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Single Case

Filgotinib to Treat Acute Severe Refractory Ulcerative Colitis: A Case Report and Review of the Literature

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Keywords

Acute severe ulcerative colitis · Refractory colitis · Rescue therapy · Janus kinase inhibitors · Filgotinib · Case report

Abstract

Introduction: Acute severe ulcerative colitis (ASUC) is a serious complication affecting 9%–15% of patients with UC within 3 months of diagnosis and up to 28% of patients during the course of the disease. Despite the use of infliximab and calcineurin inhibitors, the rate of colectomy remains high both during the hospitalization and in the 5 years after an acute episode. We present a case of ASUC that was unresponsive to conventional therapies but was successfully treated with filgotinib. ***Case Presentation:*** A 21-year-old male with a recent diagnosis of UC presented to our hospital with a severe flare. He received rescue therapy of high-dose intravenous steroids and 10 mg/kg infliximab. We observed little clinical and biochemical benefits. The patient declined the surgical option. Therefore, we decided to start a second rescue therapy with a new and rapid-acting Janus kinase inhibitor, filgotinib, due to its characteristics and pharmacokinetic profile of rapid absorption and metabolism. The patient showed an immediate clinical and biochemical response at 48 h, an endoscopic response at week 3, and an endoscopic remission at week 10. No recurrence was observed after 12 months of follow-

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up. The patient is in clinical remission with a good quality of life. ***Conclusion:*** Filgotinib may be an effective second-line therapy in an emergency setting such as ASUC in patients unresponsive to conventional therapy.

Introduction

Acute severe ulcerative colitis (ASUC) is a serious complication of UC and one of the most common reasons for hospitalization for patients with UC. ASUC affects 9%–15% of patients with UC within 3 months of diagnosis and up to 28% of patients during the course of the disease. The diagnosis is made using the modified criteria of Truelove and Witts [1], which includes the frequency of bloody stools (≥6 per day) with at least one sign of systemic toxicity such as a pulse rate >90 bpm, temperature >37.8°C, and/or hemoglobin level <10 mg/dL [1]. The risk of colectomy increases with the number of criteria present at diagnosis, ranging from 8.5% up to 48% (≥3 additional criteria). The inadequate response to an intravenous steroid course at day 3 together with a high serum C-reactive protein (CRP) level, low serum albumin level, anemia, malnutrition, and severe endoscopic lesions are other risk factors for colectomy.

Despite the introduction of infliximab and calcineurin inhibitors, the rate of colectomy remains high both during hospitalization and in the 5 years after an acute episode [2]. In addition, there is still a lack of predictive models to identify patients who are likely to fail medical rescue therapy [3]. This is particularly important because we have limited time to make a decision while trying to avoid surgery. Therefore, the use of Janus kinase (JAK) inhibitors, particularly tofacitinib, in ASUC has been investigated in recent years due to their rapid onset of action. In some case reports/series [4], and more recently in a prospective cohort study [5] and in a retrospective case-control study [6], tofacitinib has been used as sequential therapy after failure of one or more biologics or as first-line rescue in patients treated with biologics. This has led to improvement in symptoms so that colectomy was unnecessary in 77% of cases [4–8]. Long-term data for tofacitinib treatment are still needed. In a GETAID study, colectomy-free survival at 6 months was 73.6% [5], whereas in other small series, initial responders to tofacitinib required steroids at 6 months or required colectomy by week 26 [7]. In another series, all responders to tofacitinib remained colectomy-free at the 12-month follow-up [8].

These results encouraged further studies and case series with another JAC inhibitor, upadacitinib, while similar data are lacking for filgotinib. An important limitation of tofacitinib is related to his safety profile, in particular the increased risk of infection, such as herpes zoster virus and *Clostridium difficile*, compared to the other selective anti-JAK filgotinib [9].

There are still high percentages of patients undergoing emergency colectomy that impact a large number of young patients. Therefore, further studies are needed to determine new clinical strategies to manage patients with ASUC who have failed traditional rescue therapies. In this report, we present a case of ASUC that was unresponsive to conventional therapies but was successfully treated with the JAK inhibitor, filgotinib.

