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AB0535

PRESCRIPTION PATTERNS OF THE SECOND BIOLOGIC DMARD IN PSORIATIC ARTHRITIS THROUGH THE LAST DECADE: HURBIO-PsA REAL LIFE EXPERIENCE

U. Kalyoncu¹, O. Karadag¹, L. Kılıç¹, A. Akdoğan¹, I. Dogan¹, Ş. A. Bilgen¹, E. Bilgin¹, E. C. Bolek¹, A. Erden², B. Armagan², A. Sarı³, E. Duran¹, B. Farisoğulları¹, G. K. Yardımcı¹, Z. Özsoy¹, G. Ayan¹, A. İ. Ertenli¹, M. Çalgüneri¹, S. Kiraz¹. ¹Hacettepe University, Internal Medicine, Rheumatology, Ankara, Turkey; ²Ankara City Hospital, Internal Medicine, Rheumatology, Ankara, Turkey; ³Yenimahalle Research and Education Hospital, Internal Medicine, Rheumatology, Ankara, Turkey

Background: Psoriatic arthritis (PsA) is a multi-dimensional chronic disease, which can affect joints, skin and entheses. Extrapolation of the positive treatment results of anti-tumor necrosis factor (TNF) alpha agents on spondyloarthritis and rheumatoid arthritis to the treatment practice of PsA lead to a new era for the management of PsA. However, unmet needs in the management of PsA lead to development of several drugs targeting different molecules and cytokines. The impact of these developments on PsA patients who are intolerant/unresponsive to the first biological disease-modifying anti-rheumatic drugs (bDMARD) still needs to be defined.

Objectives: To explore the second biologic agent trends on PsA patients of our 10-years of single-center experience.

Methods: HURBIO-PsA (Hacettepe University Rheumatology Biologic Registry) is a single center biological disease modifying anti-rheumatic drug (DMARD) registry since 2005 on PsA patients. Until the end of the 2020, 19 different rheumatologists contributed to the development of HURBIO-PsA. Anti-TNF drugs were approved as first line bDMARD for PsA patients. Distribution of the second-line biological agents (switch from first-line biological agent because of either adverse events or unresponsiveness) was calculated according to 5-year periods starting from the 2011. Also, demographic and serologic data of RA patients were reported.

Results: A total of 225 PsA (225/443, 50.8%) patients, who was prescribed a second biological agent, was registered in HURBIO-PsA by the end of 2020. Of these patients, 74.7% was female. Mean age at the starting of bDMARD was 47.1 ± 11.6 years. 90 (40.0%) and 135 (60.0%) patients were prescribed with their second bDMARD in 2011-2015 and 2016-2020, respectively. There was a trend towards the increasing prescription of non-Anti-TNF bDMARDs as second-line over time, especially for secukinumab.

Table 1. Distribution of second biologic DMARDs in PsA patients according to 5-years periods

	2011-2015	2016-2020	Total
Adalimumab	30 (33.3)	33 (24.4)	66 (29.3)
Etanercept	33 (36.7)	8 (5.9)	41 (18.2)
Infliximab	9 (10)	15 (11.1)	24 (10.6)
Golimumab	9 (10)	5 (3.7)	14 (6.2)
Certolizumab	5 (5.6)	34 (25.2)	39 (17.3)
Anti-TNF	86 (95.6)	95 (70.4)	181 (80.5)
Secukinumab	0	26 (19.3)	26 (11.5)
Ustekinumab	0	10 (7.4)	10 (4.4)
Abatacept	4 (4.4)	2 (1.5)	6 (2.6)
Tofacitinib	0	2 (1.5)	2 (0.9)
Non-Anti-TNF	4 (4.4)	40 (29.6)	44 (19.5)
Total	90 (100)	135 (100)	225 (100)

Approval years of drugs in Turkey: Infliximab: 2003, etanercept:2004, adalimumab: 2005, golimumab: 2013, certolizumab: 2014, secukinumab: 2018, ustekinumab: 2018; abatacept and tofacitinib were given with the permission from the Ministry of Health of Turkey for off-label use authorization

Conclusion: Almost half of the PsA patients switched their anti-TNF drugs to others. Non-Anti-TNF bDMARDs, especially secukinumab, becoming more frequently used as a second-line biologic agent in PsA in recent years. These bDMARD prescription trend is appropriate to EULAR PsA recommendations.

