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Changes in Draining Tunnel Counts in the Randomized, Placebo-Controlled, Phase 2 Study of Povorcitinib (INCB054707) in Patients With Hidradenitis Suppurativa

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Introduction

- Hidradenitis suppurativa (HS) is a chronic, debilitating, inflammatory condition characterized by painful nodules and abscesses that can develop into draining tunnels and lead to scarring[1]
  - Draining tunnels are generally associated with higher levels of inflammation[2]
- Dysregulation of the Janus kinase (JAK)/signal transducer and activator of transcription pathway is involved in a wide variety of inflammatory disorders, including HS[3]
- Povorcitinib (INCB054707) is an oral, JAK1-selective, small-molecule inhibitor that demonstrated proof of concept over 8 weeks of treatment in two phase 2 studies[4] and over 16 weeks of double-blind, placebo-controlled treatment in this phase 2, dose-ranging study in HS[5]

Objective

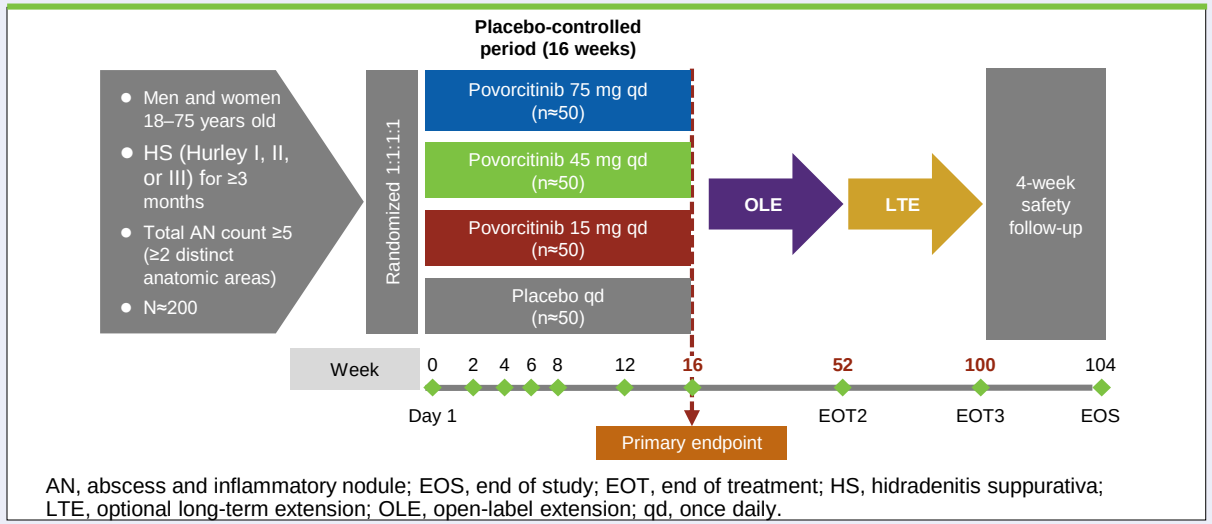
- To evaluate the effect of povorcitinib versus placebo on the following:
  - Draining tunnel counts at study visits among patients with ≥1 or ≥3 draining tunnels at baseline
  - Patient-reported outcomes (PROs) and high sensitivity C-reactive protein (hsCRP) among patients with no draining tunnels versus ≥1 and ≥3 draining tunnels at baseline

Methods

Study Design and Patients

- This was a randomized, placebo-controlled, phase 2, dose-ranging study evaluating the efficacy and safety of povorcitinib in adult patients with HS (**Figure 1**)
  - Patients were randomized 1:1:1:1 to receive 1 of 3 doses of povorcitinib (15, 45, or 75 mg) or placebo once daily for 16 weeks of double-blind treatment
  - Patients with >20 draining tunnels at screening or baseline were excluded; no minimum draining tunnel count was required

Figure 1. Study Design



AN, abscess and inflammatory nodule; EOS, end of study; EOT, end of treatment; HS, hidradenitis suppurativa; LTE, optional long-term extension; OLE, open-label extension; qd, once daily.

