

# Temporal impact of infection-related treatment emergent adverse events on patient-reported outcomes in patients with moderate to severe psoriasis – analysis of the German national registry PsoBest

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## Objectives

To describe the effects of system organ class (SOC) "infections and infestations" under systemic treatments on health-related quality of life (HRQoL) and patient benefit.

## Introduction

- Plaque psoriasis can substantially impact patients' HRQoL.<sup>1,2</sup>
- It is important to understand how skin clearance relates to patient-relevant benefits, but also how treatment emergent adverse events (TEAE), in particular infection-related TEAE (and their date of occurrence) impact HRQoL in routine practice.

## Materials and Methods

- This retrospective observational cohort study used data from the German psoriasis registry PsoBest. The assessments were carried out as per routine practice visit schedule, i.e. 0 month (RV1), 3 months (RV2), 6 months (RV3), 12 months (RV4) following new systemic treatment initiation.
- Adult patients with moderate to severe plaque psoriasis initiating systemic treatment (from index date) between January 1, 2008, and December 31, 2018, and attending a RV after ~12 months were eligible to enter the study.
- The primary analysis evaluated HRQoL (Dermatology Life Quality Index [DLQI]; scores: 0–30, higher score indicates greater impact of plaque psoriasis on patient's life) and Patient Benefit Index (PBI; 0 to 4, higher scores indicating higher benefit) 12 months after index date (RV1).
- The effect of a TEAE of SOC "infections and infestations" (per MedDRA classification) occurring under the treatment started at index date was described by considering DLQI and PBI captured up to RV4.
- The temporal effect was described through two periods:
  - if onset of infection-related TEAE occurred within the 30 days window before the PsoBest RV4
  - if onset of infection-related TEAE occurred more than 30 days before the PsoBest RV4 (Figure 1).

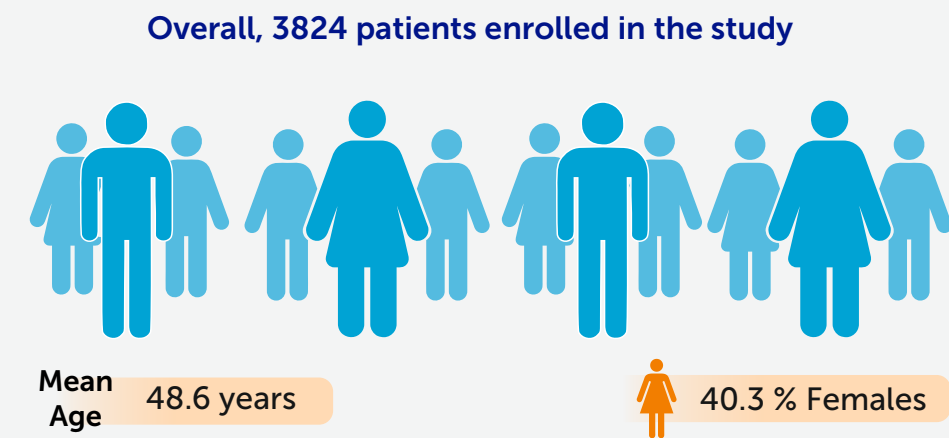
## Results

- A total of 3824 patients with plaque psoriasis met the inclusion criteria and attended the RV4, mean age was 48.6 years, 40.3% were female; full demographics and baseline characteristics have been reported previously.<sup>3</sup>
- 396 (10.4%) adverse events (AEs) and 60 (1.6%) serious AEs (SAEs) related to the SOC infections and infestations were reported up to RV4.
  - Of these, 361 AEs and 46 SAEs occurred under inclusion therapy.
  - 20 AEs/SAEs were Candida infections, of which 18 were AE's during inclusion therapy (3 received a non-biologic, 1 a tumor necrosis factor inhibitor [TNFi] biologic, 14 a non-TNFi biologic).
  - 4 AEs/SAEs were other fungal infections, of which 3 were under inclusion therapy (1 TNFi biologic, 2 non-TNFi biologics).
- The mean DLQI and PBI values at 12 months are presented for the total patient population and for the subpopulation having experienced an infection-related TEAE during inclusion therapy in Table 1.
- Fewer patients (22.2%) reported a DLQI of 0/1 with an infection-related TEAE ≤30 days before the RV4 compared to patients with an infection-related TEAE >30 days prior (46.4%) and the total sample (47.2%) (Figure 2a).
- Fewer patients (22.2%) reported a PBI of ≥3.0 with an infection-related TEAE ≤30 days before compared to patients with an infection-related TEAE >30 days prior (44.7%) and the total sample (47.2%) (Figure 2b).

