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Comparative short-term efficacy of upadacitinib versus tofacitinib for ulcerative colitis: a 24-week real-world study in Japan

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Background/Aims: Tofacitinib and upadacitinib are small-molecule compounds that inhibit the Janus kinase pathway for the treatment of refractory ulcerative colitis. Only a few reports have compared the efficacy and safety of these 2 drugs in real-world practice. We aimed to show our real-world evidence of these drugs and compare the efficacy and safety profiles in the treatment of ulcerative colitis. **Methods:** This study is a single-center retrospective analysis. Patients treated with tofacitinib or upadacitinib at our hospital between June 2018 and January 2024 who were monitored for 24 weeks were included. The primary outcome was steroid-free clinical remission at 24 weeks. Secondary outcomes were response and remission rates at each time point, time series changes in partial Mayo scores and laboratory results, treatment survival at 24 weeks, and the incidence of adverse events. **Results:** A total of 68 patients treated with tofacitinib and 34 patients treated with upadacitinib were included. Steroid-free clinical remission rate at 24 weeks was significantly higher in upadacitinib-treated patients than in tofacitinib-treated patients (64.7% vs. 38.2%). The response rates in upadacitinib-treated patients exceeded 60% after 8 weeks of treatment through to 24 weeks, and the rates were higher than those in tofacitinib-treated patients. The incidences of adverse events were 79.4% in upadacitinib-treated patients and 38.2% in tofacitinib-treated patients. The most common adverse event was acne for upadacitinib. **Conclusions:** Upadacitinib was more effective than tofacitinib in inducing remission in ulcerative colitis patients. The incidence of adverse events was significantly higher with upadacitinib than tofacitinib. **(Intest Res 2026;24:95-102)**

Key Words: Ulcerative colitis; Real-world evidence; Tofacitinib; Upadacitinib

INTRODUCTION

Ulcerative colitis (UC) is a chronic inflammatory bowel disease that presents with bloody stools and abdominal pain. Medical treatment for UC has advanced significantly in recent times with the development of molecularly targeted drugs. Tofacitinib and upadacitinib are oral small-molecule compounds that inhibit the Janus kinase (JAK) pathway, which functions as the center of the cytokine network and modulates immune and inflammatory responses.[1] Clinical trials have already demonstrated the efficacy and safety data of tofacitinib and upadacitinib, and they were approved for the treatment of refractory UC resistant to existing biological therapies in 2018 and 2022, respectively.[2,3] Although it is used in clinical practice as a new treatment for refractory UC, and several reports with real-world evidence of tofacitinib's efficacy and safety have already been accumulated,[4-13] only a few reports have focused on upadacitinib or directly compared the 2 drugs in real-world practice.

The results of a network meta-analysis of existing advanced therapies reported in 2022 revealed the superiority of upadacitinib over tofacitinib in clinical remission induction and

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endoscopic improvement, and no significant differences in the incidence of adverse events and serious adverse events were observed between tofacitinib and upadacitinib.[14,15] Regarding real-world evidence, it has been reported that upadacitinib was more effective than tofacitinib in both remission induction and maintenance treatment at 52 weeks.[16,17] Although comparative data is one of our biggest interests, it has not been sufficiently accumulated and discussed. Herein, we present real-world evidence on tofacitinib and upadacitinib and compare the efficacy and safety of these 2 JAK inhibitors in the treatment of refractory UC at the Institute of Science Tokyo Hospital.

METHODS

1. Ethical Considerations

The study was conducted according to the ethical principles of the Declaration of Helsinki and was approved by the Institute of Science Tokyo Institutional Review Board (IRB No. M2018-059). Because this study was retrospective, written informed consent was waived.