- This post hoc analysis assessed the percentage change from baseline in draining tunnel count in subgroups of patients with ≥1 draining tunnel and ≥3 draining tunnels at baseline
- Change from baseline over time for the following outcomes was assessed in subgroups of patients with no draining tunnels and those with ≥1 and ≥3 draining tunnels at baseline
  - Skin pain numerical rating scale (NRS)
  - Itch NRS
  - Hidradenitis Suppurativa Quality of Life (HiSQoL) symptom subdomain
  - hsCRP concentration

Statistical Analyses

- All subgroup analyses were summarized using descriptive statistics

Results

Patients

- At baseline, 113 patients had no draining tunnels and 96 had ≥1 draining tunnel (**Table, Figure S1** [scan QR code on slide 5])
  - Prevalence of Black race, Hurley stage III disease, prior adalimumab treatment, and elevated hsCRP concentration were higher among patients with ≥1 versus no draining tunnels at baseline

Table. Demographic and Clinical Characteristics at Baseline

Characteristic	Patients Without Draining Tunnels (n=113)	Patients With ≥1 Draining Tunnel (n=96)
Age, mean (SD), y	35.4 (10.6)	39.0 (11.3)
Women, n (%)	95 (84.1)	63 (65.6)
Race, n (%)		
White	83 (73.5)	64 (66.7)
Black	22 (19.5)	29 (30.2)
Other	8 (7.1)	3 (3.1)
BMI, mean (SD), kg/m^2	37.1 (8.7)	34.2 (8.8)
Current or former tobacco use, n (%)	66 (58.4)	55 (57.3)
HS family history, n (%)	32 (28.3)	19 (19.8)
Disease duration, mean (SD), y	10.8 (9.3)	9.8 (9.1)
Hurley stage, n (%)		
Stage I	15 (13.3)	0
Stage II	83 (73.5)	63 (65.6)
Stage III	15 (13.3)	33 (34.4)
AN count, mean (SD)	10.6 (8.3)	12.7 (8.7)
Select prior therapies for HS, n (%)		
Oral antibiotics	55 (48.7)	65 (67.7)
Adalimumab	18 (15.9)	20 (20.8)
Other biologics	4 (3.5)	8 (8.3)
Surgical intervention	13 (11.5)	19 (19.8)
None	13 (11.5)	3 (3.1)
hsCRP,* mean (SD), mg/L	10.3 (11.0)	20.9 (23.3)

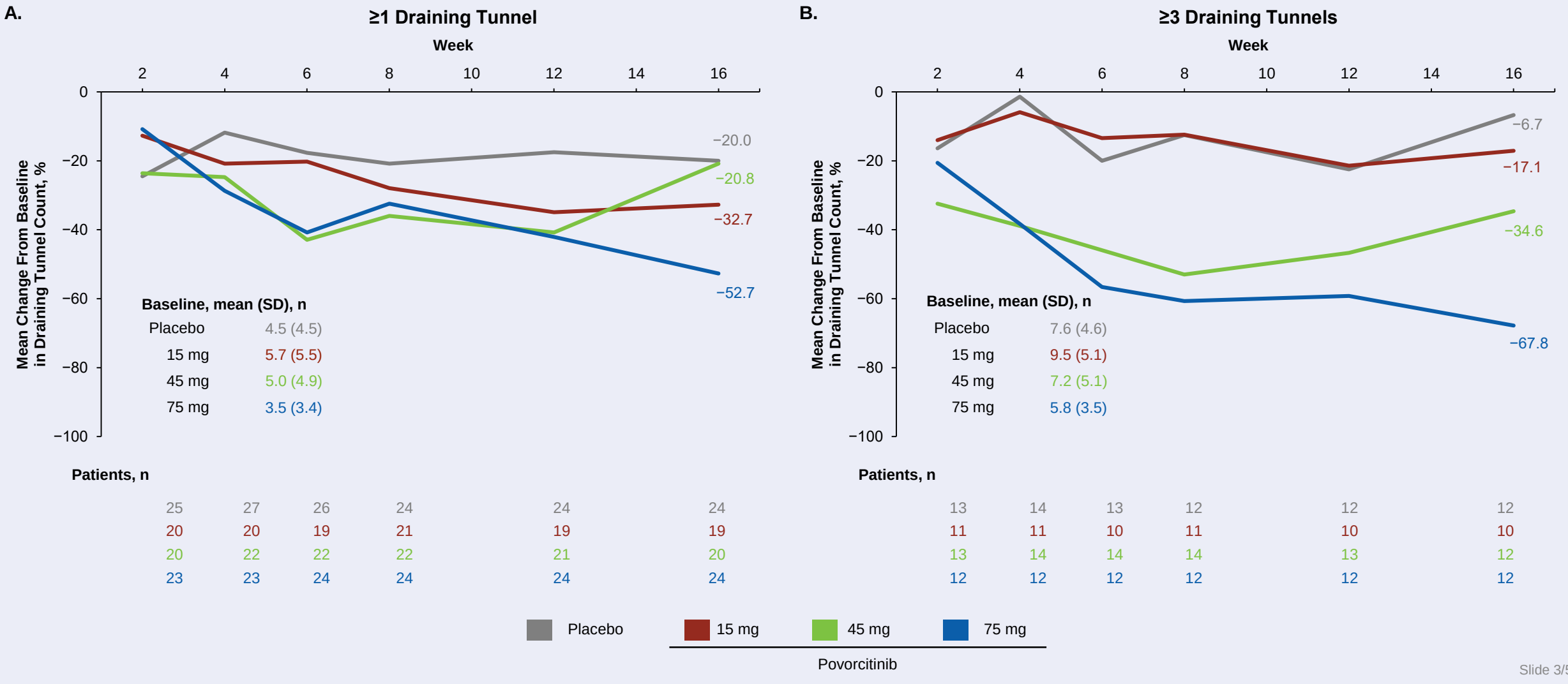
AN, abscess and inflammatory nodule; BMI, body mass index; HS, hidradenitis suppurativa; hsCRP, high sensitivity C-reactive protein.
* Normal range hsCRP concentration is <2 mg/L.

