AB0849

FATIGUE IN PSORIATIC ARTHRITIS – PREVALENCE AND IMPACT IN DAILY RHEUMATOLOGIC OUTPATIENT CARE

C. B. Vignier-Buxel¹, H. E. Langer², S. G. Werne², R. Chatelain¹. ¹*Fakultät für Gesundheit der Universität Witten/Herdecke, Evangelisches Krankenhaus Düsseldorf, Department of Dermatology, Düsseldorf, Germany;* ²*RHIO (Rheumatology, Immunology, Osteology) and RHIO Research Institute, Düsseldorf, Düsseldorf, Germany*

Background: Fatigue is a major problem in various rheumatic diseases. Only a few studies so far have focused on the occurrence of fatigue in psoriatic arthritis (PsA) (1).

Objectives: The aim of this study was to explore the prevalence and impact of fatigue in patients with PsA and its potentially association with disease activity in daily routine rheumatologic care.

Methods: 105 consecutive outpatients with definitive PsA (mean age 62 years, mean disease duration 8 years) were included in this prospective study. Patients received a clinical examination and laboratory tests. Furthermore, following assessments were used: assessment of disease activity (patient (PG) and physician global (PhG), NRS, 0-10), DAS28, CDAL, pain (NRS, 0-10), HAQ, SF-36, fatigue (NRS (0-10) and Chalder Fatigue Scale (CFS; bimodal: 0-3 no fatigue, 4-11 fatigue; Likert scale: 0-3 no fatigue, 4-33 fatigue, 19-33 severe fatigue/chronic fatigue syndrome) (2).

Results: In the CFS questionnaire 56/105 patients (53%) were classified as fatigue cases (bimodal score >4). 22/105 (21%) suffered from severe fatigue/chronic fatigue syndrome (score > 19, Likert scale). Mean fatigue was 14.9 (CFS, Likert Scale) and 4.5 (NRS). In n=47 (45%) patients fatigue was present <3 months, in 22 (21%) patients 3-6 months, whereas in n=34 (32%) >6 months. Intraday fatigue occurred in 75-100% of full daytime in 20 patients (19%).

An extensive impairment of the health related quality of life has been shown in all categories of SF36 (PF=46; RP=52, BP=42, GH=53, VI=45, SF=74, RE=51, MH=68). Fatigue strongly correlated with 6 dimensions of SF36: RP r= -0,61, BP r= -0,73, GH r= -0,66, VI r= -0,79, SF r= -0,54, MH r= -0,59.

On average disease activity was low (mean DAS28 = 2,5) with a range from 0,5 to 7,8.

Fatigue strongly correlated with the PG (r=0,72) as well as with DAS28 (r=0,49), CDAL (r=0,57), pain (r=0,71), tender joint count (r=0,41) and HAQ (r=0,57). The PhG showed only a poor correlation with fatigue (r=0,29). There was no correlation with ESR (r= -0,01), CRP (r=0,14) and swollen joint count (r=0,17).

63/105 (60%) patients were in DAS28 remission (DAS28 < 2.6) but 24/63 (38%) of them suffered from fatigue. 39/105 (37%) patients were exhibiting DAS28 disease activity (DAS28 > 2.6). All these patients suffered from fatigue, 29/39 (74%) had severe fatigue.

Conclusion: Our results show that fatigue is a major problem in PsA with relevant impact on the health related quality of life. The relatively high percentage of patients suffering from fatigue despite clinical remission or low disease activity suggests that fatigue could be an independent outcome criterion in PsA that should be considered as an additional dimension of remission.

It seems that the clinical routine assessments of disease activity including laboratory tests and PhG do not identify fatigue in PsA sufficiently. Therefore a standardized acquisition of fatigue should be part of studies and daily routine care for PsA patients.

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AB0850

CUTANEOUS LUPUS ERYTHEMATOSUS DISEASE AREA & SEVERITY INDEX (CLASI) DEMONSTRATES THRESHOLDS FOR DETECTION RESPONSE IN A PHASE 2, PLACEBO-CONTROLLED TRIAL OF USTEKINUMAB IN SLE

V. Werth¹, B. H. Hahn², G. Tsokos³, S. Rose⁴, K. Fei⁴, Y. I. Grogan⁴, R. Gordon⁴, K. H. Lo⁴, R. V. Vollenhoven⁵. ¹*Hospital of Univ of PA & Veterans Administration Med Center, PA, United States of America;* ²*UCLA, LA, United States of America;* ³*Beth Israel Hospital, MA, United States of America;* ⁴*Janssen R&D, LLC., PA, United States of America;* ⁵*Amsterdam Rheumatology and Immunology Center, Amsterdam, Netherlands*

Background: In a Phase 2 study, Ustekinumab (UST) showed improvement at week (wk) 24 in the Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) response (≥4-point improvement from baseline [BL]) vs placebo (PBO).¹ Post hoc analysis revealed that more patients (pts) on UST vs PBO achieved ≥50% improvement in total CLASI activity score.

