Rheumatoid arthritis - biological DMARDs

AB0395 IMMUNE-MEDIATED SKIN LESIONS RELATED TO BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUGS: A 22-YEAR EXPERIENCE OF A TERTIARY CENTER

Keywords: bDMARD, Skin

A. Martins[1,2], D. Santos Oliveira[1,2,3], F. R. Martins[4], R. Nicolau[5], F. Oliveira Pinheiro[1], M. Rato[1], A. Bernardo[1], S. Pimenta[1,2], M. Bernardes[1,2], L. Costa[1]. *[1]São João Universitary Hospital Center, Rheumatology, Porto, Portugal; [2]Faculdade de Medicina da Universidade do Porto - FMUP, Medicine, Porto, Portugal; [3]Faculdade de Medicina da Universidade do Porto - FMUP, CINTESIS, Porto, Portugal; [4]University Hospital Center of Algarve, Faro, Rheumatology, Faro, Portugal; [5]Centro Hospitalar Tondela - Viseu, Epe, Rheumatology, Viseu, Portugal*

Background: Biological disease-modifying antirheumatic drugs (bDMARDs) have revolutionized the treatment of chronic inflammatory rheumatic diseases. However, the physician and the patient should be aware of possible adverse reactions. Skin is one of the most frequent organs involved in bDMARD adverse reactions and immune-mediated skin lesions (IMSL) have rarely been described before in cohort studies and their incidence is unknown.
Objectives: To explore the cumulative incidence, type of lesions, management and outcomes of IMSL related to bDMARD in a large cohort of patients with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) and psoriatic arthritis (PsA).
Methods: We conducted a retrospective single-center study including patients with RA, axSpA and PsA followed at a Rheumatology Department from a University Hospital Center between April 2000 and December 2021, treated with at least one bDMARD for at least 6 months. Sociodemographic characteristics, disease duration, age at diagnosis, concomitant immunosuppressive medications, type and duration of the treatment with bDMARD and number of previous bDMARD were collected. For all patients with IMSL, age at onset, disease duration at the time of the IMSL, culprit bDMARD and duration of the treatment, specific management and outcomes were collected. Descriptive statistics for continuous variables were presented with mean and standard deviation and categorical variables were presented with absolute and relative frequencies.
Results: A total of 441 patients with RA, 386 with axSpA and 162 with PsA were included. The majority were female (63.4%), with a mean age of 54.3 ± 12.8 years. An important proportion of patients (47.6%, n=471) were taking csDMARDs and the most prescribed bDMARD was adalimumab (21.8 %), followed by etanercept (16.5%). Twenty-seven (2.7%) patients presented IMSL potentially related to the bDMARD. Regarding the patients with IMSL, 55.6% were females, mean age at the onset of IMSL was 48.4 ± 12.0 years, mean duration of the treatment with bDMARDs was 4.3 ± 4.5 years and mean duration of the treatment with the culprit bDMARD was 2.3 ± 2.1 years. The majority of patients had SpA (n= 14), followed by RA (n=10) and PsA (n=3). Adalimumab was the culprit agent in half of the patients (n=14), followed by etanercept (n=4), golimumab (n=3), infliximab (n=3), rituximab (n=2) and tocilizumab (n=1). Four patients (14.8%) needed hospitalization with the purpose of performing a clinical, laboratorial and histological investigation. In most patients, skin lesions resolved completely with topical (n=12) or systemic (n=6) treatment. IMSL led to withdrawal of bDMARD in 18 patients (66.7%). More information about the type of IMSL was described in table 1.

Table 1. Description of number of cases, age at IMSL onset, disease duration and duration of treatment with the culprit bDMARD for each type of IMSL.

Type of immune-mediated skin lesion	Number of patients, n(%)	Age at skin lesion onset, mean±SD, years	Female, n(%)	Disease duration, mean±SD, years	Duration of treatment with culprit bDMARD, mean±SD, years
Psoriasis	**12**	49.3 ± 14.5	6 (50.0)	19.5 ± 15.3	1.9 ± 1.7
Plaque psoriasis	5 (41.7)				
Palmoplantar pustulosis	4 (33.3)				
Guttate psoriasis	1 (8.3)				
Inverse psoriasis	1 (8.3)				
Undefined	1 (8.3)				
Drug-induced lupus erythematosus	**6**	40.8 ± 2.9	4 (66.7)	15.2 ± 7.8	2.4 ± 1.4
Malar Rash	1 (16.7)				
Alopecia	2 (33.3)				
Chilblains	2 (33.3)				
Subacute cutaneous LE	1 (16.7)				
LE tumidus	1 (16.7)				
Alopecia areata	3	4.4 ± 6.7	1 (33.3)	12.2 ± 627	1.2 ± 0.6
Leukocytoclastic vasculitis	2	60.9 ± 2.8	0 (0)	31.9	2.9 ± 3.6
Urticaria	2	57.3 ± 15.9	2 (100)	27.8 ± 22.1	0.9 ± 1.2
Rosacea	1	48	1 (100)	18.5	9.7
Erythema nodosum	1	60	1 (100)	40.7	2.9