Case Presentation

A 21-year-old male, with no significant prior medical history, who was diagnosed with mild left-sided UC in April 2023 and initially treated with mesalamine, presented to our hospital in May 2023 with a severe disease flare, which responded to high-dose

intravenous steroids. In July 2023, a colonoscopy revealed an extension of the disease with endoscopic evidence of severe pancolitis (Mayo endoscopic score [MES]: 3). Therefore, infliximab (5 mg/kg) was started, resulting in an initial clinical response. Immediately after the second dose, the patient went on vacation abroad and did not follow a proper lifestyle or diet. After his return to Italy, he presented to our hospital with a second severe relapse of the disease.

Personal and Family History

The patient had no personal history of relevant diseases or a family history of gastrointestinal or autoimmune diseases.

Physical Examination

At hospital admission, the patient was dehydrated, tachycardic (110 beats/min), hypotensive (100/60 mm Hg), and pyretic (38°C) with bloody diarrhea (>6 bowel movements/day) and a distended and diffusely painful abdomen (Mayo Full score 10; Truelove Witts severe).

Laboratory Testing

Laboratory tests revealed severe anemia (hemoglobin [Hb]: 6.8 g/dL; normal range: 14.0–17.0 g/dL) requiring blood transfusions and inflammation (CRP: 20.3 mg/dL; normal range: 0–0.5 mg/dL). The WBC was 28,000/μL (normal range: 4,000–11,000/μL) and fecal calprotectin was 2,800 μg/g (normal range: <50 μg/g) (Table 1). Metabolic alkalosis was detected. Infectious complications, including cytomegalovirus infection, and stool examinations were negative.

Imaging Examination

A CT scan showed distension with parietal thinning of the right colon and thickening of the left colon, lymphadenomegaly, and free fluid in the abdomen without perforation or megacolon.

Final Diagnosis

A diagnosis of severe relapse of UC was confirmed by clinical examination, laboratory testing, and endoscopy. Indeed, a proctosigmoidoscopy confirmed severe inflammation (MES: 3; UC Endoscopic Index of Severity: 12) of the rectum and the sigmoid colon (Fig. 1).

Treatment

The patient received another course of intravenous steroids with no clinical response on the 3rd day after admission. Therefore, a third dose of infliximab (10 mg/kg) was administered. He received thromboprophylaxis with low molecular weight heparin and parenteral nutrition integrated with enteral nutrition due to a severe malnutrition status (body mass index: 14). Six days after admission, the patient showed no clinical, laboratory, or imaging response, and the serological infliximab level was high (>14.4 μg/mL). We consulted the surgeon for an urgent colectomy, but the patient declined this option. We treated the patient with a second rescue therapy, filgotinib. Filgotinib is a new and rapid-acting JAK inhibitor and was chosen for its characteristics and pharmacokinetic profile of rapid absorption and metabolism.

Table 1. Evolution of clinical disease activity, endoscopic/histological activity, laboratory findings, and medical treatment

Parameter	Day 3 hospitalization (steroids + IFX)	Day 12 (48 h after filgotinib)	Week 3 (after filgotinib)	Week 10 (after filgotinib)
Partial Mayo score	10	6	0	0
MES	3	–	2	0
Histological score	Moderate inflammation	Severe inflammation, cryptic abscess	Mild inflammation	Mucosal healing
WBC	28,000	18,000	10,000	7,000
Hb in g/dL	6.8	9.0	11.0	13.0
CRP in mg/dL	20.00	10.00	2.00	0.05
Fecal calprotectin in mg/g	2,800	–	800	500
Medical treatment	Methylprednisolone (i.v. 1 mg/kg); infliximab (0.5 mg/kg); antibiotics; LMWH	Methylprednisolone (i.v. 0.5 mg/kg); filgotinib (200 mg); antibiotics; LMWH	Steroid tapering; filgotinib (200 mg); no antibiotics; no LMWH	Steroid free; filgotinib (200 mg)

CRP, C-reactive protein; Hb, hemoglobin; IFX, infliximab; i.v., intravenous; LMWH, low-molecular weight heparin; MES, Mayo endoscopic score; WBC, white blood cell.

