Effects of Sarilumab on Rheumatoid Arthritis as Reported by Patients Using the Rheumatoid Arthritis Impact of Disease Scale

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J Rheumatol 2019;46:1259-67; https://doi.org/10.3899/jrheum.180904

Hello, I'm Dr. Laure Gossec, Professor of Rheumatology at the Sorbonne Université in Paris, France.

In addition to physician-reported and lab data, use of well-defined and reliable patient-reported outcomes (PRO) is essential for drawing comprehensive conclusions regarding the outcomes of treatments for rheumatoid arthritis (RA).

In the October 2019 issue of *The Journal of Rheumatology*, we reported our findings on the effect of sarilumab on important PRO in patients with RA as assessed by the RA Impact of Disease (RAID) scale. The RAID is an internationally validated tool specifically designed for patients with RA, and it evaluates seven domains, each with a single item or question.

The domains cover seven key aspects of impact: (1) pain, (2) functional impairment, and (3) fatigue are the ones most often mentioned by patients as important. (4) Emotional and (5) physical well-being, (6) sleep, and (7) ability to cope are also important.

The seven domains can be reported separately from 0 (best) to 10 (worst). Lower scores indicate less impact of the disease on the patient. In the total RAID score, each domain is given a specific weight reflecting its importance to patients. So more weight is given to pain, functional impairment, and fatigue.

Patients completed the RAID questionnaire in two randomized double-blind sarilumab studies: TARGET (NCT01709578) and MONARCH (NCT02332590). Differences from baseline in total RAID and individual domain scores were secondary endpoints.

In TARGET, all patients received conventional synthetic disease-modifying antirheumatic drugs (DMARD). It compared the efficacy and safety of sarilumab 150 mg and 200 mg every two weeks versus placebo in patients intolerant of or who have had inadequate response to ≥ 1 tumor necrosis factor inhibitors (TNF).

MONARCH was a monotherapy superiority study that compared the efficacy and safety of sarilumab 200 mg versus adalimumab (ADA) 40 mg, both given every two weeks in patients who should not start or continue treatment with methotrexate (MTX) due to intolerance or inadequate response.

In the TARGET study, we can see that there was a slight improvement in mean total RAID score in the placebo arm, around 1 point on a 0–10 scale. Patients treated with sarilumab improved more with a very clear improvement of 2.5–3 points already at 12 weeks.

In MONARCH, improvement was of a similar magnitude in patients treated with sarilumab, and the improvement was better with ADA at Week 12 and Week 24 as well.

Treatment with sarilumab also improved individual domain scores. To compare effects, we calculated effect sizes, which are a standardized weight to measure effect and are considered clinically significant

when above 0.5. The effect sizes with sarilumab ibn both trials were greatest on the 3 key domains of pain, function, and fatigue. The effect was less important on sleep. This probably reflects that sleep disturbances and even well-being are multi-factorial in RA.

To explore more of the clinical significance of our findings, we looked at the proportions of patients responding with sarilumab. By Week 24, with a higher sarilumab dose, over 4/10 patients achieved a minimally clinically improvement in RAID score of 3 points or more. This was more than in the comparator groups.

We also assessed what could be called the RAID Patient Acceptable State, which is an absolute total RAID score of 3 points or less on a 0–10 scale. This was obtained more frequently with sarilumab than with placebo or ADA.

Please read our full paper to learn more about the improvement seen in PRO with sarilumab treatments in patients with RA.