Karnataka Biologics Cohort (KBC) Study Group experience

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After the astounding success of KRA comorbidity study (KRAC), we were very upbeat and wanted to study something smaller yet challenging in day-to-day practice. Ideas for our next collaborative study were discussed in an open-house forum during one of our local KRA meetings in Bangalore sometime in 2015. After much deliberation, we zeroed on KBC-Karnataka Biologics Cohort study with an intent to study prescription pattern, dosing, its frequency and complications (infections). Prospective data collection was considered non-feasible, and we agreed on a cross sectional design of this study.

Challenges: We received CRFs for more than 650 patients, but had to remove almost a third due to missing critical information. Cleaning up the data was a very cumbersome process largely carried out at Chanre (CRICR). The analysis of collected data and planning of manuscript was also carried out at Dr Chandrasekhar's centre.

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Prescribing patterns and safety of Biologics & Biosimilars in Immune Mediated Rheumatic Diseases- Karnataka Biologics Cohort (KBC) Study Group experience

Tuberculosis profile in Biologics experienced patients- Karnataka Biologics Cohort (KBC) Study Group experience

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Publications:

1. Shobha, Vineeta1,; Rao, Vijay2; Desai, Anu Mohan1; Jois, Ramesh3; Srikantiah, Chandrashekara4; Dharmanand, BG5; Kumar, Sharath6; Kumar, Pradeep7; Dharmapalaiah, Chethana7; Mahendranath, KM8; Prasad, Shiva9; Daware, Manisha10; Singh, Yogesh2; Karjigi, Uma3. Prescribing Patterns and Safety of Biologics in Immune-Mediated Rheumatic Diseases: Karnataka Biologics Cohort Study Group Experience. Indian Journal of Rheumatology 14(1):p 17-20, March 2019. | DOI: 10.4103/injr.injr_79_18

Summary:

This was a multi-center study conducted across 12 rheumatology centers in Karnataka, India, from January to August 2016, highlighting the real-world usage of biologics. Etanercept was the most commonly prescribed biologic, primarily for Spondyloarthropathy. The main reason for discontinuing biologics was clinical improvement, with only 4.8% of patients stopping due to adverse drug reactions (ADRs). The study also describes the prescribing patterns, pre-biologic screening, and adverse event management, with effectiveness of TB prophylaxis in preventing its reactivation.

2. Chandrashekara S, Shobha V, Rao V, Desai A, Jois R, Dharmanand BG, Kumar S, Kumar P, Dharmapalaiah C, Mahendranath KM, Prasad S, Daware MA, Singh Y, Karjigi U, Nagaraj S, Anupama KR. Incidence of infection other than tuberculosis in patients with autoimmune rheumatic diseases treated with bDMARDs: a real-time clinical experience from India. Rheumatol Int. 2019 Mar;39(3):497-507. doi: 10.1007/s00296-019-04245-4. Epub 2019 Jan 25. PMID: 30684040.

Summary: This publication focussed on infection rates in 209 ARD patients on bDMARDs. Infections occurred in 13.88% of patients, with most being minor. The study identified a higher infection risk in patients on three or more conventional DMARDs, and individuals with SLE and CTDs, or comorbidities. These findings re emphasised the need for careful monitoring in these patients.

3. Shobha V, Chandrashekara S, Rao V, Desai A, Jois R, Dharmanand BG, Kumar S, Kumar P, Dharmapalaiah C, Mahendranath KM, Prasad S, Daware MA, Singh Y, Karjigi U, Nagaraj S, Anupama KR. Biologics and risk of tuberculosis in autoimmune rheumatic diseases: A real-world clinical experience from India. Int J Rheum Dis. 2019 Feb;22(2):280-287. doi: 10.1111/1756-185X.13376. Epub 2018 Aug 30. PMID: 30168281.

Summary: Of 195 patients with AIRDs, 21 were latent TB positive and were given antitubercular prophylaxis, prior to biologics treatment. During follow-up, seven patients belonging to the negative test group (n = 174) developed TB. The negative predictive values noted for Mantoux test (n = 120) and QuantiFERON TB gold test (n = 178) were 96.52% and 96.25%, respectively. Patients on anti-TNFi were more likely to develop TB. Presence of comorbidities and steroid use increased the likelihood of developing TB by 1.5 and 4.6 times, respectively. None of patients who received prophylaxis ATT developed TB.