2. Study Design

In this retrospective study, we included patients aged ≥18 years who initiated treatment with tofacitinib or upadacitinib for refractory active UC at the Institute of Science Tokyo Hospital between June 2018 and January 2024 and monitored for at least 24 weeks. We analyzed the efficacy and safety of the 2 drugs, comparing them with each other. Based on the above-mentioned inclusion criteria, we reviewed electronic medical records and collected data on demographic features, treatment history, disease type, duration, and disease activity, which was assessed by the partial Mayo score (pMS). We also collected laboratory data. Drugs were selected based on shared decision making between the attending physicians and patients. The primary outcome was steroid-free clinical remission at 24 weeks after initiating upadacitinib or tofacitinib. The secondary outcomes were response and remission rates at 4, 8, 12, and 24 weeks; changes in clinical disease activity scores and laboratory results; treatment survival at 24 weeks; and safety profiles recorded as adverse events. Patients with a pMS ≤2 at induction, missing baseline data, clinical trial cases, who had prior colectomy, and who had initiated the therapy for different indications were excluded. We defined remission as a pMS of ≤2 and each subscore of ≤1 and 0 points of rectal bleeding, response as pMS reduction of ≥2 points and a rectal bleeding reduction of ≥1 point or ≤1, or remission status. Patients in whom there was no improvement or the disease worsened and who did not meet the above criteria or had their treatments discontinued were considered cases of treatment failure.

3. Treatment Protocol

Eligible patients were started on tofacitinib at 10 mg twice daily (b.i.d.) for ≥8 weeks as induction therapy, and the dose was reduced to 5 mg b.i.d. as maintenance therapy; otherwise, they were started on upadacitinib at 45 mg daily for ≥8 weeks (up to 16 weeks) as induction therapy, and the dose was reduced to 15 or 30 mg daily as maintenance therapy. All immune-suppressive agents (such as thiopurines, calcineurin inhibitors, and biologic agents) were discontinued before the treatment started. In patients who responded to tofacitinib induction therapy, tofacitinib was subsequently reduced to 5 mg b.i.d. for maintenance therapy. Among those who experienced disease relapse while receiving tofacitinib at a dose of 5 mg b.i.d. for maintenance treatment, the dose was subsequently increased to 10 mg b.i.d. In patients who responded to upadacitinib induction therapy, the dose of the drug was subsequently reduced to 15 or 30 mg, and among those who experienced disease relapse while receiving a 15 mg dose of upadacitinib, the dose was subsequently increased to 30 mg.

4. Statistical Analysis

Statistical analyses were performed using PRISM 10.3.0 (GraphPad, San Diego, CA, USA). The 2 groups were compared using nonparametric tests (i.e., the Mann-Whitney *U* test) for the me-

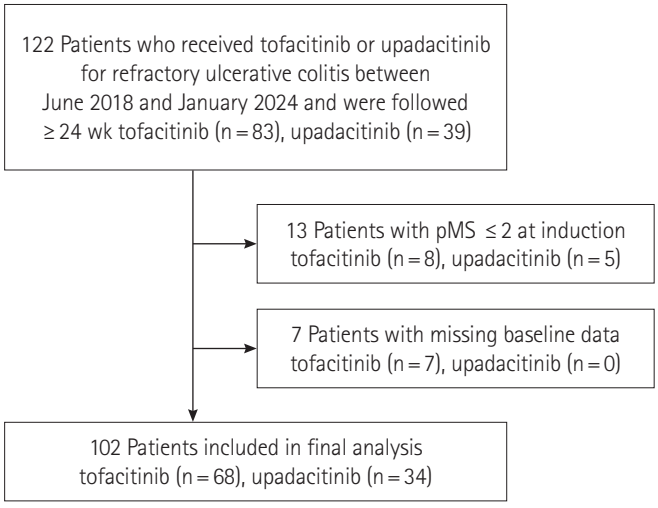

Fig. 1. Flowchart of patients enrolled in this study. pMS, partial Mayo score.

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dian values of the continuous variables and Fisher exact test for categorical variables. The Kaplan-Meier method was used to draw the survival curve of the patients who were maintained on tofacitinib or upadacitinib treatment over time. A *P*-value of <0.05 indicated statistical significance.

