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AB0425 REAL-WORLD EFFECTIVENESS OF FILGOTINIB IN BELGIAN PATIENTS WITH RHEUMATOID ARTHRITIS

Keywords: Real-world evidence, Rheumatoid arthritis, Targeted synthetic drugs

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Background: Filgotinib (FIL), a preferential Janus Kinase (JAK) inhibitor targeting the JAK1 enzyme, has demonstrated efficacy in rheumatoid arthritis (RA) in clinical trials. FIL is reimbursed in Belgium since August 2021 for adult patients with moderate to severe RA with a DAS28 score >3.7 and inadequate response or intolerance to 2 conventional DMARDs including Methotrexate. Today, limited data exist on the real-world effectiveness of FIL in RA.
Objectives: Our aim was to examine the short-term effectiveness of FIL in a heterogeneous RA population.
Methods: Patients were included from the electronic platform "Tool for Administrative Reimbursement Drug Information Sharing" (TARDIS). Data from all Belgian RA patients on biologic and targeted therapy are collected in this platform during the submission of a request for initiation or prolongation of reimbursement of these drugs. The study population included adult patients ≥18 years starting FIL between August 2021 and November 2022. Baseline characteristics (demographics, clinical characteristics, treatment history) of Belgian RA patients treated with FIL were registered. Effectiveness of FIL was determined by the patient proportion achieving remission (DAS28 <2.6), low disease activity (DAS28 ≤3.2), HAQ-DI≤0.25 (HAQ25) and minimum HAQ-DI-decrease (MCID_HAQ) since baseline of 0.22, at the first follow-up moment, structurally planned in TARDIS after 3 months. Sensitivity analyses were performed in patients starting FIL as 1st, 2nd or 3th+-line advanced therapy.
Results: In total, 405 RA patients on FIL were included, representing all newly initiated FIL patients. Table 1 gives detailed information on the demographics, clinical characteristics and treatment history. Of the 228 patients with information on treatment at the next follow-up moment, 210 (92%) continued FIL, and 6 (3%), 9 (4%), and 3 (1%) changed to a TNFi, non-TNFi and JAKi respectively. In total, 193/405 (48%) patients could be included in the effectiveness analysis. Remission and low disease activity were reached in 61% (117/193) and 81% (156/193) of patients respectively. Baseline mean ±SD DAS28 was 4.9 ±0.8. The DAS28 change was 2.5 ±1.2, resulting in a mean ±SD DAS28 of 2.4 ±1.1 at first follow-up. HAQ25 and MCID_HAQ were reached in 21% (41/193) and 70% (136/193) of patients. FIL efficacy slightly decreased with increasing line of therapy (Figure 1).

Table 1. Baseline characteristics of TARDIS patients on FIL

	Total FIL population
Number	405
Age (mean ±SD, years)	58.3 ±13.7
Disease duration (mean ±SD, years)	10.0 ±9.5
ESR (mean ±SD, mm/hour)	24.9 ±20.9
CRP (mean ±SD, mg/L)	12.4 ±15.7
SJC28 (mean ±SD)	6.5 ±4.2
TJC28 (mean ±SD)	9.0 ±5.6
DAS28 (mean ±SD, years)	4.9 ±0.9
HAQ-DI (mean ±SD, 0-3)*	1.6 ±0.6
PGA (mean ±SD, 0-100)	65.6 ±18.9
Advanced Therapy Naive yes	148/405 (36,5%)
Advanced Therapy Experienced yes	257/405 (63.5%)
2nd line	113/405 (27.9%)
3th line +	144/405 (35.5%)
Previous advanced treatment**	
TNFi,	77/226 (34.0%)
Non-TNFi,	97/226 (42.9%)
JAKi	52/226 (23.0%)

Legend: Number given are mean ± SD or number, proportion. TNFi = tumour necrosis factor inhibitor, JAKi = Janus Kinase inhibitor, HAQ= health assessment questionnaire, PGA= Patient Global assessment; CRP= C-reactive protein; ESR= erythrocyte sedimentation rate; TJC= tender joint count; SJC= Swollen joint Count; DAS28 = disease activity score based on the 28joints. Advanced Therapy naive patients were patients starting FIL as first advanced therapy. *Missing HAQ(0-3) scores were imputed by regression using age and HAQ(0-60) scores. **for 31 of 257 Advanced Therapy Experienced patients this was undefined.

