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Impact of Apremilast Treatment on Individual Domains of the Dermatology Life Quality Index Questionnaire in Patients with Psoriasis in Special Areas: 52-Week Results From EMBRACE

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Introduction & Objectives: Psoriasis in special areas impairs quality of life (QoL), even among patients (pts) with limited skin involvement (body surface area [BSA] 1-10%). Treatment guidelines recommend that pts with special area involvement and/or QoL impairment, even those with low BSA, should be considered as candidates for systemic therapy. In the EMBRACE study, the efficacy and safety of apremilast 30 mg BID (APR) was assessed over 52 weeks (wks) in pts with limited skin involvement but occurring in special areas.

Materials & Methods: EMBRACE (NCT03774875) was a phase 4, multinational, randomized, double-blind, placebo (PBO)-controlled, parallel-group trial conducted in Western Europe. Eligible pts had plaque psoriasis (≥ 6 months prior to enrollment) not controlled by topicals; lack of response, contraindication, or intolerance to conventional first-line systemics; psoriasis in ≥ 1 special area; Psoriasis Area and Severity Index score ≥ 3 to ≤ 10 ; and Dermatology Life Quality Index (DLQI) score > 10 . Pts were randomized 2:1 to receive APR or PBO from Wks 0 to 16, after which pts continued to receive APR (APR/APR) or switched from PBO to APR (PBO/APR) until Wk 52. Randomization was stratified by 5 special areas (visible locations [dorsal hand, face, neck, hairline], scalp, nails, genital area, and palmoplantar area). The primary endpoint was DLQI response (≥ 4 -point reduction) at Wk 16. In this post hoc analysis, we report mean percentage change from baseline for each of the 10 DLQI items over 52 wks and mean percentage change from baseline in DLQI total score in subgroups based on special area location, number of special areas (1, 2, and ≥ 3), and disease duration (< 5 , ≥ 5 - < 10 , ≥ 10 - < 20 , and ≥ 20 years). Data are summarized descriptively.

Results: Among the 277 pts randomized, mean (SD) baseline DLQI was 18.2 (4.9) (PBO: 18.5 [4.9]; APR: 18.1 [4.9]). Significantly more pts achieved DLQI response at Wk 16 with APR vs PBO (73.3% vs 41.3%; $P < 0.0001$).¹ Least squares mean change from baseline in DLQI was also significantly greater with APR vs PBO at Wk 16 (-8.7 vs -3.4; $P < 0.0001$).¹ A total of 221 pts (PBO: 69, APR: 152) entered the extension phase and 158 (PBO/APR: 53, APR/APR: 105) completed Wk 52. Among pts who completed Wk 52, mean age at baseline was 50.5 years, 60.8% were men, and mean psoriasis duration was 17.7 years (**Table 1**). The DLQI items with the most impact at baseline were "how itchy, sore, painful, stinging" (Q1), "how embarrassed, self-conscious" (Q2), and "influenced clothes you wear" (Q4) (**Table 1**). Greater improvements were seen in each DLQI item with APR vs PBO at Wk 16 except "prevented working or studying" (Q7a), although this item had a limited sample size (**Figure 1**). At Wk 52, improvements in all DLQI items were maintained in the APR/APR group and similar improvements were seen in the PBO/APR group (**Figure 1**). Greater improvements were seen in DLQI total score with APR vs PBO at Wk 16 regardless of special area type (**Figure 2**), number of special areas involved (**Figure 3**), or disease duration. Improvements were maintained through Wk 52.

Conclusion: In pts with psoriasis in special areas and QoL impairment, greater improvements were seen in almost all DLQI items with APR vs PBO at Wk 16 in a post hoc analysis. APR/APR and PBO/APR pts experienced similar improvements by Wk 52. Improvements in DLQI were consistent regardless of special area location, number of special areas, or disease duration.

