

Biosimilars and retention rates in patients with ankylosing spondylitis

Sirs,

We have read with great interest the article by Kim *et al.* that has been published recently in *Clinical and Experimental Rheumatology*. The article deals with the retention rate and the long-term safety of biosimilar CT-P13 in patients with ankylosing spondylitis (AS) (1). The data were derived from the Korean College of Rheumatology Biologics Registry. A total of 244 patients were included, of whom 203 (83.2%) received CT-P13 biosimilar as first-line therapy, while the rest, 41 patients a second-line therapy. After 4 years of follow-up, the retention rate of CT-P13 in the overall patient-population was 66%. They concluded that CT-P13 demonstrated encouraging drug retention rates as well as reasonable long-term efficacy and safety profile in Korean AS patients without considering several parameters such as the nocebo effect (1).

Between January 2003 and December 2017, 198 patients with AS were investigated by our group in order to estimate the size of the unmet needs in the treatment of AS. The patients were treated according to the European, United States and Canadian guidelines for AS (2-5). All patients were treated with anti-tumour necrosis factor alpha (anti-TNF- α) agents and all were naïve to biologics. After a follow-up of 14 years, only 16 patients had inadequate response to therapy or side-effects. We concluded that the size of unmet needs for AS treatment was 10.1% (6). In a subsequent study, we evaluated 88 patients who were treated with reference infliximab (RI). All patients were in clinical remission and were asked to switch from RI to biosimilar infliximab (BI). The allocation of patients was done randomly using an internet-based alloca-

tion programme. Patients switched to BI were compared with a matched-control group of patients receiving continuous RI. The switching period was from January 2017 to June 2017 and the patients were followed-up until December 2018. Of these, 45 switched to BI while 43 continued receiving the RI. After 18 months of treatment, all patients of both groups remained in clinical remission. No significant adverse events were noted between groups. However, 5 patients from the BI group (4 nocebo effects, 1 recurrent infection) and 3 from the maintenance group receiving RI (1 inadequate response, 2 recurrent infections) discontinued the study. We concluded that BI is equivalent to RI in maintaining AS in clinical remission for 18 months (7).

We believe that, anti-TNF- α treatment in naïve AS patients may lead to sustained clinical remission with high retention rates (8). BI has showed comparative effectiveness and similar toxicity profile with RI, as well as high retention rates (9-10). To this end, rheumatologists must follow the international guidelines for AS treatment but also the shared-decision making pathway with their patients in order to minimise the nocebo effect. It is our strong belief that treatment strategies are more important than drugs to manage these patients (11).

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