SYSTEMIC THERAPY ELIGIBILITY CRITERIA OF THE INTERNATIONAL PSORIASIS COUNCIL MAY REDUCE UNDERTREATMENT OF PSORIASIS PATIENTS WITH LOW BODY SURFACE AREA INVOLVEMENT ASSOCIATED WITH HIGH DISEASE BURDEN

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BACKGROUND

- While many advanced therapies exist for PsO, measures based on extent of skin manifestations (e.g., body surface area (BSA) and Psoriasis Area and Severity Index [PASI]) are used for reimbursement and therapeutic decisions, as systemic therapies are traditionally reserved for patients with moderate-severe disease per label.
- In 2020, the International Psoriasis Council (IPC) outlined three criteria (i.e., BSA ≥10%, sensitive body area involvement, failure of topical therapy control) that should be considered when estimating severity of PsO and therefore patient evaluating eligibility for systemic therapy.

OBJECTIVES

- To understand level of agreement between physicians and the IPC criteria for eligibility for systemic therapy
- Investigate whether the IPC criteria for eligibility for systemic therapy would identify patients with low BSA associated with significant disease burden or worse outcomes

METHODS

- Data were drawn from the Adelphi PsO Disease Specific Programme (DSP), a cross-sectional (with aspects of retrospective data collection) survey of physicians and their consulting adult PsO patients in the US, France, Germany, Italy, Spain, and the UK between 2018-2019.
- Physicians during routine care categorized patients as having mild, moderate, or severe PsO; the latter two were combined into a single moderate-severe category (eligible for systemic therapy per label).
- Severity of PsO was then retrospectively classified dichotomously based on eligibility for systemic therapy according to IPC criteria, using the most current clinical markers.
- Agreement regarding eligibility for systemic therapy between physician assessments and IPC criteria was assessed.

Table 1: Agreement on PsO Severity Between Clinician and IPC Criteria

		Clinician Assessment (N=3,866)			
		Agreement (%)	Disagreement (%)	McNemar's p-value	Kappa (95% CI)
IPC Criteria	BSA ≥10%	84	16	<0.0001	0.68 (0.65-0.70)
	Sensitive Body Area Involvement[a]	66	34	<0.0001	0.35 (0.32-0.38)
	Topical Therapy Failure	48	52	<0.0001	0.02 (-0.01-0.05)
	Meets Any of Above Criteria	55	45	<0.0001	0.17 (0.15-0.19)

Note: BSA%, Sensitive Body Area are based on most current patient assessment by MD

a. sensitive body locations included: scalp, neck, face, buttock, groin, soles of feet, toes, palms of hand, fingers, nails

Takeaway 1: Prior to the IPC systemic therapy criteria publication, there was unmet need regarding patient burden recognition outside of BSA involvement

Presented at ISPOR 2024, May 5-8

RESULTS

- 3,866 PsO patient assessments from G5 countries + US were analyzed
- Disagreement based on severity was significant (1740 [Dis] compared to 2126 [Agr])

Table 2: Patient Demographics and Current Disease Activity for Cohorts with Agreement or Disagreement Between Clinician Assessments and IPC Criteria for PsO Severity

	Agreement and Disagreement Cohorts			
	Agreement between Clinician and IPC		Disagreement between Clinician and IPC	
Characteristic	Mild N = 442	Moderate/Severe N= 1684	Clinician Mild N= 1702	Clinician Severe N= 38
Age (years)				
n	200	749	824	15
Mean (SD)	45.8 (15.3)	42.9 (14.47)	45.9 (14.1)	42.9 (11.2)
Median (Q1,Q3)	43.5 (34.5, 57.0)	42.0 (32.0, 52.0)	45.0 (35.0, 56.0)	42.0 (33.0, 50.0)
Min, Max	16.0, 90.0	13.0, 88.0	17.0, 88.0	27.0, 63.0
Race, n (%)				
Caucasian	387 (87.6%)	1472 (87.4%)	1490 (87.5%)	35 (92.1%)
Other Races	55 (12.4%)	212 (12.6%)	212 (12.5%)	3 (7.9%)
Sex, n (%)				
Female	202 (45.7%)	756 (44.9%)	738 (43.4%)	18 (47.4%)
Male	239 (54.1%)	927 (55.0%)	960 (56.4%)	20 (52.6%)
Provider & Patient Country of Residence				
France	78 (17.6%)	286 (17.0%)	230 (13.5%)	3 (7.9%)
Germany	19 (4.3%)	342 (20.3%)	237 (13.9%)	2 (5.3%)
Italy	96 (21.7%)	189 (11.2%)	311 (18.3%)	4 (10.5%)
Spain	104 (23.5%)	159 (9.4%)	329 (19.3%)	6 (18.4%)
UK	85 (19.2%)	237 (14.1%)	243 (14.3%)	14 (36.8%)
USA	60 (13.6%)	471 (28.0%)	352 (20.7%)	8 (21.1%)
Body Mass Index (kg/m²)				
n	411	1602	1647	36
Mean (SD)	25.6 (4.4)	26.5 (5.1)	26.06 (4.4)	26.9 (7.1)
Median (Q1, Q3)	25.1 (4.4)	25.7 (23.2, 28.5)	25.7 (23.1, 28.1)	24.5 (22.8, 27.9)
Min, Max	16.1, 48.9	16.6, 69.1	15.6, 64.0	19.0, 51.5
Current Body Surface Area (BSA%)				
n	442	1679	1691	38
Mean (SD)	1.4 (2.0)	19.7 (15.8)	3.95 (5.1)	4.0 (2.4)
Median (Q1, Q3)	0 (0, 2.0)	15.0 (10.0, 25.0)	2.0 (1.0, 5.0)	5.0 (2.0, 6.0)
Min, Max	0, 9.0	0, 100.0	0, 75.0	0, 8.0
Sensitive Location Involvement, n (%)				
Yes	0	1474 (87.5%)	1051 (61.8%)	0
No	442 (100%)	210 (12.5%)	651 (38.2%)	38 (100%)
Topical Failure				
Yes	0	888 (52.7%)	1256 (73.8%)	0
No	361 (81.7%)	415 (24.6%)	319 (18.7%)	21 (55.3%)
Missing	81 (18.3%)	381 (22.6%)	127 (7.5%)	17 (44.7%)

