Association of DLQI 0/1 with absolute PASI by age and sex in patients with psoriasis treated with certolizumab pegol: Three-year results from three phase 3 trials

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Objective

To explore the association between absolute Psoriasis Area Severity Index (PASI) and Dermatology Life Quality Index (DLQI) by age and sex in three trials of certolizumab pegol (CZP), in patients with moderate to severe plaque psoriasis.

Background

- Psoriasis negatively impacts patient health-related quality of life (HRQoL) and is associated with social stigmatisation and psychological distress.[1]
- Response to biologic treatment in psoriasis has been associated with patient demographics and other disease-related factors.[2]
- It is important to understand how improved clinical outcomes translate to improvements in HRQoL and whether age and sex may contribute to response heterogeneity.[2]

Methods

- Data were pooled from the CIMPASI-1, CIMPASI-2 and CIMPACT phase 3 trials.[3,4]
- Study designs have been reported previously.[3,4]
- Here, DLQI 0/1 (no impact on patient's life)[5] rates are reported in patients achieving absolute PASI=0, PASI >0–≤2, PASI >2–≤3, PASI >3–≤5 and PASI >5 at Week 48 and Week 144 for all patients, and by age and sex.
- Data are reported as observed case (OC).

Results

- Baseline characteristics are presented in **Table 1**.
  - DLQI and PASI values at baseline were comparable across demographic subgroups.
- Patient disposition through Week 144 is shown in **Figure 1**.
- Lower absolute PASI scores were associated with a greater likelihood of achieving DLQI 0/1 at Week 48 and Week 144 (**Figure 2A−B**).
- At Week 144, across all randomised patients, 86.5% of those with PASI=0 had DLQI 0/1; for those with PASI >0–≤2, PASI >2–≤3, PASI >3–≤5, and PASI >5, 63.1%, 56.8%, 33.3%, and 19.5% had DLQI 0/1, respectively (**Figure 2B**).
- A similar pattern was observed across subgroups split by age and sex, with higher proportions of patients achieving DLQI 0/1 in those who had PASI=0 at Week 48 and Week 144 (**Figure 2A−B**).
- This trend, whereby higher proportions of patients who achieved PASI=0 also achieved DLQI 0/1 compared with other PASI bands, was strongest for females ≤45 years of age at Week 144 (**Figure 2B**).
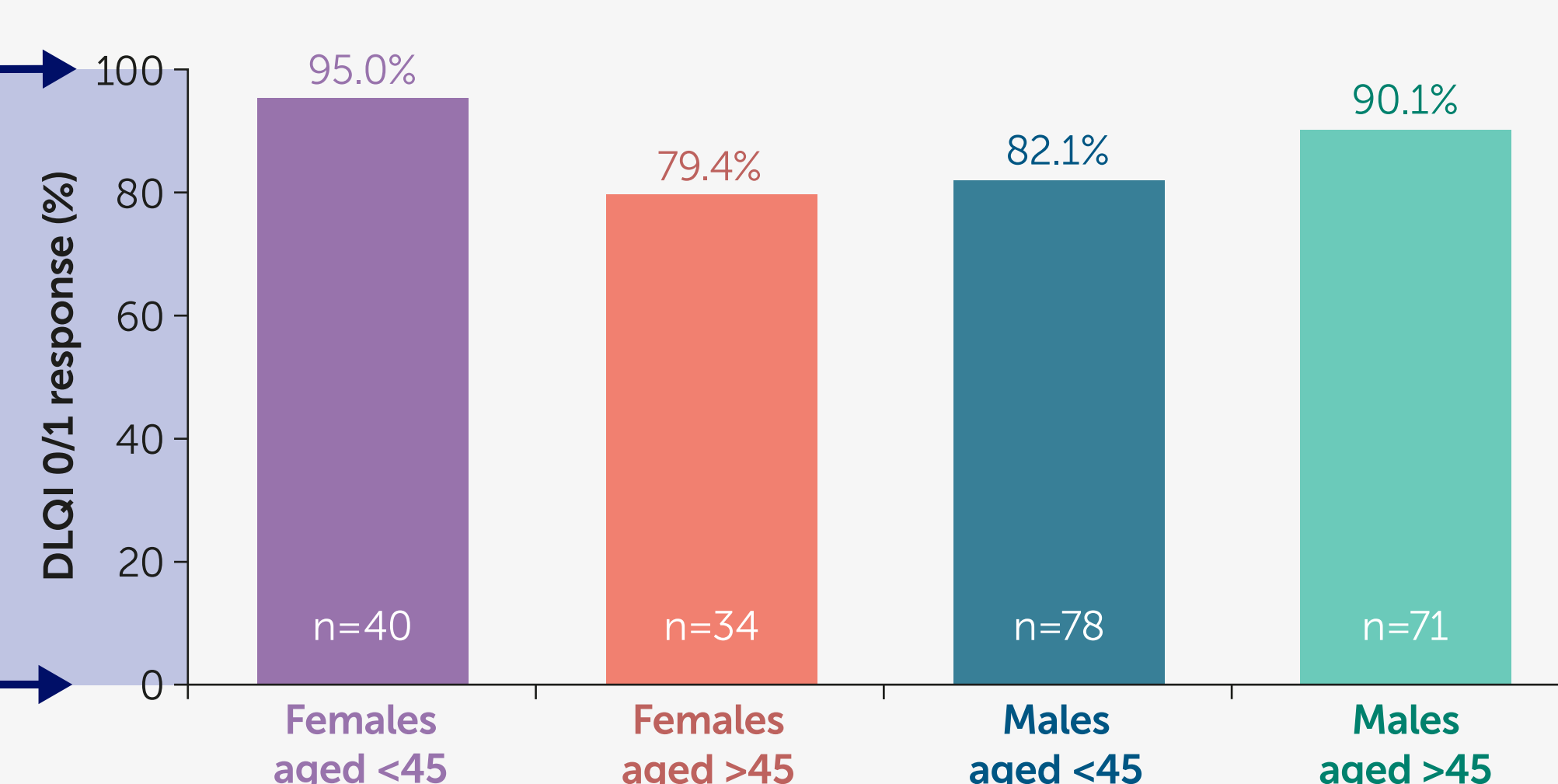
Conclusions

