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1 Characteristics of patients with psoriasis with Psoriasis Area and Severity
2 Index < 10 treated with biological agents: results from the French PsoBioTeq
3 cohort

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15 M. Beylot-Barry is a consultant for Abbvie, Celgene, Janssen-Cilag, Lilly, Novartis, Medac
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3
4 Dear Editor,

5 The decision to initiate systemic therapy in psoriasis is based mainly on disease severity
6 assessments, determined using physicians-derived scores. A commonly used assessment is the
7 Psoriasis Area and Severity Index (PASI), with an absolute value of 10 or more indicating
8 severe disease.¹ How patients perceive the severity of psoriasis and physicians' evaluations
9 may be discordant, especially when lesions involve visible areas or are associated with
10 itching. Such lesions can have a greater impact on quality of life (QoL),² as evaluated using
11 patient-reported outcomes such as the Dermatology Life Quality Index (DLQI). Analysis of
12 the Swedish PsoReg registry found that patients with high PASI and low DLQI were more
13 likely to receive biologics than those with low PASI and high DLQI.³ A retrospective study of
14 54 patients showed that DLQI guides therapeutic decisions in patients with PASI ≤ 6 , with
15 improvement of both disease and QoL scores following systemic therapy.⁴ A recent
16 international Delphi consensus challenged the severity criteria,⁵ and guidelines^{1,6} propose
17 considering systemic therapy when psoriasis involves impactful areas or is recalcitrant to
18 topical therapy, whatever the PASI.

19 To understand better the determinants of clinical decisions other than disease severity, we
20 aimed to describe the clinical profiles and main outcomes of patients with PASI <10 for
21 whom biologics were initiated in the real-life French PsoBioTeq cohort.⁷ The PsoBioTeq
22 study was approved by the 'Comite d'Evaluation de l'Ethique des Projets de Recherche
23 Biomedicale du GHU Nord' (JMD/MDM/177-11) and was registered on Clinical Trials.gov
24 (NCT01617018).

25 Between July 2012 to July 2016, 1027 patients initiated biologics and had available PASI data
26 at inclusion. We compared patients with PASI <10 vs. ≥ 10 for baseline variables (socio-

1 demographic data, choice of biologic, type and location of psoriasis, PASI and DLQI,
2 treatment response and drug survival. Descriptive analysis used n (%), mean (SD) and
3 survival curves with the Kaplan-Meier method. Groups were compared using the chi-squared,
4 Fisher, Student's t or log-rank test, as appropriate.

5 Table 1 presents the characteristics of the 1027 patients. Among them, 403 (39.2%) had PASI
6 <10. We found no difference between groups for age and socioprofessional categories.
7 Women more frequently had PASI <10 (43.4% vs. 32.2%, $p < 0.001$). Body mass index also
8 differed, with obese patients less often having PASI <10 (25.3% vs. 34.6%, $p=0.01$). In the
9 whole cohort, 91.4% of patients presented plaque-type psoriasis, without any difference
10 between PASI groups. Psoriasis restricted to visible areas (face, palms, nails, folds) was most
11 frequent in the PASI <10 group (5.0% vs. 1.2%, $p<0.001$). DLQI >10 was more frequent in
12 the PASI ≥ 10 group (52.0% vs. 33.8%). However, 52.7% of the 256 patients with a very low
13 PASI (0-6) had DLQI > 10.

14 Before initiating biologics, 90.7% of all study patients received at least one systemic
15 conventional treatment. The two most frequently prescribed first-line biologics in the cohort
16 were adalimumab and ustekinumab, with a different distribution between the 2 groups
17 (adalimumab 36.0% vs. 45.7%; ustekinumab 32.8% vs. 27.2% in PASI <10 and ≥ 10 groups,
18 respectively).

19 Biologic drug survival did not differ significantly across the two PASI groups: median
20 survival 23.2 months (range 19.3-27.9) in the PASI <10 group and median 27 months (range
21 23.1-31.8) in the PASI ≥ 10 group ($p=0.23$). Time to achieve $\geq 75\%$ reduction of baseline
22 PASI was significantly delayed in the PASI <10 group: median time of 12.2 months (range
23 10.2-14.0) vs 6.7 months (range 6.3-7.1); $p<0.001$. Time to achieve a DLQI of 0 or 1 did not
24 statistically differ between the two groups ($p=0.13$).

