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W J C C World Journal of Clinical Cases

Contents Thrice Monthly Volume 12 Number 24 August 26, 2024 **EDITORIAL** 5448 Diagnostic challenges from conflicting results of tests and imaging Yu R 5452 Are case reports valuable? Exploring their role in evidence based medicine and patient care Suvvari TK 5456 Recent advances in managing obstructive sleep apnea Nag DS, Chatterjee A, Patel R, Sen B, Pal BD, Wadhwa G 5462 Importance of risk assessment, endoscopic hemostasis, and recent advancements in the management of acute non-variceal upper gastrointestinal bleeding Maity R, Dhali A, Biswas J 5468 Navigating treatment resistance: Janus kinase inhibitors for ulcerative colitis Soldera J 5473 Clues for diagnosing misplaced central venous catheter in the right ascending lumbar vein during right femoral venous access Tokumine J, Moriyama K, Yorozu T **MINIREVIEWS** 5476 Exploration of the complex origins of primary constipation Zeng XL, Zhu LJ, Yang XD **ORIGINAL ARTICLE Retrospective Study** 5483 Influence of humanistic care-based operating room nursing on safety, recovery, and satisfaction after radical surgery for colorectal carcinoma Wang XP, Niu M 5492 Correlation between TEX14 and ADAM17 expressions in colorectal cancer tissues of elderly patients and neoplasm staging, invasion, and metastasis Chen G, Cong LH, Gu CJ, Li P 5502 Assessment of early factors for identification or prediction severe acute pancreatitis in pregnancy Mei LF, Gan Q, Hu J, Li YX, Tian R, Shi CJ 5513 Application value of machine learning models in predicting intraoperative hypothermia in laparoscopic surgery for polytrauma patients

Zhu K, Zhang ZX, Zhang M



Contents

Thrice Monthly Volume 12 Number 24 August 26, 2024

Clinical Trials Study

Effectiveness of the A3 robot on lower extremity motor function in stroke patients: A prospective, 5523 randomized controlled trial

Zhang LJ, Wen X, Peng Y, Hu W, Liao H, Liu ZC, Liu HY

5534 Effect of dietary with Zhibai dihuang pills and gonadotropin-releasing-hormone-analogue on girls with precocious and rapidly progressive puberty

Wang XM, Li W, Yang LQ, Luo R, Zhang CC

Randomized Controlled Trial

5542 Clinical efficacy, bone density, and follow-up in implant and orthodontic treatment for inclined adjacent teeth

Yang Y, Zhou SC, Ma YH, Wang X, Dong QS

5549 Information-motivation-behavioral guided nursing for stroke patients with pulmonary dysfunction: A randomized controlled trial

Peng X, Ni HQ, Liu YM, Zhu JL, Bai YT

5558 Application of buried auricular point combined with Wenjing Sanhan prescription in arteriosclerosis obliterans patients with resting pain

Li YP, Su T, Xue XL, Shi HR, Su ZH, Li J

Clinical and Translational Research

5568 Computed tomography-based radiomics predicts the fibroblast-related gene EZH2 expression level and survival of hepatocellular carcinoma

Yu TY, Zhan ZJ, Lin Q, Huang ZH

CASE REPORT

5583	Endometrial carcinoma with cervical stromal invasion: Three case reports		
	Liu MM, Liang YT, Jin EH		

- 5589 IgG4-related sclerosing cholangitis associated with essential thrombocythemia: A case report Wu ZN, JI R, Xiao Y, Wang YD, Zhao CY
- 5596 Are all primary omental infarcts truly idiopathic? Five case reports

Kar H, Khabbazazar D, Acar N, Karasu Ş, Bağ H, Cengiz F, Dilek ON

5604 Seven-years post allogeneic hematopoietic stem cell transplantation pure red cell aplastic anemia cured with daratumumab: A case report and review of literature

Deng B, Gao R, Yang B, Lei WB, Xue MF, Wang JS, Zhao P

5613 Splenic subcapsular hematoma following endoscopic retrograde cholangiopancreatography: A case report and review of literature

