Patient-Reported Symptoms Improved with Stringent Control of Swollen Joints in Patients with Psoriatic Arthritis: Results from Two Phase 3 Studies of Bimekizumab

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Objective

To investigate the association between achieving stringent control of swollen joint count (SJC) and reductions in patient-reported pain and fatigue severity in patients with psoriatic arthritis (PsA), using data from two phase 3 studies.

Introduction

- PsA is characterised by joint and skin inflammation and associated with debilitating symptoms of pain and fatigue.[1]
- Previous research has shown that pain and fatigue in patients with PsA may be driven by inflammatory symptoms.[2,3]
- Consequently, understanding the association between clinically-assessed inflammatory features and patient-reported symptoms is of interest.

Methods

- The association between SJC (0 [complete resolution], 1–3, ≥4) and improvements in patient-reported pain and fatigue was analysed; pain and fatigue were assessed using the arthritis Pain Visual Analog Scale (Pain VAS) and Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue (observed case).*
  - Patients with SJC 1–3 were pooled due to low patient numbers in these groups.
- Patients with PsA from the following two clinical studies evaluating subcutaneous bimekizumab (BKZ) 160 mg every 4 weeks (Q4W) were included: BE OPTIMAL (NCT03895203; biologic disease-modifying antirheumatic drug [bDMARD]-naïve), BE COMPLETE (NCT03896581; tumour necrosis factor inhibitor inadequate response/intolerance [TNFi-IR]). To be eligible for inclusion in the studies, patients were required to have SJC ≥3 out of 66 joints.
- Both studies had a 16-week double-blind, placebo-controlled period; BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W).
- Patients completing Week 52 of BE OPTIMAL or Week 16 of BE COMPLETE were eligible for BE VITAL (NCT04009499; open-label extension), in which all patients received BKZ 160 mg Q4W.
- Data are reported here for all patients, pooled regardless of treatment arm.
- Associations are reported at Weeks 16, 52 and 104 for BE OPTIMAL and Weeks 16, 52/40 and 100/88 for BE COMPLETE (Pain VAS collected at Weeks 52 and 100 and FACIT-Fatigue collected at Weeks 40 and 88 in BE COMPLETE).

Results

- 710/852 (83.3%) bDMARD-naïve and 322/400 (80.5%) TNFi-IR patients completed Week 104/100. There were no ongoing patients in BE OPTIMAL at Week 104, and two ongoing patients in BE COMPLETE at Week 100.
- Numerical differences in baseline scores indicated slightly lower SJC, pain and fatigue in bDMARD-naive patients compared with TNFi-IR patients:
  - bDMARD-naïve/TNFi-IR mean (standard deviation) SJC 9.2 (6.7)/9.9 (7.7), Pain VAS 55.2 (23.9)/59.5 (24.3), FACIT-Fatigue 37.0 (9.7)/35.6 (10.3).
- Patients experiencing lower SJC demonstrated greater improvements from baseline in Pain VAS at Week 16 than patients with higher SJC; these trends persisted through Week 52 and Week 104/100 (**Figure 1A**).
- Furthermore, with lower SJC, greater proportions of patients achieved a substantial improvement (≥50% improvement from baseline)[4] in Pain VAS (**Figure 1B**) and Pain VAS score ≤15 at all timepoints assessed: Weeks 16, 52 and 104/100 (**Table**).
- The association between lower SJC and improvements in FACIT-Fatigue, including change from baseline and achievement of minimal clinically important difference in FACIT-Fatigue score, was less pronounced than Pain VAS, possibly due to the multifaceted nature of fatigue in PsA;[5] the association was most pronounced at Week 16 (**Figure 2**).

Conclusions

Attaining stringent control of SJC was associated with greater improvements in patient-reported pain at Weeks 16, 52 and 104/100 in patients with PsA; the association between lower SJC and reduced fatigue was less pronounced but still present. Notably, the most substantial improvements were observed with SJC=0, indicating complete resolution may be an important treatment goal for patients with PsA.

Summary

We analysed the **association** between **swollen joint count** (SJC), a clinically-assessed sign of inflammation, and **patient-reported pain** and **fatigue** severity in patients with **PsA** who were **bDMARD-naïve** (BE OPTIMAL) or **TNFi-IR** (BE COMPLETE)

With **complete resolution of SJC (SJC=0)**, bDMARD-naïve and TNFi-IR patients achieved greater improvements in Pain VAS or FACIT-Fatigue at 2 years (OC)

Improvements in Pain VAS score:[a]
Change from baseline: **–34.7** (baseline score: 53.6) to **–39.5** (baseline score: 56.9)
≥50% improvement from baseline in Pain VAS score: **70.6%** to **75.4%** patients

