Clinical: Therapy and Observation

Abstract citation ID: jjae190.1023
P0849
Real-world efficacy and safety of filgotinib in ulcerative colitis: results from the ENEIDA registry

L Rodríguez-Lago[1], L. Cudero[2], C. Martínez Pascual[3], A. Mínguez[4], R. Ferreiro-Iglesias[5], L. Arranz[6], A.M. Royo[7], D. Martín-Rodríguez[8], M.D.L.Á. Mejías[9], M. Calafat[10], M. Calvo[11], C.J. Gargallo-Puyuelo[12], A. Granja[13], J. Santos-Fernández[14], P. Ucha[15], D. Ceballos[16], M.D. Martín-Arranz[17], I. Ferrer[18], L. Ramos[19], P. Almela[20], A. Fernández-Clotet[21], O. García-Bosch[22], J.M. Huguet[23], M.L. Lozano[24], S. Riestra[25], E. Sese[26], G. Torres[27], A.M. Trapero[28], P. Varela[29], E. Domènech[10], M. Barreiro-de Acosta[5] on behalf of the ENEIDA registry of GETECCU
[1]*Hospital Universitario de Galdakao, Department of Gastroenterology, Galdakao, Spain* [2]*Hospital Universitario 12 de Octubre, Gastroenterology Department, Madrid, Spain* [3]*Hospital Clínico Universitario Virgen de La Arrixaca, Hospital Clínico Universitario Virgen de La Arrixaca, Murcia, Spain* [4]*Hospital Universitario y Politécnico La Fe, Gastroenterology Department, Valencia, Spain* [5]*Hospital Clínico Universitario de Santiago de Compostela, Gastroenterology Department, Santiago de Compostela, Spain* [6]*Hospital Universitario Nuestra Señora de Candelaria, Gastroenterology Department, La Laguna, Spain* [7]*Hospital Universitario Miguel Servet, Gastroenterology Department, Zaragoza, Spain* [8]*Hospital Infanta Cristina, Gastroenterology Department, Parla, Spain* [9]*Hospital General Universitario de Ciudad Real, Gastroenterology Department, Ciudad Real, Spain* [10]*Hospital Universitari Germans Trias i Pujol, Gastroenterology Department, Badalona, Spain* [11]*Hospital Universitario Puerta de Hierro, Gastroenterology Department, Mahadahonda, Spain* [12]*Hospital Clínico Universtario Lozano Blesa, Gastroenterology Department, Zaragoza, Spain* [13]*Hospital Universitario de Fuenlabrada, Gastroenterology Department, Fuenlabrada, Spain* [14]*Complejo Asistencial Universitario de Palencia, Gastroenterology Department, Palencia, Spain* [15]*Hospital Álvaro Cunqueiro, Gastroenterology Department, Vigo, Spain* [16]*Hospital Universitario de Gran Canaria Dr. Negrín, Gastroenterology Department, Las Palmas de Gran Canaria, Spain* [17]*Hospital Universitario La Paz, Gastroenterology Department, Madrid, Spain* [18]*Hospital de Manises, Gastroenterology Department, Manises, Spain* [19]*Hospital Universitario de Canarias, Gastroenterology Department, La laguna, Spain* [20]*Hospital General Universitario de Castellón, Gastroenterology Department, Castellón, Spain* [21]*Hospital Clinic de Barcelona, Gastroenterology Department, Barcelona, Spain* [22]*Hospital de Sant Joan Despí Moisés Broggi, Gastroenterology Department, Sant Joan Despí, Spain* [23]*Hospital General Universitario de Valencia, Gastroenterology Department, Valencia, Spain* [24]*Hospital Universitario de Cáceres, Gastroenterology Department, Cáceres, Spain* [25]*Hospital Universitario Central de Asturias, Gastroenterology Department, Oviedo, Spain* [26]*Hospital Universitari Arnau de Vilanova, Gastroenterology Department, Lleida, Spain* [27]*Hospital General de Granollers, Gastroenterology Department, Granollers, Spain* [28]*Hospital Universitario de Jaén, Gastroenterology Department, Jaén, Spain* [29]*Hospital Universitario de Cabueñes, Gastroenterology Department, Gijón, Spain*

Background: Ulcerative colitis (UC) is a chronic inflammatory disorder characterized by periods of relapse and remission. Current treatment options aim to achieve mucosal healing and sustain long-term remission, yet many patients experience treatment failure. Filgotinib (FIL), a selective JAK1 inhibitor, has emerged as a promising therapeutic agent in UC management with favorable outcomes in clinical trials. This study aimed to evaluate the real-world efficacy and safety of FIL in patients with moderate-to-severe UC.

Methods: We conducted a multicenter, observational, retrospective study involving adult patients with moderate-to-severe UC who were treated with FIL within the ENEIDA registry, a nationwide prospectively-maintained database. Data were collected from 28 Spanish IBD units between 12/2021 and 10/2024. Patients were eligible if they had an established diagnosis of UC, had been initiated on FIL and without previous colectomy. The primary outcome was clinical remission (partial Mayo ≤2 with no subscore >1 and no rectal bleeding) at week 12 and 52, along with its safety profile.

Results: A total of 91 patients were included (mean age of 37.5 years (SD 18), 63% male, and a median disease duration of 83 months [IQR, 35-148], 65% non-smokers, 15% extraintestinal manifestations). Most of them had extensive (49%) or left-sided colitis (42%). Prior exposure to anti-TNF was present in 89%, vedolizumab in 43%, and ustekinumab in 38%, with 18% also exposed to JAK inhibitors. The majority of patients had Mayo 2 or 3 endoscopic score (87%). All but 2 patients started FIL 200 mg bid (98%) and 27% received concomitant steroids or immunosuppressants (5%).

Steroid-free clinical remission was 42% and 48% after 12 and 52 weeks, respectively (Figure 1). FIL persistence was 64% with median treatment duration of 6 months (IQR, 3.8-9.7). Those previously exposed to JAK inhibitors showed a 80% and 40% persistence after 12 and 52 weeks, respectively. This subgroup showed similar steroid-free clinical remission rates of 33% and 17%, respectively. Overall, hospital admission was indicated in 7% and colectomy in 1%.

FIL was generally well-tolerated, with 18% of patients reporting at least one adverse event, 19% of them considered as serious, including herpes zoster infection in 2% (both vaccinated, 1 severe infection requiring FIL withdrawal), with no cardiovascular or thromboembolic events reported.

Conclusion: In this real-world, multicenter observational study, FIL demonstrated its efficacy in the induction and maintenance of clinical remission in patients with active UC. The real-world safety profile was consistent with previous data, with no unexpected adverse events. These findings support FIL as a valuable therapeutic option in the management of UC.

Figure(s)/Table(s): see next page