Clin Rheumatol (2017) 36:1589–1593
DOI 10.1007/s10067-017-3700-z

ORIGINAL ARTICLE

# Minimal disease activity in patients with psoriatic arthritis treated with ustekinumab: results from a 24-week real-world study

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Received: 9 April 2017 / Revised: 17 May 2017 / Accepted: 22 May 2017 / Published online: 31 May 2017


**Abstract** Psoriatic arthritis (PsA) is a chronic inflammatory joint disease affecting around 40% of psoriasis patients. Minimal disease activity (MDA) criteria have been proposed to identify a state of low disease activity, one of the principal goals of treatment for psoriatic disease. This study investigated treatment with ustekinumab (UST) in the context of a real-world setting. Thirty-four PsA patients who had failure or inadequate response to conventional synthetic disease-modifying antirheumatic drugs or to anti-tumour necrosis factor alpha were enrolled. Demographic and clinical features, MDA criteria, and the impact of psoriatic skin manifestations on patients' quality of life (QoL) using the dermatology life quality index (DLQI) questionnaire were evaluated at baseline and after 24-week treatment. Adverse events were recorded. At week 24, 70.5% of patients ($n = 24$) achieved MDA. A sub-analysis of dermatological indices of the MDA criteria showed that the psoriasis area severity index score was significantly improved and body surface area was significantly decreased at 24 weeks compared with that at baseline (both $p < 0.001$). For the rheumatologic indexes, tender joint count, swollen joint count, and tender entheseal points were all significantly improved at 24 weeks of therapy (all $p < 0.01$ vs. baseline). Mean DLQI value decreased approximately four-fold, and there were no safety concerns. The achievement of MDA as well as the significant improvement in DLQI and lack of adverse events in the context of a real-life setting shown here confirms the efficacy and safety of UST in PsA.

**Keywords** Minimal disease activity · Psoriatic arthritis · Ustekinumab

## Introduction

Psoriatic arthritis (PsA), a chronic inflammatory joint disease which occurs in up to 40% of patients suffering from psoriasis [1, 2], can be variably associated with extra-cutaneous comorbidities [3–6]. Arthritis, dactylitis, enthesitis, and involvement of the axial skeleton in the form of sacroiliitis and spondylitis, in combination with a positive personal or family history of psoriasis, represent the main aspects for addressing disease diagnosis [7–10].

PsA is also associated with a variable grade of functional impairment, which is responsible for poor quality of life (QoL) due to its negative impact on patients' psychological functioning and daily living activities [11, 12].

The principal goals of psoriatic disease treatment are the achievement of clinical remission or low disease activity, the inhibition of structural damage, and the improvement of patients' QoL [13, 14]. However, there are no clear criteria for defining remission in PsA. In 2010, minimal disease activity (MDA) criteria were introduced to identify a state of low disease activity [15, 16]; patients are classified as achieving MDA if they fulfil at least five out of the seven MDA outcome measures.

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An increased understanding of the inflammatory pathways involved in psoriatic disease has improved therapeutic strategies due to the introduction of agents directed against specific molecular targets, such as the tumour necrosis factor alpha (TNF-α) and interleukin (IL)-12/IL-23 [17–20]. In particular, the biological drug ustekinumab (UST) is a fully human monoclonal antibody that binds with high specificity and affinity to the p40 subunit shared by IL-12 and IL-23, which are essential components of the T helper (Th)1 and Th17 inflammatory pathways and key mediators in both psoriasis and PsA pathogenesis [21]. Similarly to TNF-α antagonists, several clinical trials have shown UST to be efficacious in treating articular as well as cutaneous aspects of psoriasis and in inhibiting structural damage progression [22–28]. Moreover, both anti-TNF-α and anti-IL-12/23 have proven to be effective and safe in children and in the elderly population [29–31]. Although randomized clinical trials are the gold standard in evaluating the effects of treatments, they are conducted under rigorously controlled settings and may not be generalizable across practical, real-world situations, where conditions differ significantly from the trial context [32]. Hence, the essential role of real-world studies in the assessment of drugs is increasingly recognized, even if data collected under real-life practice circumstances are still lacking for PsA therapies.

The present real-world study aimed firstly to investigate the achievement of MDA after 24-week treatment with UST in patients with active PsA and secondly to evaluate the dermatology life quality index (DLQI).

## Methods

### Patients

An observational study was conducted in a cohort of PsA patients at their first use of UST. Patients were enrolled from those attending the Dermatology and Rheumatology Units of the University of Naples "Federico II" from January to December 2015. The study protocol followed the principles of the Declaration of Helsinki and all patients provided their written informed consent prior to participation.

Eligible participants were consecutive adult patients (≥18 years of age) of both sexes, with a diagnosis of PsA classified on the basis of the Classification Criteria for Psoriatic Arthritis (CASPAR) criteria [9], who had failed or had an inadequate response to conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) or to anti-TNF-α. Failure or inadequate response was defined as the presence of at least three swollen joints (SJC) ≥3 and three tender joints (TJC) ≥3. Exclusion criteria included contraindications to UST use [33] and previous treatment with UST for psoriasis or PsA.