Guo CY, Wei YX



	World Journal of Clinical Cases
Conter	Thrice Monthly Volume 12 Number 24 August 26, 2024
5622	"Keyboard sign" and "coffee bean sign" in the prenatal diagnosis of ileal atresia: A case report
	Fei ZH, Zhou QY, Fan L, Yin C
5628	Treatment of nasopharyngeal carcinoma and prevention of non-alcoholic Wernicke's disease: A case report and review of literature
	Ma YY, He XC, Gao Y, Ma TT, Cheng G, Yue CW

Contents

Thrice Monthly Volume 12 Number 24 August 26, 2024

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EDITORIAL

Navigating treatment resistance: Janus kinase inhibitors for ulcerative colitis

Jonathan Soldera

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Abstract

The management of refractory ulcerative colitis (UC) and acute severe UC (ASUC) is challenging due to the lack of standardized approaches in cases resistant to multiple treatments. In this editorial, I investigate the efficacy and safety of Janus kinase inhibitors, particularly upadacitinib and tofacitinib, in controlling severe and refractory disease. I highlight a notable case report by Xu et al, which explores the case of a patient with primary nonresponse to two classes of biologics and two fecal microbiota transplants who exhibited a remarkable response to upadacitinib. Furthermore, I discuss the use of tofacitinib in refractory UC and ASUC, either as monotherapy or in combination with biologics, which has shown promising response rates. Additionally, emerging evidence of upadacitinib efficacy in ASUC is presented. Overall, these cases emphasize the complex nature of managing refractory ASUC and the potential of small-molecule therapies to achieve remission. Further research is needed to refine treatment strategies for patients with treatment-resistant UC.

Key Words: Inflammatory bowel disease; Ulcerative colitis; Janus kinase inhibitor; Upadacitinib; Tofacitinib; Infliximab

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Core Tip: This editorial explores the efficacy and safety of Janus kinase inhibitors, specifically upadacitinib and tofacitinib, in refractory ulcerative colitis (UC) and acute severe UC (ASUC). Highlighting a compelling case report, it underscores the potential of these small-molecule therapies, either alone or in combination with biologics, to achieve and maintain disease remission. Furthermore, it emphasizes the importance of considering overlapping infections in ASUC and the need for prompt recognition by colorectal surgeons. This editorial advocates for further research to refine treatment strategies for patients with treatment-resistant UC, shedding light on promising therapeutic approaches.

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INTRODUCTION

Managing ulcerative colitis (UC), especially cases of refractory acute severe UC (ASUC), poses significant challenges due to poor patient response or intolerance to conventional and biological treatments. There is no standardized approach for cases resistant to multiple treatments. However, recent research has shed light on the efficacy and safety of small-molecule Janus kinase inhibitors, such as upadacitinib^[1] and tofacitinib^[2], in controlling severe and refractory disease.

JANUS KINASE INHIBITORS FOR REFRACTORY ULCERATIVE COLITIS

A report by Xu et al[3] describes the case of a patient who showed primary nonresponse to two biologics and two fecal microbiota transplants (FMT) but exhibited a remarkable response to upadacitinib[3]. It should be noted that FMT for ASUC is considered an off-label indication. The available evidence supporting its use remains primarily anecdotal, and its application should be restricted to the treatment of Clostridioides difficile (C. difficile) infection, or to clinical trials, according to the American Gastroenterology Association[4,5].

Despite limited evidence, both upadacitinib and tofacitinib have shown promise in the management of refractory UC, either as monotherapy or in combination with biologics as rescue therapy. At our center, we have extensive experience in employing off-label combined therapy for ASUC. I am particularly inclined to share a specific case that I believe would enrich the ongoing discussion initiated by Xu et al[3], presenting an alternative approach.

JANUS KINASE INHIBITORS AS RESCUE THERAPY FOR ULCERATIVE COLITIS REFRACTORY TO INFLIXIMAB

A 57-year-old male patient with a decade-long history of UC presented with recurrent symptomatic episodes despite several treatments. Initially responsive to mesalazine 4 g daily and a course of prednisone, the patient relapsed after a few years. Subsequent treatment with azathioprine 150 mg daily and mesalazine 4 g daily controlled the disease for another few years. However, his symptoms recurred, requiring the use of oral enteric budesonide 9 mg daily. Despite these interventions, his symptoms worsened, leading to fecal incontinence and anemia.