Lower absolute PASI after treatment was generally associated with a greater likelihood of observing DLQI 0/1 at Weeks 48 and 144.

The relationship between higher levels of skin clearance and no effect on a patient's life (DLQI 0/1) at Week 144 was most evident in female patients aged ≤45 years with PASI=0.

Summary
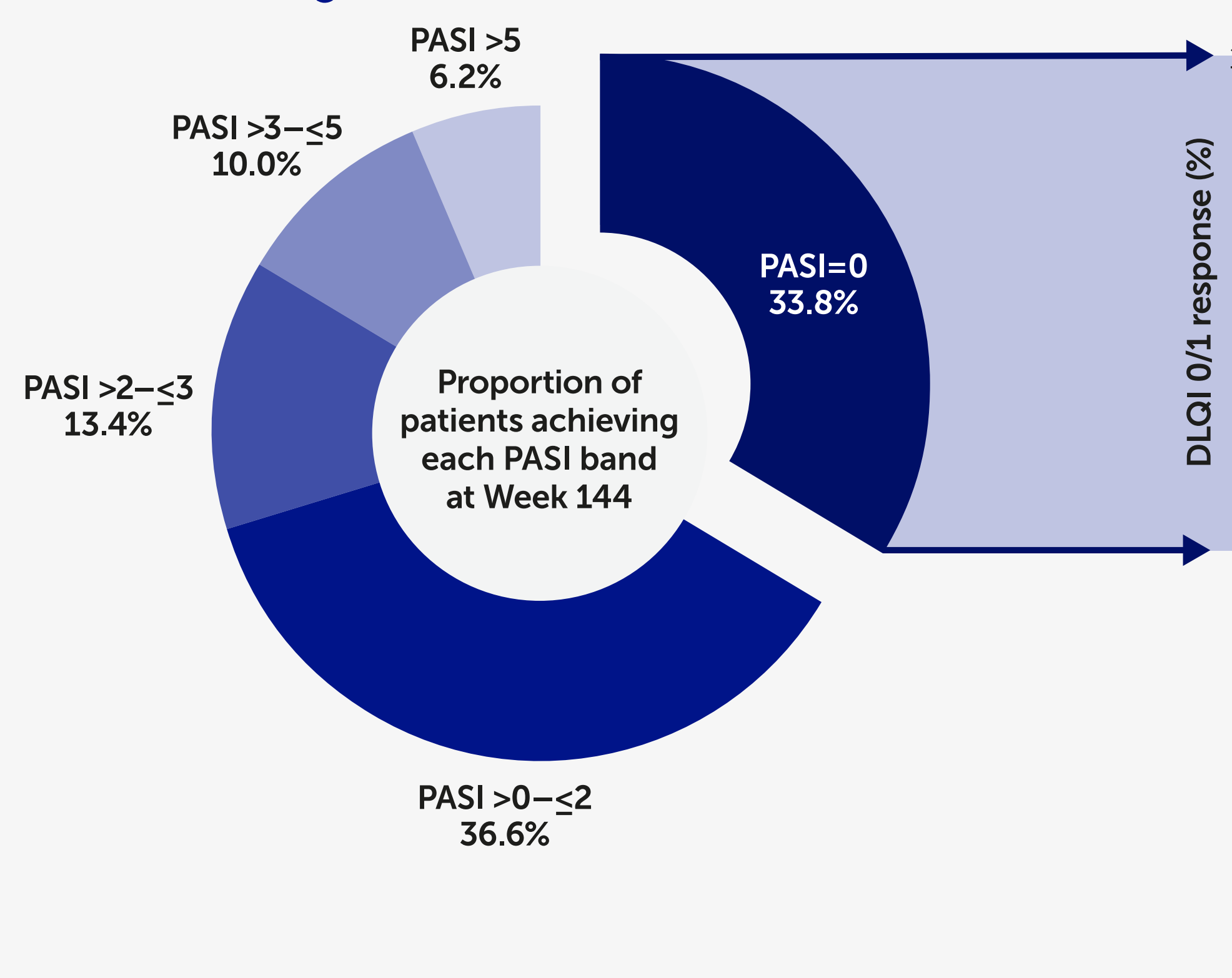
DLQI 0/1 response in patients achieving PASI=0 at Week 144