## Conclusion

- Overall, occurrence of TEAE did not have impact on HRQoL in the long term. The impact was only seen within the first 30 days.
- Further research is needed to explore the infection-related TEAEs within this SOC and their influence on HRQoL and patient benefit.

## Summary



The impact on HRQoL was confined within the first 30 days following onset of infection-related TEAE

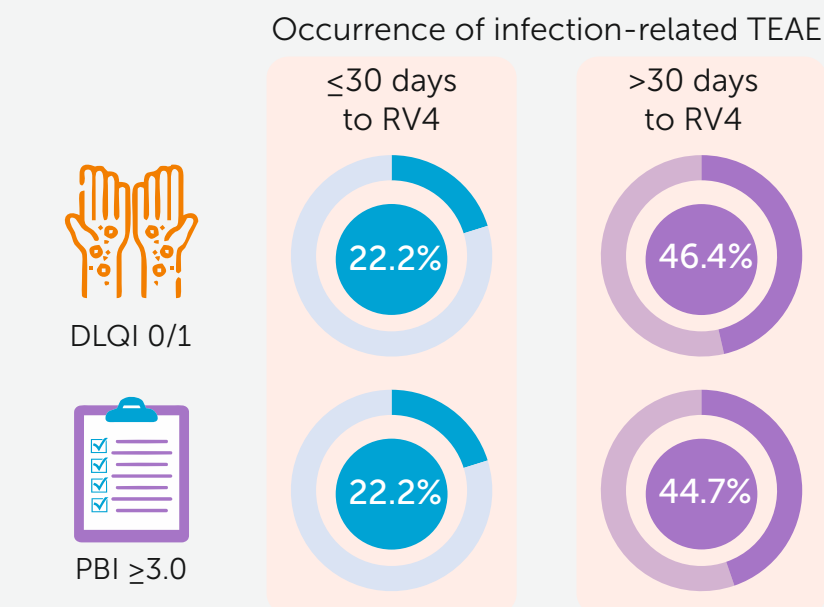


Table 1 DLQI and PBI in relation to SOC infections and infestations TEAEs up to 12 months

Reported DLQI / PBI values at 12 months RV	Total sample up to RV4		Infection-related TEAE during Inclusion therapy up to RV4		Infection-related TEAE during Inclusion therapy ≤30 days prior to RV4		Infection-related TEAE during Inclusion therapy >30 days prior to RV4	
	n/N	Mean ±SD	n/N	Mean ±SD	n/N	Mean ±SD	n/N	Mean ±SD
DLQI	3701/3824	3.7±5.0	382/394	4.1±5.4	32/36	6.6±6.9	350/358	3.9±5.2
PBI	3352/3824	2.8±1.0	335/394	2.7±0.9	27/36	2.4±1.0	308/358	2.8±0.9

Inclusion therapy refers to the systemic therapy started at the index date.

Figure 1 DLQI and PBI assessment scheme in relation to SOC infections and infestations TEAEs up to 12 months