Improvements in FACIT-Fatigue score:[b]
Change from baseline: **5.5** (baseline score: 38.0) to **6.1** (baseline score: 37.0)
FACIT-Fatigue MCID achievement:[c] **56.5%** to **56.6%** patients

Lower SJC was **associated** with **greater improvements** in patient-reported **pain and fatigue**, although the association was less pronounced for fatigue. **Complete resolution of SJC** may be an **important treatment goal** for promoting the **greatest improvements** in **pain** and **fatigue**

[a] Pain VAS scores range from 0–100; higher scores indicate worse status; **[b]** FACIT-Fatigue scores range from 0–52; lower scores indicate worse status; **[c]** Minimal clinically important difference in FACIT-Fatigue defined as change from baseline ≥4 in patients with FACIT Fatigue ≤48 at baseline.

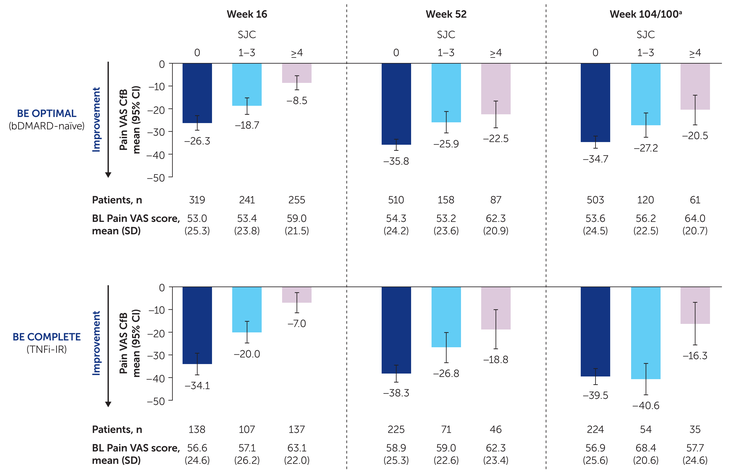
Table Association of SJC with improvements in pain at Weeks 16, 52 and 104/100 (OC)

	BE OPTIMAL (bDMARD-naïve)			BE COMPLETE (TNFi-IR)		
	SJC			SJC		
	0	1–3	≥4	0	1–3	≥4
≥30% improvement from baseline in Pain VAS score (Pain30), n/N (%)						
Week 16	201/319 (63.0)	130/241 (53.9)	77/255 (30.2)	101/138 (73.2)	58/107 (54.2)	38/137 (27.7)
Week 52	406/510 (79.6)	102/158 (64.6)	51/87 (58.6)	182/225 (80.9)	45/71 (63.4)	21/46 (45.7)
Week 104/100[a]	384/503 (76.3)	74/120 (61.7)	31/61 (50.8)	186/224 (83.0)	42/54 (77.8)	18/35 (51.4)
≥70% improvement from baseline in Pain VAS score (Pain70), n/N (%)						
Week 16	122/319 (38.2)	67/241 (27.8)	31/255 (12.2)	70/138 (50.7)	25/107 (23.4)	12/137 (8.8)
Week 52	285/510 (55.9)	56/158 (35.4)	21/87 (24.1)	126/225 (56.0)	25/71 (35.2)	8/46 (17.4)
Week 104/100[a]	288/503 (57.3)	50/120 (41.7)	10/61 (16.4)	127/224 (56.7)	25/54 (46.3)	4/35 (11.4)
Pain VAS score ≤15, n/N (%)						
Week 16	145/320 (45.3)	73/241 (30.3)	38/255 (14.9)	74/138 (53.6)	34/107 (31.8)	16/137 (11.7)
Week 52	303/510 (59.4)	70/158 (44.3)	25/87 (28.7)	123/225 (54.7)	26/71 (36.6)	11/46 (23.9)
Week 104/100[a]	313/503 (62.2)	50/120 (41.7)	12/61 (19.7)	136/224 (60.7)	19/54 (35.2)	5/35 (14.3)

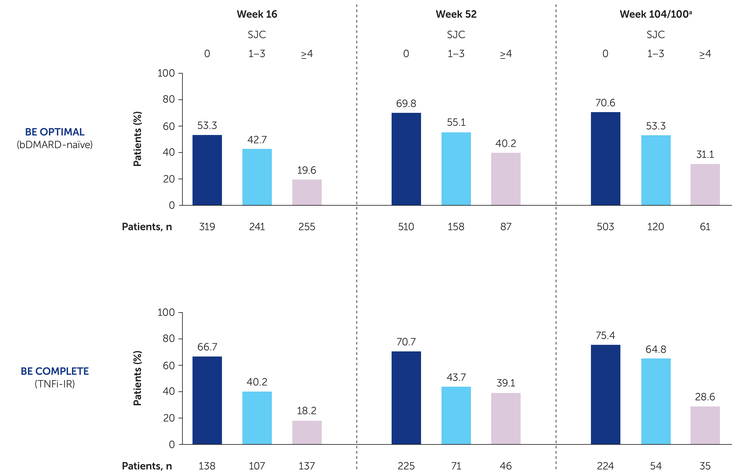
Randomised set. **[a]** Pain VAS collected at Week 100 in BE COMPLETE.