Results and conclusions

- Lower absolute PASI scores were generally associated with a greater likelihood of achieving DLQI 0/1.
- The highest proportion of patients acheiving DLQI 0/1 at Week 144 was observed in the subgroup of females aged ≤45 years with PASI=0.

Table 1 — Baseline characteristics

	Females aged ≤45 (n=165)	Females aged >45 (n=185)	Males aged ≤45 (n=341)	Males aged >45 (n=329)	Overall (N=1,020)
Age (years), mean ± SD	33.8 ± 7.6	57.6 ± 7.3	34.6 ± 7.1	55.9 ± 7.0	45.5 ± 13.2
Caucasian, n (%)	153 (92.7)	175 (94.6)	321 (94.1)	313 (95.1)	962 (94.3)
Weight (kg), mean ± SD	78.4 ± 23.7	82.5 ± 18.1	93.8 ± 21.4	98.3 ± 22.2	90.7 ± 22.8
BMI, mean ± SD	29.0 ± 8.4	31.5 ± 6.9	29.3 ± 6.5	31.8 ± 6.7	30.4 ± 7.1
Duration of psoriasis (years), mean ± SD	16.5 ± 9.4	24.3 ± 17.0	13.2 ± 8.1	20.4 ± 12.6	18.1 ± 12.5
PASI, mean ± SD	18.5 (6.2)	19.8 (7.1)	20.6 (8.2)	20.6 (8.2)	20.1 (7.7)
BSA (%), mean ± SD	22.5 ± 11.7	24.8 (13.2)	26.6 ± 15.8	26.5 ± 16.9	25.6 ± 15.2
PGA, n (%)					
3: moderate	134 (81.2)	138 (74.6)	225 (66.0)	211 (64.1)	708 (69.4)
4: severe	31 (18.8)	47 (25.4)	116 (34.0)	118 (35.9)	312 (30.6)
DLQI, mean ± SD	14.8 (7.1)	14.9 (7.6)	14.0 (7.4)	12.9 (6.9)	13.9 (7.3)
Any prior systemic therapy for psoriasis, n (%)	112 (67.9)	139 (75.1)	251 (73.6)	228 (69.3)	730 (71.6)
Prior biologic therapy, n (%)	40 (24.3)	50 (27.0)	107 (31.4)	107 (32.5)	304 (29.8)
anti-TNF	20 (12.1)	23 (12.4)	34 (10.0)	48 (14.6)	125 (12.3)
anti-IL-17	15 (9.1)	24 (13.0)	66 (19.4)	46 (14.0)	151 (14.8)
anti-IL-12/23	5 (3.0)	10 (5.4)	16 (4.7)	20 (6.1)	51 (5.0)

