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AB0546

5 YEARS FOLLOW-UP OF PSORIATIC ARTHRITIS PATIENTS TREATED ACCORDING TREAT-TO-TARGET STRATEGY. PRELIMINARY RESULTS

P. Tremaskina¹, E. Loginova¹, T. Korotaeva¹, S. Glukhova², A. Lila^{1,3}, V.A. Nasonova Research Institute of Rheumatology, Spondyloarthritis and psoriatic arthritis, Moscow, Russian Federation; ²V.A. Nasonova Research Institute of Rheumatology, medical and social problems in rheumatology, Moscow, Russian Federation; ³Medical Academy of Continuing Professional Education, Rheumatology, Moscow, Russian Federation

Background: The concept of treat to target (T2T) in psoriatic arthritis (PsA) has been established recently and already shown its benefits [1]. But the long-term outcomes of the T2T have not been studied yet.

Objectives: To study 5 years (yrs) follow-up of PsA patients (pts) treated according to T2T strategy at the early stage.

Methods: 35 (M/F=17/18) PsA pts fulfilling CASPAR criteria, who were treated according to T2T strategy at the early stage (PsA duration≤2 yrs) within 24 months (mos) were analyzed. At the time of evaluation mean age is 42.7±11.2 yrs, median (Me) PsA duration 72 [60;95] mos, psoriasis duration 120 [88;180] mos. All pts underwent standard clinical examinations of PsA before started T2T therapy and at follow-up. Within 24 mos of T2T strategy all pts were taking Methotrexate (MTX) monotherapy in increasing dose up to 25mg/wk and 18 out of 35 (51%) pts received MTX in combination with iTNF. When T2T study was stopped all pts were treated according to standard care with NSAIDs, bDMARDs, MTX, tsDMARDs based on PsA activity and physician decision. The number of pts achieved minimal disease activity (MDA, 5 of 7) and remission by DAPSA (≤4)/low disease activity (LDA)≤14 at the 24 mos of T2T strategy and at 5 yrs follow-up were calculated. The results are presented in the form of mean values, median, upper and lower quartiles.

Results: Me duration of follow-up is 68 [53.5;81.5] mos. At 24 mos Me DAPSA 3.48 [0.45;21.76], remission by DAPSA (REM-DAPSA) were seen in 20 out of 35 (57%) pts, LDA-DAPSA in 4 (12%) pts, moderate activity (MoA) by DAPSA in 6 (17%) pts and high disease activity by DAPSA (HDA-DAPSA) in 5 (14%) pts. MDA was noted in 21 out of 35 (60%) pts. At 5 yrs Me DAPSA 7.4 [2.22;13.87], REM-DAPSA was noted in 12 (34%) pts, LDA-DAPSA in 14 (40%), MoA-DAPSA in 5 (14%), HDA-DAPSA in 4 (12%) pts. MDA was observed in 17 of 35 pts (49%). Among 20 pts who had REM-DAPSA at 24 mos only 6 pts (30%) remained in remission at 5 yrs follow-up and 12 out of 21 pts (57.14%) remained in MDA status.

Conclusion: In early PsA pts remission and MDA are achievable goal of T2T strategy. But most pts lost remission/MDA after this strategy was changed to a standard care, despite being in remission/MDA status before change of therapy. Further investigations of the long-term outcomes of T2T strategy in PsA, including radiographic outcomes are needed.

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AB0547

ASSOCIATION BETWEEN ACHIEVEMENT OF LOW DISEASE ACTIVITY OR REMISSION WITH IMPROVEMENT IN QUALITY OF LIFE IN UPADACITINIB-TREATED PATIENTS IN THE PHASE 3 SELECT-PsA 1 AND 2 STUDIES

A. Kavanaugh¹, P. J. Mease², K. Douglas³, F. Behrens⁴, D. Haaland⁵, P. Palominos⁶, A. Lertratanakul³, M. Lane³, R. Lippe⁷, D. Aletaha⁸, P. Nash⁹.

