Real-world data on secukinumab use for psoriatic arthritis and ankylosing spondylitis

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Dear Editor

We have read the article entitled 'The role of secukinumab in the treatment of psoriatic arthritis and ankylosing spondylitis' by Leticia Garcia-Montoya and Helena Marzo-Ortega published in *Therapeutic Advances in Musculoskeletal Disease* (2018; 10: 169–180).[1] The authors clearly described the pathophysiology underlying the new monoclonal antibody, interleukin (IL)-17A inhibitor. They also reported its efficacy in phase III clinical trials for use in psoriatic arthritis (PsA) and ankylosing spondylitis (AS). This has led to its recommendation as a potential first-line biologic treatment in updated guidelines, competing with the traditional Anti TNF therapies.[2,3]

As IL-17A inhibitor is a relatively new biologic treatment option, it was pertinent to evaluate the real-world clinical results achievable for those patients with PsA and AS. We, therefore, retrospectively audited the use of secukinumab within the Rheumatology Department at Musgrave Park Hospital, Belfast.

The patients included in the clinical review had to have been prescribed secukinumab for at least 4 months. All patients were assessed to see if they had no response, partial response or good response to treatment. This was ascertained by both the patient's subjective feedback to the treatment and a consultant rheumatologist's objective clinical assessment documented in their medical notes. In addition to this, those patients with full data sets for clinical scores pretreatment were reassessed post treatment and percentage change calculated.

To carry out this calculation, we first created a modified Assessment in Spondyloarthritis International Society (ASAS) score for those with AS.[4] Firstly a patient could achieve either no response or a 20%, 50% or 70% improvement in their Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). They then also had to have at least a corresponding percentage improvement in their pain Visual Analogue Score (VAS) and they then achieved a modified ASAS score of 20, 50 or 70, respectively. For those with PsA and predominant peripheral arthritis, we then also modified the American College of Rheumatology (ACR) score.[5] To reach a modified ACR 20, 50 or 70 score, again a patient had to achieve a 20%, 50% or 70% improvement in both tender and swollen joint score, along with a corresponding percentage improvement in either their pain VAS score or inflammatory markers (CRP or ESR).

There were 45 patients that had been prescribed secukinumab for at least 4 months, on the appropriate dosing schedules, within the Belfast trust up until February 2018. There were 25 females and 20 males. Of these patients, 36 had PSA, 5 of which had predominant axial disease and 9 had AS, with an age range of 27–75 years.

All patients had been on a biologic agent prior to secukinumab use. The majority of PsA and AS patients had failed at least two or three anti-TNF biologic therapies.

In the first analysis at 4 months, 80% of patients were clinically deemed to have had at least a partial response, with 20% of patients reporting no benefit. Of those that had reported a response, 20 patients out of 45 (44%) were recorded as having a good response. A partial response meant, in practice, that a patient would continue on treatment as they had been deemed to have had a definite clinical improvement from baseline. For those patients who had objective validated assessment undertaken, we calculated response scores.

There were 30 (66.7%) patients with enough documentation to establish a modified ASAS/ACR response. Of these patients, 21 had PsA with predominant peripheral arthritis and nine had predominant axial disease. In terms of those with peripheral arthritis, 18 had a recorded pain VAS

with an average score of 70.8 mm. For 23 patients, the average baseline tender 68 joint score was 18.2 (range 0–48) and swollen 66 joint score of 6.8 (0–23). For those patients with follow up scores, the average VAS score was 55.7 mm ($n = 14$). For joint scores ($n = 21$), the average tender joint score was 9.5 (0–43), and swollen joint score was 1.6 (0–7). In total, 11 out of 21 (52%) patients with PsA demonstrated at least a modified ACR 20 score, with 38% of patients achieving an ACR 50, and 14% achieving an ACR 70.

When looking at axial disease response the baseline ($n = 12$) BASDAI score was 7.685 (range 3–10) and pain VAS score was 82.9 mm (60–100). For those with follow-up scores ($n = 9$) the average BASDAI score was 7.24 (2.8–10) and VAS score was 75 mm (20–100). In terms of the clinical response, three out of nine patients (33%) achieved a modified ASAS 20 score, and one out of nine patients achieved an ASAS 70 score. Interestingly, of the six patients who had not reported an improvement in BASDI scores at all, four did feel a clinical improvement, suggesting limitations around the BASDAI calculations when performed in real-life clinical settings.

Overall, 34 patients remained on treatment beyond 4 months, and, of those patients, 17 out of 34 (50%) have an ongoing good response, 9 (26%) have an ongoing partial response and 8 (24%) have subsequently stopped treatment. There are 11 patients who have been assessed on secukinumab at 12 months and, of those, 5 (45%) have an ongoing good response, 3 (27%) have an ongoing partial response and 3 (27%) have stopped treatment.

Six patients had side effects on treatment at 4 months, including oral thrush that responded to oral antifungals, and five patients had recurrent chest infections. Three patients had to stop treatment at 4 months. These included one of the patients who had recurrent infections, a patient that developed nausea whilst on the drug and one patient who had low mood. These symptoms were not felt to be attributable to the medication as they have not improved off treatment and are still under investigation. None of the adverse effects were reported as serious.

In summary, this audit describes real-world outcomes for secukinumab use within the Belfast Trust for PSA and AS patients.* We recognise that this was retrospective, based on a small number of patients with available data in clinical practise and used modified criteria created by the authors based on validated tools. However the results suggest secukinumab is an effective treatment in the clinical setting in those who have failed prior Anti TNF therapy. Results are less impressive than those already witnessed amongst phase III trials, which may be a reflection of a higher prevalence of nonbiologic naive patients that we assessed. Ongoing experience and analysis of secukinumab use is required to get a conclusive feel for its effectiveness and side effect profile.

*All clinical data and analysis are available in hard copy form on site in Musgrave Park Hospital.

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Conflict of interest statement

Ashley Elliott has presented the audit results on behalf of Novartis and received honourarium for that.

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