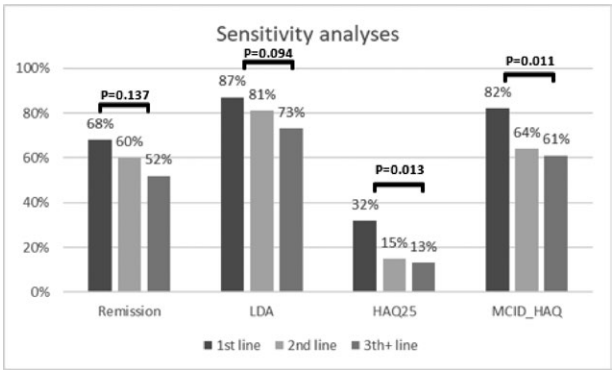

Figure 1. Effectiveness outcomes of FIL per treatment line

Conclusion: FIL treatment offered promising clinical outcomes after 3 months in most patients with moderately to severely active RA in a real-world setting.
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AB0426 PROFILE OF REFRACTORY RA PATIENTS FOR TARGETED THERAPIES IN REAL LIFE

Keywords: bDMARD, Rheumatoid arthritis, Targeted synthetic drugs

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Background: A proportion of RA patients fails to respond to their first targeted therapy (TT), and response decreases with increasing TTs exposures. EULAR have defined refractory RA (refRA) patients as a failure of two or more TTs of differing mechanisms of action.
Objectives: We aimed to determine the clinical and therapeutic profile of refRA and describe the patterns of drug sequencing.
Methods: Cross-sectional, observational study with RA patients diagnosed according to ACR/EULAR 2010 criteria, and exposed to TT over the last 20 years was performed. We classified patients in 1) non-refRA (1 or 2 TTs) and 2) refRA (at least 3 TTs). We analyzed the different lines of treatment with TTs, its duration treatment and reasons for discontinuation of treatment.
Results: 544 RA patients undergoing TTs were included, 122 from them were considered as refRA (at least 3 lines of TTs). RefRA patients showed younger age at diagnosis than non-refRA (P<0.001) but there is no differences on time of disease evolution until de 1st TT in both groups. Anti-TNF was the treatment of choice for the 1stline therapy, however is less likely to be administered in non-refRA rather than refRA (P<0.001) (table 1). "Cycling" after the first-line TTs was frequent in refRA (P<0.001), but from the 3rd-line of treatment "switching" is the main choice and different TTs differing mechanisms of action were used. The absence of conventional DMARD treatment is more likely in refRA, as well as a reduction in the treatment duration as increase the number of treatment lines administered. Secondary non-response in 1st and 2nd TTs were the main reason for discontinuing treatment (P<0.001) in refRA, being the adverse event more frequent as cause of discontinuing treatment in non-refRA (P=0.005). Analyzing the reason for discontinuing treatment and excluding the "other reasons", if the cause of discontinuing treatment in refRA is a primary non-response, near of the 30% of patients discontinue in 2nd-line by the same reason; and if the cause for discontinuation in 1st-line is an adverse effect, the 33% of patients discontinue in 2nd-line by the same reason (see image).
Conclusion: RefRA patients showed lower age at diagnosis. Anti-TNF was the most frequent TT both in 1st and 2nd line of treatment; and as from the 3rd-line there is a switching for TTs with mechanisms of action. Despite to secondary non-response is the most common cause of discontinuation in first and second-line in refRA, we observed a tendency to reiterate in the second-line of treatment the reason for discontinuation of the first-line of treatment.