4CPS-310

TOFACITINIB EFFECTIVENESS AND SAFETY RESULTS: REAL WORLD DATA

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Background and importance:
Tofacitinib is an oral JAK inhibitor indicated for the treatment of rheumatoid arthritis, psoriasis arthritis and ulcerative colitis. The efficacy and safety of tofacitinib have been shown in several randomized clinical trials.

Aim and objectives:
To evaluate the effectiveness and safety of tofacitinib in all indications used in a real-world cohort of patients at a third level hospital.

Materials and methods:
This is a retrospective observational study of patients who received tofacitinib since 2017 to March 2020. Demographic, clinical characteristics at baseline and outcomes analyzed were: age, sex, diagnosis, number of days with tofacitinib, prior lines of treatment, objective response and adverse effects.

Results:

A total of 30 patients were treated with tofacitinib since 2017 to March 2020, 23 female and 7 male, the median age was 55(48-62); 40% of patients were overweight. 23 patients were diagnostic with rheumatoid arthritis, 3 patients with psoriasis arthritis, 1 patient with vitíligo, 1 patient with alopecia areata and 1 patient with polyarthritis. Total of 50% of patients were pre-exposed to at least one biological agent and all of the patients were pre-exposed to methotrexate, leflunomide and/or hydroxychloroquine. The median time to stop tofacitinib was 307 (114-557) days. Reasons to stop tofacitinib were: insufficient response (n = 9), infection (n = 1), headache (n = 3), hematemesis (n=1), pregnant (n=1). 15 patients continue in treatment with tofacitinib with a good response. Elevation of liver enzymes, or changes in the levels of lymphocytes, neutrophils, and hemoglobin have not been detected in any patient. 30% of patients had adverse events; adverse events more frequent were infections in 13% patients and cefalea also in 13% patients.

Conclusions and relevance:
The efficacy and safety of tofacitinib have been demonstrated in clinical trials. This retrospective analysis of real-life data shows that tofacitinib is also effective and safe in a real-life setting but only 50% of the patient cohort achieved response on a dose of tofacitinib 5 mg bid. Due to the size of the group, these results should be interpreted with caution; future analysis in clinical practice is necessary.