AB0754 COMPARISON OF COMPOSITE INDICES TAILORED FOR PSORIATIC ARTHRITIS TREATED WITH csDMARDs AND bDMARDs: A LONGITUDINAL OBSERVATIONAL STUDY

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Background: Remission or low disease activity should be the target of therapy in chronic inflammatory arthritis as well as in Psoriatic arthritis (PsA). In a complex disease such as PsA, several methods are available to define remission that comprise the assessment of different clinical features.

Objectives: The aim of this study was to compare the composite indices tailored for PsA in both patients treated with csDMARDs and bDMARDs.

Methods: Adult PsA patients classified with CASPAR criteria and with >6 months follow up treated with first csDMARDs and bDMARDs were consecutively enrolled in our outpatient clinic. To assess disease activity, composite indices tailored for PsA namely DAPSA, cDAPSA, PASDAS, MDA (5/7) and MDA (7/7) were used. DAPSA and cDAPSA score ≤ 4 , MDA 7/7 and PASDAS ≤ 1.9 identified remission while MDA 5/7 and PASDAS < 3.2 the minimal disease activity and inactive disease criterion¹⁻⁵.

Results: One hundred nine PsA patients were enrolled. Of this, 79 patients were in stable treatment with bDMARDs and 30 with csDMARDs. Overall, 28 (25.6%), 23 (21.1%), 19 (17.4%), 54 (49.5%), 13 (11.9%) and 35 (32.1%) PsA patients were in cDAPSA remission, DAPSA remission, MDA 7/7, MDA 5/7, PASDAS ≤ 1.9 and PASDAS < 3.2 . Patients in bDMARDs had a significantly low median DAPSA, cDAPSA and PASDAS score than patients treated with csDMARDs (table 1). Overall, the concordance between the indices ranging from slight to good.

Table 1. Demographic and clinical disease activity characteristics in patients treated with bDMARDs and csDMARDs

	bDMARDs (n=79)	csDMARDs (n=30)	P value
Female/male	38/41	16/14	ns
Mean age (SD), years	52.7 (12.4)	51.6 (12.3)	ns
Disease duration (SD), years	7.8 (9.3)	6.6 (8.2)	ns
PASI, median (25th-75th percentile)	0.3 (0-0.6)	1.5 (0-3.2)	0.02
Enthesitis (LEI) median (25th-75th percentile)	0 (0-1)	1 (0-3)	<0.01
CRP, mg/dl (25th-75th percentile)	0.3 (0.16-0.49)	0.3 (0.2-0.76)	ns
PASDAS, median (25th-75th percentile)	3.28 (2.69-3.72)	4.43 (3.73-4.76)	<0.01
MDA 5/7, n (%)	49 (62)	5 (16.6)	<0.01
MDA 7/7, n (%)	16 (20.2)	3 (10)	ns
DAPSA, median (25th-75th percentile)	6.8 (3.7-9.57)	18.1 (16.5-31.5)	<0.01
cDAPSA, median (25th-75th percentile)	6.5 (3.5-9.5)	17.5 (11.2-26.9)	<0.01

PASI: psoriasis area severity index; LEI: Leeds enthesitis index; CRP: C-reactive protein; PASDAS: psoriatic arthritis disease activity score; MDA: minimal disease activity; DAPSA: disease activity index for psoriatic arthritis.

Conclusions: PsA patients in bDMARD are more likely to reach a status of MDA and remission in respect to csDMARDs. PASDAS ≤ 1.9 and MDA 7/7 seem to be stringent remission criteria.

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AB0755 DEPRESSION AND ANXIETY MAY CONTRIBUTE TO HIGHER DISEASE ACTIVITY AND WORSE QUALITY OF LIFE IN PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease with variable types of joint involvement, extra-articular features, including skin psoriasis, and with well-known comorbidities such as depression and anxiety¹. Composite Psoriatic Disease Activity Index (CPDAI) adequately assesses disease activity in this complex condition². To date, no study has evaluated the relationship between depression/anxiety scores and CPDAI in PsA.

Objectives: The aim of this study was to compare 1) depression/anxiety scores; 2) physician-assessed and patient-reported outcome measures (PROMs) between patients with CPDAI ≤ 4 suggesting low disease activity versus with CPDAI > 4 reflecting moderate or severe disease activity in PsA.

