Background and importance Tofacitinib and baricitinib are oral Janus kinase inhibitors (JKi) approved for the treatment of rheumatoid arthritis (RA), offering an alternative in patients who have not responded or tolerated previous treatment lines because of adverse effects, complications or other reasons. In pivotal clinical trials, patients had higher DAS28-ESR than our patients and were less pretreated with biologic disease modifying antirheumatic drugs (bDMARDs). Lower effectiveness in real world compared with clinical trials has been reported. We conducted a retrospective study to evaluate effectiveness in our patients.

Aim and objectives To assess the effectiveness and safety of JKi in patients with RA in a clinical setting.

Material and methods This observational retrospective study included patients with RA in a third level hospital, from 2016 to 2019. Clinical data were collected from the hospital medical records and ‘patient and treatments registry programme’ of our local government: demographic, indications, previous and current treatments, discontinuity of treatment and reasons, effectiveness and safety data.

Clinical disease impact, defined by the disease activity score, DAS28-ESR, was evaluated during patient monitoring. Mean (SD) DAS28-ESR at baseline and at follow-up after JKi treatment were analysed.

Variance analysis (ANOVA) and the $\chi^2$ test were applied (SPSS) to evaluate treatment effect (time=0 vs follow-up data).

Results Fifty-three patients were included with a mean age of 63.9±13.3 years and 46 (86.8%) were women. Previous non-bDMARDs treatments were: methotrexate (n=39, 73.6%), leflunomide (n=34, 64.2%), hydroxychloroquine (n=15, 28.3%) and sulfasalazine (n=9, 17.0%).

Disease activity was categorised as: remission (DAS28-ESR <2.6), low disease activity (2.6 < DAS28-ESR <3.2), moderate disease activity(3.2 < DAS28-ESR <5.1) and high disease activity (DAS28-ESR >5.1). At the beginning of the study, one patient had DAS28-ESR <2.6 (1.9%) and during the monitoring period, nine patients reached DAS28-ESR >2.6 (17.0%) at some point. Mean DAS28-ESR was 4.97±1.32 at baseline; during follow-up, mean DAS28-ESR decreased to 0.69±1.44 (10.3±30.8%) (p<0.001).

Patients were classified by treatment received: tofacitinib group (ToFG (n=44, 83.0%)) and baricitinib group (BarG (n=9, 17.0%)). Number of bDMARDs used before JKi:
- ToFG: 0 (n=7, 15.9%), 0–3 (n=22, 50.0%), >3 (n=15, 34.1%).
- BarG: 0 (n=2, 22.2%), 0–3 (n=3, 33.3%), >3 (n=4, 44.4%).

At follow-up, mean DAS28-ESR decreased: ToFG, 0.64 ±1.44 (9.3±32.0%) and BarG, 0.98±1.44 (15.6±23.0%).

Twelve patients discontinued JKi: baricitinib (n=3, 33.3%) and tofacitinib (n=9, 20.5%). Reasons for discontinuation, baricitinib and tofacitinib, respectively, were due to:
- lack of effectiveness (n=2, 22.2%) and (n=5, 9.4%);
- lack of adherence (n=1, 11.1%) and (n=2, 3.8%);
- adverse effects (n=0, 0%) and (n=1, 9.1% oedema and dyspnoea); and
- patient’s choice (n=0, 0%) and (n=1, 1.9%).

Conclusion and relevance Our study suggests that JKi could be effective in real world settings after switching from other multiple bDMARDs. The results showed a modest benefit of JKi in complicated and over treated patients with diverse backgrounds, as found in daily practice.
TEN YEAR ANALYSIS OF THE USE OF INFliximab IN ULCERATIVE COLITIS

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Background and importance Analysis of data obtained in the ‘real world’ setting is acquiring great importance in the healthcare environment. It is important to know the results obtained with different treatments outside the ideal environment offered by clinical trials.

Aim and objectives To describe and analyse the results obtained with infliximab (IFX) over a 10 year period in patients diagnosed with ulcerative colitis (UC).

Material and methods This was a retrospective descriptive study conducted in a third level hospital that included all patients diagnosed with UC who started IFX treatment between January 2005 and December 2014. Follow-up was up to 31 July 2015. The following clinical data were recorded: age, sex, time in treatment, previous biological lines, definitive or temporary suspensions of treatment and reason, dose modifications and values for C reactive protein (CRP) before starting and at the end of treatment. Dosage modifications were recorded as those that implied a treatment pattern not described in the technical data sheet. Treatment interruptions were considered to be those of a duration ≥ 6 months. Data were recorded using the OncoWin computer application and the electronic medical record stored in SAP.

Results A total of 32 patients were included in the study (59.4% men, mean age 37.7 years (12–72)). Mean follow-up time was 52.5 months (8–109); 93.8% of patients received IFX as first line therapy. Mean baseline CRP was 19.92 mg/L (0.70–84.94), and 7.82 (0.10–30.90) at the end of treatment. A total of 71% of patients discontinued treatment definitively: 6.3% for infusional reactions, 31.2% for inefficacy, 25.0% for remission of the disease and 9.4% for other reasons. In addition, 28.7% of patients received only the three IFX induction doses, of which 78% were not able to control the disease. Only 9.4% of patients temporarily interrupted treatment, with an average interruption time of 28.7 months (7–41); 12.5% of patients required dose modifications to control the disease.

Conclusion and relevance With the present work we wanted to show the long term results of IFX in UC in clinical practice. IFX can be an effective tool to control disease symptoms in the long term. Its use, administering only three induction doses, does not seem to be useful, with about 80% ineffectiveness rate.

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