AB0541

PREDICTING THE INITIATION OF BIOLOGIC DMARDs IN EARLY PSORIATIC ARTHRITIS WITHIN 1-YEAR OF TREAT-TO-TARGET STRATEGY

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Background: According to the EULAR recommendations and treat-to-target (T2T) strategy synthetic (s) DMARDs are the first-line of PsA therapy and biologic (b) DMARDs are the second one [1]. The value of early intervention by bDMARDs in PsA has been demonstrated recently [2]. But factors which can predict bDMARDs initiation have not been evaluated yet.

Objectives: To identify prognostic factors for initiation of bDMARDs within 1-year of T2T strategy in early PsA.

Methods: 70 patients (pts) (M/F=35/35) with active early PsA fulfilling the CASPAR criteria treated by T2T strategy were included. Mean age 36.9±10.2 years (yrs), PsA duration 11.3±10.6 months (mos.), psoriasis duration 80.6±89.9 mos. Median DAPSA = 29.4 [23.1;36.0]. At baseline (BL) all pts were given therapy with Methotrexate (MTX) s/c with escalating dose from 5 to 25 mg/wk, then over a period of 12 mos pts with ineffectiveness of MTX were added bDMARDs. At BL and every 3 month of therapy all pts underwent standard clinical examinations of PsA activity. DAPSA, ESR (mm/h), CRP (mg/l), the number of pts with dactylitis, enthesitis by LEI and plantar fascia, BSA (%), HAQ and fatigue by FACIT (Functional Assessment of Chronic Illness Therapy) Fatigue Scale (Version 4), BMI (kg/m²) were evaluated. DAPSA > 28 indicate high activity, a score FACIT < 30 - severe fatigue, BMI > 25 overweight and obese. At 12 mos. pts were divided into two groups. Group 1 included 42 pts who were treated with MTX only and group 2 - 28 pts those with added bDMARDs during 12 mos. Multi-dimensional step-by-step discriminant analysis was used to identify a group of signs associated with the need to initiate bDMARDs within 12 mos.

Results: Comparative analysis of two groups showed the following features proved to be the most informative at BL and at 3 mos. of sDMARDs therapy with MTX: high PsA activity by DAPSA ≥ 30 (p = 0.009), BMI (kg/m²) ≥ 27 (p = 0.019), entesitis ≥ 1 (p = 0.005), ESR ≥ 20 mm/h (p = 0.007), FACIT < 30 (p = 0.074), male sex (p = 0.098). Early PsA pts with combination of these features at the first visit and at 3 mos. of MTX monotherapy have more chance to initiate bDMARDs in comparison to pts without them. Area Under ROC Curve (AUC) 0.892; 95% CI (0.818-0.966). Sensitivity/ Specificity of model 82% / 76% accordingly. (Figure 1).

Figure 1.

Conclusion: It is a combination of features from first visit to clinic and at 3 mos. of MTX monotherapy – high PsA activity by DAPSA, male gender,

persistent entesitis, obesity, ESR increase and severe fatigue by FACIT - that constitutes a prognostic factor for the initiation of bDMARDs at an early-stage of PsA. These factors should be considered in clinical practice to avoid losing time for the early initiation of bDMARDs and improved outcomes of PsA.

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EVALUATION OF APREMILAST USE IN THE ROUTINE CLINICAL PRACTICE IN PATIENTS WITH PSORIATIC ARTHRITIS NAÏVE TO BIOLOGICAL TREATMENTS

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Background: Apremilast is a non-biologic systemic agent approved for the treatment of plaque psoriasis, oral ulcers of Behcet's disease and PsA with proven efficacy in clinical trials [1,2]. However, more real-world evidence of apremilast use and effectiveness is needed to identify the patient profile most likely to benefit from this treatment [3].

Objectives: To evaluate the persistence of apremilast treatment in patients with PsA naïve to biological treatments in routine clinical practice and assess its effectiveness. Baseline clinical characteristics on patients who started apremilast were also evaluated.

Methods: Observational, prospective, multicenter (20 centers) study including consecutive adult patients with PsA naïve to biological therapies who had started treatment with apremilast during the previous 5 to 7 months and were followed-up during 12 months. Variables recorded were persistence of treatment with apremilast at 6 months (6mo) and number of swelling joints, presence of enthesitis and dactylitis, and disease activity, measured by the Disease Activity in Psoriatic Arthritis (DAPSA) score and Physician Global Assessment (PGA) of psoriasis, collected at baseline (BL) (i.e., apremilast treatment start) and 6mo; comorbidities were retrospectively collected at BL. Categorical and quantitative variables were compared using McNemar's and Wilcoxon test, respectively. Data sets analyzed included all assessable patients.

Results: Of the 60 patients recruited at the time of this interim analysis, 54 (90.0%) [mean (SD) age 53.4 (13.9) years] were assessable; 41 (75.9%) of these continued treatment with apremilast at 6mo. At BL, 34 (63.0%) patients had at least one comorbidity, the most frequent being cardiovascular disease (n=15, 27.8%), including hypertension (n=8, 14.8%), metabolic/endocrine disease (n=18, 33.3%), including obesity (n=8, 14.8%) and dyslipidemia (n=10, 18.5%). Psychiatric disease (i.e., depression) (n=5, 9.3%) and neoplasia (n=8, 14.8%) were also observed. The number of swelling joints decreased from median (Q1, Q3) 4.0 (2.0, 7.0) at BL to 1.5 (0.0, 4.0) at 6mo (p=0.0012). Patients with dactylitis and enthesitis decreased from 19 (35.2%) and 16 (29.6%) at BL to 10 (18.5%) and 9 (16.7%) at 6mo (p=0.0225 and p=0.0391), respectively. The distribution of patients in the different disease activity categories according to DAPSA scale changed between BL and 6mo, indicating a favorable disease evolution (Figure 1 next page). According to PGA, at BL (n=53), disease activity was categorized as mild in 18.0%, as moderate in 72.0%, and as severe in 10% of patients and, at 6mo (n=54), as mild in 70.6%, as moderate in 25.5%, and as severe in 3.9% of patients. Fifteen (27.8%) patients interrupted treatment permanently (n=13, 24.1%) or temporarily (n=2, 3.7%), due to no/partial response (n=8, 14.8%), tolerability issues leading to adverse events (n=3, 5.6%), patient decision (n=2, 3.7%), and other reasons (n=2, 3.7%) after a mean (SD) treatment of 3.05 (2.20) months.