RESULTS

1. Background Characteristics

In our study, of the 83 patients treated with tofacitinib at our hospital, 68 were included in the final analysis, as 8 patients with inactive disease and 7 without baseline data were excluded. Of the 39 patients treated with upadacitinib, 34 patients were included and 5 patients with inactive disease were excluded (Fig. 1). The background characteristics of the study participants are summarized in Table 1. No significant differences were found except for JAK inhibitor exposure. The median ages of the participants in the tofacitinib and upadacitinib groups were 38.8 years (interquartile range [IQR], 27.2–48.9 years) and 44.2 years (IQR, 27.3–51.1 years), the median disease durations were 7.0 years (IQR, 3.0–10.7 years) and 8.3 years (IQR, 3.7–11.3 years), the extended disease type rates were 69.1% and 82.4%, the median pMS were 6 (IQR, 4–7) and 6 (IQR, 5–7), and the median Mayo endoscopic scores were 3 (IQR, 2–3) (n=33) and 3 (IQR, 3–3) (n=18), respectively. As for laboratory tests, there were also no significant differences in the white blood count, hemoglobin level, albumin level, and C-reactive protein titer between the 2 groups. Most of the patients experienced previous advanced therapy in both groups; however, the proportion of JAK inhibitor-naïve participants was 95.6% for tofacitinib but 47.1% for upadacitinib (Table 1).

Table 1. Background Characteristics of Patients

Characteristics	Tofacitinib (n=68)	Upadacitinib (n=34)	*P*-value
Male sex	41 (60.3)	18 (52.9)	0.5274
Age (yr)[a]	38.8 (27.2–48.9)	44.2 (27.3–51.1)	0.4742
Disease duration (yr)[a]	7 (3.0–10.7)	8.3 (3.7–11.3)	0.7386
Disease type			0.2334
Extended	47 (69.1)	28 (82.4)	
Left-sided	21 (30.9)	6 (17.6)	
Partial Mayo score	6 (4–7)	6 (5–7)	0.2667
Mayo endoscopic score[b]	3 (2–3)	3 (3–3)	0.3583
Mayo score[b]	9 (7–10)	9 (8–10)	0.2614
White blood cell counts ($\times 10^3/\mu L$)	6,600 (5,450–9,225)	6,450 (1,900–24,300)	0.8170
Hemoglobin (g/dL)	12.7 (10.7–14.2)	13.0 (9.2–16.5)	0.3587
Albumin (g/dL)	3.8 (3.2–4.1)	3.9 (1.8–4.7)	0.4083
C-reactive protein (mg/dL)	0.42 (0.13–1.94)	0.42 (0.03–13.20)	0.7599
Corticosteroid			0.4883
Refractory	1 (1.5)	2 (5.9)	
Resistance	28 (41.2)	14 (41.2)	
Dependent	36 (52.9)	18 (52.9)	
Advanced therapy exposed	65 (95.6)	34 (100)	0.5489
No. of exposed advanced therapy			0.1141
1	24 (35.3)	7 (20.6)	
≥2	41 (60.2)	27 (79.4)	
Janus kinase inhibitor-naïve	65 (95.6)	16 (47.1)	<0.0001[c]

Values are presented as number (%) or median (interquartile range).
[a]The age and disease duration were calculated in months and expressed in years.
[b]The number of patients in the Mayo endoscopic and Mayo scores are n=33 (tofacitinib) and 18 (upadacitinib).
[c]Statistical significance was calculated using Mann-Whitney *U* test and Fisher exact test; *P*<0.0001.