1 In conclusion, we found that 39% of patients in the PsoBioTeq cohort in whom biologics
2 were initiated had PASI <10 at initiation. This was not the consequence of a high frequency
3 of non-plaque-type psoriasis, such as palmo-plantar pustulosis, for which PASI is not
4 appropriate. The main differences between patients from the two groups were that patients
5 with PASI <10 were more frequently women and not obese and had higher-frequency
6 involvement of impactful areas. Such localisations have a known impact on social well-
7 being.² One third of these patients reported a significant impact on QoL (DLQI >10), and this
8 reached 52.7% in the low-PASI (0-6) subgroup. These characteristics might explain the
9 decision to start biologics in some of these patients, even if the PASI score was low.
10 Therapeutic maintenance was favorable in the PASI<10 group, although no formal
11 comparison can be made with the PASI > 10 group due to differences in therapeutic regimen
12 between the two groups.

13 Altogether, this study is in accordance with increasing evidence that, in addition to PASI, the
14 decision to initiate biologics considers patient-specific treatment goals, especially for
15 impactful skin sites, with lack of disease control under conventional treatments.^{5,6,8} More data
16 are needed to address the needs of patients with limited disease severity and high impact of
17 psoriasis on QoL to plan for appropriate therapeutic intervention.

18

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1 **Table 1: Characteristics of the 1027 patients who initiated biologics and had reported**
 2 **baseline Psoriasis Area and Severity Index (PASI)**

	PASI <10 (n=403)	PASI ≥10 (n=624)	Total (n=1027)	p- value
Main psoriasis data: n (%)				
Plaques	357 (90.8%)	548 (91.8%)	905 (91.4%)	0.60
Other forms	36 (9.2%)	49 (8.2%)	85 (8.6%)	
Missing	10	27	37	
Restricted to impactful areas	19 (5%)	7 (1.2%)	26 (2.7%)	0.0005
Missing	20	46	66	
DLQI >10	134 (33.8%)	318 (52%)	452 (44.8%)	<0.0001
Missing	6	12	18	
Socio-demographic data				
Age (year)				0.45
Median age	45	46	46	
Range	19; 83	18; 84	18; 84	
Female: n (%)	175 (43.4%)	201 (32.2%)	376 (36.6%)	0.0003
BMI: n (%)				
<25	137 (38.5%)	187 (34.2%)	324 (35.9%)	0.012
25-30	129 (36.2%)	170 (31.1%)	299 (33.1%)	
> 30	90 (25.3%)	189 (34.6%)	279 (30.9%)	
Missing	47	78	125	
Therapeutic interventions received before biologic initiation				
Topical	377 (97.4%)	566 (97.3%)	943 (97.3%)	
UVB-therapy	113 (30.4%)	195 (35.5%)	308 (33.4%)	
PUVA-therapy	197 (52.5%)	324 (57.3%)	521 (55.4%)	
Conventional systemic(s)*	376 (93.3%)	555 (89%)	931 (90.7%)	
First biologic at inclusion: n (%)				
				0.006
Etanercept	113 (28%)	140 (22.4%)	253 (24.6%)	
Infliximab	13 (3.2%)	29 (4.6%)	42 (4.1%)	
Adalimumab	145 (36%)	285 (45.7%)	430 (41.9%)	
Ustekinumab	132 (32.8%)	170 (27.2%)	302 (29.4%)	
Biologic drug survival, in months: median [range]				
	23.2 [19.3-27.9]	27 [23.1-31.8]		0.23
Time to achieve PASI75, in months: median [range]				
	12.2 [10.2-14.0]	6.7 [6.3-7.1]		0.0001
Time to achieve DLQI(0/1),** in months: median [range]				
	61.6 [13.3-61.6]	15.0 [9.5-28.29]		0.13

3 * at least one conventional systemic therapy

4 ** in the patients with baseline DLQI >1 (335 for PASI <10 group and 556 for PASI ≥10
 5 group)