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Miscellaneous

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Safety Of Targeted Therapies In Immune Mediated Inflammatory Diseases: Combined Data From Four Countries Of Latin America

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Has this paper been previously presented at another conference?: No

Background/Objectives: Biologic and targeted synthetic disease-modifying antirheumatic drugs (ts/bDMARDs) play a pivotal role in the treatment of Immune-mediated inflammatory diseases (IMID). Additionally, in the last few years, biosimilars and generic targeted synthetic (ts) DMARDs have been introduced. The aim of this study is to

determine the frequency and severity of adverse event (AE) of patients under ts/bDMARDs in patients with IMID in three BIOBADA Registries in four Latin American countries.

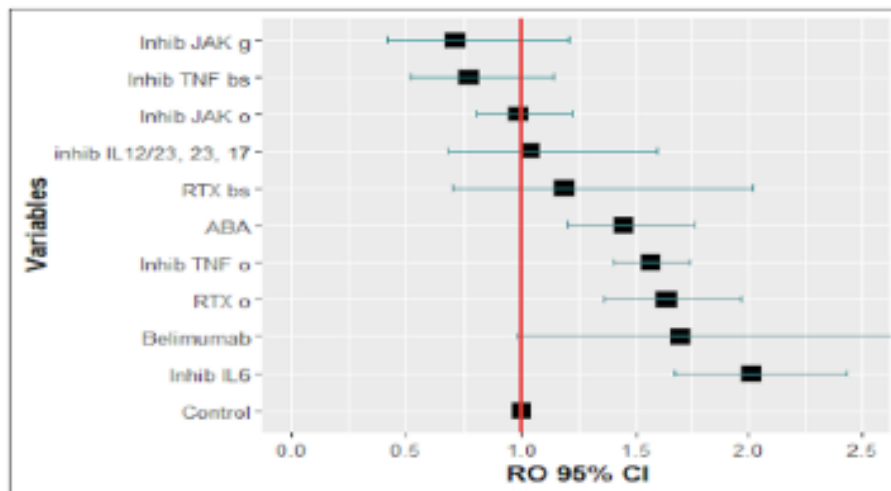
Methods: Data from four BIOBADA Registries from Latin America were collected, including Argentina, Mexico, Paraguay, and Uruguay (the last two countries are included at the same registry). For this analysis, those patients with IMID, who had started at least one biological or small molecule drug until October 2023 were included.

Results: A total of 8951 patients were included, 89% were women, the mean age at treatment initiation was 48.7 ± 8.4 years. The most common diagnosis was rheumatoid arthritis with 73% followed by psoriatic arthritis with 7.5%. 12993 treatment cycles were administered, of which 8888 (68.4%) corresponded to ts/bDMARDs and 4105 (31.6%) to controls. Of the ts/bDMARDs the most frequent were the original TNF inhibitors (anti-TNF α) with 59.7%, the original Rituximab (RTX α) with 8.7%, IL-6 inhibitor with 8.2 and the original JAKs inhibitors with 7.6%. A total of 8106 AEs were reported of which 908 (11.2%) were severe and 84 (1.0%) were mortal. the 28.1% of the total number of treatment cycles had at least 1 AE. Infections were the most frequently observed AE with 41.6% (1446), followed by skin disorders 8.5% (296), benign and malignant neoplasms 3.9% (137) and blood disorders 3.8% (131) among the most frequent. In the multivariate analysis, cycles with IL-6 inhibitors were significantly associated with an increased risk of developing EA (OR= 2.0 IC [95%, 1.7-2.4] $p < 0.001$), as well as with anti-TNF α (OR= 1.6 [IC 95%, 1.4-1.7] $p < 0.001$) and RTX α (OR= 1.6 [IC 95%, 1.4-2.0] $p < 0.001$), figure 1. Also having a longer time of disease evolution at the beginning of the treatment cycle (OR= 1.0

IC 95 [% , 1.01-1.02] $p < 0.001$), having chronic obstructive pulmonary disease (OR= 1.6 I [C 95%, 1.2-2.1] $p < 0.001$), hypertension (OR= 1.3 IC [95%, 1.2-1.4] $p < 0.001$) were shown to have the same effect.

Image 1:

Figure 1: Association to develop at least one adverse event per treatment cycle



OR = Odds Ratio, CI = Confidence Interval

Conclusion: We describe the real-life safety with targeted therapies in three BIOBADA Registries in four Latin American countries, being comparable to that found in other cohorts

Disclosure of Interest: None Declared

Keywords: Adverse events, Safety, Targeted therapies