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AB0845

TOFACITINIB IMPROVES DISEASE ACTIVITY AND PATIENT-REPORTED OUTCOMES (PROs) IN PATIENTS (PTS) WITH ACTIVE PSORIATIC ARTHRITIS (PSA) IN REAL CLINICAL PRACTICE.

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Background: PsA is a disease with multiple manifestations; it has significant impact on physical and emotional aspects of pts' life. PROs as well as disease activity are an important instrument for assessing treatment response. Tofacitinib (TF) is an oral Janus kinase inhibitor; in RCT TF demonstrated efficacy in active PsA pts concerning PROs [1] but there is currently no evidence from real clinical practice.

Objectives: to study the influence of TF on disease activity and PROs in 3/6 months (mo) of therapy in pts with active PsA in clinical practice.

Methods: 41 (M/F=24(58.5%)/17(41.5%)) PsA pts fulfilling the CASPAR criteria were included. Mean age 42.4±10.3 years (yrs), median (Me) PsA duration 72 [35;120] mo, pts had inadequate response to conventional synthetic disease-modifying antirheumatic drugs (csDMARDs, mostly Methotrexate)/biological (b) DMARDs (29% of pts). Pts were treated with TF 5 mg twice daily after signing consent participation forms. At baseline (BL) and in 3/6 mo of therapy PsA activity was evaluated by Tender Joint Count (TJC68), Swollen Joint Count (SJC66); PGA, physician global assessment by Visual Analog Scale (VAS), DAPSA. PROs were measured by PtGA VAS, PtPain VAS, BASDAI, HAQ, DLQI, RAPID, FACIT, PsAID12, Patient-Acceptable Symptom State (PASS) of PsAID12≤4. PsAID12 was analyzed as a change above the minimal clinical important difference (MCID) -1.25 points [2]. Higher PsAID12 scores are considered to be worse and correspond to poorer PsA-specific health-related quality of life. M±SD, Me [Q25; Q75], %, t-test, Pearson- χ^2 , Mann-Whitney tests were performed. All p<0.05 were considered to indicate statistical significance.

Results: At BL 87.8% of pts had high PsA activity by DAPSA. By 3/6 mo of therapy significant improvement in all PsA activity indexes and PROs were observed (table 1) (for all p<0.0001). By 6 mo of therapy DAPSA remission was seen in 11 out of 41 pts (26.8%). After 3/6 mo of therapy all PsAID12 domains demonstrated significant improvement (p<0.0001) (Figure 1). The PsAID12 improvement above MCID in -1.25 points reached 90.2% of pts by 6 mo. In 3/6 mo of therapy PsAID12 PASS was achieved in 66.7%/71.8% pts accordingly.

Table 1. Change in all evaluated parameters from BL to 3/6 mo.

Parameters, M±SD	BL	3 mo	6 mo
TJC68	18.1 ±9.8	6.3±6.9*	4.9±5.0**
SJC66	12.8±7.7	3.7±4.3*	2.5±4.0**
BASDAI	6.0±1.7	2.2±1.63*	1.77±1.42**
DAPSA	44.2±17.1	15.2±12.4*	11.8±9.4**
CRP (mg/l)	27.4±29.3	5.1±7.8*	6.2±11.6**
PtPain, VAS, mm	65 [50; 75]	20 [10;30]*	18 [5;30]*
PtGA, VAS, mm	70 [50; 80]	23 [14; 35]*	20 [10; 30]**
ESR (mm/h)	32±25.5	14.8±16.3*	13.6±16.3**
Total PsAID12 score (over past week, 0-10)	5.18±2.14	2.07±1.65*	1.68±1.48**
PsAID12 PASS, %	25.6	66.7	71.8
HAQ	1 [0.625; 1.5]	0.5 [0.125; 0.875]*	0.5 [0; 0.875]**
DLQI	5 [2; 12]	2 [0; 6]*	2 [0; 4]**
FACIT	29 [23;38]	39.5 [31.5; 48]*	38 [32;45]**
RAPID	16 [13.3; 18.6]	6.5 [3.7; 9.1]*	5 [2.3; 8.3]**

*p<0.0001 – differences from BL to 3 mo; ** p<0.0001 – differences from BL/6 mo;

Figure 1. PsAID12 domains at BL and at 3/6 mo of TF treatment.

Conclusion: In real clinical practice TF provides significant and clinically considerable improvement of PsA activity and PROs, including pain, psychological and emotional status.

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AB0846

HIGH DEGREE OF CLASSIFICATION CRITERIA FULFILLMENT AMONG PATIENTS WITH CLINICAL PSORIATIC ARTHRITIS DIAGNOSES IN SWEDEN

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Background: The clinical diagnosis of psoriatic arthritis (PsA) may be challenging. In Sweden, the vast majority of PsA cases are diagnosed within rheumatology or internal medicine (IM). Knowledge of the correspondence between clinical ICD diagnoses and classification criteria fulfillment is crucial to interpret studies identifying cases based on ICD codes.

Objectives: To assess the degree to which patients with clinical PsA diagnoses in Sweden fulfill established PsA classification criteria.