Outcome and Follow-Up

After 48 h, the patient showed an improved clinical response with resolution of abdominal pain and improvement of the diarrhea. A laboratory response (Hb: 9 g/dL; CRP: 10 mg/dL; WBC 18,000/μL) was also observed (Table 1). At week 3, the patient's laboratory tests continued to improve (Hb: 11 g/dL; CRP: 2 mg/dL; fecal calprotectin 800 μg/dL) (Table 1). We performed a proctosigmoidoscopy that showed a partial endoscopic response (MES: 2) (Fig. 1). The patient was asymptomatic and was discharged and followed closely for the 1st month. At week 10, the colonoscopy showed an endoscopic remission (MES: 0) and mild histological activity (Fig. 1). No adverse events were reported, except for mild self-limiting hypertransaminasemia at the 3-week follow-up. After 12 months of follow-up, no recurrence was observed, and the patient was in clinical remission with a good quality of life.

Discussion

ASUC refractory to steroids and conventional therapies remains a challenging problem. Surgical management is the only option after the failure of medical therapies. However, it is often associated with a higher morbidity, and it is not always accepted by the patient. In this case, we treated the patient with filgotinib, an oral selective JAK1 inhibitor, after a case of ASUC that was unresponsive to steroids and infliximab. To the best of our knowledge, this is the first study regarding treatment of ASUC with filgotinib.

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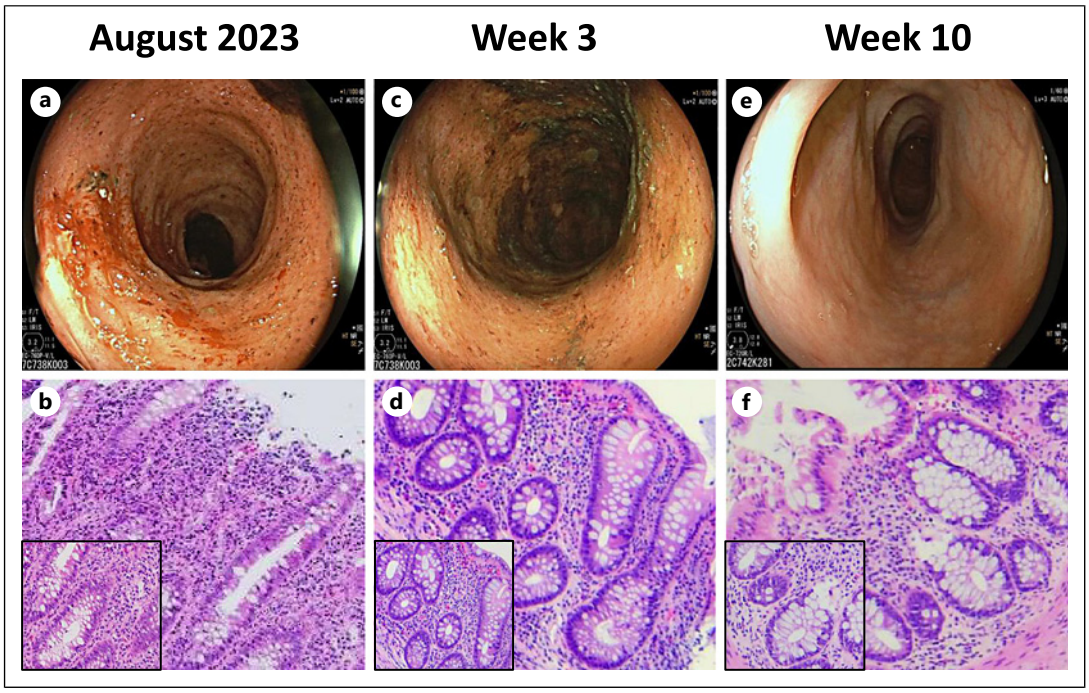

Fig. 1. Evolution of endoscopic and histological findings after filgotinib treatment. **a** The rectum during the baseline endoscopy showed severe relapse of the disease with ulcers and spontaneous bleeding (MES: 3). **b** Paraffin-embedded sections of biopsy samples taken from our patient during the baseline endoscopy showed severe inflammation with chronic mononuclear infiltrate and neutrophilic infiltration, crypt distortion, and increase of eosinophils. Original magnification was ×10, and higher magnification (×20) is shown in the insert. **c** The rectum during the endoscopy 3 weeks after starting treatment with filgotinib showed moderate relapse of the disease with a reduced vascular pattern, friability, erosions, and marked erythema of the mucosa (MES: 2). **d** Paraffin-embedded sections of biopsy samples taken from our patient during the endoscopy 3 weeks after starting treatment with filgotinib showed moderate inflammation with chronic mononuclear infiltrate and neutrophilic infiltration, moderate crypt distortion, and mild increase of eosinophils. Original magnification was ×10, and higher magnification (×20) is shown in the insert. **e** The rectum during the endoscopy 10 weeks after starting treatment with filgotinib showed remission of the disease with normal mucosa and vascular pattern (MES: 0). **f** Paraffin-embedded sections of biopsy samples taken from our patient during the endoscopy 10 weeks after starting treatment with filgotinib showed mild inflammation with chronic mononuclear infiltrate and mild crypt distortion. Original magnification was ×10, and higher magnification (×20) is shown in the insert.