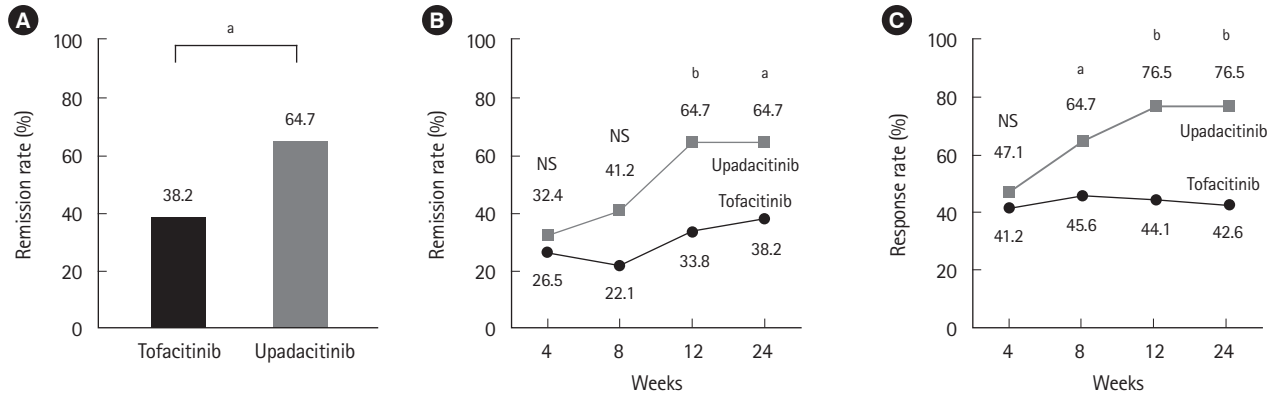

Fig. 2. Remission and response rates in the whole cohort. (A) Remission rates at 24 weeks of tofacitinib (n = 68) and upadacitinib (n = 34). Time series data in remission (B) and response (C) rates of tofacitinib (n = 68) and upadacitinib (n = 34) up to 24 weeks. Statistical significance was analyzed using a Fisher exact test; [a]$P < 0.05$, [b]$P < 0.01$. NS, not significant.

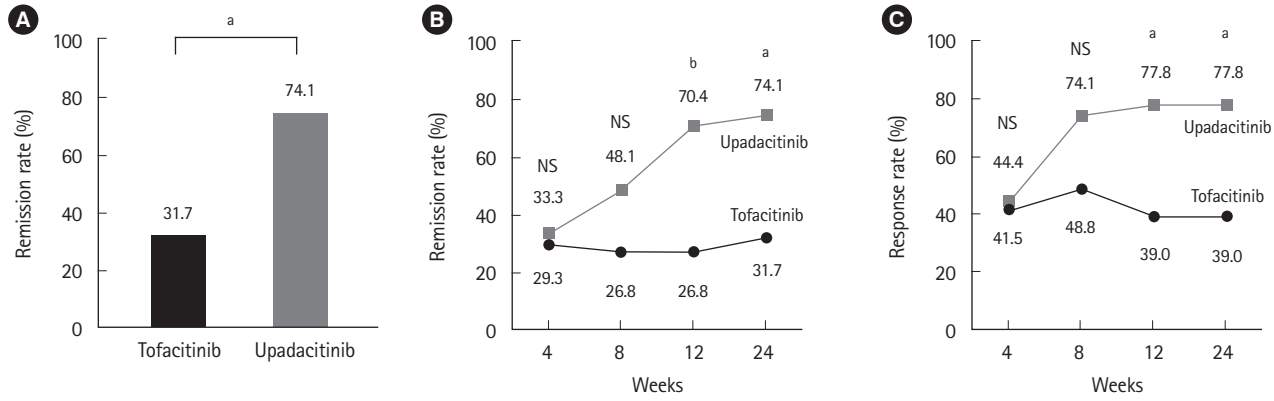

Fig. 3. Remission and response rates in patients exposed to multiple advanced therapies. (A) Remission rates at 24 weeks of tofacitinib (n = 41) and upadacitinib (n = 2). Time series data in remission (B) and response (C) rates of tofacitinib (n = 41) and upadacitinib (n = 27) up to 24 weeks. Statistical significance was analyzed using a Fisher exact test; [a]$P < 0.01$, [b]$P < 0.001$. NS, not significant.

2. Primary and Secondary Outcomes

The primary outcome was the comparative steroid-free remission rates at 24 weeks. The clinical remission rate for upadacitinib was significantly higher than for tofacitinib (64.7% vs. 38.2%, $P < 0.05$) (Fig. 2A). Time series data of the remission rates at each time point are shown in Fig. 2B. The clinical response rates were also significantly higher for upadacitinib compared to tofacitinib at 8 weeks (64.7% vs. 45.6%, $P < 0.01$), as well as 24 weeks (76.5% vs. 42.6%, $P < 0.01$) (Fig. 2C). In patients who had multiple prior advanced therapy exposures (including JAK inhibitors), upadacitinib's remission rate at 24 weeks was 74.1% (n = 20) whereas tofacitinib's was 31.7% (n = 13), and the difference between them was significant (Fig. 3A). Time series data of the remission and response rates at each time point are shown in Fig. 3B and C. The clinical remission and response rates were also significantly higher for upadacitinib compared to tofacitinib at 12 weeks. Furthermore, analyzing for prior JAK inhibitor exposure, upadacitinib showed a 77.8% (n = 14) response rate at 24 weeks whereas tofacitinib needed more cases (n = 3) (Supplementary Fig. 1A). In the tofacitinib group, upadacitinib exposed was zero, and filgotinib exposed was 4.4% (n = 3), with a response rate of 66.7% (n = 2) in filgotinib exposed patients. In the upadacitinib group, tofacitinib exposed was 29.4% (n = 10), and filgotinib exposed was 23.5% (n = 8), with response rates of 70.0% (n = 7) and 87.5% (n = 7), respectively. As for JAK inhibitor-naïve patients, tofacitinib's response rate at 24 weeks was 41.5% (n = 27) whereas upadacitinib's was 75.0% (n = 12) (Supplementary Fig. 1B), presenting statistical significance. In patients who continued the treatment for 24 weeks, the dose of tofacitinib was reduced from 10 to 5 mg b.i.d. (82.8%) at a median of 12 weeks (range, 12–22 weeks). Upadacitinib's daily dose was re-

