Moderate to severe scalp psoriasis is associated with severe impact on quality of life: an analysis of patient-reported outcomes in PSORIATYK SCALP, a scalp-specific phase 3b/4 trial with deucravacitinib

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Introduction

- Deucravacitinib, an oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, is approved in the US, EU, and other countries for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy[1-4]
- Scalp involvement may occur in up to ~80% of patients with psoriasis[5]
  - Under guidelines jointly issued by the American Academy of Dermatology and the National Psoriasis Foundation, psoriasis may be considered severe when it occurs in certain areas of the body, including the scalp[6]
  - The International Psoriasis Council classifies patients with scalp psoriasis as candidates for systemic therapy[7]
- PSORIATYK SCALP (NCT05478499), a 52-week, phase 3b/4, multicenter, randomized, double-blinded, placebo-controlled trial, assessed the efficacy and safety of deucravacitinib in patients with moderate to severe scalp psoriasis and total body surface area (BSA) involvement ≥3%
  - At Week 16, deucravacitinib achieved statistical superiority vs placebo for the primary endpoint (scalp-specific Physician Global Assessment [ss-PGA] score of 0 or 1) and all key secondary endpoints (≥90% improvement from baseline in Psoriasis Scalp Severity Index [PSSI], change from baseline in the patient-reported scalp-specific itch numeric rating scale, and static Physician Global Assessment score of 0 or 1)[8]

Objective

- To assess the impact of scalp disease on patient quality of life (QoL) in subgroups of patients with BSA 3%–10% and BSA >10%

Methods

Study design

- Patients eligible for inclusion in PSORIATYK SCALP were aged ≥18 years with moderate to severe scalp psoriasis
  - PSSI ≥12
  - ss-PGA ≥3: 0 = none; 1 = very mild; 2 = mild; 3 = moderate; 4 = severe
  - Scalp surface area (SSA) involvement ≥20%
  - Total BSA involvement ≥3%

PRO measures

- Dermatology Life Quality Index (DLQI)
  - Skin-disease–specific measure assessing 6 QoL domains
  - Range: 0–30, with higher scores indicating worse QoL[9]
    - 0–1: no effect on QoL
    - 2–5: small effect on QoL
    - 6–10: moderate effect on QoL
    - 11–20: very large effect on QoL
    - 21–30: extremely large effect on QoL
- Four numeric rating scale (NRS) measures for scalp-specific itch, pain, and flaking, and whole-body itch
  - NRS measures describe the symptom's worst level of severity over the preceding 24 hours on an 11-point scale from 0 (none) to 10 (worst imaginable)
  - Scores ≥4 indicate moderate to severe symptoms[10,11]
- Global Assessment Psoriasis Symptoms-Scalp (GAPS-S)
  - Patients indicate the current severity of scalp psoriasis symptoms on a Likert-type scale (none, mild, moderate, or severe)
- Scalpdex
  - A validated, scalp-dermatitis-specific QoL measure based on the Skindex instrument, comprising symptoms, emotions, and function subscales[12]
    - The total score represents the average of all 23 items
  - Range: 0–100, with higher scores indicating worse QoL
  - No severity bands have been determined for Scalpdex to aid score interpretation
    - Skindex severity thresholds suggest that symptoms score ≥52, emotions score ≥39, function score ≥37, and total score ≥44 indicate severe impact on QoL[13]

Analyses

- Baseline scores for DLQI, the 4 NRS measures, GAPS-S, and Scalpdex subscale and total scores are described for patients with BSA 3%–10% and for patients with BSA >10%
  - To assess the burden of disease at baseline, data are pooled between the treatment arms

Results

Patient population

- The analysis included 154 patients, with a mean (SD) BSA involvement of 10.3% (9.1)
  - BSA 3%–10%: n = 108; mean (SD) BSA: 5.9% (2.0)
  - BSA >10%: n = 46; mean (SD) BSA: 20.8% (10.6)
- Demographics and baseline clinical characteristics for each BSA subgroup appear in the **Table**