Results *(cont'd.)*

Draining Tunnel Count Over Time in Patients With ≥1 Draining Tunnel at Baseline

- Draining tunnel counts decreased over time with povorcitinib treatment among patients with ≥1 draining tunnel at baseline (n=96; **Figure 2A**); similar trends were observed in the subgroup of patients with ≥3 draining tunnels at baseline (n=51; **Figure 2B**)

Figure 2. Percentage Change From Baseline in Draining Tunnel Count Over Time

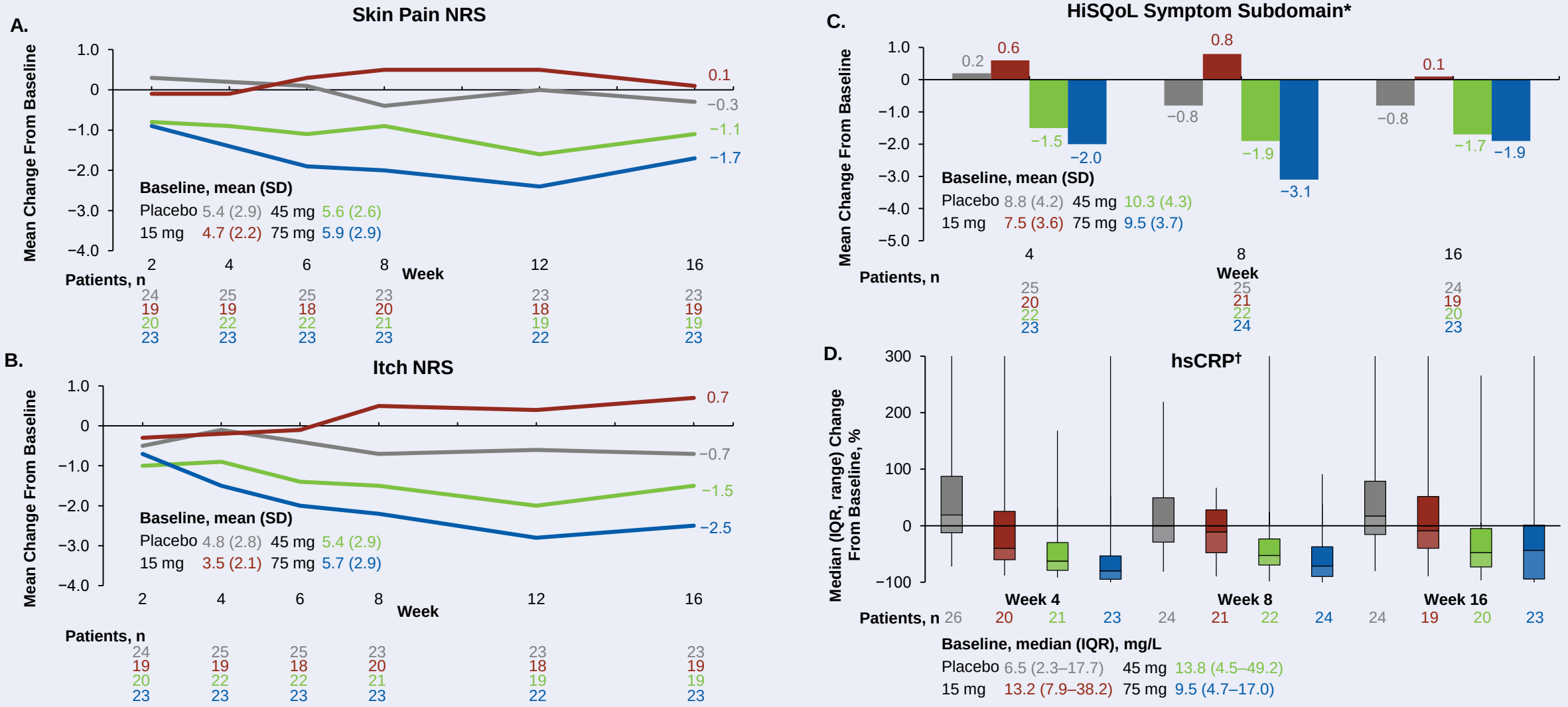


Results *(cont'd.)*

PROs and Markers of Inflammation Over Time

- Povorcitinib treatment was generally associated with improvements in HS symptoms and reduction in the inflammatory marker hsCRP in patients with ≥1 draining tunnel at baseline (**Figure 3**) as well as those with no draining tunnels or ≥3 draining tunnels (**Figures S2–S5** [scan QR code on slide 5])