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AB0536

EFFICACY OF TNF INHIBITORS IN MONOTHERAPY VERSUS COMBINATION THERAPY WITH csDMARDs IN PORTUGUESE PATIENTS WITH PSORIATIC ARTHRITIS: A REAL-WORLD STUDY

F. Oliveira Pinheiro¹, B. M. Fernandes¹, S. Garcia¹, M. Rato¹, D. Fonseca², D. Santos Oliveira^{1,3}, A. Martins¹, F. R. Martins⁴, P. Madureira¹, M. Bernardes^{1,5},

L. Costa¹. ¹Centro Hospitalar Universitário de São João, Rheumatology Department, Porto, Portugal; ²Centro Hospitalar Vila Nova de Gaia/Espinho, Rheumatology Department, Vila Nova de Gaia, Portugal; ³Faculty of Medicine, University of Porto, Center for Health Technology and Services Research (CINTESIS), Porto, Portugal; ⁴Centro Hospitalar Universitário do Algarve, Rheumatology Department, Faro, Portugal; ⁵Faculty of Medicine, University of Porto, Medicine Department, Porto, Portugal

Background: Tumor necrosis factor inhibitors (TNFi) are a key therapeutic weapon in psoriatic arthritis (PsA), and can be used as monotherapy or in combination with other csDMARDs, which are usually used as first line therapy in these patients, although its efficacy is not as well documented as in other rheumatic diseases. The optimal use of iTNF in PsA, as monotherapy or in combination therapy with csDMARDs, is still under debate.

Objectives: We aimed to compare the response to treatment with TNFi in monotherapy and combined with csDMARDs, as first biologic, in patients with PsA.

Methods: Retrospective study that included PsA patients followed at our Rheumatology department under TNFi as first biologic, fulfilling CASPAR classification criteria and registered in Reuma.pt. Clinical and laboratory data were collected at the start of the first iTNF and in the last visit of 2019. Disease activity was assessed using CDAI, SDAI, DAS28(4V), BASDAI, ASDAS, and the response measured using the BASDAI50, ASDAS, ASAS, ACR and PsARC responses. Comparison between groups was performed using the chi-square test, Mann-Whitney U/t-test (categorical and continuous variables, respectively). Logistic regression analyses were performed to determine predictors of bDMARD failure, and survival analysis to measure persistence under the first bDMARD regarding csDMARD status at baseline.

Results: We included 99 patients, 47 (47.5% females) with a mean age of 47.9 ± 11.7 years at the start of the first iTNF. Fifty-one patients (51.5%) had symmetric polyarthritis, 26 (26.3%) spondyloarthritis, 16 (16.2%) asymmetric oligoarthritis, 3 (3.0%) distal arthritis and 1 (1.0%) arthritis mutilans. Sixty-three percent were under corticosteroid therapy and 77.8% under csDMARD therapy at the start of the first iTNF (mostly methotrexate, in 55.6% of patients under csDMARD). Etanercept (41, 41.4%), golimumab (25, 25.3%), adalimumab (22, 22.2%), infliximab (9, 9.1%) and certolizumab (2, 2.0%) were the iTNF started in these patients.