¹University of California San Diego, Division of Rheumatology, Allergy and Immunology, San Diego, California, United States of America; ²Swedish Medical Center/Providence St. Joseph Health and University of Washington, Rheumatology, Seattle, Washington, United States of America; ³AbbVie Inc., Immunology, North Chicago, United States of America; ⁴Rheumatology and Fraunhofer ITMP - Translational Medicine and Pharmacology, Goethe University, Rheumatology, Frankfurt, Germany; ⁵McMaster University, Hamilton, Ontario and The Waterside Clinic, Rheumatology, Barrie, Ontario, Canada; ⁶Hospital de Clinicas de Porto Alegre, Rheumatology Service, Porto Alegre, Brazil; ⁷AbbVie Deutschland GmbH & Co. KG, Immunology, Wiesbaden, Germany; ⁸Medical University of Vienna, Währinger Gürtel, Department of Medicine III, Division

of Rheumatology, Vienna, Austria; ⁹Griffith University, Rheumatology Research Unit, Sunshine Coast, Brisbane, Queensland, Australia

Background: The efficacy and safety of upadacitinib (UPA) in patients (pts) with active psoriatic arthritis (PsA) was demonstrated in the phase 3 SELECT-PsA 1 and SELECT-PsA 2 clinical trials.^{1,2}

Objectives: To explore the relationship between achievement of low disease activity (LDA) or remission (REM) and pt-reported outcomes (PROs) in SELECT-PsA 1 and 2.

Methods: The SELECT-PsA program enrolled pts with prior inadequate response or intolerance to ≥1 non-biologic disease-modifying antirheumatic drug (DMARD; SELECT-PsA 1) or ≥1 biologic DMARD (SELECT-PsA 2). Pts were randomized to 56 weeks (wks) of blinded treatment with UPA 15 or 30 mg once daily (QD), placebo switched to UPA 15 or 30 mg QD at Wk 24, or adalimumab (SELECT-PsA 1 only) 40 mg every other wk. LDA and REM were evaluated using the minimal disease activity (MDA; fulfillment of 5 out of 7) criteria and the Disease Activity index for Psoriatic Arthritis (DAPSA; cutoff ≤4), respectively. PROs assessed included Health Assessment Questionnaire-Disability Index (HAQ-DI), 36-Item Short-Form Survey physical component summary (SF-36 PCS), 5-Level EuroQol 5-Dimension (EQ-5D-5L) Index, and EQ-5D-5L Visual Analog Scale (VAS). Integrated data through Wk 56 from SELECT-PsA 1 and 2 from the full analysis set with both continuous UPA 15mg and 30mg groups were analyzed by responder status at Wks 24 and 56. Changes from baseline (BL) in PROs were analyzed using mixed effects repeated measures models (fixed effects for study, current use of non-biologic DMARDs, treatment group, visit, responder status, and continuous BL PROs). As-observed data were used in the models.

Results: A total of 1281 pts were included in the analysis (UPA 15mg, n=640; UPA 30mg, n=641). MDA was achieved by 33% (UPA 15mg) and 40% (UPA 30mg) of patients at Wk 24, and 40% (UPA 15mg) and 43% (UPA 30mg) at Wk 56; and DAPSA-REM by 10% (UPA 15mg) and 17% (UPA 30mg) at Wk 24, and 16% (UPA 15mg) and 18% (UPA 30mg) at Wk 56. Pts who achieved MDA or DAPSA-REM (responders) at Wk 56 achieved larger reductions in HAQ-DI and larger increases in SF-36 PCS, EQ-5D-5L Index and EQ-5D-5L VAS compared with non-responders (Table 1) (all p<0.0001; statistical significance was exploratory in nature). MDA or DAPSA-REM response at Wk 24 was also associated with greater PRO improvements at Wk 56 (Figure 1). Consistent with the results presented for MDA and DAPSA-REM, patients who achieved Very Low Disease Activity or DAPSA-LDA also experienced greater improvements in PROs than those who did not.

Table 1. Change from BL in PROs at Wk 56 by MDA and DAPSA-REM responder status at Wk 56