Objectives: To examine the relationships of CLASI activity responses to SLEDAI-2K (S2K) mucocutaneous disease responses.

Methods: Adults with SLE (S2K ≥6, ≥1 BILAG A and/or ≥2 BILAG B scores) despite standard of care (SOC) therapy were enrolled. Pts (n=102) were randomized (3:2) to UST ~6 mg/kg IV or PBO at wk 0, followed by UST 90 mg SC or PBO every 8 wks beginning at wk 8 + SOC. S2K index measures complete improvement from BL; S2K Responder Index-50 (S2K RI-50) evaluates partial improvement (≥50%) in S2K rash. CLASI rash: sum of erythema and scale/hypertrophy score. In post hoc analysis, improvement in CLASI activity score at wk 24 was calculated using increasing thresholds of BL disease activity and various cut points of improvement to define treatment response.

Results: Complete improvement from BL in rash was concordant between CLASI and S2K (correlation coefficients [r] ≥0.997, Table 1). There was less agreement between CLASI and S2K RI-50 for assessing partial improvement in rash. Treatment difference (UST vs PBO) in % pts achieving partial improvement in rash was observed for CLASI (60% vs 38.5%), but not S2K RI-50 (51.1% vs 50%). Complete improvement from BL in mucosal ulceration was congruent between CLASI and S2K (r=1). Both instruments demonstrated greater proportions of responders to UST vs PBO. Treatment differences between UST and PBO in achieving ≥20%, ≥35%, and ≥50% improvement from BL in total CLASI activity score were noteworthy at various thresholds of disease activity (Table 2).

Table 1. CLASI Activity Scores vs SLEDAI-2K Activity

24-Week Improvement	Treatment	Activity Measure % (n/N*)		r**
100%	PBO	CLASI Rash	SLEDAI-2K Rash	
		30.8 (8/26)	30.8 (8/26)	1.0000
	UST	28.9 (13/45)	31.1 (14/45)	0.9997
	PBO	38.5 (10/26)	50.0 (13/26)	0.9996
≥50%	UST	60.0 (27/45)	51.1 (23/45)	0.8693
		CLASI	SLEDAI-2K	
		Mucosal Ulcer	Mucosal Ulcer	
	PBO	66.7 (8/12)	69.2 (9/13)	1.0000
100%	UST	89.5 (17/19)	89.5 (17/19)	1.0000

*N=Evaluated pts with BL SLEDAI rash present, total CLASI activity score >0, and CLASI rash or mucosal ulcer activity scores >0 in analyses of subcomponents; **Calculated using tetrachoric correlation.

Table 2. Differences in Partial Improvement in Total CLASI Activity Score at Various BL Disease Activity Thresholds

CLASI Total Activity Score	Improvement Threshold (%)	PBO % (n/N*)	UST % (n/N*)	Difference % (UST vs PBO)
BL >0	≥20	54.8 (17/31)	74.5 (38/51)	19.7
	≥35	41.9 (13/31)	60.8 (31/51)	18.9
	≥50	41.9 (13/31)	54.9 (28/51)	13.0
BL ≥4	≥20	58.8 (10/17)	71.9 (23/32)	13.1
	≥35	35.3 (6/17)	62.5 (20/32)	27.2
	≥50	35.3 (6/17)	53.1 (17/32)	17.8
BL ≥6	≥20	53.8 (7/13)	72.0 (18/25)	18.2
	≥35	30.8 (4/13)	60.0 (15/25)	29.2
	≥50	30.8 (4/13)	52.0 (13/25)	21.2
BL ≥8	≥20	58.3 (7/12)	70.6 (12/17)	12.3
	≥35	33.3 (4/12)	58.8 (10/17)	25.5
	≥50	33.3 (4/12)	47.1 (8/17)	13.8

*N=Evaluated pts with BL total CLASI activity score >0, ≥4, ≥6, ≥8 based on post hoc analyses

Conclusion: CLASI demonstrated partial improvement in active mucocutaneous disease that was not captured by S2K RI-50. Treatment effect favoring UST vs PBO was observed across range of thresholds of BL CLASI activity and cut points used to define improvement, which have previously been shown to be clinically meaningful.² Findings are based on a limited sample size and treatment duration; results will be confirmed in an ongoing Phase 3 UST trial (NCT03517722).

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