Table. Demographics and baseline clinical characteristics

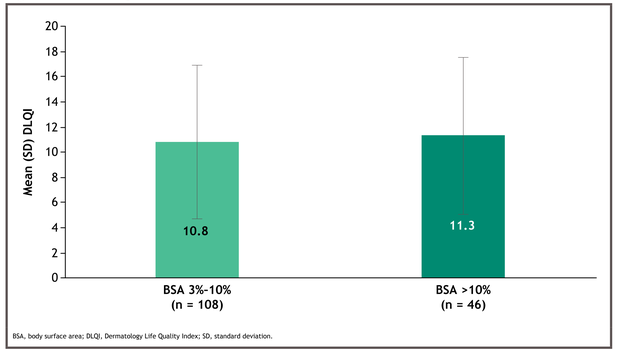
Characteristic	BSA 3%–10% (n = 108)	BSA >10% (n = 46)
Age, years, mean (SD)	41.9 (14.4)	45.2 (15.7)
Female, n (%)	51 (47.2)	14 (30.4)
White, n (%)	100 (92.6)	40 (87.0)
Weight, kg, mean (SD)	87.9 (24.7)	91.5 (26.0)
PSSI, mean (SD)	32.2 (12.5)	35.1 (13.8)
ss-PGA, n (%)		
3	79 (73.1)	29 (63.0)
4	29 (26.9)	17 (37.0)
SSA, mean (SD)	54.0 (23.1)	60.8 (23.8)
BSA, mean (SD)	5.9 (2.0)	20.8 (10.6)
PASI, mean (SD)	6.9 (3.1)	17.2 (6.1)
sPGA, n (%)		
2	10 (9.3)	1 (2.2)
3	87 (80.6)	36 (78.3)
4	11 (10.2)	9 (19.6)

BSA, body surface area; PASI, Psoriasis Area and Severity Index; PSSI, Psoriasis Scalp Severity Index; SD, standard deviation; SSA, scalp surface area; sPGA, static Physician Global Assessment; ss-PGA, scalp-specific Physician Global Assessment.

PROs at baseline by subgroup

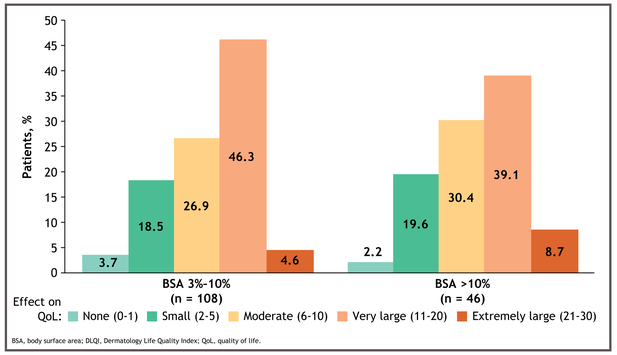
- Mean DLQI scores were similar between the subgroups and indicated a very large effect on QoL (**Figure 1**)
- DLQI category distributions were similar between the subgroups, with patients most frequently reporting a very large effect on QoL (**Figure 2**)
- Mean scalp-specific NRS scores were similar between the subgroups and indicated moderate to severe symptoms (**Figure 3**)
  - Mean whole-body itch scores were numerically worse for patients with BSA >10% (**Figure 3**)
- The proportion of patients reporting severe scalp psoriasis symptoms was numerically greater in the BSA >10% subgroup (**Figure 4**)
- Mean Scalpdex subscale and total scores were numerically worse for patients with BSA 3%–10% than for those with BSA >10% (**Figure 5**)

Figure 1. Mean DLQI scores at baseline



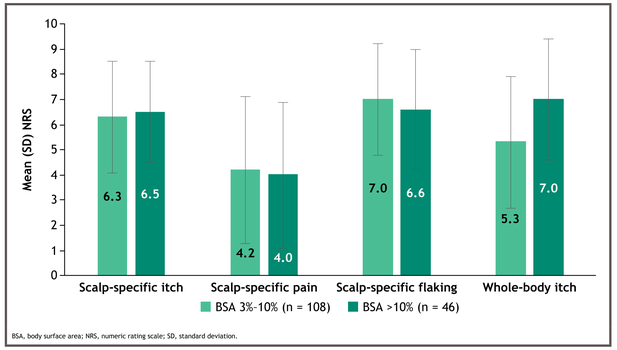
BSA, body surface area; DLQI, Dermatology Life Quality Index; SD, standard deviation.