Figure 3. PROs and hsCRP Over Time in Patients With ≥1 Draining Tunnel at Baseline



HiSQoL, Hidradenitis Suppurativa Quality of Life; hsCRP, high sensitivity C-reactive protein; IQR, interquartile range; NRS, numerical rating scale; PRO, patient-reported outcome. * Includes questions related to pain, odor, drainage, and itch. † Y-axis truncated at 300 for readability.

Conclusions

- **The presence of draining tunnels was associated with elevated hsCRP in patients with HS**
- **Povorcitinib treatment was associated with dose-dependent reductions in draining tunnel count over time through Week 16, especially among patients with a higher draining tunnel count at baseline**
- **Povorcitinib 45 mg and 75 mg improved HS symptoms and reduced inflammation as measured by hsCRP in patients with and without draining tunnels at baseline**

Disclosures

JSK has served as a speaker for AbbVie and as a consultant for AbbVie, Bayer, ChemoCentryx, Incyte Corporation, InflaRx, Janssen, Novartis, Pfizer, and UCB. MMO is a consultant for AbbVie, Azora, Bluefin, Boehringer Ingelheim, ChemoCentryx, Incyte, InflaRx, Innovaderm, Novartis, Pfizer, and Vyne. AA received honoraria as a consultant or advisory board participant from AbbVie, Boehringer Ingelheim, InflaRx, Janssen, Novartis, and UCB; and received honoraria as an investigator for Boehringer Ingelheim and Processa. FGB has received honoraria for participation in advisory boards, in clinical trials, and/or as a speaker from AbbVie, AbbVie Deutschland, Boehringer Ingelheim, Incyte, Janssen-Cilag, Novartis, and UCB. CCZ reports consultancy/advisory board disease-relevant honoraria from AbbVie, Bayer, Incyte, InflaRx, Janssen-Cilag, Novartis, Regeneron, and UCB and speaker fees from AbbVie and UCB; he is President of the EHSF e.V., coordinator of the ALLOCATE Skin group of the ERN Skin and chair of the ARHS Task Force group of the EADV; he is editor of the EADV News; he is co-copyright holder of IHS4 on behalf of the EHSF e.V.; and his employer has received disease-relevant grants from AbbVie, Boehringer Ingelheim, InflaRx, Novartis, and UCB for his participation as clinical investigator. KB, LLS, and ZX are employees and shareholders of Incyte. ABK is a consultant and investigator for AbbVie, Bristol Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB; is an investigator for AnaptysBio and Incyte; is a consultant for Bayer, Boehringer Ingelheim, Concert, EvoImmune, Moonlake, Sonoma Bio, and Ventyx; receives fellowship funding from AbbVie and Janssen; and serves on the Board of Directors for Almirall. MLP is a consultant and/or investigator for AbbVie, AnaptysBio, Eli Lilly, Incyte, Janssen, Novartis, Pfizer, Trifecta Clinical (in conjunction with Acelyrin, Aristea, and Moonlake), and UCB.