All patients were treated with UST 45 or 90 mg (based on weight ≤100 or >100 kg, respectively) subcutaneous injection, administered at weeks 0 and 4, then every 12 weeks, according to the manufacturers' instructions [33].

At baseline (W0), patients' demographic and clinical features were recorded, focusing on age, gender, vital signs, family and personal medical history, comorbidities, PsA clinical subset and disease duration, and previous and/or actual anti-psoriatic therapies (including anti-TNF-α, csDMARDs, and steroids).

Clinically important aspects of the disease, such as arthritis, psoriasis, enthesitis, pain, patient-assessed global disease activity, and physical functions, were evaluated through outcome measures of MDA criteria as follows: TJC, SJC, psoriasis activity and severity index (PASI), body surface area (BSA), patient pain visual analogic scale (VAS), patient global assessment of disease activity (PtGA), health assessment questionnaire (HAQ), and tender entheseal points. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) were also recorded at week 0 and week 24.

In addition, the DLQI questionnaire was used to assess the impact of skin manifestations of psoriasis on a patients' QoL over the previous week (on a scale of 0–30) [34]. Both MDA and DLQI outcomes were collected at baseline and after 24-week treatment. In order to evaluate the safety profile of UST, the appearance of adverse events was also recorded during this period.

### Statistical analysis

The Mann-Whitney test was used to calculate statistical differences between baseline and week 24. $p$ values <0.05 were considered to be statistically significant. All statistical analyses were performed using GraphPad Prism 4.0 (GraphPad Software Inc., La Jolla, CA, USA).

## Results

Thirty-four patients (23 males, 11 females; mean age 53.4 years) with active PsA were enrolled. The mean duration of PsA was 8.8 years. For the PsA clinical subsets, 26 patients (76.5%) showed a predominant peripheral involvement; the most common clinical form was oligo-arthritis (12 patients; 34.3%), followed by enthesitis (7 patients; 20.6%), dactylitis (4 patients; 11.8%), and both dactylitis and enthesitis (3 patients; 8.8%). Only eight patients (23.5%) had predominance of axial disease. Previous treatments included csDMARDs and anti-TNF-α biological drugs. Notably, all 34 patients had experienced therapy with at least one csDMARD; 21 patients (61.7%) had received treatment with two csDMARDs and only 1 patient (2.9%) had undergone therapy with three csDMARDs. The most widely used csDMARD

was methotrexate (28 patients; 82.3%), followed by cyclosporine (24 patients; 70.5%), and sulfasalazine (4 patients; 11.7%). For prior anti-TNF-α biologic therapy, 24 patients (70.5%) had been treated with at least one agent, whereas 6 (17.4%) and 10 (29.4%) patients had been managed with two or three different biologics, respectively.

Twenty-four patients (70.5%) achieved MDA after 24-week treatment with UST (W24) (Fig. 1). A sub-analysis of dermatological indices of the MDA criteria showed that the PASI score was significantly improved and BSA was significantly decreased at 24 weeks compared with that at baseline (both $p < 0.001$) (Table 1). For the rheumatologic indexes, TJC, SJC, and tender entheseal points were all significantly improved at 24 weeks of therapy (all $p < 0.01$ vs. baseline) (Table 1). There was also a significant improvement in patient pain VAS, PtGA, and HAQ after 24-week treatment with UST (all $p < 0.01$ vs. baseline), as reported by the patients' self-assessment of their disease (Table 1).

There was a significant difference between the levels of CRP from week 0 (median CRP level 2.01 ± 2.7 mg/dl) to week 24 (versus median CRP level 0.57 ± 0.8 mg/dl) ($p < 0.01$). Regarding the levels of ESR, there was also an improvement from week 0 (median ESR level 24 ± 21.48) to week 24 (versus median ESR level 16.6 ± 13.9) ($p$ = n.s.).

In addition, there was a significant decrease in the impact of skin manifestations of psoriasis on a patients' QoL based on the DLQI questionnaire after 24-week treatment with UST compared with that at baseline (16.6 vs. 4.3, $p < 0.001$). No adverse events were reported during the treatment period.

**Table 1** Outcome measures (mean ± SD) of minimal disease activity (MDA) criteria at baseline (W0) and after 24-week (W24) treatment with ustekinumab

| MDA criteria | W0 | W24 | *p* value |
|---|---|---|---|
| TJC (0–68) | 7.0 ± 4.2 | 1.6 ± 1.4 | 0.001 |
| SJC (0–66) | 1.5 ± 1.5 | 0.3 ± 0.5 | 0.01 |
| PASI (0–72) | 15.4 ± 9.5 | 1.8 ± 4.2 | 0.001 |
| BSA (%) | 58 ± 17.2 | 3 ± 10.5 | 0.001 |
| Patient pain VAS (0–100 mm) | 53 ± 18.4 | 9.6 ± 7.6 | 0.01 |
| PtGA (0–100 mm) | 58.1 ± 15.8 | 10.3 ± 7.9 | 0.01 |
| HAQ (0–3) | 1.2 ± 0.8 | 0.1 ± 0.4 | 0.01 |
| Tender entheseal points (0–13) | 2.1 ± 3.5 | 0.5 ± 1.2 | 0.01 |
| MDA (%) | 0 | 70.5 | 0.01 |

*BSA* body surface area, *HAQ* health assessment questionnaire, *PASI* psoriasis activity and severity index, *PtGA* patient global assessment of disease activity, *SD* standard deviation, *SJC* swollen joint count, *TJC* tender joint count, *VAS* visual analogic scale, *MDA* minimal disease activity.