Figure 1 Association of SJC with improvements in pain at Weeks 16, 52 and 104/100 (OC)

A) Change from baseline in Pain VAS score



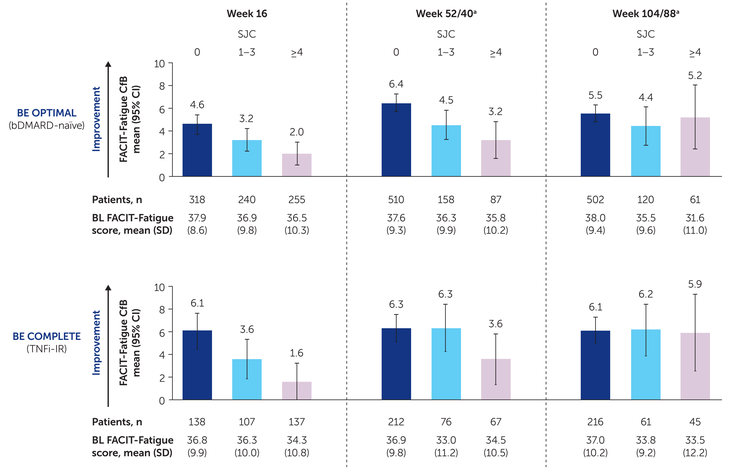
B) ≥50% improvement from baseline in Pain VAS score (Pain50)[b]



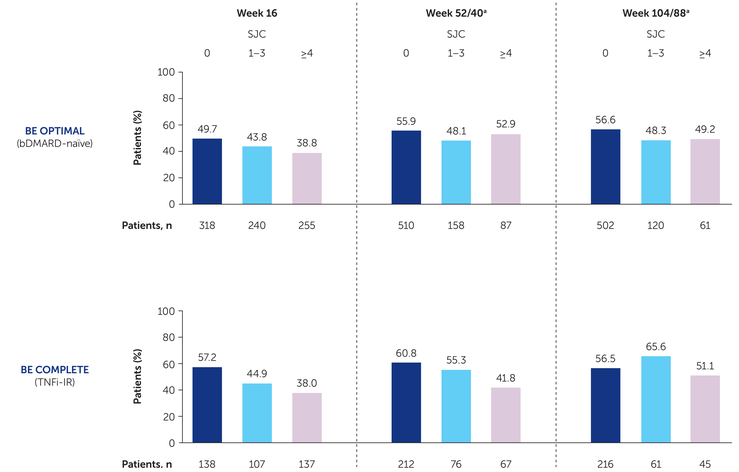
Randomised set. **[a]** Pain VAS scores were collected at Week 100 in BE COMPLETE; **[b]** Pain50 represents a substantial improvement in pain.[4]

Figure 2 Association of SJC with improvements in fatigue at Weeks 16, 52/40 and 104/88 (OC)

A) Change from baseline in FACIT-Fatigue score



B) FACIT-Fatigue MCID achievement[b]



Randomised set. **[a]** FACIT-Fatigue scores were collected at Week 40 and Week 88 in BE COMPLETE; **[b]** FACIT-Fatigue MCID defined as change from baseline ≥4 in patients with FACIT-Fatigue ≤48 at baseline.

*Pain VAS was assessed using the Patient's Assessment of Arthritis Pain. Pain VAS scores range from 0–100; higher scores indicates worse status FACIT-Fatigue scores range from 0–25; lower scores indicate worse staus. **bDMARD:** biologic disease-modifying antirheumatic drug; **BKZ:** bimekizumab; **BL:** baseline; **CfB:** change from baseline; **CI:** confidence interval; **FACIT-Fatigue:** Functional Assessment of Chronic Illness Therapy-Fatigue; **MCID:** minimal clinically important difference; **OC:** observed case; **Pain30/50/70:** ≥30%/50%/70% improvement from baseline in Pain VAS; **PsA:** psoriatic arthritis; **Q2W:** every 2 weeks; **Q4W:** every 4 week; **SD:** standard deviation; **SJC:** swollen joint count; **TNFi-IR:** tumour necrosis factor inhibitor inadequate response or intolerance; **VAS:** visual analog scale.

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