Conclusion: IMSL related to bDMARDs are unusual events with an estimated cumulative incidence of 2.9%, in our sample. The most frequent IMSL were psoriasis and cutaneous manifestations of DILE and the most frequent culprit bDMARD was adalimumab. The majority of patients didn't need hospitalization and presented complete resolution of IMSL. IMSL led to withdrawal of the bDMARD in 2/3 of patients.
REFERENCES: NIL.
Acknowledgements: NIL.
Disclosure of Interests: None Declared.
DOI: 10.1136/annrheumdis-2023-eular.2044

AB0396 DISCONTINUATION AND EFFECTIVENESS OF ORIGINATOR AND BIOSIMILAR TNFI IN PATIENTS WITH RHEUMATOID ARTHRITIS: REAL WORLD DATA FROM A RHEUMATOID ARTHRITIS REGISTRY IN CANADA

Keywords: Rheumatoid arthritis, Outcome measures, bDMARD

M. Movahedi[1,2], A. Cesta[1], X. LI[1], C. Bombardier[1,2]. *[1]Toronto General Hospital Research Institute, Ontario Best Practice Initiative, Toronto, Canada; [2]University of Toronto, Institute of Health Policy, Management and Evaluation, Toronto, Canada*

Background: In recent years, biosimilars, highly similar copies of originator biologics, have been available in clinical practice to patients with Rheumatoid Arthritis (RA) in Canada. The Ontario government is expected to implement a policy mandating a switch from originator biologics to biosimilars. We may be able to anticipate the outcomes of implementing such a policy by analyzing the existing data for patients already using biosimilars in Ontario.
Objectives: We aimed to describe discontinuation and disease activity in patients starting an originator or biosimilar TNFi, using real-world data from the Ontario Best Practices Research Initiative (OBRI), Canada.
Methods: Patients with active RA enrolled in the OBRI and initiating an originator or biosimilar TNFi between 1st Jan 2015 and 30st March 2022 were included. We investigated time to discontinuation by using Kaplan-Meier (KM) survival curves in the two groups. Due to a small number of biosimilar users, curves were not statistically compared. Using clinical disease activity index (CDAI), disease status was also described for patients with available data at 12 months after treatment.
Results: A total of 494 patients started an originator TNFi (n=401) or biosimilar TNFi (n=93) with mean (SD) disease duration of 12.0 (9.4) and 9.7 (9.3) years, respectively. In the originator group, 81.5% were female and mean age (SD) was 57.2 (11.9) years. In the biosimilar group, 82.8% were female and mean (SD) age was 59.2 (11.5) years. The originator group was less likely to have prior biologic use (31.9%) compared to the biosimilar group (58.1%). The mean (SD) baseline CDAI was lower in the originator group [17.2 (11.6)] compared to the biosimilar group [22.6 (13.7)]. Over a mean follow-up of 25.9 months, discontinuation was reported in 154 (38.4%) and 21 (22.6%) originator and biosimilar groups, respectively. The mean survival (standard error) in originator group was 49.5 (1.85) months and 56.1 (4.70) months in biosimilar group. The retention rate (95% Confidence Interval) at 12 months was 74.8% (70.1%-78.9%) in the originator group and 84.6% (74.4%-91.0%) in the biosimilar group (Table 1). At 12 months after treatment initiation, disease activity was similar in the two groups (mean of CDAI: 14.0 vs.13.0).
Conclusion: In this real-world data descriptive study, we found that the proprtion of patients who remained on their medication in the biosimilar group was numerically higher than the originator TNFi. We also found that disease activity after 12 months after initiation was numerically similar in both groups. Next steps include, comparing discontinuation and disease activity between the two groups using a statistical regression analysis adjusting for potential confounders.

Table 1. Survival rate over 2 years of follow-up by treatment group

	TNFi Biosimilar N=93	Originator TNFi N=401
Number of discontinuation	21	154
Probability of survival		
6 month (%, (95%CI))	92.9 (84.9-96.8)	88.4 (84.7-91.2)
12 months (%, (95%CI))	84.6 (74.4-91.0)	74.8 (70.1-78.9)
18 months (%, (95%CI))	77.8 (65.9-85.9)	69.8 (64.7-74.2)
24 months (%, (95%CI))	70.9 (57.5-80.8)	65.9 (60.7-70.6)

Acknowledgements: We aknowledge the OBRI investigators.
Disclosure of Interests: Mohammad Movahedi: None declared, Angela Cesta: None declared, Xiuying Li: None declared, Claire Bombardier Grant/research support from: OBRI was funded by peer reviewed grants from CIHR (Canadian. Institute for Health Research), Ontario Ministry of Health and Long-Term Care (MOHLTC), Canadian. Arthritis Network (CAN) and unrestricted grants from: Abbvie, Amgen, Aurora, Bristol-Meyers Squibb, Celgene, Hospira, Janssen, Lilly, Medexus, Merck, Novartis, Pfizer, Roche, Sanofi, & UCB.
DOI: 10.1136/annrheumdis-2023-eular.2062