Takeaway 2: Stratification of cohorts showed no major notable differences in patient demographic characteristics. Disagreement was most notable with underdiagnosis of PsO severity regardless of physician country of practice, driven largely by sensitive location and topical failure criteria

Table 3: Biologic/TNF Use by Cohorts

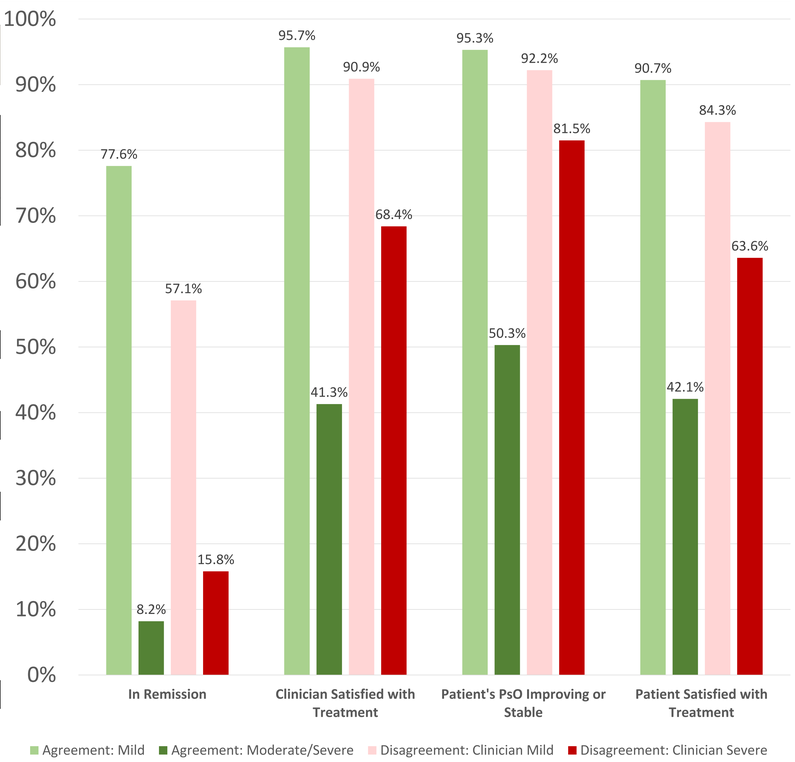
		Agreement and Disagreement Cohorts (N=3,866)			
		Agreement between Clinician and IPC		Disagreement between Clinician and IPC	
		Mild	Severe	Clinician Mild	Clinician Severe
Medication Class	Biologic/TNF*	223 (50.5%)	525 (31.2%)	773 (45.4%)	13 (34.2%)
	Oral Systemics†	168 (38.0%)	822 (48.8%)	799 (46.9%)	19 (50.0%)

* Included: ustekinumab, infliximab, etanercept, adalimumab, golimumab

† Included: methotrexate, cyclosporine, acitretin, apremilast, fumarate

Takeaway 3: Less than half of the patients in the Disagreement Cohort were on biologic therapy, suggesting an opportunity to improve current treatment guidance

Figure 1: Outcomes of Interest



Takeaway 4: PsO patients classified as severe by IPC but mild by clinician (light red bar) experienced notably worse outcomes than the mild agreement cohorts (light green bar), including in remission rates and treatment satisfaction

CONCLUSION

- The level of disagreement prior to publication of IPC criteria for PsO severity was significant among clinicians, with highest discordance found with clinicians estimating lower PsO severity.
- The snapshot frequencies of biologic/TNF inhibitor use across all groups are low, but may be confounded by the dynamic nature of severity of disease indicating an inherent limitation of cross-sectional study designs.
- IPC criteria for systemic therapy eligibility may effectively identify patients with significant PsO burden who may otherwise be missed by clinician assessment of BSA alone.
- Adoption of the IPC criteria into clinical trials, clinical practice, and reimbursement decisions by payers is considered due to the potential to reduce undertreatment of PsO and therefore improvement of patient outcomes.

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