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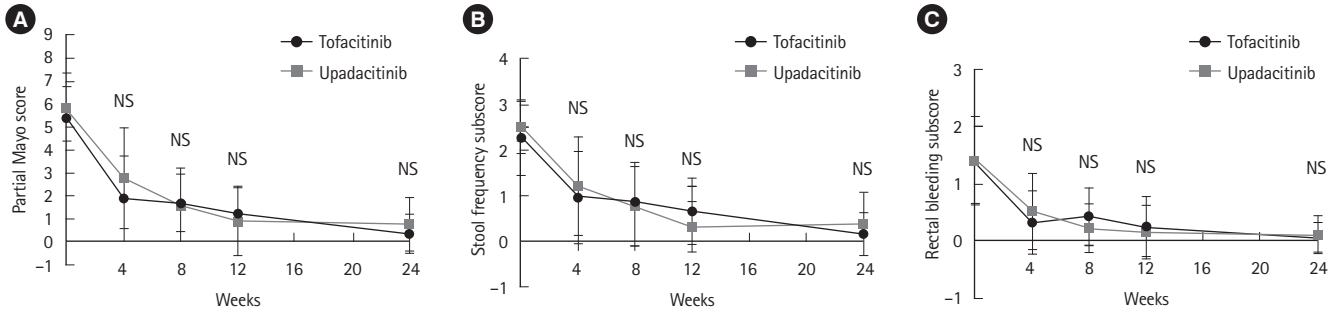

Fig. 4. Time series data up to 24 weeks. Partial Mayo score (A), stool frequency subscore, (B) and rectal bleeding subscore (C) in patients who had responded tofacitinib (n = 29) and upadacitinib (n = 26) at 24 weeks. Data are presented as the mean ± standard deviation. Statistical significance was analyzed using the Mann-Whitney *U* test. NS, not significant.

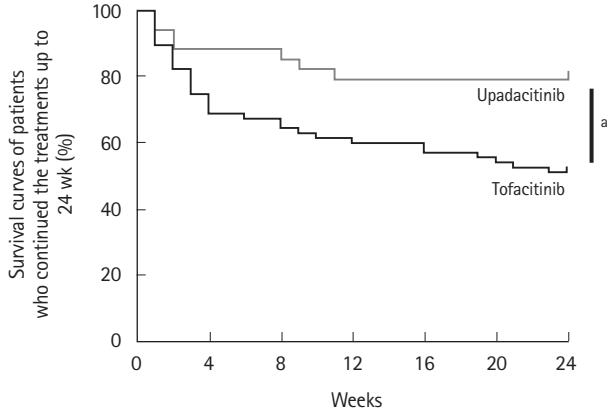

Fig. 5. Survival curves of patients who continued with either of the treatments up to 24 weeks. Kaplan-Meier curves were drawn using the log-rank (Mantel-Haenszel) test. [a]*P* < 0.05.