Patients who started iTNF as monotherapy had more frequent involvement of axial skeleton compared with combined therapy (54.5% vs 19.5%, p=0.001), were less exposed to corticosteroids (26.3% vs 72.6%, p<0.001) and had higher mean BASMI (3.7±1.8 vs 3.0±0.8, p=0.021) and BASFI (6.7±1.3 vs 4.7±2.5, p=0.036). Patients who were on iTNF monotherapy at the last consultation (43.4%) had lower mean tender (1.0±1.5 vs 3.6±4.3, p=0.002) and swollen (0.2±0.7 vs 0.8±1.0, p=0.012) joint counts, median patient VAS (30±46 vs 50±44, p=0.023), mean CDAI (5.6±4.4 vs 8.7±4.9, p=0.019), SDAI (6.2±4.6 vs 9.1±5.1, p=0.032), and DAS28(4V) (2.2±0.8 vs 2.7±0.9, p=0.047). iTNF failure was not significantly different in both groups. In the regression models, we found that basal DAS28(4V) (OR 1.874, 1.147-3.062 95%CI; p=0.012) was a predictor of first iTNF failure; there were no differences regarding csDMARD status.

When evaluating only patients without spondyloarthritis, we found that, at the last visit, iTNF monotherapy patients still had less exposure to corticosteroids (26.9% vs 54.3%, p=0.002), fewer mean tender (0.7±1.0 vs 2.6±4.4, p=0.006) and swollen (0.2±0.7 vs 1.1±2.5, p=0.025) joint counts, with no other differences observed. In the regression models, we found no differences regarding csDMARD status in these patients, while adalimumab (OR 0.009, 0.001-0.139 95% CI; p=0.009) was a negative predictor of bDMARD failure. Survival analysis revealed no differences between mono- and combined therapy.

Conclusion: We can conclude that the differences observed regarding csDMARD status in patients with PsA are mainly due to different patterns of arthritis, namely, predominance of axial involvement. In patients without spondyloarthritis, iTNF monotherapy did not differ significantly in terms of response to treatment and disease activity measures, nor does monotherapy predict bDMARD failure and treatment response. These results suggest that iTNF monotherapy is possible in PsA without compromising treatment response.

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AB0537

PSORIATIC ARTHRITIS BURDEN, QUALITY OF LIFE AND FUNCTIONAL ABILITY IMPAIRMENTS IN PATIENTS INITIATED ON APREMILAST IN THE ROUTINE CARE IN GREECE: INTERIM RESULTS FROM THE MULTICENTER PROSPECTIVE STUDY "APPROACH"

P. Katsimpri¹, D. Vassilopoulos², G. Katsifis³, G. Vosvotekas⁴, D. Bogdanos⁵, P. Sidiroopoulos⁶, P. Vounotrypidis⁷, A. Georgountzos⁸, A. Bounas⁹, A. Garyfallos¹⁰, S. Gazi¹¹, P. Georgiou¹², E. Kataxaki¹³, C. Papagoras¹⁴, A. Elezoglou¹⁵, S. N. Liossis¹⁶, A. Tzioufas¹⁷, P. Voulgari¹⁸, F. Satra Tzoufra¹⁹, Z. Anagnostopoulos¹⁹, N. Antonakopoulos¹⁹, P. Sfrikakis²⁰. ¹"Attikon" University Hospital, Rheumatology and Clinical Immunology Unit, 4th University Pathology