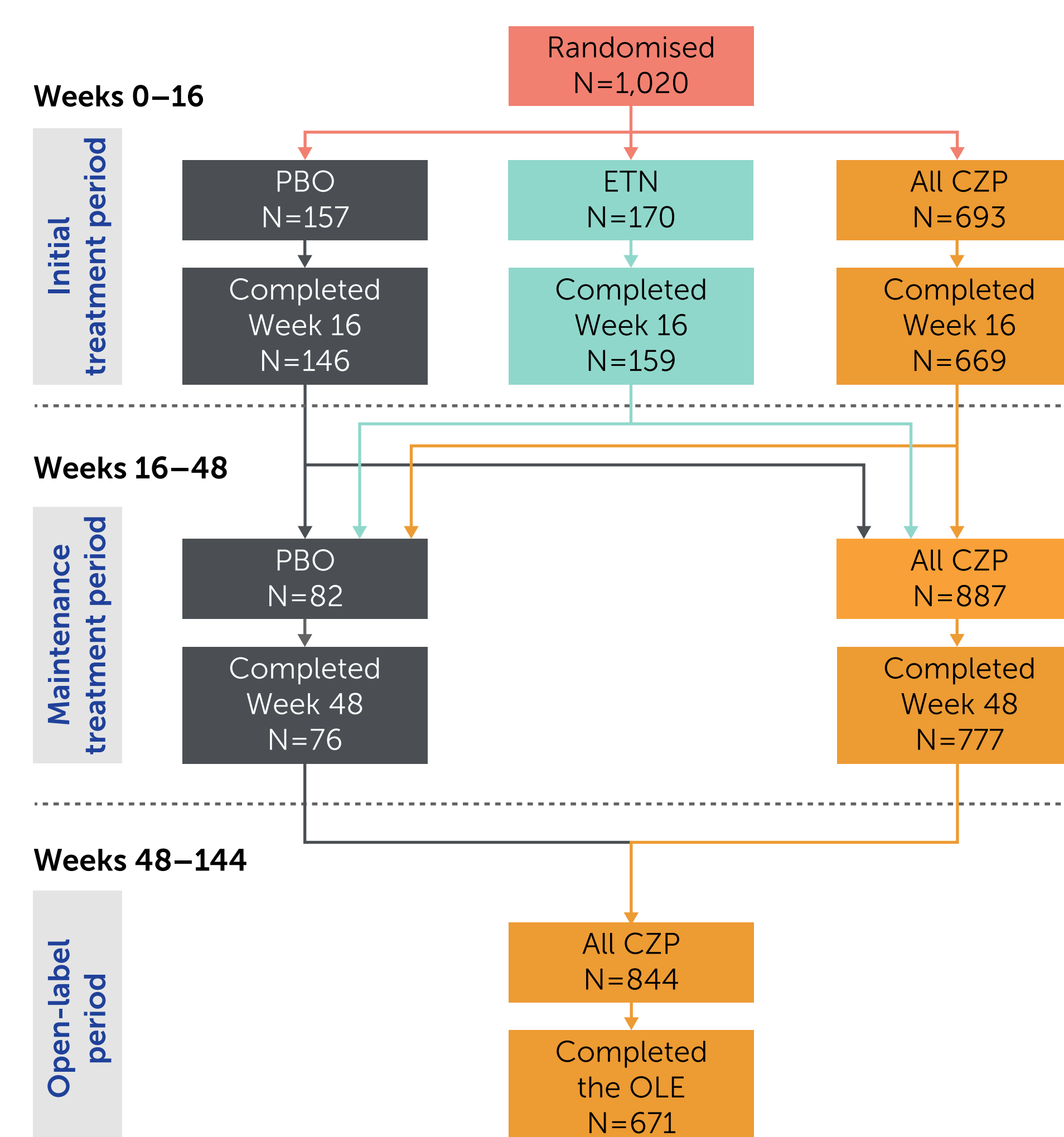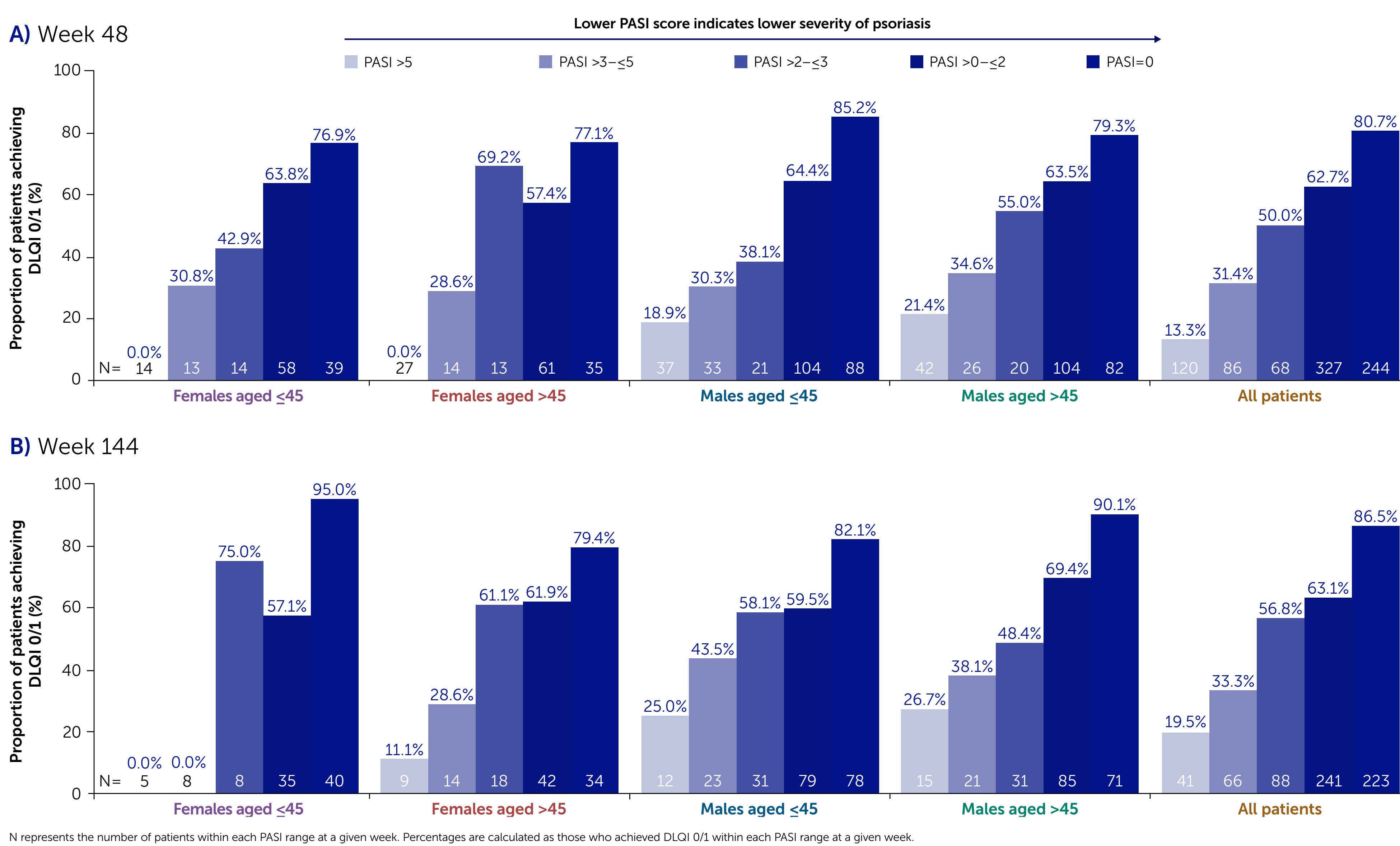### Figure 1 — Patient disposition (pooled across CIMPASI-1, CIMPASI-2 and CIMPACT)

Figure 2 — Proportion of patients achieving DLQI 0/1 by absolute PASI bands

N represents the number of patients within each PASI range at a given week. Percentages are calculated as those who achieved DLQI 0/1 within each PASI range at a given week.