Psoriatic arthritis patient profiles are different between RCTs of bDMARDs and a real-world study over the same timeframe (PsABio) – a literature review with meta-analysis.

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INTRODUCTION

Psoriatic arthritis (PsA) is a very heterogeneous disease; patient profiles in RCTs may not reflect patients from usual clinical practice.

OBJECTIVE

- To compare characteristics of PsA patients between RCTs of bDMARDs, and a real-world study (PsABio).

Randomized Controlled Trials **Vs** Real-World Evidence

METHODS

- Data Sources:
  - (a) Literature review and meta-analysis of phase III RCTs of bDMARDs in PsA published between 2015-2020
  - (b) International observational study of PsA patients starting a bDMARD enrolled in 2015–2018 (PsABio, NCT02627768[1])

Baseline data: SJC, TJC, enthesitis, dactylitis, skin involvement (BSA), CRP (mg/dL) and PROs (HAQ, disease activity, pain)

Statistics: *Meta-analysis was performed on RCT data, using the Mantel-Haenszel method with random effects.*

RESULTS

Overall, 10 RCTs (total 5654 participants) were analysed and compared to 930 PsABio participants (Table 1).
Demographic data were similar across studies. SJC/TJC were higher in RCTs than in PsABio. Enthesitis and dactylitis were more frequent in RCTs, as well as psoriasis extension (Figure 1). In contrast, patient reported disease impact was high and similar in both sources (Figure 2).
Overall, almost half (44%) of PsABio participants would not have fulfilled the RCT inclusion criteria due to too low disease activity.

Figure 1. Baseline clinimetric characteristics.

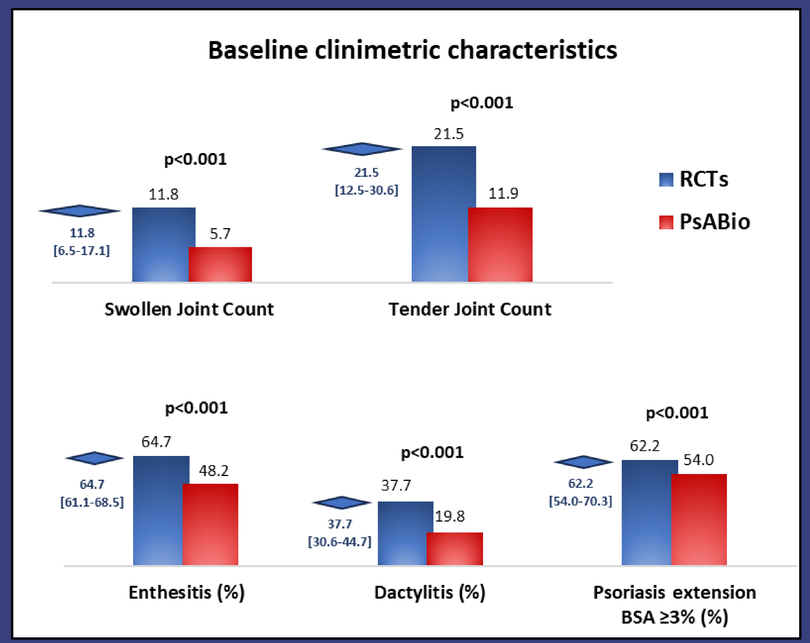

Figure 2. Baseline patient reported outcomes (PROs).

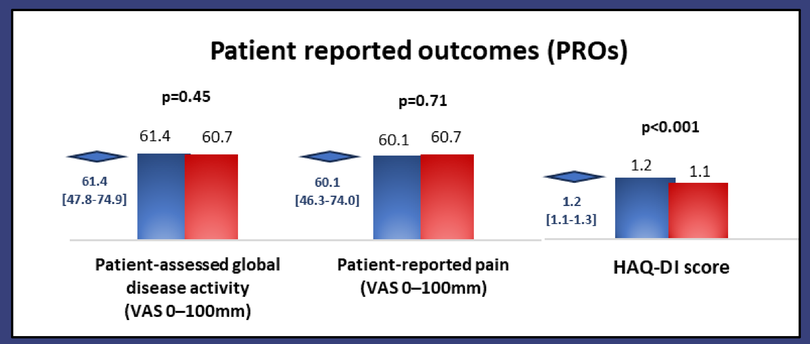

Table 1. Comparison of baseline characteristics from a real-world study (PsABio) and pooled data from 10 bDMARD phase III RCTs.

	RCTs Pooled frequency (%) or pooled mean (CI)	PsABio Frequency (%) or mean (SD)	p-value
Total number of patients who began treatment	5654	930	-
Age (years)	48.6 (41.3 to 56.0)	49.7 (12.5)	<0.001
Female sex	50.7% (48.1 to 53.2)	55.2%	0.012
BMI, kg/m²	30.6 (23.6 to 37.6)	28.1 (5.8)	<0.001
Time since PsA diagnosis (years)	6.3 (1.6 to 10.9)	6.8 (7.4)	0.029
MTX ongoing at baseline	49.6% (37.1 to 62.1)	35.7%	<0.001
Previous bDMARDs			
None	72.0% (51.3 to 91.8)	50.4%	<0.001
1	19.4% (5.6 to 31.7)	33.0%	<0.001
≥2	8.6% (2.3 to 14.3)	16.6%	<0.001
Psoriatic nail disease	67.6% (59.8 to 75.3)	40.1%	<0.001
Physician's global assessment of disease activity (VAS 0–100mm)	59.7 (48.1 to 71.2)	54.1 (20.1)	<0.001
CRP (mg/dL) - (normal range: 0–0.5)	1.1 (-0.1 to 2.3)	1.4 (2.8)	0.002

CONCLUSIONS

In conclusion, RCTs largely represent patients with polyarticular, highly active PsA; in contrast, in routine clinical practice, many patients receiving biologics have mild/moderate joint disease, and often limited psoriasis.
However, patients with PsA starting a bDMARD in both settings reported high and similar physician global assessment and patient-reported disease burden, while CRP was higher in PsABio, supporting the decision to start a bDMARD therapy in clinical practice.

IMPACT

Our study found substantial differences between profiles from PsA patients included in RCTs vs real-life, which highlights the need for cautious extrapolation of RCT data to clinical practice.

[1]Gossec L, et al. Long-term effectiveness and persistence of ustekinumab and TNF inhibitors in patients with psoriatic arthritis: Final 3-year results from the PsABio real-world study. Ann. Rheum. Dis. 2023;82:496–506.