Methods: PsA patients fulfilling the CASPAR criteria were recruited. Patients un-

derwent musculoskeletal and skin assessments (TCJ68, SJC66, Leeds enthesitis index, dactylitis digit score and PASI) and they have completed questionnaires on physical function and health-related quality of life (HAQ, PsAQoL, DLQI, EQ-5D, BASDAI, BASFI, ASQoL, BRAF-NRS, pain and general health VAS). Patients were assessed for depression/anxiety using the Hospital Anxiety and Depression Scale (HADS-A and HADS-D) and Penn State Worry Questionnaire (PSWQ). Data were analyzed using Mann Whitney, Chi-square tests and linear regression model.

Results: 100 PsA patients were recruited; 57 presented with CPDAI ≤ 4 (age 52.7 $\pm$ 9.46 years) and 43 with CPDAI > 4 (age 52 $\pm$ 11.82 years). Patients with CPDAI > 4 had significantly higher TCJ68 ($p < 0.001$), Leeds enthesitis index ($p = 0.015$) and significantly worse HAQ, BASDAI and ASQoL scores. There was no significant difference in other items of CPDAI between the two groups. Patients with CPDAI > 4 had significantly higher HADS-D, HADS-A and PSWQ scores ($p < 0.001$; $p < 0.001$; $p = 0.001$, respectively) and significantly worse PROMs, including PsAQoL, EQ-5D score, BASFI, BRAF-NRS, pain and general health VAS (Table 1). Multiple regression analysis revealed significant relationship between PsAQoL, BASFI and CPDAI ($B = 0.311$, $p = 0.0093$; $B = 0.568$, $p < 0.0001$, respectively).

Table 1. Comparison of patient-reported outcome measures between CPDAI ≤ 4 and CPDAI > 4 groups

PROMs	CPDAI ≤ 4 n=57	CPDAI > 4 n=43	p value
HADS-D	2.32 $\pm$ 2.53	5.27 $\pm$ 3.13	<0.0001
HADS-A	3.44 $\pm$ 2.74	5.98 $\pm$ 2.81	<0.0001
PSWQ	38.7 $\pm$ 13.23	46.95 $\pm$ 12.22	0.001
PAIN VAS	2.07 $\pm$ 2.02	4.41 $\pm$ 2.07	<0.0001
ghVAS	76.73 $\pm$ 20.95	66.6 $\pm$ 20.15	0.005
BRAF-NRS	12.35 $\pm$ 4.51	16.41 $\pm$ 4.76	<0.0001
PsAQoL	1.68 $\pm$ 2.47	6.17 $\pm$ 5.15	<0.0001
EQ-5D SCORE	0.82 $\pm$ 0.15	0.66 $\pm$ 0.19	<0.0001
BASFI	1.53 $\pm$ 1.33	4.26 $\pm$ 1.74	<0.0001

Mann-Whitney test. Results are presented as mean $\pm$ SD.

Conclusions: This is the first study assessing the relationship between depression/anxiety and CPDAI in PsA. We have found significantly higher HADS-D, HADS-A, PSWQ scores and worse PROMs in patients with CPDAI > 4 compared to those with CPDAI ≤ 4 . Based on our results there is significant relationship between depression/anxiety, physical function, quality of life and disease activity in psoriatic arthritis.

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AB0756 PRIMARY EFFICACY AND SAFETY OF ADALIMUMAB IN NAIL PSORIASIS FROM THE FIRST 26 WEEKS OF A PHASE-3, RANDOMIZED, PLACEBO-CONTROLLED TRIAL WITH SUBANALYSIS IN PATIENTS WITH AND WITHOUT PSORIATIC ARTHRITIS

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Background: Psoriasis (Ps) disease burden for patients (pts) with psoriasis (Ps) and concomitant fingernail Ps plus psoriatic arthritis (PsA) is higher compared with pts with Ps alone.

Objectives: We report safety and efficacy of originator adalimumab (ADA) in pts with fingernail Ps, and also for pts with or without concomitant PsA.

Methods: Results are reported from the double-blind PBO-controlled, Period A in which 217 pts with moderate to severe plaque Ps and fingernail Ps were included and randomized 1:1 to receive 40 mg ADA every other week (eow) from wk 1 (initial 80 mg dose at wk 0), or matching PBO, for 26 wks. The primary endpoints were the proportion of pts with $\geq 75\%$ improvement in modified Nail Ps Severity Index (mNAPSI 75) and the proportion of pts with Physician's Global Assessment of Fingernail Psoriasis (PGA-F) of clear (0) or minimal (1) with ≥ 2 -grade reduction from baseline (primary in US only; for regulatory purposes). Missing data were handled by multiple imputation. Safety was assessed using treatment-emergent adverse events (AEs).

Results: Of the 217 randomized pts (108 PBO, 109 ADA), 84.3% were male; mean age was 46.7 years; 188 (86.6%) completed 26 wks of treatment or early escaped to Period B according to protocol. Both primary endpoints were met: total fingernail mNAPSI 75 was achieved by 3.4% PBO vs 46.6% ADA ($p < 0.001$), and PGA-F 0 or 1 with ≥ 2 grades improvement was achieved by 6.9% vs 48.9% ($p < 0.001$). At baseline, 28.6% had PsA (29.6% PBO, 27.5% ADA) with mean

duration 7.91 years [SD 8.314]. Total fingernail mNAPSI 75 was achieved by 0.5% PBO vs 61.5% ADA of pts with PsA and 4.6% PBO vs 40.9% ADA without PsA ($p < 0.001$ for both groups). PGA-F 0 or 1 with ≥ 2 -grade reduction was achieved by 4.4% PBO vs 59.3% ADA with PsA and 7.9% PBO vs 44.9% ADA without PsA ($p < 0.001$ for both groups). Adverse events (AEs) in Period A were reported by 55.6% PBO vs 56.9% ADA (with PsA: 56.3% PBO vs 56.7% ADA; without PsA: 55.3% PBO vs 57.0% ADA without PsA); serious AEs by 4.6% PBO vs 7.3% ADA (with PsA: 9.4% PBO vs 10.0% ADA; without PsA: 2.6% PBO vs 6.3% ADA).

Conclusions: The primary results demonstrated that in this population, ADA was more effective than PBO for the treatment of fingernail Ps, and significantly improved signs and symptoms, both overall and regardless of the presence or absence of PsA; no new safety risks were identified with ADA treatment for 26 wks.

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AB0757 IMPACT OF DISEASE ACTIVITY ON PHYSICAL FUNCTION AND HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) is a chronic progressive inflammatory disease characterized by peripheral arthritis, dactylitis, axial joint involvement and extraarticular features. Disease consequences such as chronic pain, severe joint damage and fatigue may adversely effect on a patient's physical function and health-related quality of life (QoL) to perform daily activities.

Objectives: The aim of this study was to investigate the potential relationship between physical function and health-related QoL and disease activity measures in patients with PsA.

Methods: For all participating patients, quality of life, functional and disease activity measures were measured by different ways: Nottingham Health Profile (NHP), psoriatic arthritis quality of life (PsAQoL), Ankylosing Spondylitis Quality of Life (ASQoL), SF36 health survey, Health Assessment Questionnaire (HAQ), BASFI, VAS pain, DAS28, BASDAI and acute phase markers including ESR and CRP. Patients with PsA were discriminated into low and high disease activity according to BASDAI (≥ 6 vs ≤ 4).

Results: A total of 186 patients with PsA (116 female, 70 male, mean age 43.9 $\pm$ 12.6) who met CASPAR criteria were included. Their mean symptom duration was 7.9 $\pm$ 9.1 years. Patients with higher BASDAI score (≥ 6) had significantly higher scores on all important items including health related QoL, fatigue, pain, and functional status. Correlation coefficients between disease

activity and various health related QoL measurements were given in Table 1. SF36 physical component score was significantly correlated with VAS-pain, BASDAI and DAS28 compared to SF36 mental component. Also, physical activity subscore of NHP was found higher correlated with disease activity indices for PsA in all NHP sections. Other quality of life measurements including PsQoL, HAQ and ASQoL were also significantly correlated with disease activity measurements.

Conclusions: Psoriatic arthritis has a major impact on patients' lives. Variable disease activity measurements were found correlated with all important QoL measurements including NHP, SF36, PsQoL, HAQ and ASQoL. In patients with PsA, high disease activity may lead to severe impairments in daily activities and influence on participation in society.

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AB0758 AUDIT ON USTEKINUMAB DRUG SURVIVAL IN A DISTRICT GENERAL HOSPITAL VERSUS PSUMMIT 1 TRIAL RESULTS

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Background: Psoriatic arthritis (PsA) is an immune mediated inflammatory disorder that affects 10–30% of patients with psoriasis. Ustekinumab, a monoclonal anti-IL-12/23p40 antibody, is approved for the treatment of PsA and plaque psoriasis¹. PSUMMIT 1 was one of two phase 3 trials of ustekinumab in adults with active PsA². In England, use of medication is subject to guidance from National Institute for Health and Care Excellence (NICE). [TA340] recommend that Ustekinumab is a possible treatment, alone or with methotrexate, for adults with active psoriatic arthritis when treatment with non-biological disease-modifying antirheumatic drugs has not worked well enough if: treatment with tumour necrosis factor (TNF) alpha inhibitors is not suitable for them, or the person has had a TNF alpha inhibitor before³. We audited the survival data from our cohort of patients in district general hospital (DGH) against data from PSUMMIT trial.

Objectives: Our objectives were to evaluate drug survival of Ustekinumab in PsA, to compare real world data with that from PSUMMIT trial.

Methods: Our biologics database was searched for patients currently receiving Ustekinumab treatment for Psoriatic Arthritis and those who have had treatment failures. Length of treatment was recorded and any adverse effects which caused the treatment to be stopped. Analysis of treatment non-responders was performed including previous biologics/drug use. We then compared our results to those in the treatment arms (Ustekinumab 45mg or 90mg) of the PSUMMIT trial at week 24 and 52.

Results:

Table 1

	Ustekinumab 45mg	Ustekinumab 90mg
DGH (n=20)	15	5
PSUMMIT (n=409)	205	204

Table 2

	DGH		PSUMMIT	
	(Ust 45mg)	(Ust 90mg)	(Ust 45mg)	(Ust 90mg)
Week 24 withdrawal	4/15	0/5	8/205	7/204
Reasons:				
Adverse effects	3		4	3
Inefficacy	1		2	1
Other (consent, lost follow up)			4	3
Week 52 withdrawal	0/8	0/3	17/197	15/197
Reasons:				
Adverse effects			2	5
Inefficacy			7	3
Other (consent, lost follow up)			8	7

Treatment Failure group (DGH): All patients had had at least one anti-TNF agent prior to Ustekinumab therapy. One patient had trialed 3, two had two, one had one. They had been stopped either due to inefficacy or intolerance.

Conclusions: Ustekinumab has been shown to be a generally well tolerated drug. Our treatment group had proportionally more treatment failures than the PSUMMIT trial (4/20 20% vs 24/409 5.8%). There is the obvious criticism that our patient numbers are very small. For eligibility in PSUMMIT trial the patients had to be anti-TNF naïve. In NHS England, Ustekinumab is not NICE approved as a first line agent except in certain circumstances. Therefore, our patients have had

Abstract AB0757 – Table 1. Correlation coefficients between disease activity and various health related QoL measurements in patients with PsA [r (p)]

	VAS –pain	DAS 28	BASDAI	ESR	CRP
NHP-pain	0.571 (<0.001)	0.326 (<0.001)	0.644 (<0.001)	0.250 (0.003)	0.187 (0.027)
NHP-physical activity	0.599 (<0.001)	0.335 (<0.001)	0.652 (<0.001)	0.277 (<0.001)	0.111 (0.191)
NHP-fatigue	0.425 (<0.001)	0.324 (<0.001)	0.530 (<0.001)	0.287 (<0.001)	0.082 (0.337)
NHP-sleep	0.236 (0.003)	0.118 (0.162)	0.308 (<0.001)	0.113 (0.181)	-0.026 (0.764)
NHP-social isolation	0.214 (0.008)	0.299 (<0.001)	0.272 (<0.001)	0.080 (0.345)	-0.019 (0.824)
NHP-emotional reaction	0.315 (<0.001)	0.281 (<0.001)	0.326 (<0.001)	0.085 (0.315)	-0.023 (0.790)
SF36 physical component	-0.581 (<0.001)	-0.333 (0.005)	-0.449 (<0.001)	-0.346 (0.004)	-0.336 (0.005)
SF36 mental component	-0.439 (<0.001)	-0.232 (0.057)	-0.366 (<0.001)	-0.250 (0.038)	-0.198 (0.102)
PsAQoL	0.451 (<0.001)	0.285 (<0.001)	0.484 (<0.001)	0.103 (0.223)	-0.005 (0.955)
HAQ	0.428 (<0.001)	0.294 (<0.001)	0.386 (<0.001)	0.097 (0.246)	0.134 (0.107)
ASQoL	0.459 (<0.001)	0.459 (<0.001)	0.489 (<0.001)	0.220 (0.081)	0.068 (0.593)