Clinic, Athens, Greece;² General Hospital of Athens "Hippokratio", Department of Medicine, National and Kapodistrian University of Athens, Athens, Greece;³ Athens Naval hospital, Rheumatology, Athens, Greece;⁴ Euromedica General Clinic of Thessaloniki, Rheumatology, Thessaloniki, Greece;⁵ University General Hospital of Larissa, Department of Rheumatology and Clinical Immunology, Faculty of Medicine, School of Health Sciences, University of Thessaly, Larissa, Greece;⁶ General University Hospital of Heraklion, Rheumatology, Heraklion, Greece;⁷ 424 General Military Hospital, Rheumatology, Thessaloniki, Greece;⁸ General Hospital of Athens "G. Gennimatas", Rheumatology, Athens, Greece;⁹ General Clinic of Patras "Olympion", Rheumatology, Patras, Greece;¹⁰ General Hospital of Thessaloniki "Ippokratio", Rheumatology, Thessaloniki, Greece;¹¹ General Hospital of Attica "KAT", Rheumatology, Athens, Greece;¹² General Hospital of Patras "Ag. Andreas", Rheumatology, Patras, Greece;¹³ General Hospital of Elefsina "Thrasio", Rheumatology, Athens, Greece;¹⁴ University Hospital of Alexandroupolis, Rheumatology, Alexandroupolis, Greece;¹⁵ Asklepieion General Hospital of Voula, Rheumatology, Athens, Greece;¹⁶ Patras University Hospital, Rheumatology, Patras, Greece;¹⁷ General Hospital of Athens "Laiko", Department of Pathophysiology, School of Medicine, University of Athens, Athens, Greece, Athens, Greece;¹⁸ Medical School, University of Ioannina, Rheumatology Clinic, Department of Internal Medicine, Ioannina, Greece;¹⁹ Genesis Pharma S.A., Medical, Athens, Greece;²⁰ General Hospital of Athens "Laiko", First Department of Propeudeutic and Internal Medicine, Athens University Medical, Athens, Greece

Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease associated with substantial psychosocial burden and health-related quality of life (HRQoL) and functional ability impairments.

Objectives: To characterize the profile of patients with PsA initiating therapy with apremilast in routine care settings, in terms of the physician-assessed clinical disease burden and the patient-reported generic and disease-related HRQoL and functional disability.

Methods: This is an ongoing 52-week multicenter, prospective study conducted in the Greek healthcare environment. Eligible patients are bio-naïve adults with active peripheral PsA, inadequate (within the first 12 months of treatment) response/intolerance to a prior conventional synthetic disease-modifying antirheumatic drug (csDMARD), and no prior use of tofacitinib, initiating apremilast as per the approved label. Data are being collected by physician assessments, as performed in routine clinical practice, and by patient-reported outcomes. 170 patients enrolled in the study; data at apremilast initiation (baseline) from the first 100 eligible consenting patients are presented in this interim analysis as per protocol.

Results: 99 evaluable patients were consecutively enrolled in 19 rheumatology departments between 15-Apr-2019 and 13-Jan-2020. At baseline (Table 1) [mean (SD) age: 53.8 (11.7) years], 43.4% of the patients had at least one (30.3% had ≥2) ongoing comorbidity other than PsA/PSO. The median [interquartile range (IQR)] PsA and psoriasis duration were 1.9 (1.0-3.5) and 7.5 (3.9-16.8) years, respectively. All subjects were on csDMARD while 24.2% received combination therapy, oral non-steroid anti-inflammatory drugs (32.3%), topical treatments (20.2%) and systemic steroids (11.1%). Based on the Clinical Disease Activity in PsA (cDAPSA) score, 58.6% of the patients had moderate, and 29.3% high disease activity. In the EuroQol (EQ) 5-Dimensions (5D) 5-Levels questionnaire, 93.9, 82.8, 82.8, 73.7, and 51.5% of the patients reported problems in 'pain/discomfort', 'anxiety/depression', 'usual activities', 'mobility', and 'self-care', respectively. The median (IQR) baseline UK-weighted EQ-5D index and EQ-Visual Analogue Scale scores were 0.55

