab. Results are HR, 95% CIs, and P values.

bDMARD/JAKi (No. patients)	SAE (255 events)	Infectious SAE (134 events)
Adalimumab (407)	0.66 (0.49 to 0.91), p = 0.010	0.54 (0.15 to 0.83), p = 0.005
Etanercept (276)	0.64 (0.46 to 0.91), p = 0.014	0.54 (0.34 to 0.87), p = 0.011
Certolizumab (80)	0.40 (0.16 to 0.96), p = 0.039	0.30 (0.09 to 1.04), p = 0.057
Tofacitinib (59)	0.09 (0.01 to 0.65), p = 0.012	Not done
Rituximab (53)	0.60 (0.30 to 1.22), p = 0.161	0.24 (0.07 to 0.82), p = 0.023
Golimumab (53)	0.47 (0.18 to 1.19), p = 0.111	0.30 (0.07 to 1.30), p = 0.108
Abatacept (32)	0.53 (0.19 to 1.49), p = 0.229	0.53 (0.15 to 1.84), p = 0.315
Tocilizumab (29)	1.14 (0.53 to 2.46), p = 0.733	1.47 (0.57 to 3.81), p = 0.427