	UPA 15mg QD (n=640)		UPA 30mg QD (n=641)	
Least squares mean change from BL (95% CI), unless stated otherwise	Non-responder	Responder	Non-responder	Responder
MDA, n ^a	386	254	368	273
HAQ-DI	-0.26 (-0.30, -0.61* (-0.66, -0.22)	-0.56 (-0.56)	-0.27 (-0.31, -0.69* (-0.74, -0.23)	-0.64 (-0.64)
SF-36 PCS	5.25 (4.60, 5.90)	12.63* (11.84, 13.41)	5.09 (4.42, 5.75)	13.84* (13.08, 14.59)
EQ-5D-5L Index	0.11 (0.09, 0.12)	0.25* (0.23, 0.26)	0.10 (0.09, 0.12)	0.27* (0.25, 0.28)
EQ-5D-5L VAS	9.3 (7.8, 10.9)	23.3* (21.4, 25.1)	9.0 (7.4, 10.5)	26.1* (24.4, 27.9)
DAPSA-REM, n ^a	539	101	526	115
HAQ-DI	-0.36 (-0.39, -0.63* (-0.71, -0.32)	-0.55 (-0.55)	-0.39 (-0.43, -0.71* (-0.78, -0.35)	-0.63 (-0.63)
SF-36 PCS	6.99 (6.39, 7.59)	14.54* (13.22, 15.86)	7.43 (6.82, 8.03)	15.16* (13.91, 16.40)
EQ-5D-5L Index	0.14 (0.13, 0.15)	0.27* (0.24, 0.30)	0.15 (0.14, 0.16)	0.29* (0.26, 0.31)
EQ-5D-5L VAS	12.7 (11.3, 14.0)	26.7* (23.7, 29.8)	13.3 (11.9, 14.7)	30.0* (27.1, 32.8)

*p<0.0001 vs non-responder (statistical significance was exploratory in nature)^an may vary by PRO assessed

Conclusion: Among UPA-treated pts with PsA, improvements in quality of life and physical function were greater in pts who achieved MDA or DAPSA-REM than in those who did not. Despite DAPSA-REM being a more stringent measure (achieved by a smaller proportion of patients), these improvements were similar between MDA and DAPSA-REM responders.

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Figure Change from BL in PROs at Wk 56 by MDA and DAPSA-REM responder status at Wk 24

BL, baseline; DAPSA, Disease Activity Index for Psoriatic Arthritis; EQ-5D-5L, 5-Level EuroQol 5-Dimension Index; HAQ-DI, Health Assessment Questionnaire-Disability Index; LS, least squares; MDA, minimal disease activity; PRO, patient-reported outcome; REM, remission; SF-36 PCS, 36-Item Short-Form Survey physical component summary; VAS, Visual Analog Scale; Wk, week

Figure 1.

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AB0548

EFFECTIVENESS OF IXEKIZUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS FROM A REAL-WORLD EUROPEAN SURVEY

W. Tillett^{1,2}, V. Navarro-Compán³, N. Booth⁴, T. Holzkaemper⁵, J. Hill⁵, E. Lubrano⁶, T. Truer². ¹Royal National Hospital for Rheumatic Diseases, Department of Rheumatology, Bath, United Kingdom; ²University of Bath, Department of Pharmacy and Pharmacology, Bath, United Kingdom; ³University Hospital La Paz, IdiPaz, Madrid, Spain; ⁴Adelphi Real World, Adelphi Real World, Bollington, United Kingdom; ⁵Eli Lilly & Company, Eli Lilly & Company, Indianapolis, United States of America; ⁶Università degli Studi del Molise, Academic Rheumatology Unit, Dipartimento di Medicina e Scienze della Salute "Vincenzo Tiberio", Campobasso, Italy

Background: Limited real world (RW) data are available for IL-17A blocker ixekizumab (Ixe), approved for psoriatic arthritis (PsA) in EU Feb 2018.

Objectives: Describe RW outcomes for PsA patients (pts) receiving Ixe.

Methods: Cross-sectional, observational study of PsA pts treated with Ixe in the 2020 Adelphi PsA Plus Program (FR, DE, ES & UK). Rheumatologists recruited the first 6 consecutive consulting Ixe pts and provided demographics, PsA manifestations, clinical measures (66 swollen joint count (SJC), 68 tender joint count (TJC), psoriasis area and severity index [PASI], body surface area [BSA] affected by psoriasis [PsO]), rheumatologist-recorded pt measures (skin/joint pain & fatigue [0-10 numeric rating scales (NRS)], health assessment questionnaire [HAQ-DI]) & prescribed dose. All outcomes recorded for pts with scores available at Ixe initiation (I) & at last assessment (LA).

Results: 124 rheumatologists provided data for 698 Ixe pts, mean age 49 years (19-79), 48% female, mean BMI 27 (18-44), 56% dermatologist co-managed and mean time diagnosed 6 years (0-35). At Ixe initiation, 78% of pts with known BSA had concomitant mod-sev-PsO defined as BSA≥10% (mean 19.8, n=428) and mean PASI 26.3 (n=164). The predominant PsA phenotype was polyarthritic in 49% (n=345), mono/oligoarthritic in 30% (n=208), axial in 12% (n=81) and enthesitic in 8% (n=55). Previous treatment before Ixe included ≥1 conventional synthetic DMARD (csDMARD) for 71% of pts. Of bio-experienced pts (57%), 40% had received ≥2 biologics. Mean Ixe treatment duration (n=698) 39.4 weeks (wks, 0-170), of which 575 (82%) had received >12 wks of Ixe. 71% of pts received label recommended dose (80mg every 4wks). 52% pts received csDMARD in combination with Ixe. In the RW, Ixe improved TJC, SJC, joint pain, BSA, fatigue and HAQ-DI, Table 1.