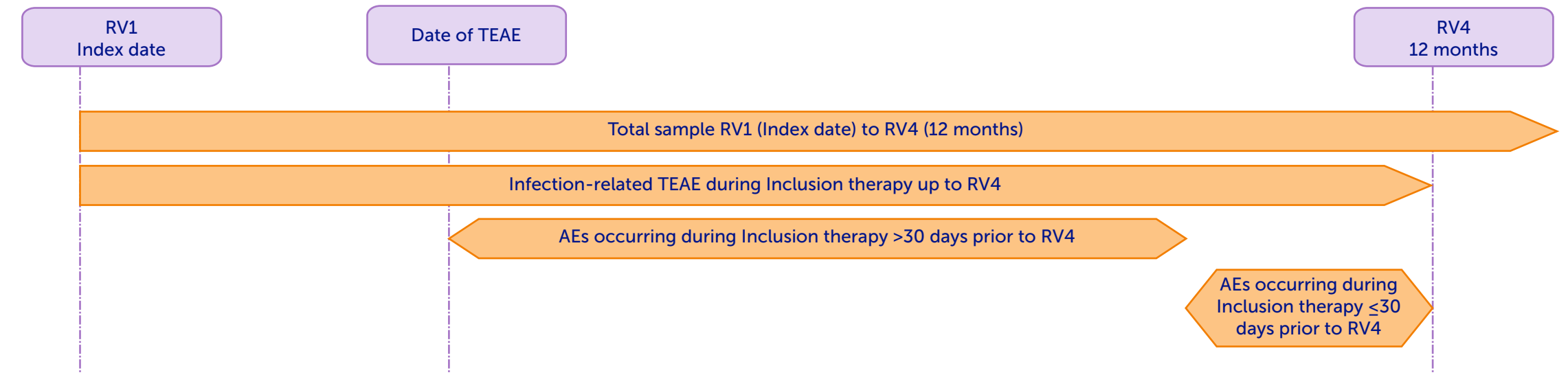
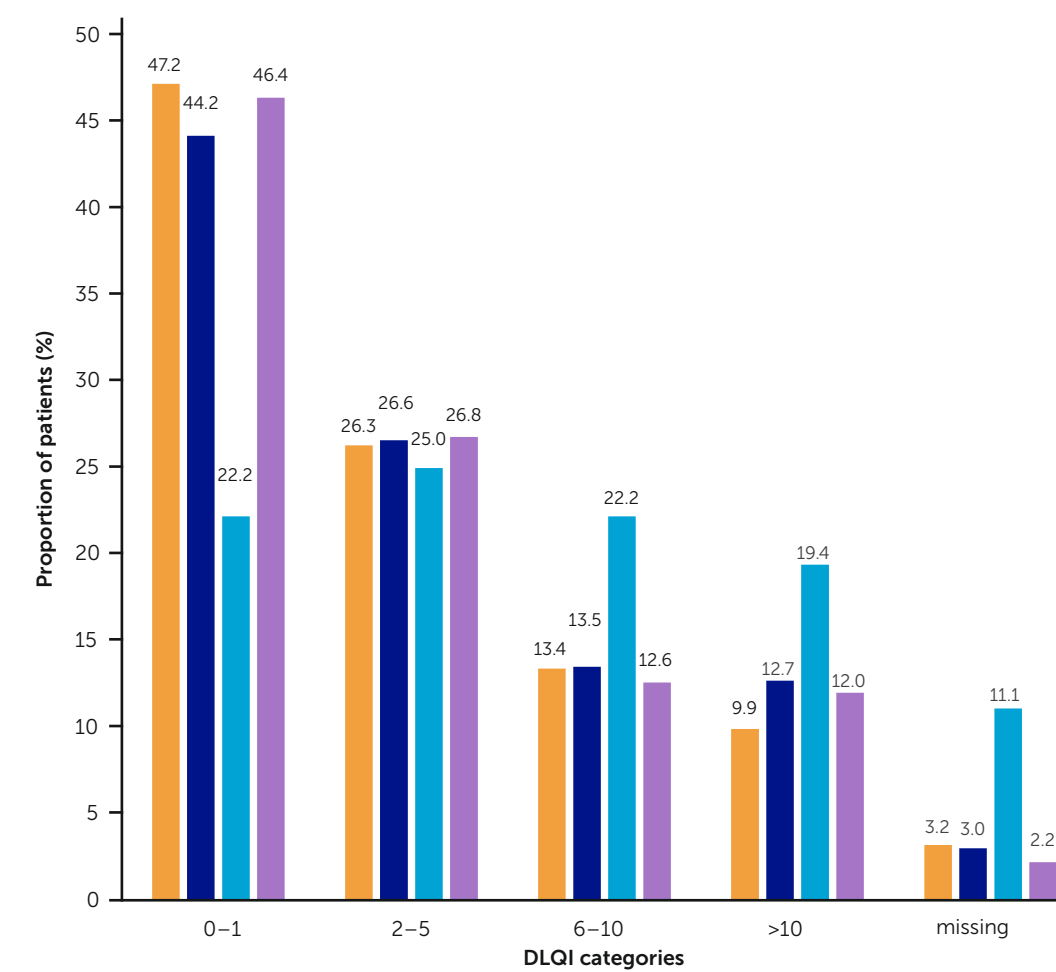
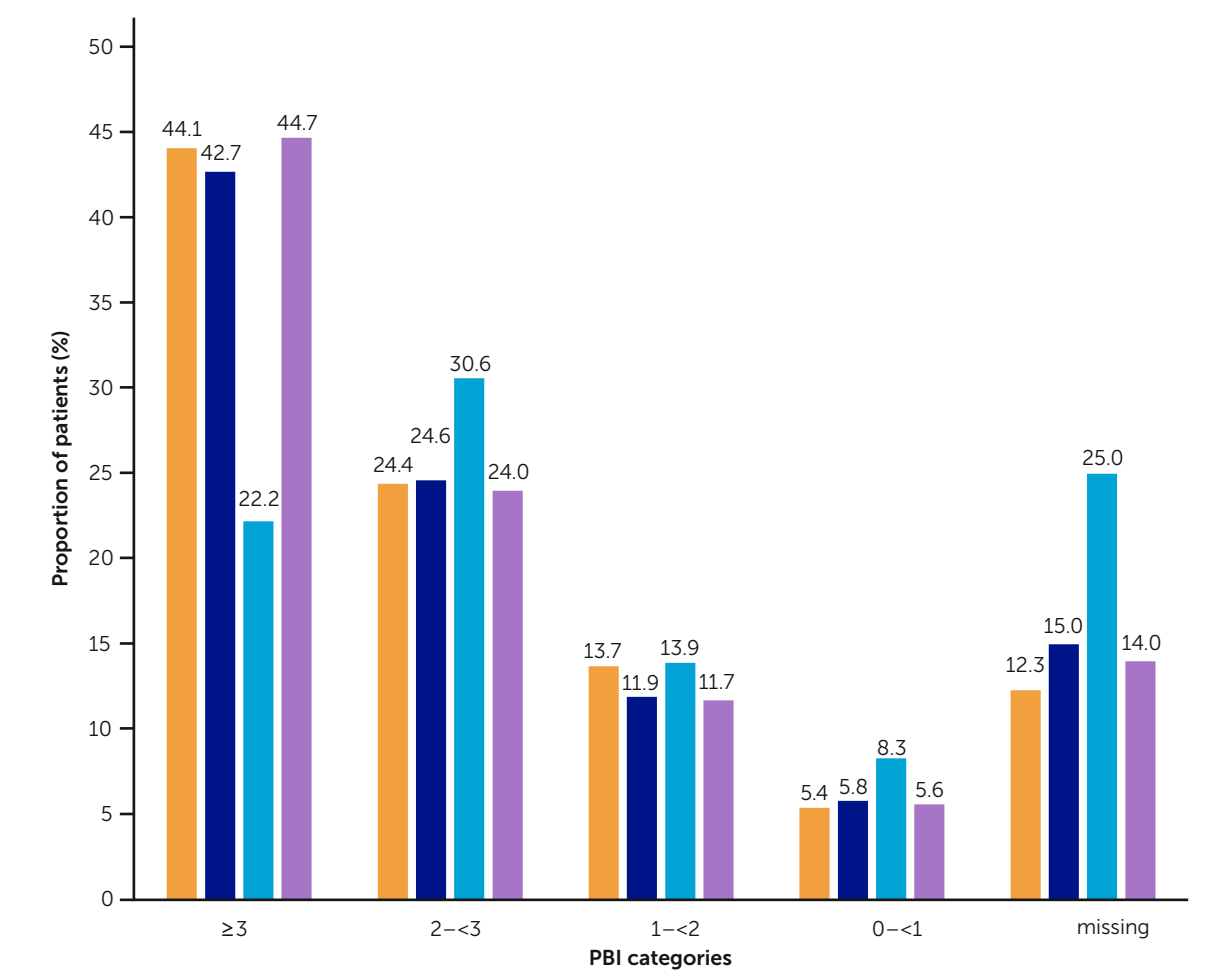


Figure 2 Proportion of patients in relation to SOC infections and infestations TEAEs up to 12 months

A) DLQI categories



B) PBI categories



AE: adverse event; DLQI: Dermatology Life Quality Index (scores: 0–30, higher score indicates greater impact of plaque psoriasis on patient's life); HRQoL: health-related quality of life; PBI: Patient Benefit Index (0 to 4, higher scores indicating higher benefit); RV: routine visit; SAE: serious adverse event; SOC: system organ class; TEAE: treatment emergent adverse event; TNFi: tumor necrosis factor inhibitor.

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References: 1. Obradors et al. Qual Life Res 2016;25(11):2739–2754; 2. Augustin et al. Arch Dermatol Res. 2009;301(8):561–571; 3. Augustin et al. Value of skin clearance on patient reported quality of life and treatment benefit, in patients with moderate to severe psoriasis in Germany - Analysis from the National psoriasis register PsoBest. Presented at the 7<sup>th</sup> Congress of the Skin Inflammation & Psoriasis International Network (SPIN 2022), 2022, Paris, France.

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