## Discussion

Patients with PsA can be refractory or show loss of response to csDMARDs and anti-TNF-α therapy [35]. The switch to the anti-IL-12/23 p40 monoclonal antibody UST has been shown to be an efficacious and safe therapeutic strategy in randomized clinical trials [22–26]. Observational cohort studies can be useful to implement data gained from these trials. In this survey, we evaluated the efficacy and safety of UST in PsA patients in the context of a real-world setting. To the best of our knowledge, this is the first study which has applied the MDA criteria, which have already been validated as disease-specific indicators of disease activity [15, 16], for evaluating the efficacy of UST in PsA subjects. Our results showed that 24-week treatment with UST was efficacious for the majority of patients with active PsA, with approximately 70% of patients achieving a low disease activity state, as defined by the MDA criteria. Moreover, the approximately fourfold decrease in DLQI score as well as the statistically significant improvement in HAQ value at week 24 compared with that at baseline suggests that patients experienced an improvement in their QoL. It is well known that both psoriasis and PsA can negatively impact on QoL, limiting daily life and working performances, resulting in restrictions to social and recreational activities as well as productive life, with patients with concomitant PsA being affected to a much greater degree [11, 36, 37]. Therefore, improving QoL should be considered one of the major objectives of psoriasis and PsA treatments. While this fact is already highlighted in the dermatological literature by studies which considered QoL (evaluated by the DLQI questionnaire) as a major criterion for the introduction of systemic agents in patients with mild psoriasis [38–40], there is a scarcity of attention on this topic in the rheumatologic literature, especially regarding mild or limited forms of disease.

We propose that the DLQI questionnaire should be added to the MDA criteria since PsA usually develops after psoriasis so that articular involvement and skin lesions often coexist in the same patient. Whilst the HAQ focuses on the impact of

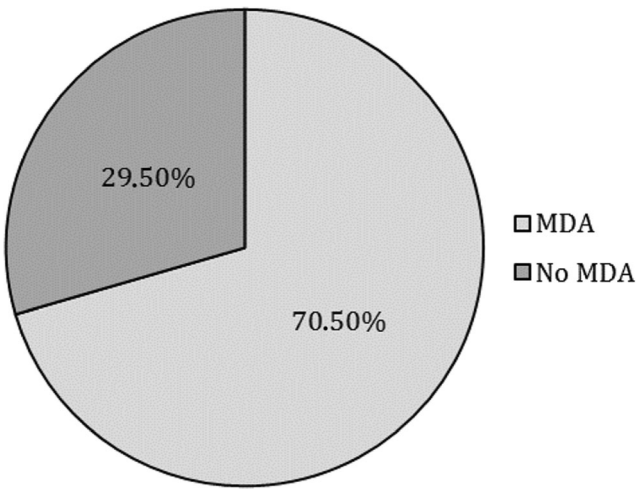


**Fig. 1** The percentage of patients achieving minimal disease activity (MDA) at week 24

PsA on daily life activities (such as walking, dressing up, washing hair, and lifting weights), the DLQI assesses the impact of skin appearance (scaling, erythema) and symptom-related (itch, burning sensation) impairment on everyday life. Indeed, using both the HAQ and DLQI questionnaires may better define a state of MDA in PsA patients since they usually show both aspects (cutaneous and articular) of the psoriatic disease.

In our real-world study, there were no concerns regarding the safety profile of UST, which is in keeping with results from its use in clinical trials on PsA, including randomized trials [22–28]. However, our study has limitations due to its small sample size, lack of instrumental evaluation of patients' involved joints, and the short duration (24 weeks) of both UST treatment and MDA criteria assessment, which may restrict generalization of the results.

In conclusion, the achievement of MDA as well as the significant improvement in DLQI and lack of adverse events in the context of a real-life setting shown here confirms the efficacy and safety of UST in PsA. This study adds strength to the possibility of a therapeutic switch to the anti-IL-12/23 p40 monoclonal antibody in PsA patients with failure or inadequate response to csDMARDs or anti-TNF-α drugs. Further real-world studies to evaluate MDA criteria are needed to assess the long-term effects of UST in PsA treatment, with emphasis on its impact on QoL using specific indices such as the DLQI. Ultimately, achieving a state of well-being and good QoL should be considered as one of the major objectives for the treatment of psoriasis and PsA.

**Compliance with ethical standards**

**Funding sources** None.

**Disclosures** None.

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