Methods: Four hundred patients with ≥1 outpatient physician visit to one of five rheumatology or IM departments (3 university/2 county departments, spread across Sweden) 2013-2015 with a main ICD-10 diagnosis of PsA (L40.5/M07.0-M07.3), were randomly selected from the Swedish National Patient Register (80 cases/site). Based on a structured medical record review, positive predictive values (PPV) of a clinical PsA diagnosis (i.e. ≥1 visit with a PsA ICD-10 code) for fulfillment of the following classification criteria were assessed: CASPAR,[1] Moll & Wright,[2] Vasey & Espinoza,[3] and Modified ESSG criteria for PsA,[4] respectively (as well as for any of these); ASAS criteria for peripheral or axial spondyloarthritis (SpA) [5]; and the 1987 ACR criteria for rheumatoid arthritis (RA).[6] Subanalyses regarding CASPAR fulfillment were also performed restricted to patients with available rheumatoid factor and peripheral X-ray status (central CASPAR items; n=227), and among patients with ≥2 ICD codes for PsA, of which ≥1 from a rheumatology/IM department (n=353).

Results: Out of 400 clinically diagnosed PsA patients, 343 (86%) fulfilled any of the 4 PsA classification criteria, with a PPV for CASPAR fulfillment of 69% (rising to 73-82% in the subanalyses; **Figure 1**). Substantial overlap was seen

regarding fulfillment of the 4 PsA criteria (Figure 2A). Moreover, 86% fulfilled the ASAS peripheral or axial SpA criteria, while the 1987 ACR definition of RA was met by 27% – in both cases with the great majority also classifiable as PsA (Figure 2B). Most patients not fulfilling any PsA criteria had either no verified arthritis or polyarticular disease (Table). Overall, only 6.5% of the clinical PsA diagnoses were judged as clearly wrong by the rheumatologists performing the medical record assessments.

Conclusion: The validity of clinical ICD-10 diagnoses for PsA in the Swedish National Patient Register is good, with a PPV of 86% for the fulfillment of established PsA classification criteria.

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Patient characteristics (n=400), stratified by classification criteria fulfillment

	Fulfilling any PsA criteria n=343	Not fulfilling any PsA criteria n=57
Male sex, %	46	44
Age, yrs; mean (SD)	59 (14)	62 (15)
Symptom duration, yrs; mean (SD)	18 (12)	16 (13)
Psoriasis, %	89	47
Nail psoriasis, %	38	11
Arthritis, %	93	58
Monoarthritis, %*	7.9	0
Oligoarthritis, %*	45	22
Polyarthritis, %*	47	78
DIP-joint arthritis, %	28	7.0
Dactylitis, %	28	1.8
Enthesitis, %	42	19
Inflammatory back pain, %	27	5.3
RF positive, %	5.8	14
ACPA positive, %	4.4	3.5
Arthritic X-ray changes in hands/feet, %	33	21

* % of patients with arthritis of known distribution. Missing data: 0-4%, except for RF (33%), ACPA (37%) and X-ray changes (20%).

Figure 1. Fulfillment of classification criteria for psoriatic arthritis

* CASPAR, Moll & Wright, Vasey & Espinoza or Modified ESSG. † Among patients with available data regarding rheumatoid factor and peripheral X-ray status, n=227. # Among patients with >=2 ICD codes for psoriatic arthritis in the Swedish National Patient Register, of which >=1 as main diagnosis from a rheumatology or internal medicine department, n=353. PsA, psoriatic arthritis; CASPAR, Classification criteria for Psoriatic Arthritis; ESSG, European Spondyloarthropathy Study Group.

Figure 2. Overlap of classification criteria fulfillment

* CASPAR, Moll & Wright, Vasey & Espinoza or Modified ESSG. CASPAR, Classification criteria for Psoriatic Arthritis; ESSG, European Spondyloarthropathy Study Group; PsA, psoriatic arthritis; ACR, American College of Rheumatology; RA, rheumatoid arthritis; ASAS, Assessment of SpondyloArthritis International Society; SpA, spondyloarthritis.

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AB0847

HIGH TOLERABILITY OF USTEKINUMAB IN THE TREATMENT OF PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS – RESULTS OF THE NON-INTERVENTIONAL STUDY SUSTAIN

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Background: Several biologics available for the treatment of psoriatic arthritis (PsA) have demonstrated effectiveness. A major aim of the treating physician is to find the safest treatment for his patients.

Objectives: In this work we analyzed the safety of ustekinumab in the treatment of PsA in a real-world setting.

Methods: The SUSTAIN study is a prospective, multi-center non-interventional study in Germany designed to evaluate long term effectiveness and safety, quality of life, and other patient reported outcomes in patients with active PsA under treatment with ustekinumab in routine clinical care over the course of 160 weeks. Treatment with ustekinumab is according to the label recommendations. In the third interim analysis we evaluated the data of 336 included patients till week 112.

Safety was evaluated based on the following parameters: numbers of adverse events (AEs), serious AEs (SAEs), and physicians' / patients' assessment of tolerability of treatment with ustekinumab. AEs are either reported by the subject voluntarily or are obtained by means of subject interviews at study visits. AE definitions, attribution rules, and severity criteria were pre-specified in the study plan. All AEs / SAEs were recorded and described including information on date of onset, seriousness, severity, outcome, action taken, and relationship to treatment as evaluated by the physician. All AEs were followed to satisfactory resolution or a clinically stable endpoint.

Results: For this analysis 336 patients (57% women) at 75 centers were included. Data for key study visits were obtained for the following numbers of patients: 310 patients at week 4, 237 patients at week 40, 160 patients at week 76, and 108 patients at week 112. A total of 88 SAEs (9.0% of all reported AEs) have been documented through the data cut-off date including SAEs of