1. Mrowietz U, Barker J, Conrad C, et al. *J Eur Acad Dermatol Venereol.* 2023;37:348-355.

Table 1. Baseline demographics and clinical characteristics

	PBO/APR (n=53)	APR/APR (n=105)
Age, years, mean (SD)	33.5 (12.1)	39.0 (11.3)
Male, n (%)	31 (58.5)	65 (63.9)
BSD, %, mean (SD)	7.7 (4.9)	7.1 (3.9)
Primary manifestation for stratification*, n (%)		
Scalp	20 (29.0)	36 (23.7)
Nails	16 (23.2)	36 (23.7)
Palmo/plantar	7 (10.1)	17 (11.3)
Genitals	10 (14.5)	21 (13.8)
Visible locations	16 (23.2)	42 (27.6)
Number of special areas, n (%)		
1	17 (32.1)	37 (35.2)
2	22 (41.5)	44 (41.9)
≥3	14 (26.4)	24 (22.9)
Duration of psoriasis, years, mean (SD)	20.4 (14.2)	16.3 (13.5)
<5 years, n (%)	9 (17.0)	19 (18.1)
≥5 and <10 years, n (%)	4 (7.6)	26 (24.8)
≥10 and <20 years, n (%)	16 (30.2)	29 (27.6)
≥20 years, n (%)	24 (45.8)	31 (29.5)
DLQI (0-30), mean (SD)	17.7 (4.7)	17.6 (4.5)
Primary manifestation subgroup		
Scalp	18.4 (5.0)	17.9 (3.9)
Nails	17.8 (5.0)	17.8 (4.4)
Palmo/plantar	18.2 (4.2)	18.6 (5.2)
Genitals	16.3 (4.4)	17.7 (4.1)
Visible locations	18.3 (4.9)	17.9 (4.5)
Number of special areas subgroup		
1	17.0 (4.8)	18.1 (4.8)
2	17.9 (4.7)	17.7 (4.4)
≥3	18.3 (5.4)	18.0 (4.2)
Disease duration subgroup		
<5 years	18.7 (3.7)	18.4 (4.4)
≥5 and <10 years	19.8 (7.9)	17.8 (4.9)
≥10 and <20 years	18.0 (5.5)	17.6 (4.1)
≥20 years	16.8 (4.0)	18.0 (4.7)
DLQI item (0-3), n mean (SD)		
Q1: How itchy, sore, painful, stinging	2.5 (0.7)	2.4 (0.7)
Q2: How embarrassed, self-conscious	2.3 (0.7)	2.3 (0.7)
Q3: Interfered with shopping, house, yard	1.7 (0.8)	1.7 (0.8)
Q4: Influenced clothes you wear	2.2 (0.8)	2.1 (0.8)
Q5: Affected social, leisure activity	1.9 (0.9)	1.9 (0.7)
Q6: Made it difficult to do any sports	1.2 (1.0)	1.4 (1.0)
Q7a: Prevented working or studying	0.4 (1.0)	0.5 (1.1)
Q7b: if no problem at work or studying†	1.8 (0.6)	1.2 (0.7)
Q8: Problem with partner, friends, relatives	1.6 (0.8)	1.7 (0.7)
Q9: Caused any sexual difficulties	1.3 (1.1)	1.6 (1.0)
Q10: How much of a problem is treatment	1.8 (1.0)	1.6 (1.0)
Number of prior conventional systemic therapies, n (%)		
0	10 (18.9)	26 (24.8)
1	21 (39.6)	38 (36.2)
2	12 (22.6)	18 (17.1)
≥3	10 (18.9)	23 (21.9)
Number of prior biologic therapies, n (%)		
0	46 (86.8)	97 (92.4)
1	6 (11.3)	7 (6.7)
2	0	1 (1.0)
≥3	1 (1.9)	0