Acknowledgments

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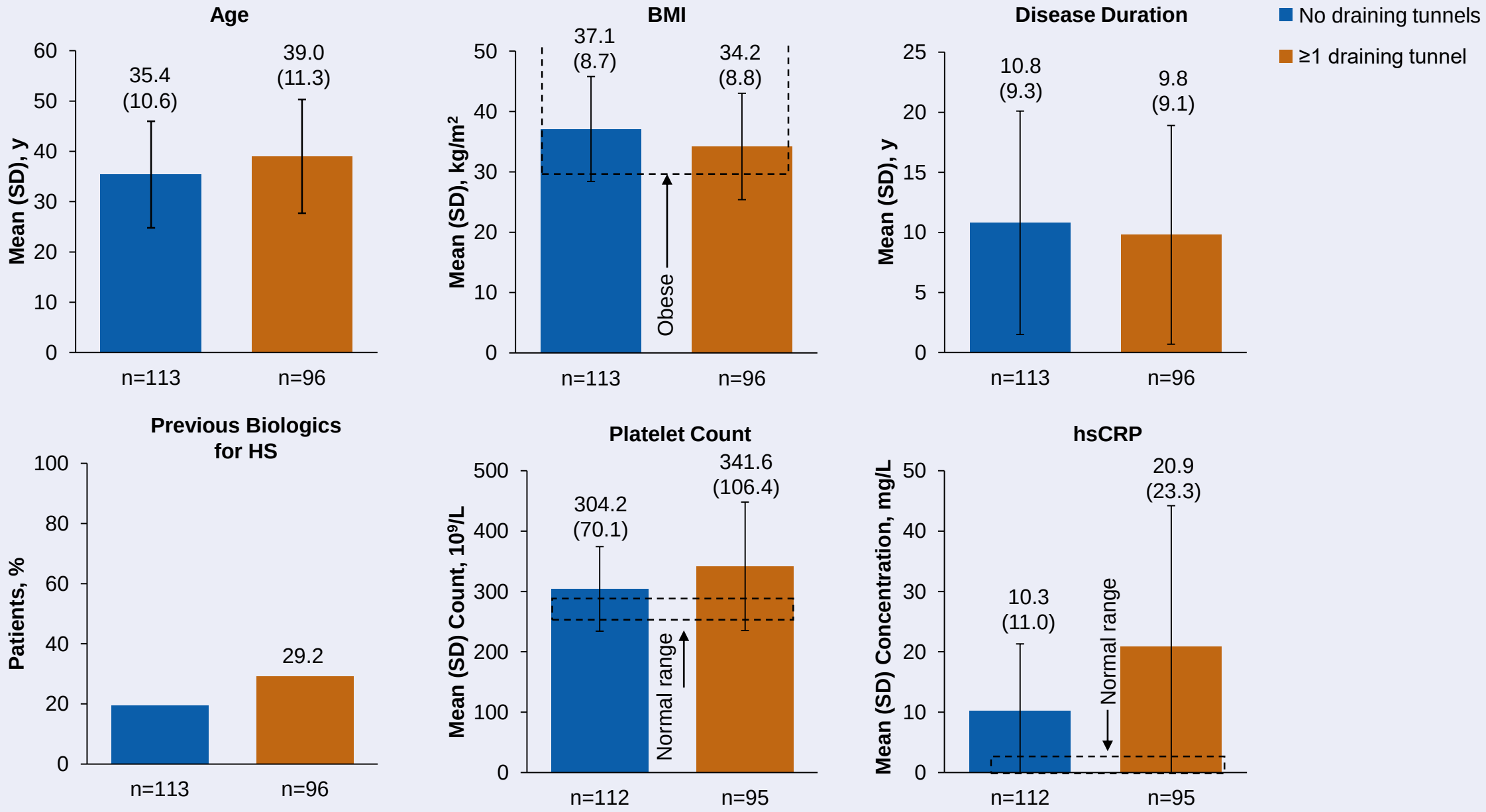
1. Sabat R, et al. *Nat Rev Dis Primers*. 2020;6(1):18. **2.** Navrazhina K, et al. *J Allergy Clin Immunol.* 2021;147(6):2213-2224. **3.** Solimani F, et al. *Front Immunol.* 2019;10:2847. **4.** Alavi A, et al. *Br J Dermatol.* 2022;186(5):803-813. **5.** Kirby JS, et al. Efficacy and safety of the Janus kinase 1 inhibitor povorcitinib (INCB054707) in patients with hidradenitis suppurativa: results from a randomized, placebo-controlled, phase 2 dose-ranging study. Presented at: 31st Annual European Academy of Dermatology and Venereology Congress (EADV); September 7-10, 2022; Milan, Italy, and online.

To download a copy of this poster and supplemental material, scan code.

