Filgotinib for Rheumatoid Arthritis: an observational cohort to assess clinical effectiveness in a single centre in Scotland

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Background, Objectives and Methods

Background

- Filgotinib (Jyseleca) is a JAK 1 preferential inhibitor which in 2021 was approved for use in the UK in moderate or severe rheumatoid arthritis, either as monotherapy or alongside a conventional DMARD. Clinical efficacy was demonstrated in the FINCH 1-3 trials[1-3] but evidence of real-world effectiveness is currently limited.

- A reduced dose of 100mg is recommended for patients over 75 years, or with moderate or severe renal impairment.

- Following results from the ORAL surveillance clinical trial of Tofacitinib[4], and preliminary data from an observational study involving Baricitinib, in 2023, the EMA issued guidance advising caution using JAK inhibitors in patients over 65 years, smokers and those at increased risk of MACE, VTE or cancer[5].

Objectives and Methods

- RA patients starting Filgotinib in NHS Lothian in a 9 month sample between December 2021 and August 2022 had data captured at 2 time points, December 2022[6] and updated September 2023 for BSR 2024. We recorded baseline data including time since diagnosis of RA, previous and current treatment, duration of treatment with Filgotinib, and discontinuation reason if applicable. Pre-existing co-morbidity and VTE, MACE, malignancy and ILD incident events during treatment were recorded. DAS28-CRP scores before and during treatment were recorded where available.

- The objective of our study is to assess clinical effectiveness through drug survival and disease activity score, along with assessing discontinuation reasons and the incidence of relevant adverse events or side effects.

JAK, janus kinase; DMARD, disease-modifying anti-rheumatic drug; EMA, European Medicines Agency; MACE, major adverse cardiovascular event; VTE, venous thromboembolism; RA, rheumatoid arthritis; ILD, interstitial lung disease

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Results

Figure 1 – DAS28-CRP before and during Filgotinib treatment

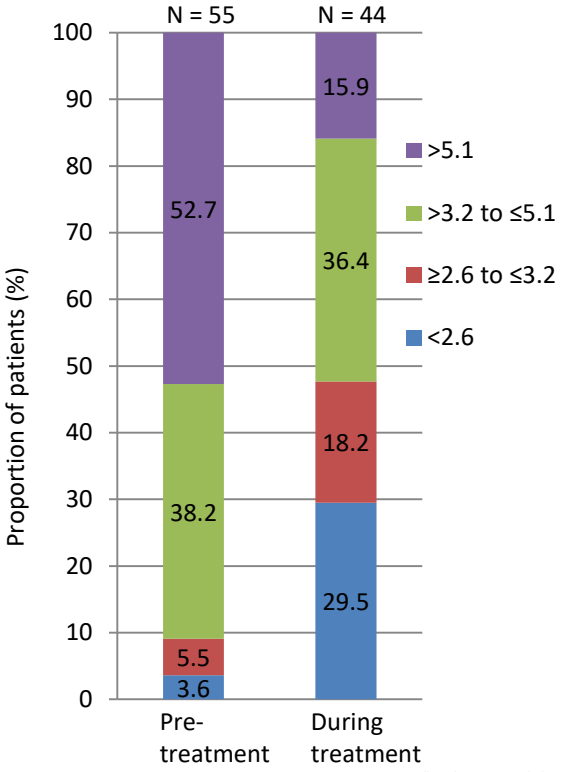


Table 1 – Baseline characteristics

Baseline characteristics	N = 145
Age (median, IQR)	64 (57-72)
Male	39 (26.9%)
Female	106 (73.1%)
Disease duration	
1-5 years	29 (20.0%)
Over 5 years	116 (80.0%)
ACPA and/or RF positive	105 (72.4%)

Table 2 – Previous treatment

Previous treatment	N = 145
csDMARD only	25 (17.3%)
Single anti-TNF bDMARD	45 (31.0%)
Other single bDMARD/tsDMARD	16 (11.0%)
Multiple bDMARD/tsDMARDs	59 (40.7%)

Table 3 – Treatment with Filgotinib

Filgotinib treatment	N = 145
Dose	
100mg	37 (25.5%)
200mg	108 (74.5%)
Filgotinib monotherapy	54 (37.2%)
with Glucocorticoid	10 (6.9%)
Filgotinib with Methotrexate	30 (20.7%)
with Glucocorticoid	7 (4.8%)
Filgotinib with other csDMARD	39 (26.9%)
with Glucocorticoid	5 (3.5%)

Table 4 – Reasons for stopping treatment

Discontinuation reason	N = 41
Lack of efficacy	15 (36.6%)
Loss of effect	10 (24.4%)
Adverse event	5 (12.2%)
Side effects	6 (14.6%)
Other	5 (12.2%)

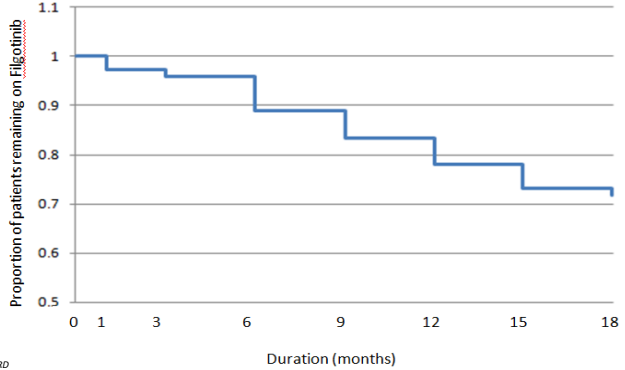
Table 5 – Baseline comorbidities

Baseline comorbidities	
ILD	12
MACE	10
Prior malignancy	8
VTE	6

Table 6 – Events during treatment

Events during treatment	
ILD	1
MACE	0
Malignancy	3
VTE	2

Figure 2 – Proportion of patients continuing treatment



DAS28-CRP, Disease activity score in 28 joints using C-reactive protein; ACPA, anti-citrullinated protein autoantibodies; RF, rheumatoid factor; csDMARD, conventional synthetic DMARD; anti-TNF, anti-tumour necrosis factor; bDMARD, biologic DMARD; tsDMARD, targeted synthetic DMARD

Conclusions

- 71.7% of patients remained on Filgotinib treatment at median duration of 447 days, suggesting good patient tolerability and clinical effectiveness.

- DAS28-CRP scores also indicate clinical effectiveness, with mean pre-treatment score of 5.1 and during treatment 3.5. Formal disease assessment scoring was only recorded in a minority of patients.

- 3 patients were diagnosed with lung cancer during treatment, and 2 patients developed VTE. No new MACE occurred during treatment. Prescribers should consider individual patient's risk profiles when commencing Filgotinib.

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