Figure 2. DLQI categorization at baseline



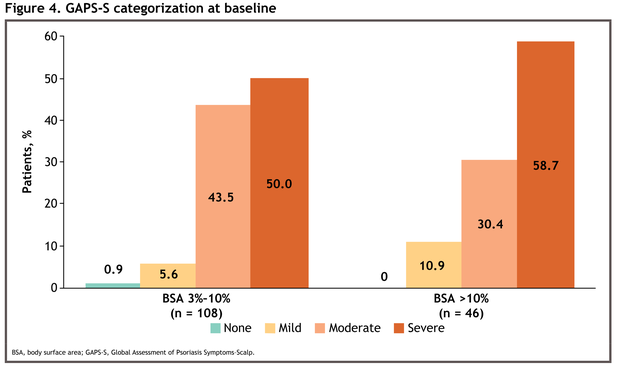
BSA, body surface area; DLQI, Dermatology Life Quality Index; QoL, quality of life.

Figure 3. Mean NRS scores at baseline



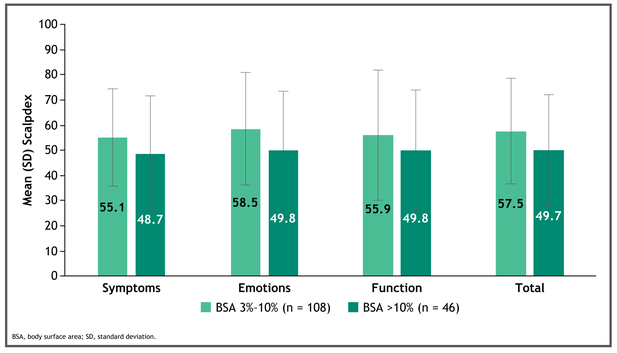
BSA, body surface area; NRS, numeric rating scale; SD, standard deviation.

Figure 4. GAPS-S categorization at baseline



BSA, body surface area; GAPS-S, Global Assessment of Psoriasis Symptoms-Scalp.

Figure 5. Mean Scalpdex scores at baseline



BSA, body surface area; SD, standard deviation.

Conclusions

- Moderate to severe scalp psoriasis was associated with a substantial impact on QoL across various measures among patients in both BSA subgroups (BSA 3%–10% and BSA >10%)
  - While DLQI scores were similar between the BSA subgroups, scalp-specific QoL measured by Scalpdex was numerically worse in patients with less extensive overall disease (BSA 3%–10%)
- Scalp symptoms may drive the impact on QoL in patients in both subgroups
  - Patients reported moderate to severe scalp psoriasis symptoms and severe impact to QoL measured by DLQI and Scalpdex
- Scalp disease may disproportionately affect QoL relative to total BSA involvement in patients with psoriasis

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Acknowledgments

- This study was sponsored by Bristol Myers Squibb
- Medical writing and editorial assistance was provided by Eleanor Bush, MA, of Peloton Advantage, LLC, an OPEN Health company, funded by Bristol Myers Squibb

Disclosures

- **SRF:** Research, speaking, and/or consulting support: AbbVie, Accordant, Almirall, Alvotech, Amgen, Arcutis, Arena Pharmaceuticals, Argenx, Biocon, Boehringer Ingelheim, Bristol Myers Squibb, Caremark, Dermavant, Eurofins, Forte Biosciences, Galderma, GSK/Stiefel, Helsinn, Informa, Janssen, Leo Pharma, Lilly, Menlo, Merck, Mylan, National Biological Corporation, National Psoriasis Foundation, Novan, Novartis, Ortho Dermatologics, Pfizer, Qurient Therapeutics, Regeneron, Samsung, Sanofi, Sun Pharma, Teladoc, UCB, UpToDate, and vTv Therapeutics; Founder and part owner: Causa Research; Shareholder: Sensal Health
- **A-BD-M:** No conflicts of interest reported
- **AF:** Educational support to attend conferences, consultant, or speaker: AbbVie, Almirall, Boehringer Ingelheim, Janssen, Leo Pharma, Lilly, Novartis, Sanofi, Pfizer, and UCB
- **WB:** No conflicts of interest reported
- **AN, EB, C-YC, BB, and RD:** Employees and shareholders: Bristol Myers Squibb
- **DT:** Scientific advisory board member, research, speaking, and/or consulting support: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Galderma, Janssen-Cilag, Leo Pharma, Lilly, Novartis, Pfizer, Regeneron, Roche-Posay, Sanofi, Target RWE, and UCB

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Presented at the American Academy of Dermatology Annual Meeting; March 7-11, 2025; Orlando, Florida

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