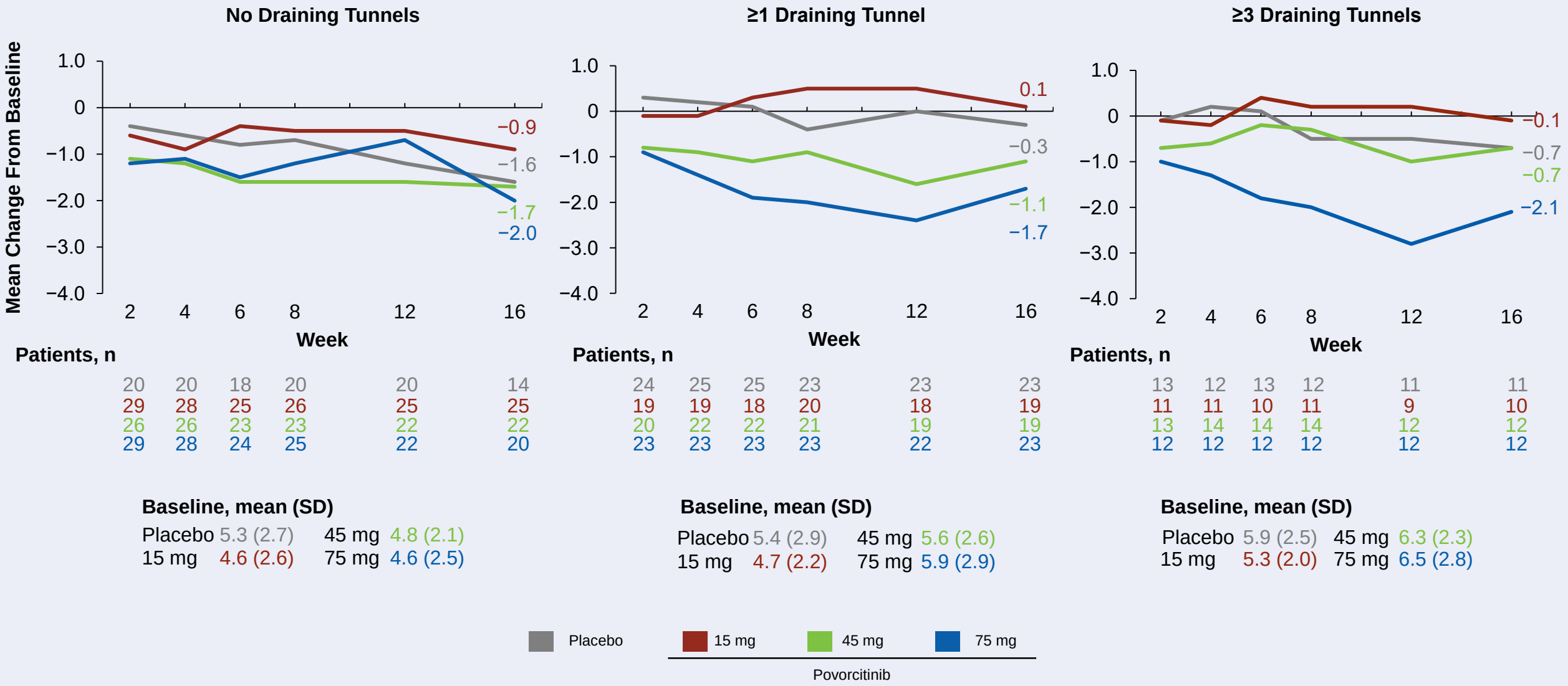
Supplemental Figure 1. Key Demographic and Clinical Characteristics at Baseline



BMI, body mass index; HS, hidradenitis suppurativa; hsCRP, high sensitivity C-reactive protein.
Dashed lines indicate obese BMIs (≥30 kg/m²) and normal range of platelet counts for individuals 20–49 years of age (250–290 × 10⁹/L),[1] and hsCRP (<2 mg /L) concentration, respectively.

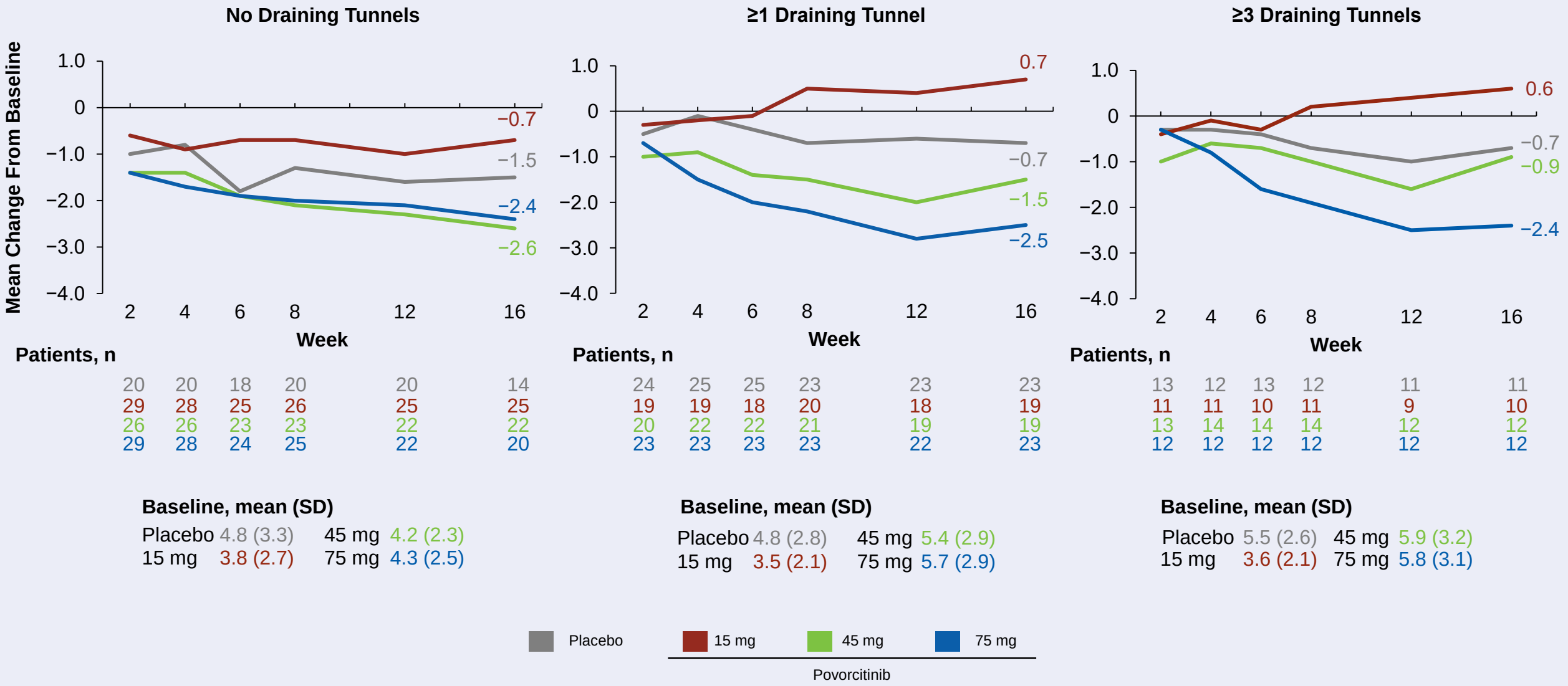
1. Segal JB, Moliterno AR. *Ann Epidemiol.* 2006;16(2):123-130.