Table 1. Baseline characteristics

	N	%/Mean/ Median
Women, %	57/99	57.6
Peripheral joint involvement only, %	92/99	92.9
Polyarthritis (≥5 joints), %	69/99	69.7
cDAPSA (range: 0-154), median (IQR)	99	22.0 (16.0-29.0)
Number of SJC (0-66) / TJC (0-68), median (IQR)	99	4 (2-8) / 6 (2-10)
Active psoriasis (BSA>0%), %	83/99	83.8
BSA score, median (IQR)	77/83	5.0 (2.0-12.0)
Nail involvement, %	38/96	39.6
Enthesitis and/or dactylitis, %	30/95	31.6
Dactylitis, %	11/95	11.6
Finger and toe Dactylitis Severity Score (DSS) (range: 0-60), median (IQR)	10/11	2.0 (1.0-6.0)
Enthesitis, %	22/95	23.2
LEI score (range: 0-14), median (IQR)	22	2.0 (1.0-2.0)
Extra-articular manifestations (mainly fatigue), %	10/99	10.1
Comorbidities in ≥15% of the patients		
Hypertension, Essential hypertension, %	23/99	23.2
Dyslipidemia, hypercholesterolemia, (type V) hyperlipidemia, %	15/99	15.2
Total PsAID12 score (range: 0-10), mean (SD)	98	4.6 (2.0)
Total HAQ-DI score (range: 0-3), median (IQR)	99	1.0 (0.5-1.4)

(0.44-0.70) and 50.0 (40.0-70.0), respectively. The median (IQR) Health Assessment Questionnaire-Disability Index (HAQ-DI) and mean (SD) PsA Impact of Disease 12-item (PsAID12) scores were 1.0 (0.5-1.4) and 4.6 (2.0), respectively.

Conclusion: More than 8 out of 10 bio-naïve patients initiated on apremilast in the routine clinical care in Greece have at least moderate disease activity, active psoriasis, and problems with pain/discomfort, anxiety/depression, and performance of usual activities at a median of 2 years post-diagnosis. HAQ-DI and PsAID12 scores indicate moderate impairment of physical functionality and PsA-related HRQoL. The findings underscore considerable disease burden early in the disease course.

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AB0538

POOLED SAFETY RESULTS FROM TWO PHASE-3 TRIALS OF GUSELKUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS THROUGH 1 YEAR

C. T. Ritchlin¹, P. Rahman², P. Helliwell³, W. H. Boehncke⁴, I. McInnes⁵, A. B. Gottlieb⁶, S. Kafka⁷, A. Kollmeier⁸, E. C. Hsieh^{8,9}, X. L. Xu⁸, M. Shawi¹⁰, S. Sheng¹¹, P. Agarwal¹¹, B. Zhou¹¹, P. Ramachandran¹², P. J. Mease¹³. ¹University of Rochester, School of Medicine and Dentistry, Rochester, United States of America; ²Memorial University of Newfoundland, Discipline of Medicine, Faculty of Medicine, St. Johns, Canada; ³University of Leeds, Clinical Rheumatology, Leeds, United Kingdom; ⁴Geneva University Hospitals, Department of Dermatology, Geneva, Switzerland; ⁵University of Glasgow, Director of Dermatology, Glasgow, United Kingdom; ⁶Icahn School of Medicine/Mt Sinai, Department of Dermatology, New York, United States of America; ⁷Janssen Scientific Affairs, MED GROUP RHEUM TA, Horsham, United States of America; ⁸Janssen Research & Development, LJ IMMUNOLOGY CLINIC, Spring House, United States of America; ⁹University of Pennsylvania Medical Center, Division of Rheumatology, Philadelphia, United States of America; ¹⁰Janssen Scientific Affairs, GMA COMMERCIAL OPS, Horsham, United States of America; ¹¹Janssen Research & Development, CLINICAL BIOSTATS PA, Spring House, United States of America; ¹²Janssen Research & Development, MSA US PA, Spring House, United States of America; ¹³Swedish Medical Center/Providence St Joseph Health and University of Washington School of Medicine, Department of Internal Medicine, Seattle, United States of America

Background: DISCOVER 1 & 2, two double-blind, phase-3, psoriatic arthritis (PsA) trials of guselkumab (GUS, an IL-23 inhibitor), demonstrated significant improvement with GUS vs placebo (PBO) in signs and symptoms of PsA, with good tolerability, at week (w) 24 during the PBO-controlled period.^{1,2} Beyond w24, all patients (pts) switched to GUS. Continued treatment maintained efficacy through w52.^{3,4}

Objectives: To describe pooled safety results from the DISCOVER 1 & 2 trials through 1-year of GUS treatment.