In recent years, there have been increasing efforts to find alternative therapies in this particular clinical setting. JAK inhibitors, especially tofacitinib, may be a promising therapy for ASUC due to their rapidity of action and their pharmacodynamic properties. A recent systematic review [10] analyzed several studies, including a multicenter observational study with retrospective and prospective data collection, a single-center case-control retrospective study, 7 case series, and 5 case reports. The rate of colectomy in tofacitinib-treated patients was 23.9% with a follow-up period ranging from 30 days to 14 months. This rate of colectomy was less than the rate observed in patients treated with infliximab and cyclosporine at 12 months (35% and 45%, respectively) [11].

The most common adverse events in patients treated with tofacitinib were infections (herpes zoster, viral pneumonia, *C. difficile* infection, cytomegalovirus-related colitis). Less common adverse events were nausea, vomiting, and venous thromboembolic events [10]. In

the multicenter retrospective and prospective GETAID study [5], 55 patients received tofacitinib as a rescue therapy. At week 14, 33% of patients were in steroid-free clinical remission. The colectomy-free survival was 78.9% at 3 months and 73.6% at 6 months. Among the retrospective studies, Berinstein et al. [6] showed that tofacitinib (10 mg three times daily) with concomitant steroids may be effective in inducing a clinical response in patients with ASUC who had previously received biologics and were hospitalized.

Recently, a single-center, double-blind, placebo-controlled randomized trial revealed that tofacitinib as add-on therapy to corticosteroids significantly improved treatment responsiveness in patients with ASUC at day 7. In these patients, the cumulative probability of requiring rescue therapy (starting infliximab or undergoing colectomy) was significantly lower at 90 days [12]. New trials concerning the use of tofacitinib in ASUC, such as the open-label phase 2 TRIUMPH trial and the open-label randomized TOCASU trial, are now ongoing.

There are also published case studies and case series regarding the use of upadacitinib, another JAK inhibitor, as treatment for ASUC. These studies have revealed encouraging results in the short-term response in terms of colectomy-sparing and steroid-free remission, but the follow-up has only been up to 6 months [13, 14]. Gilmore et al. [13] used upadacitinib as salvage therapy in 6 patients with ASUC who were previously treated with infliximab. At week 8, the patients showed clinical, biochemical, ultrasound, and endoscopic improvement. In particular, 4 patients were in clinical remission, 3 patients achieved biochemical remission, and 3 patients also had ultrasound remission. Follow-up continued up to week 16. One patient underwent colectomy at week 15 due to refractory disease. No significant adverse events were reported. In a recent multicenter study, Berinstein et al. [15] treated 25 patients with ASUC with upadacitinib and intravenous steroids. Fifteen patients experienced steroid-free clinical remission, whereas 6 patients underwent colectomy (24%).

Based on these encouraging data on the use of JAK inhibitors to treat patients with ASUC, we decided to treat our patient with filgotinib. Filgotinib is a JAK1 preferential inhibitor, with once-daily dosing, rapid onset of action, few serious adverse events, and no drug-drug interactions and is metabolized in a non-CYP450-dependent fashion. Filgotinib is approved for the treatment of rheumatoid arthritis and more recently for the treatment of moderate-to-severe UC, even in patients who experienced failure to previous biological agents.

In the randomized, double-blind phase 2b/3 SELECTION study, both patients who were biological-naïve (26.1%) and biological-experienced (11.5%) were treated with filgotinib (200 mg). The patients achieved clinical remission at week 10 compared with patients receiving placebo. Moreover, they also showed a higher rate of Mayo clinic score remission, endoscopic remission, and histological remission. The rates of adverse events, serious adverse events, and serious infections were similar between the filgotinib and placebo groups [16].