Table 1. Outcomes for pts receiving Ixe >12weeks (n=575)

	Overall	BSA ≥10% at Ixe initiation	Mod-sev-PsO physician judgement	Predominant mono/oligo arthritis	Predominant polyarthritic	With csDMARD	Without csDMARD
BSA, n	356	270	254	98	184	188	168
mean [SD]							
Ixe initiation (I)	19.8 [14.8]	24.7 [13.5]	23.1 [13.6]	17.4 [15.0]	20.9 [15.0]	21.8 [15.0]	17.4 [14.2]
Last Assessment (LA)	6.6 [7.5]	9.3 [8.7]	7.9 [7.9]	5.0 [6.0]	7.6 [8.4]	7.3 [7.9]	5.9 [7.1]
Mean weeks on Ixe	43	41	41	50	41	41	46
TJC*, n	125	72	86	39	72	56	69
mean [SD, %<5]							
I	12.2 [10.6, 29]	14.4 [11.3, 18]	12.9 [11.1, 21]	6.4 [8.2, 59]	15.4 [10.8, 12]	13.0 [9.9, 25]	11.5 [11.1, 32]
LA	4.1 [6.4, 77]	5.2 [7.7, 71]	3.6 [6.3, 80]	1.1 [1.4, 97]	6.2 [7.7, 64]	3.4 [3.9, 73]	4.6 [7.8, 80]
SJC*, n	145	82	102	44	84	60	85
mean [SD, %<5]							
I	14.8 [13.5, 33]	18.8 [14.4, 22]	16.3 [13.8, 26]	7.2 [8.5, 68]	18.2 [13.6, 12]	14.5 [12.0, 37]	15.1 [14.8, 31]
LA	4.8 [8.7, 79]	7.0 [10.7, 66]	5.1 [9.3, 75]	0.9 [1.9, 95]	6.6 [9.0, 68]	3.1 [7.8, 90]	5.9 [9.1, 71]
Joint pain (NRS 0-10), n	575	270	349	166	291	294	281
mean [SD]							
I	6.6 [1.7]	6.7 [1.7]	6.7 [1.7]	6.2 [1.8]	7.0 [1.5]	6.6 [1.7]	6.6 [1.6]
LA	2.7 [1.9]	3.0 [2.1]	2.8 [2.0]	2.1 [1.6]	3.0 [2.1]	2.8 [1.9]	2.5 [1.9]
Fatigue (NRS 0-10), n	575	270	349	166	291	294	281
mean [SD]							
I	5.4 [2.5]	5.8 [2.4]	5.7 [2.5]	4.7 [2.5]	5.7 [2.4]	5.7 [2.4]	5.1 [2.5]
LA	2.6 [2.1]	2.7 [2.1]	2.7 [2.2]	2.0 [1.9]	2.9 [2.2]	2.7 [2.1]	2.6 [2.1]
HAQ DI, n	59	41	42	10	28	31	28
mean [SD, %<0.5]							
I	1.8 [0.7, 5]	1.9 [0.6, 0]	1.8 [0.7, 2]	1.9 [0.7, 10]	1.8 [0.8, 7]	1.9 [0.6, 3]	1.7 [0.8, 7]
LA	0.8 [0.6, 41]	0.8 [0.6, 32]	0.8 [0.7, 45]	0.7 [0.7, 60]	0.7 [0.6, 36]	0.7 [0.5, 32]	0.7 [0.8, 50]

*Additional analysis for pts whose fatigue/joint pain rating improved (from ≥4 at Ixe initiation to ≤3 at LA), their mean TJC was 2.7 & SJC 4.3 at LA for fatigue, TJC 1.7 & SJC 2.7 at LA for joint pain. When BSA was not recorded, physician judgement of PsO severity was used. No imputation of missing data.

Conclusion: We report RW outcome data amongst pts treated with Ixe including mono/oligo arthritis and a limited sample of enthesitis and dactylitis pts. Our results are consistent with clinical trial populations across disease domains, including an improvement in joint pain.