SAFETY OF DISEASE-MODIFYING ANTI-RHEUMATIC DRUGS IN SPONDYLOARTHRITIS: A RETROSPECTIVE REVIEW FROM A SOUTH AFRICAN RHEUMATOLOGY CENTRE

Keywords: Spondyloarthritis, Disease-modifying Drugs (DMARDs)

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Background: The long-term immune-suppressive effects of Disease Modifying Antirheumatic Drugs (DMARDs) have long been a concern for serious adverse effects (SAE). Other developing countries, e.g. Brazil, used their registry to report a higher incidence of serious infections in the bDMARD treated patients compared with sDMARDs [1]. There are no published articles about the true incidence and nature of SAEs in Spondyloarthritis (SpA) patients treated with bDMARDs in the South African context.

Objectives: To describe the incidence of SAEs amongst patients with SpA treated with b- and s-DMARDs at a rheumatology centre in the Western Cape, South Africa.

Methods: A retrospective medical record review was conducted, involving patients with SpA seen at a private rheumatology clinic in Stellenbosch, Western Cape, between the 1 January 2014 and 31 December 2021. Demographic, clinical, and patient reported SAEs were recorded for those treated with b- and s-DMARDs. Incidence of SAEs was calculated and presented with 95% confidence intervals.

Results: Incidence of SAEs recorded between 1 January 2014 and 31 December 2021. A total of 92 patients were included, 59 bDMARD exposed and 33 sDMARD treated only with sDMARDs (bDMARD naïve). The accumulated exposure was 300 person-years (p-y) for those on bDMARD and 140 p-y for those on sDMARDs only. Twenty two SAEs were reported during the study period: 14 Infective, 4 major adverse cardiac events, 3 malignant (prostate, uterine, and thymoma), and 1 pulmonary complication. Twenty SAEs occurred whilst on a DMARD, one occurred 37 days after stopping etanercept, and a single SAE was excluded as it occurred 2 years after stopping infliximab. All SAEs were associated with hospitalisation and there were two deaths (one related to multi-organ failure, the other COVID-19 related). The SAE incidence for the sDMARD control group was 2.1/100 p-y (95% CI, 0.5-5.8/100 p-y) and 6.0/100 p-y (95% CI, 3.7-9.3/100 p-y) in the bDMARD study group. Of the anti-TNF inhibitors assessed, etanercept had the lowest SAE incidence at 3.8 events/100 p-y (95% CI, 1.2-9.3/100 p-y) (see Table 1).

Conclusion: The preliminary results of this retrospective review of SpA patients attending a private rheumatology clinic in a developing country suggests that infliximab treated patients were 5.5 times more likely to develop an SAE compared to patients on sDMARDs. Overall patients exposed to monoclonal antibodies were 3.2 times as likely to develop an SAE compared to those receiving sDMARDs, with respiratory infections the most commonly reported SAE.

REFERENCE: