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Impact of Psoriasis Area and Severity Index (PASI) on patient reported outcomes in patients with psoriasis: Results from the Corrona Psoriasis Registry

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Background

- Psoriasis (PsO) is an immune mediated chronic inflammatory disease, which has significant impact on health related quality of life (HRQoL). Disease severity and assessment of patient reported outcomes (PROs) has become increasingly important for defining effective treatment options.
- The objective of this study is to examine the association between disease severity measured by Psoriasis Area and Severity Index (PASI) and patient reported outcomes (PROs) at enrollment in the Corrona Psoriasis Registry, a prospective observational cohort of PsO patients.

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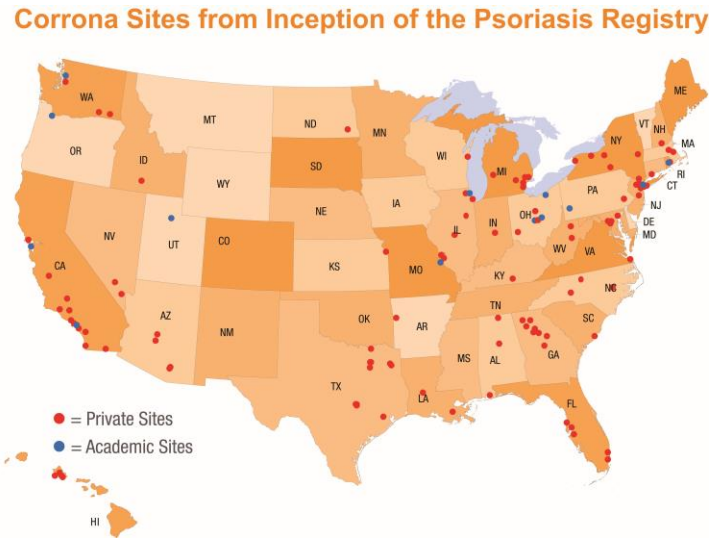
Data Source and Study Population

Data Source: Corrona Psoriasis Registry

The Corrona PsO registry, in collaboration with the National Psoriasis Foundation (NPF), was launched in April 2015 targeting to recruit approximately 200 sites with ~10,000 patients and an expected follow-up of at least 8 years and to study the comparative effectiveness, safety and treatment patterns of approved systemic therapies in a real world setting.

- As of October 31 2016, the National Psoriasis Foundation and Corrona have recruited 90 private and academic practice sites across 33 states in the United States, with 189 participating dermatologists.
- There are n=2095 patients with psoriasis participating in the registry.
- Data is collected from both the participating dermatologists and patients approximately **every 6 months** during routine outpatient visits.



Study Population: All patients aged ≥18 years with dermatologist-diagnosed psoriasis enrolled in the Corrona Psoriasis Registry as of May 31st 2016 were included. Additional eligibility criteria included initiation of a systemic biologic or non-biologic psoriasis treatment:

- On the enrollment date (incident users), OR
- Within the 12 months preceding the enrollment date (prevalent users).

Study Measures and Assessments

Demographics*	• Age • Gender • Height • Weight • Education	• Body Mass Index (BMI) • Work status • Insurance type • Smoking Status
Treatment History	• Prior Medication (Biologic and Non-biologic systemics) • Treatment initiation at enrollment visit (incident user) • Treatment initiation in the previous 12 months (prevalent user)	
Disease Characteristics	Disease Severity: • Body Surface Area (BSA) • Investigator's Global Assessment (IGA) • Psoriasis Area and Severity Index (PASI): 0-72 • Psoriasis disease duration • History of comorbidities	
Patient Reported Outcomes	• Pain, Itch and Fatigue (VAS 0-100) • Euro-QoL Overall health state VAS (0-100) • Dermatology Quality of Life Index (DLQI) • Work Productivity and Activity Impairment (WPAI)	

Patient Reported

Physician Reported

Patient Reported

BSA: Affected percent of body surface area 0-100%.
IGA: 0= Clear, 1= Almost Clear, 2= Mild, 3= Moderate, 4= Severe.
EQ-VAS: Self-rated "health state today" is reported on a visual analogue scale from 0-100. The recall period is 1 day.
DLQI: Dermatology Quality of Life Index. Overall DLQI scores range from 0–30; higher scores indicate greater effect on the patient's life (lower QoL). The recall period is 1 week.
WPAI**:** Four subdomains measure absenteeism, presenteeism, work productivity, and activity impairment. WPAI scores range from 0–100%; higher scores indicate greater impairment and less productivity. The recall period is 1 week.
*All Demographics are patient reported with the exception of height, weight and BMI.

Methods

Population Cohorts: Disease severity cohorts were categorized based on PASI severity scores (0-72):

- *Mild*: 0 ≤ PASI ≤ 5
- *Moderate*: 5 < PASI ≤ 12
- *Severe*: 12 < PASI ≤ 20
- *Very Severe*: 20 < PASI

Statistical Analysis:

- ***Descriptive analysis***: demographics, disease severity, comorbidities, QoL measures and PROs are presented descriptively by PASI disease severity cohorts, *at registry enrollment*
  - Means and standard deviations (SD) are reported for continuous variables. Medians, and interquartile ranges (IQR) are reported for other variables in addition to mean (SD).
  - Statistical comparisons among the cohorts were made using ANOVA for continuous variables and chi-squared for categorical variables.

- ***Modeling*:** Multi-variable logit regression analysis was conducted to examine the relationship between PROs, including QoL measures at enrollment, as a function of PASI (continuous measure). Models were adjusted for age, sex, duration of PsO and incident/prevalent use of the drug.

Patient demographics at registry enrollment by PASI groups

- There were n=1526 patients included in this study; 61.3% with mild PASI, 26.7% moderate, 7.9% severe and 4.1% very severe.
- Mean age and mean body mass index were comparable among the groups, mean body weight was 88.0 kgs in the 'mild' PASI group and 98.0 kgs in the 'very severe' PASI group.

Characteristics	PASI Distribution Groups			
	0 ≤ PASI ≤ 5 "Mild" N=935	**5 < PASI ≤ 12 "Moderate" N=408**	**12 < PASI ≤ 20 "Severe" N= 120**	**PASI > 20 "Very Severe" N=63**
Demographics				
Age (yrs), *mean (SD)*	50.9 ±14.5	50.1 ±14.4	50.1 ±15.1	49.7 ±12.4
Gender* Male, *n (%)*	458 (49%)	243 (60%)	67 (56%)	42 (67%)
Body weight* (kg), *mean (SD)*	88.0 ±22.6	90.4 ±24.7	90.7 ±24.8	98.0 ±30.2
BMI (kg/m^2), *mean (SD)*	30.3 ±6.9	30.8 ±7.8	31.2 ±8.1	32.3 ±8.2
Insurance Type**, n (%)				
Private*	712 (76%)	298 (73%)	75 (63%)	45 (71%)
Medicare	182 (19%)	62 (15%)	25 (21%)	10 (16%)
Medicaid*	97 (10%)	53 (13%)	23 (19%)	8 (13%)
No Insurance	26 (3%)	16 (4%)	6 (5%)	5 (8%)

*p-value <0.05; **Total of all insurance types may not add up to N (100%), as patients can have multiple insurance coverage; BMI: Body Mass Index.

Patient demographics at registry enrollment by PASI groups

- Work status was comparable among the groups; education level and smoking status differed among the groups (table).

Characteristics	PASI Distribution Groups			
	0 ≤ PASI ≤ 5 "Mild"	**5 < PASI ≤ 12 "Moderate"**	**12 < PASI ≤ 20 "Severe"**	**PASI > 20 "Very Severe"**
Education*, n (%)	n=935	n=408	n=120	n=63
12th grade or less	63 (7%)	34 (8%)	13 (11%)	6 (10%)
High school graduate/GED	213 (23%)	81 (20%)	29 (24%)	12 (19%)
Some college/Associate degree	320 (34%)	109 (27%)	42 (35%)	22 (35%)
College graduate or higher	339 (36%)	184 (45%)	36 (30%)	23 (37%)
Work Status, *n (%)*	n=935	n=406	n=120	n=63
Full time	531 (57%)	234 (58%)	64 (53%)	36 (57%)
Part time	78 (8%)	32 (8%)	9 (8%)	7 (11%)
Work at home	60 (6%)	30 (7%)	7 (6%)	6 (10%)
Student	26 (3%)	7 (2%)	4 (3%)	0 (0%)
Disabled	70 (7%)	32 (8%)	18 (15%)	7 (11%)
Retired	170 (18%)	71 (17%)	18 (15%)	7 (11%)
Smoking*, *n (%)*	n=930	n=405	n=119	n=63
Current smoker	153 (16%)	76 (19%)	30 (25%)	9 (14%)
Former smoker	340 (37%)	128 (32%)	30 (25%)	24 (38%)
Never smoked	437 (47%)	201 (50%)	59 (50%)	30 (48%)

* p-value <0.05

Disease characteristics at registry enrollment by PASI groups

- Patients had an overall mean disease duration of 15.7 years and 41% had concurrent PsA diagnosis. Overall, about half of the patients had cardiovascular or diabetes risk factors and about one-fifth reported depression and anxiety.
- Overall, 46% of patients were biologic naïve and 46% also had non-biologic systemic usage (data not shown).

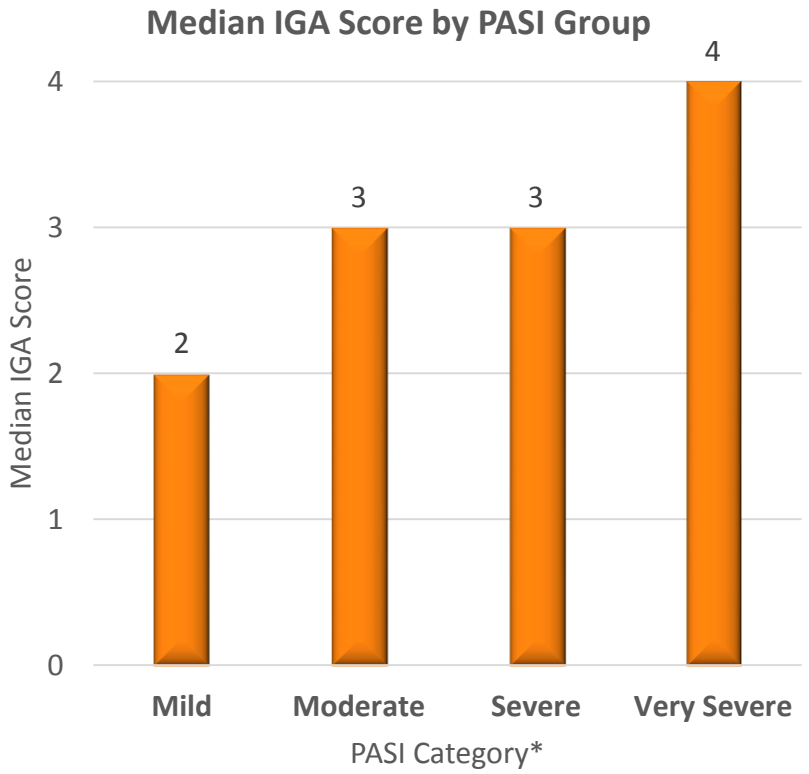
Disease Characteristics	PASI Distribution Groups			
	0 ≤ PASI ≤ 5 "Mild"	**5 < PASI ≤ 12 "Moderate"**	**12 < PASI ≤ 20 "Severe"**	**PASI > 20 "Very Severe"**
Psoriasis duration (yrs), *n*	n=932	n=407	n=120	n=63
mean (SD)	15.8 ±13.8	15.0 ±13.0	17.3 ±14.1	17.5 ±12.9
median (IQR)	11.0(4.0,25.0)	11.0(5.0,22.0)	15.0(5.0,25.0)	15.0(7.0,25.0)
Psoriatic Arthritis diagnosis, *n (%)**	403 (43%)	145 (36%)	41 (34%)	30 (48%)
Comorbidities**				
CVD, *n (%)*	119 (13%)	41 (10%)	14 (12%)	8 (13%)
CV/Diabetes risk factors, *n (%)*	447 (48%)	199 (49%)	60 (50%)	32 (51%)
Diabetes Mellitus, *n (%)**	117 (13%)	60 (15%)	25 (21%)	14 (22%)
Lymphoma / Malignancy, *n (%)*	41 (4%)	27 (7%)	4 (3%)	2 (3%)
Crohn's Disease, *n (%)*	4 (0%)	3 (1%)	1 (1%)	0 (0%)
Depression, *n (%)*	175 (19%)	81 (20%)	22 (18%)	13 (21%)
Anxiety, *n (%)*	173 (19%)	68 (17%)	23 (19%)	11 (17%)
Prior Medication				
Biologic Naïve, *n (%)**	436 (47%)	194 (48%)	53 (44%)	16 (25%)
Prior non-biologic systemic usage count,				
Count of patients, n (%)*	416 (44%)	174 (43%)	62 (52%)	43 (68%)
Count of drugs: *median (IQR)*	1.0(1.0,2.0)	1.0(1.0,2.0)	1.0(1.0,2.0)	1.0(1.0,2.0)

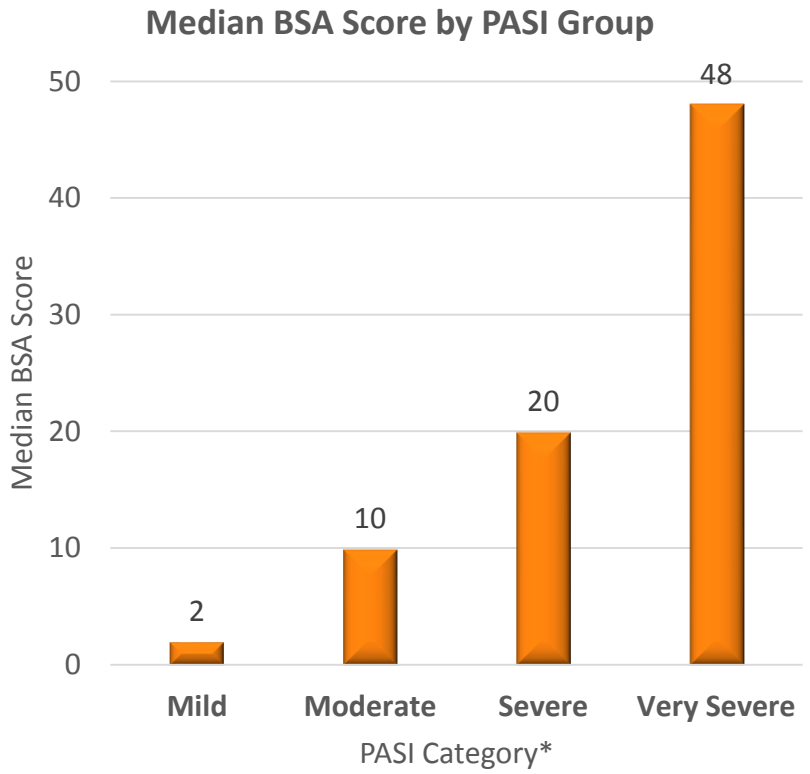
*p-value <0.05; CVD, Cardiovascular disease, SD, Standard deviation; IQR, Interquartile range; **Comorbidities, physician reported; CVD: Revascularization procedures (CABG, stent, angioplasty), Ventricular arrhythmia, Cardiac arrest, Acute coronary syndrome, Coronary artery disease, Transient ischemic attack, Hemorrhage with/without hospitalization (serious bleed), Deep vein thrombosis, Peripheral arterial disease, Pulmonary embolism, Carotid artery disease. Malignancy: Breast, Lung, Skin (excluding non-melanoma skin cancer) & Other.

Disease severity – BSA and IGA at registry enrollment by PASI groups

IGA: Median (figure) and mean IGA score increased as PASI severity increased. Mean IGA score of the overall population was 2.2; and 1.7, 3.0, 3.3 and 3.7 for *mild, moderate, severe, very severe* categories respectively.

BSA: Median (figure) and mean BSA score increased as PASI severity increased. Mean BSA of the overall population was 9.1; and 3.6, 11.8, 22.8, 47.9 for *mild, moderate, severe, very severe* categories respectively.



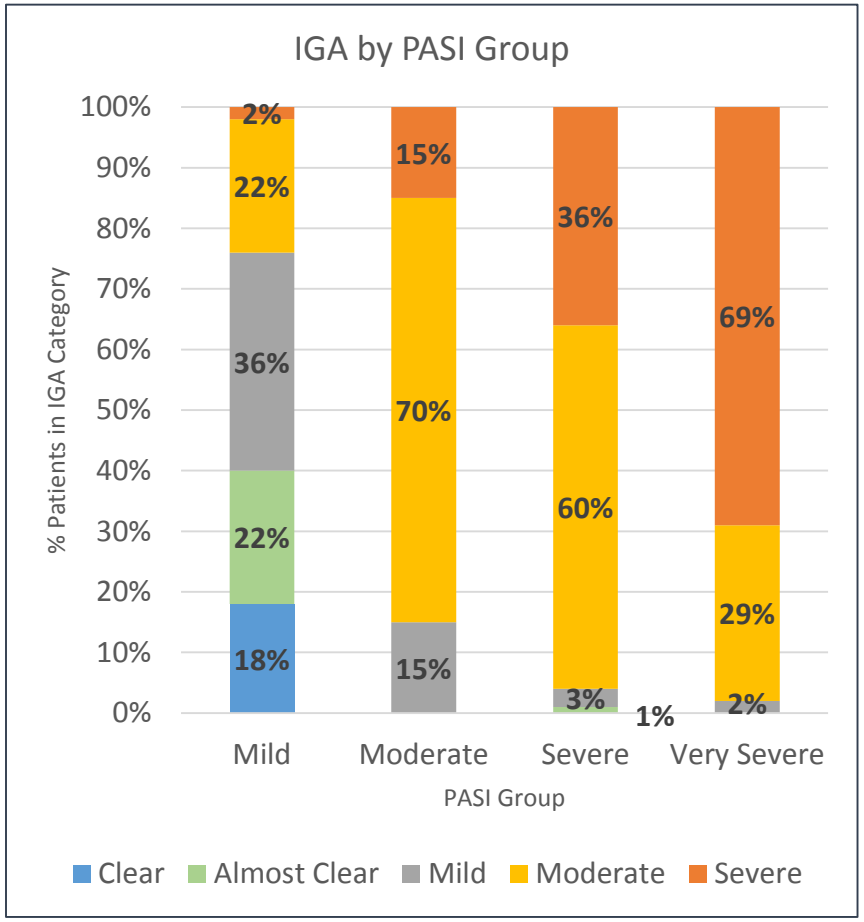


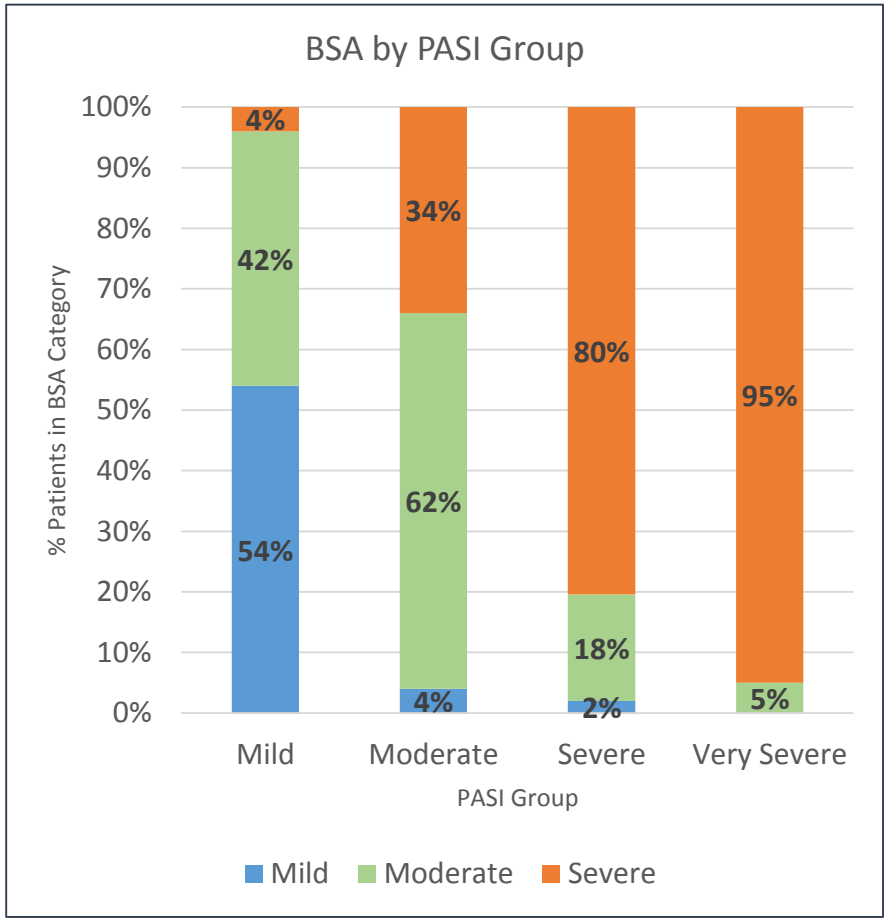
*p-value <0.0001

Disease severity categories – BSA and IGA at registry enrollment by PASI groups

IGA: A higher proportion of patients had moderate/severe IGA in the moderate/severe/very severe PASI groups - 85%, 96% and 98% respectively.

BSA: Similarly, more than half of the patients were in moderate/severe BSA category in the moderate/severe/very severe PASI groups - 86%, 98% and 95% respectively.



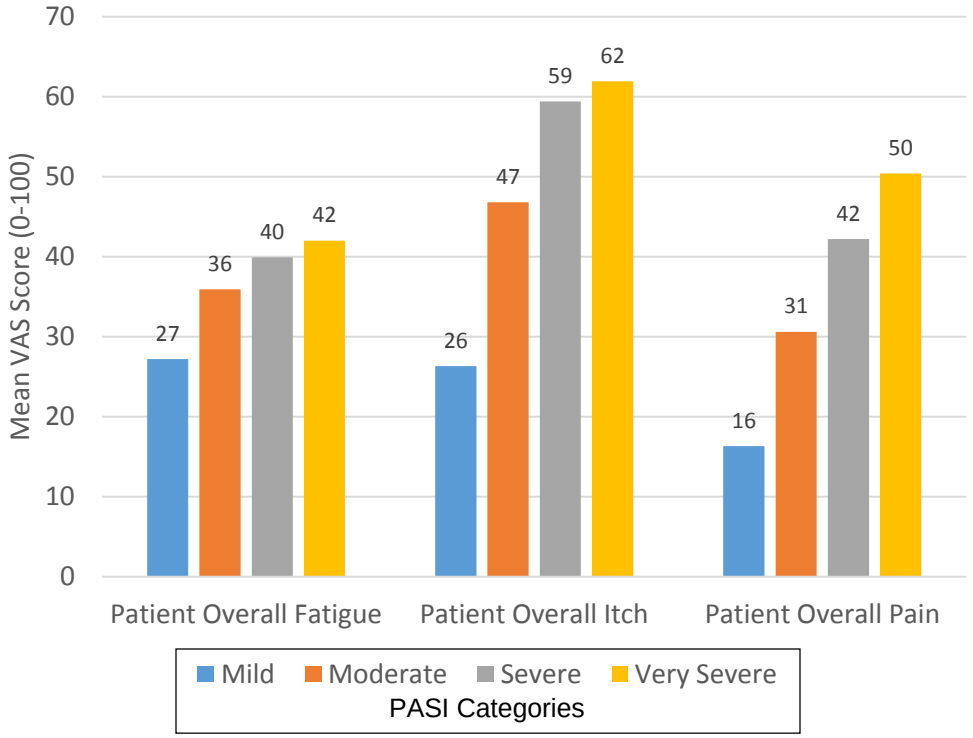


Body Surface Area (BSA): A disease severity measure characterized by the amount of body surface area affected. It is reported as percent involvement on a scale of 0-100%; Categorical BSA is divided into the following categories: [0,3)= Mild, [3,10]= Moderate, (10,100]= Severe. Investigator Global Assessment (IGA): A 5-point tool used to measure disease severity on a scale of 0-4, where 0=clear, 1=almost clear, 2=mild, 3=moderate and 4=severe.

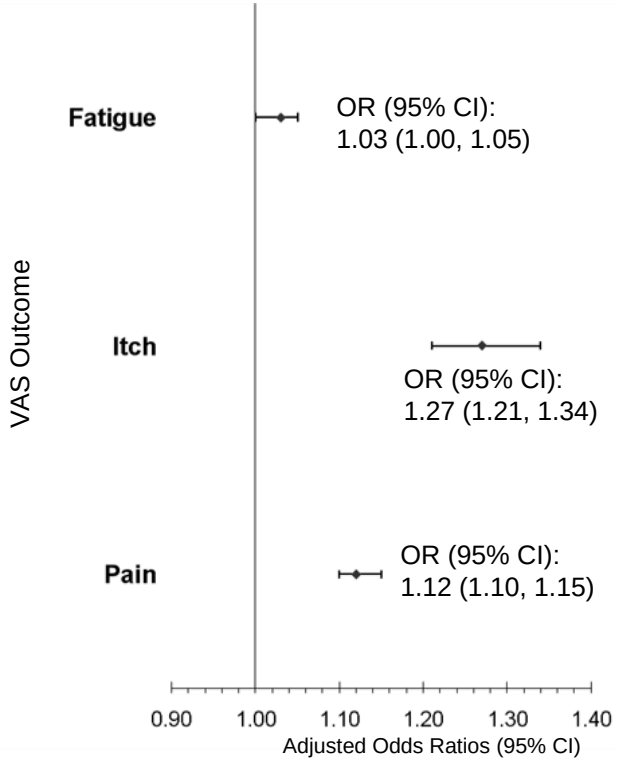
Patient reported fatigue, itch and pain at registry enrollment by PASI group

- Mean scores for patient reported pain, itch and fatigue were higher in the more severe categories for disease severity.
- Regression results confirmed the associations – increase in fatigue, itch and pain was significantly associated with increased PASI.

Fatigue, Itch and Pain by PASI Group



VAS Outcome Odds Ratios based on change in PASI*

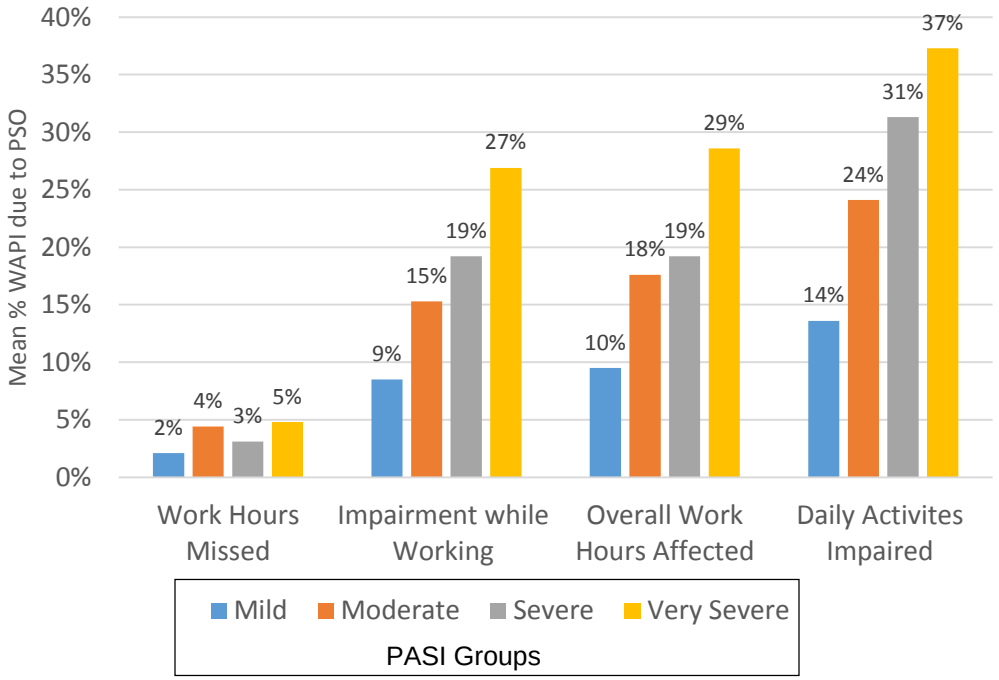


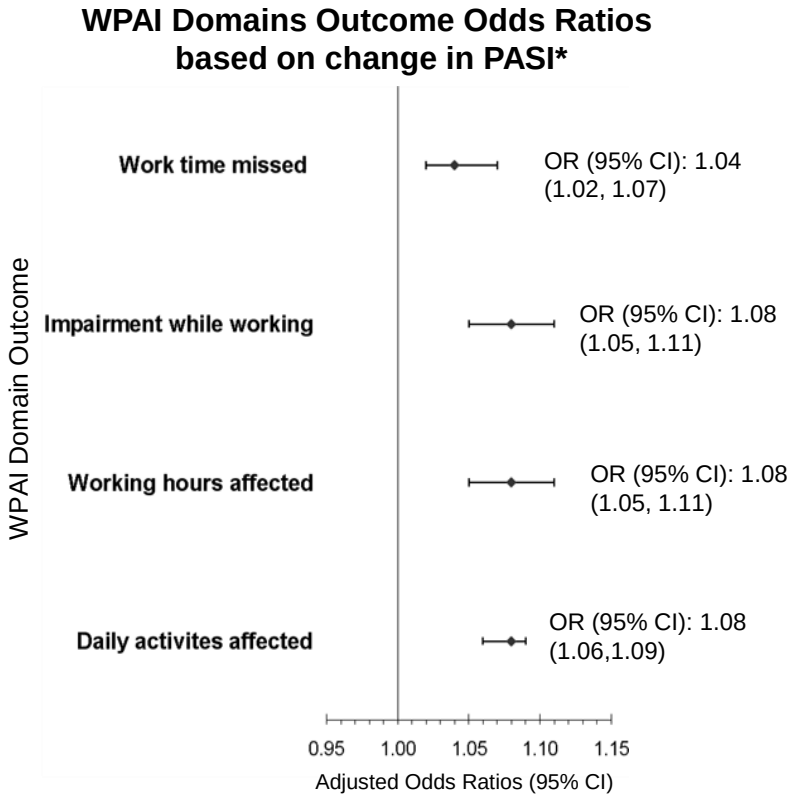
*p-value <0.05; OR: Odds Ratio represents the odds of increasing from "none" to "some" level of fatigue, itch and pain, respectively, for each unit increase in PASI while holding all other variables constant; CI: Confidence Interval: CIs that do not include 1 indicate statistically significant OR.

Work productivity and activity impairment (WPAI) at registry enrollment by PASI group

- Patients with higher disease severity (in categories: moderate/severe/very severe) reported more impairment while working and more overall daily activity impairment.

- Ordinal regression results confirmed the associations – decreased work productivity or increased impairment was significantly associated with an increase in PASI.

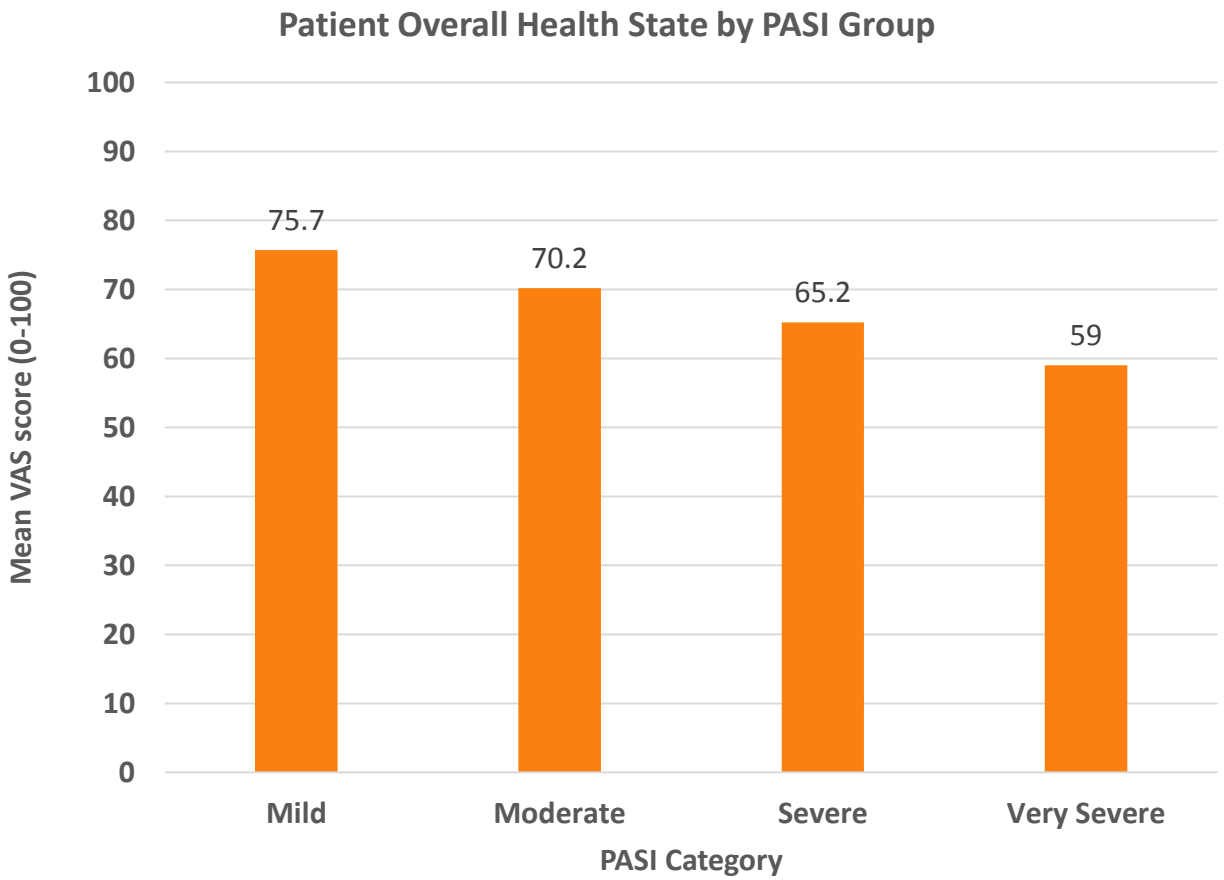




*p-value <0.05; OR: Odds Ratio represents the odds of increasing from "None" to "Some" level of reduced productivity or increased impairment within each respective domain for each unit increase in PASI while holding all other variables constant; CI: Confidence Interval: CIs that do not include 1 indicate statistically significant OR.

Patient overall health state (EQ-5D) at registry enrollment by PASI group

Overall health status of patients decreased as disease severity increased, with a mean score of 75.7 in the mild PASI group vs. a mean score of 59 in the very severe PASI group(figure).

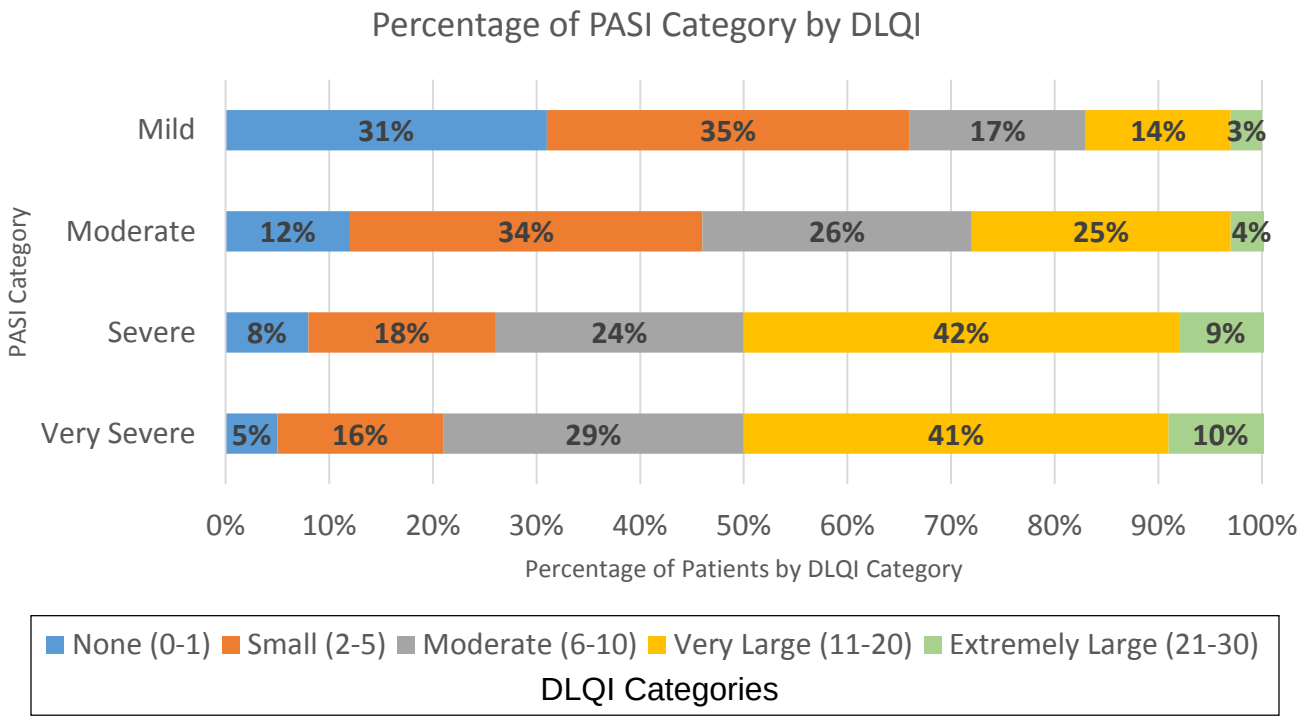


The ordinal regression outcome shows an odds ratio of 0.94 (95%CI: 0.93, 0.96) meaning subjects have a 6% increase in odds of moving to a worse health state for each 1 unit increase in PASI.

Dermatology quality of life index (DLQI) at registry enrollment by PASI group

More than 50% of the patients in severe/very severe category for PASI reported very large/extremely large effect on life (51% in both groups) as measured by DLQI, with a mean (SD) score increasing from 5.3 (5.6) in the mild category to 11.3 (6.6) in the very severe category for PASI.

Dermatology Quality of Life Index	PASI Distribution Groups				*p*-Value
	0 ≤ PASI ≤ 5 "Mild"	5 < PASI ≤ 12 "Moderate"	12 < PASI ≤ 20 "Severe"	PASI > 20 "Very Severe"	
DLQI (Score: 0-30), *n*	n=931	n=408	n=120	n=63	
mean (SD)	5.3 ±5.6	7.7 ±5.8	10.7 ±6.6	11.3 ±6.6	<0.0001
median (IQR)	3.0(1.0,8.0)	7.0(3.0,11.5)	11.0(5.5,15.0)	11.0(7.0,17.0)	



The ordinal regression outcome shows an odds ratio of 1.21 when no DLQI is present versus when any DLQI is present meaning that patients will have a *21% higher odds of having some DLQI* (versus none) in their weekly QoL *for each unit increase in PASI*.

CONCLUSIONS

- Mean scores for BSA and IGA were higher for the more severe PASI categories.
- Higher PASI scores are significantly associated with poorer patient reported outcomes and quality of life measures.

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Author Disclosures

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