In a maintenance study, a significantly higher proportion of patients in the filgotinib (200 mg) group had clinical, endoscopic, and histological remission at week 58 than in the placebo group (37.2%, 15.6%, and 38.2% vs 13.5%, 6.1%, and 13.3%). The same results were seen in the filgotinib (100 mg) group. The rates of adverse events and serious adverse events were also similar between the filgotinib and placebo groups. In particular, no thromboembolic events were diagnosed in the patients treated with filgotinib, and the incidence of herpes zoster was very low (<1%) [16, 17].

In this case report, our patient failed conventional therapies and declined colectomy. The decision to administer filgotinib was multidisciplinary and based on several observations. First, filgotinib has favorable pharmacological properties, such as rapid onset of action and a half-life of 7 h, which allows the response to be assessed within a few days and minimizes surgical complications in the case of urgent colectomy. Moreover, due to the selectivity of JAK1

and lack of immunogenicity, filgotinib showed a good safety profile, offering a valid alternative to tofacitinib, particularly in patients at increased risk of thromboembolic or infectious events. Data from rheumatoid arthritis studies showed that filgotinib was associated with the lowest likelihood of developing herpes zoster infection compared to the other JAK inhibitors.

As is well known, hospitalized immunosuppressed patients are at higher risk of developing infections such as *C. difficile* and Herpes Zoster, which can worsen the course of the disease, reduce the response to drugs, and promote disease flare-ups. Therefore, using an anti-JAK agent with a reduced risk of these complications can be a valid option.

After the initiation of filgotinib, our patient achieved a rapid clinical, biochemical, and endoscopic remission. Similar to the results of the SELECTION studies, this improvement remained stable, and after 12 months of follow-up our patient was still in stable remission. We did not observe any serious adverse events, but the patient did experience mild self-limiting hypertransaminasemia at week 3. Obviously, a longer follow up period is needed, both to assess the potential occurrence of adverse events and because the risk of colectomy remains high in the 5 years after an acute episode.

Conclusion

This is the first case of a patient with ASUC refractory to steroids and infliximab who was treated with filgotinib. Due to its pharmacodynamic properties, efficacy, and safety, filgotinib may be an effective second-line therapy in an emergency setting such as ASUC after a case-by-case analysis and multidisciplinary discussion. Our results were in line with recent studies supporting the efficacy and safety of JAK inhibitors (tofacitinib and upadacitinib) in patients with ASUC. Therefore, further studies and randomized trials are needed to define the efficacy and safety of filgotinib in patients with ASUC who are refractory to first-line therapies.

The treatment of ASUC is one of the most challenging goals in the management of inflammatory bowel disease. Treatment with urgent colectomy remains common despite rescue therapies with infliximab or cyclosporine. Surgical options are not always accepted by patients, especially young patients, and are associated with long-term complications, which can severely impact patient quality of life. Janus kinase inhibitors, which have rapid absorption, action, and metabolism, may be optimal candidates for the treatment of patients with ASUC who are refractory to conventional therapies, thus reducing the need for colectomy.

The CARE Checklist has been completed by the authors for this case report, attached as online supplementary material (for all online suppl. material, see https://doi.org/10.1159/000545263).

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Statement of Ethics

The present study was approved on 2 August 2024 by the Direzione Sanitaria of the ASL Napoli Centro – Ospedale del Mare – Prot. No. 0235457. Written informed consent was obtained from the patient on 22 July 2024 for anonymized publication of the patient's medical case and any accompanying images.

Conflict of Interest Statement

The authors of the manuscript are solely responsible for the manuscript development and content. The authors have no conflicts of interest to declare.

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Author Contributions

G.Ve., S.S., P.M., R.A., A.D., M.M., M.L., A.T., F.S., G.Vi., and L.L. were involved in the diagnosis and management of the patient in this case report; G.Ve. and S.S. equally contributed to idea conception, writing the first draft and editing the subsequent versions, and supervision of all aspects of the manuscript's generation. All authors read and approved the final manuscript.

Data Availability Statement

The data that support the findings of this study are not publicly available due to patient privacy but are available from the corresponding author upon reasonable request.

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