Tests for C. difficile toxins A and B and immunohistochemistry for cytomegalovirus were negative. Colonoscopy revealed worsening of UC (Figure 1), prompting initiation of biologic therapy with infliximab induction at a dose of 5 mg/ kg. Although the patient reported a mild reduction in the frequency of bloody stools upon initiation of infliximab, fecal incontinence persisted. Despite dose escalation to 500 mg every 4 wk, his symptoms persisted, indicating a partial response to infliximab. Another colonoscopy was performed, which demonstrated improvement of mucosal damage, but without resolution of UC (Figure 2).

Tofacitinib 5 mg twice daily was introduced as adjunctive therapy alongside infliximab, replacing azathioprine, with the aim of achieving disease remission, as suggested in the case series by Gilmore *et al*[6]. Over the subsequent 3 months, the patient's symptoms gradually improved, with a reduction in stool frequency and resolution of fecal incontinence and bleeding. Treatment with tofacitinib was then interrupted, and the patient was maintained on infliximab 5 mg/kg/dose infusions every 6 wk, adjusted to infliximab serum levels, and azathioprine 100 mg daily. He has remained in deep remission for the last 3 years, with a Mayo endoscopic score of 0 (Figure 3).

There are two crucial points I believe warrant discussion. First, the possibility of overlapping infections in ASUC (i.e., C. difficile and cytomegalovirus) was ruled out before escalation of therapy [7-9]. Second, colorectal surgeons must be aware that the clinical condition of patients with refractory UC or ASUC can rapidly deteriorate, requiring urgent colectomy[10,11].

There is increasing evidence supporting the utilization of tofacitinib in cases of infliximab-refractory ASUC[12]. A previous randomized controlled trial reported a response rate as high as 83% in ASUC patients refractory to corticosteroids after 7 d of tofacitinib treatment[13]. Similarly, a retrospective study demonstrated a response rate of 87.5% [14].



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Figure 1 Colonoscopy. Pre-biologic. Ulcerative colitis with friability and ulcers, Mayo endoscopic score 2. A: Transition zone in the transverse colon; B: Sigmoid colon.



Figure 2 Colonoscopy. Pre-Tofacitinib. Improvement, but still presenting ulcerative colitis with patchy areas of friability and ulcers, Mayo endoscopic score 2. A: Transition zone in the transverse colon; B: Sigmoid colon.



Figure 3 Colonoscopy. Maintenance therapy with infliximab, three years after tofacitinib was withdrawn. Scarred mucosa, Mayo endoscopic score 0. A: Transition zone in the transverse colon; B: Sigmoid colon.

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Moreover, a noteworthy case series administered a higher dose of tofacitinib to eleven ASUC patients, achieving disease control in nine of them. Subsequently, these patients were transitioned to infliximab for maintenance therapy [15].

Tofacitinib has been investigated in combination with other biologics for the management of ASUC[16], including its use as replacement therapy for azathioprine alongside infliximab, demonstrating both efficacy and safety [6]. Of note, a systematic review revealed that the use of tofacitinib in ASUC led to a pooled 90-day and 6-month colectomy-free rate of 79.9%[17].

Although the use of tofacitinib as monotherapy in this setting has been extensively researched, some reports have also described the efficacy of upadacitinib in ASUC. For instance, a case report documented a positive response to upadacitinib in a patient for whom treatment with infliximab, adalimumab, and tofacitinib had previously failed [18]. A case series evaluating upadacitinib in ASUC resistant to steroids has demonstrated comparable efficacy to previous case series with tofacitinib, with 5 out of 6 patients showing improvement^[19]. As upadacitinib has recently been approved for use in UC, promising results have been described in several recent case series of ASUC. One study reported steroid-free remission in 6 out of 9 patients^[20], while another showed a response rate of 83% among 25 patients^[21].

CONCLUSION

In conclusion, both cases underscore the complexity of managing refractory ASUC and highlight the potential synergistic effect of employing small molecule therapies either in combination or sequentially with biologics to achieve and sustain disease remission. Further studies are warranted to elucidate the optimal treatment strategies for patients who have completely or partially failed multiple available therapies.

FOOTNOTES

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