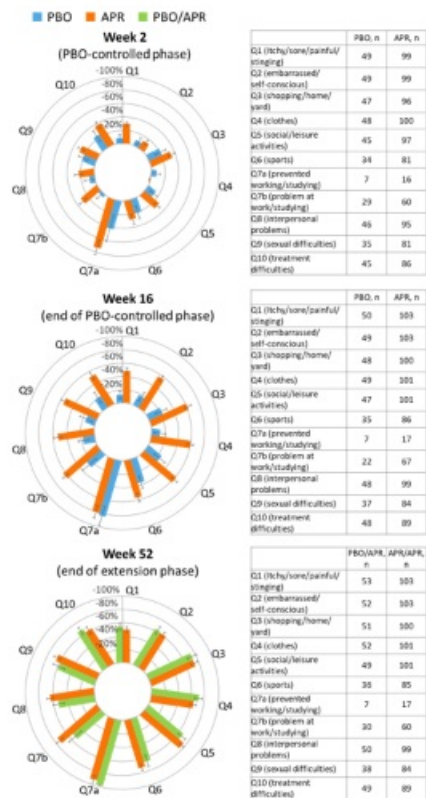
Patients who completed Week 52.

*For the purposes of stratification, if a patient presented with multiple special areas, they were allocated to the special area group which was most severe, as determined by the patient.

†PBO: n=40, APR: n=85.

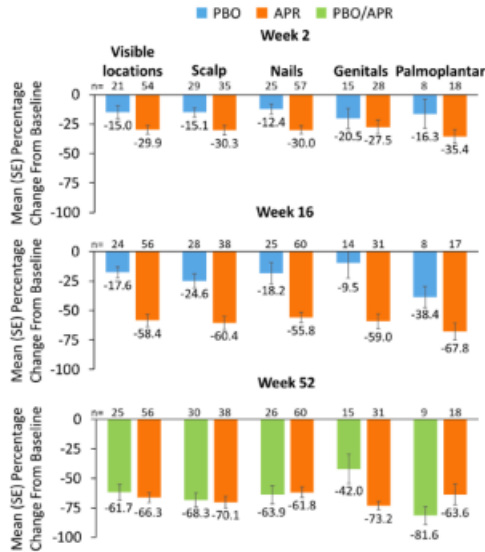
APR, apremilast; DLQI, Dermatology Life Quality Index; PBO, placebo; SD, standard deviation.

Figure 1. Mean percentage change from baseline in each DLQI item over time



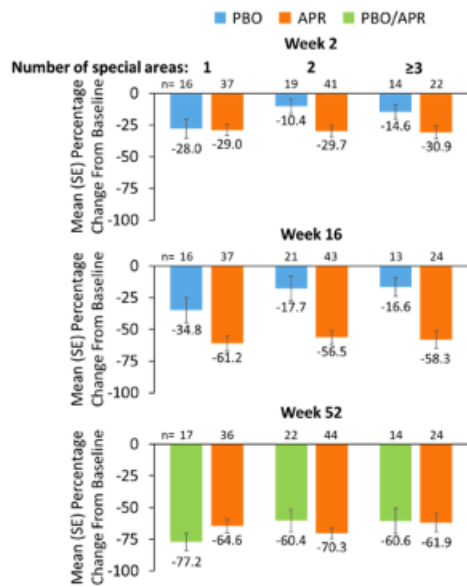
Shown are mean (SE) percentage change from baseline. Patients who completed Week 52. Data as observed.
Q1: Itchy, sore, painful, stinging; Q2: How embarrassed, self-conscious; Q3: Interfered with shopping, home, yard; Q4: Influenced clothes you wear; Q5: Affected social, leisure activity; Q6: Made it difficult to do any sports; Q7a: Prevented working or studying; Q7b: Problem at work or studying; Q8: Problem with partner, friends, relatives; Q9: Caused any sexual difficulties; Q10: How much of a problem is treatment.
APR, apremilast; DLQI, Dermatology Life Quality Index; PBO, placebo; SE, standard error.

Figure 2. Mean percentage change from baseline in DLQI total score over time by special area location



Patients who completed Week 52. Data as observed.

Figure 3. Mean percentage change from baseline in DLQI total score over time by number of special areas



Patients who completed Week 52. Data as observed.