Supplemental Figure 2. Change From Baseline in Skin Pain NRS



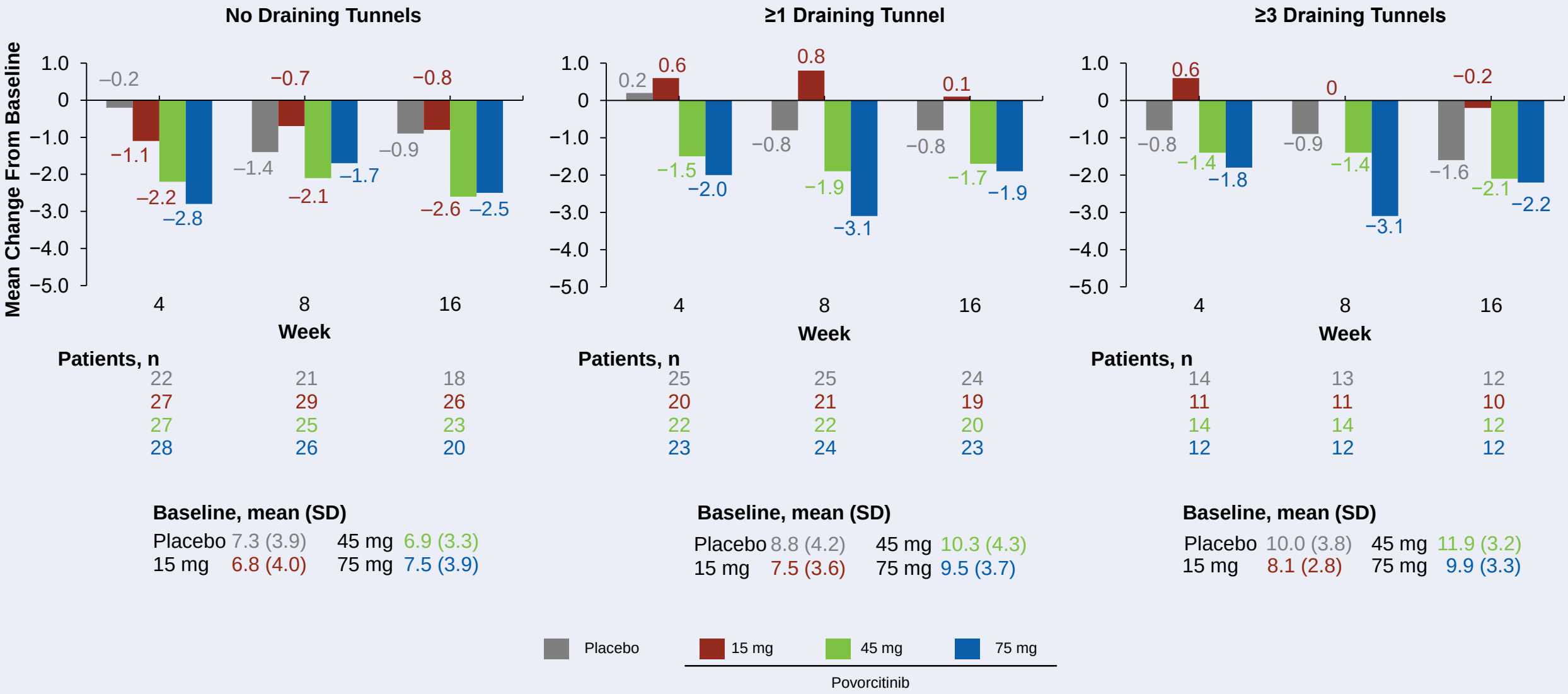
NRS, numerical rating scale

Supplemental Figure 3. Change From Baseline in Itch NRS



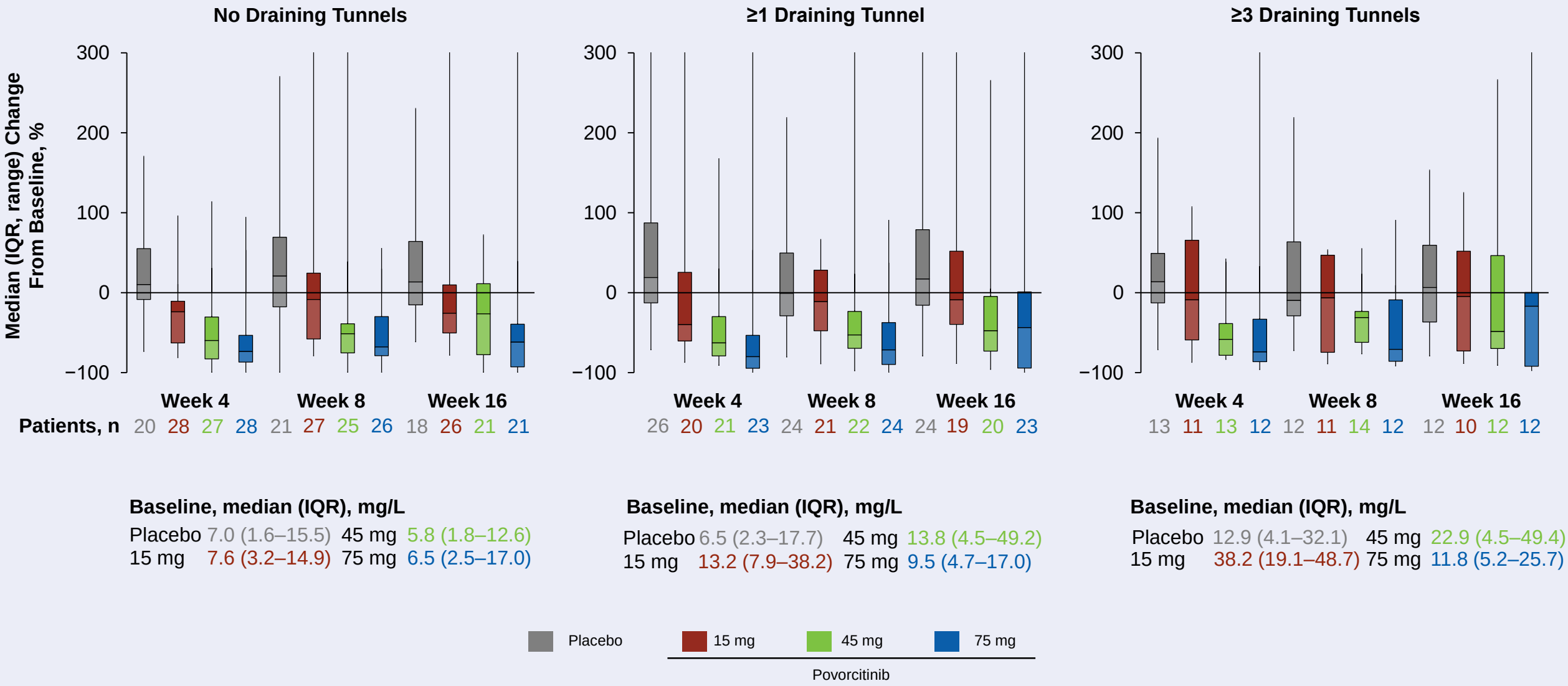
NRS, numerical rating scale

Supplemental Figure 4. Change From Baseline in HiSQoL Symptom Subdomain*



HiSQoL, Hidradenitis Suppurativa Quality of Life.
* Includes questions related to pain, odor, drainage, and itch.

Supplemental Figure 5. Percentage Change From Baseline in hsCRP*



hsCRP, high sensitivity C-reactive protein; IQR, interquartile range.
* Y-axes truncated at 300 for readability.