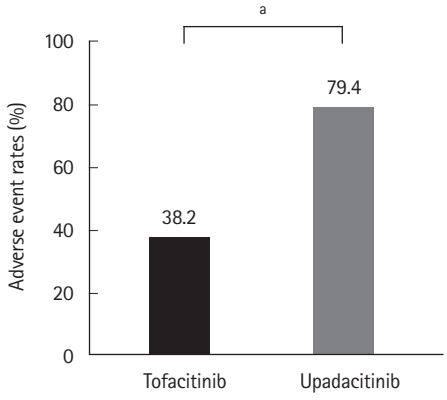

Fig. 6. Adverse event rates during tofacitinib (n = 68) and upadacitinib (n = 34) therapy. Statistical significance was analyzed using a Fisher exact test; [a]*P* < 0.001.

duced from 45 mg to 30 mg (92.3%) or 15 mg (7.7%) at a median treatment duration of 9 weeks (range, 8–12 weeks).

Next, we analyzed whether there were any differences in changes in clinical scores and results of laboratory tests in patients who were response at 24 weeks. Graphical representations of the pMS, stool frequency subscore, and rectal bleeding subscore are shown in Fig. 4. There were no significant differences in these scores between tofacitinib and upadacitinib at any time point. Changes in the white blood cell count, albumin level, C-reactive protein titer, and erythrocyte sedimentation rate were compared at every time point and no differences in these parameters were found between the 2 groups (data not shown). The treatment continuation rate at 24 weeks was significantly higher for upadacitinib at 80% compared with 50% for tofacitinib (Fig. 5). The most common reasons for treatment discontinuation were treatment failure, with rates of 51.5% for tofacitinib and 14.7% for upadacitinib.

3. Adverse Events

For safety analyses, significantly higher rates of adverse events were observed with upadacitinib 79.4% (n = 27) than with tofacitinib 38.2% (n = 26) during treatment (Fig. 6). Infections were the most common adverse events in tofacitinib observed in 19.1% of patients (n = 13). In upadacitinib-treated patients, skin disorders were the most common, with acne occurring in 47.1% of patients (n = 16). Herpes zoster infection was observed in 1.5% of tofacitinib-treated patients (n = 1) and 5.9% of upadacitinib-treated patients (n = 2), and no case of thrombosis was observed with either tofacitinib or upadacitinib. As for severe adverse events, there was 1 case of drug-induced pneumonia in a tofacitinib-treated patient and 1 case of recurrent urinary tract infection in an upadacitinib-treated patient which required hospitalization and resulted in treatment discontinuation. As for other adverse events, a case of dyspnea in a tofacitinib-treated patient and another case of high serum creatine-phosphokinase level in an upadacitinib-treated pa-

Table 2. Adverse Events

Adverse events	Tofacitinib (n = 68)	Upadacitinib (n = 34)
Infections	13 (19.1)	12 (35.3)
Herpes zoster	1 (1.5)	2 (5.9)
Creatine phosphokinase elevation	1 (1.5)	1 (2.9)
Dyslipidemia	6 (8.8)	1 (2.9)
Acne	1 (1.5)	16 (47.1)
Severe adverse events	1 (1.5)	1 (2.9)

Values are presented as number (%).

tient led to treatment discontinuation (Table 2).

DISCUSSION

In the present study, we presented comparative efficacy and safety data of tofacitinib and upadacitinib in real-world practice for the treatment of refractory UC. Comparing 2 JAK inhibitors in real-world practice requires focus on the patient background in which both drugs were used. In our study, tofacitinib and upadacitinib were used for patients with similar backgrounds, and there were no significant differences except for previous JAK inhibitor use. Although our cohort consisted of mostly advanced therapy-exposed cases, both JAK inhibitors were effective and showed high treatment response and remission rates. The remission rates at 24 weeks were 64.7% in upadacitinib-treated patients and 38.2% in tofacitinib-treated patients, with the rates differing significantly between the 2 groups. The response rates in upadacitinib-treated patients exceeded 60% after 8 weeks of treatment through to 24 weeks, and the rates were higher than those in tofacitinib-treated patients during the same period. In patients exposed to multiple advanced therapies, response rates of both drugs were also favorable, and upadacitinib showed a significantly higher rate than tofacitinib at 12 and 24 weeks. Our data show that the response rate was expected to reach a plateau at 8 weeks for tofacitinib and 12 weeks for upadacitinib, regardless of whether the patient had been previously treated with advanced therapy, as shown in Figs. 2 and 3. Also, the upadacitinib response rate in JAK inhibitor-exposed patients was as high as that in advanced therapy-exposed patients (Supplementary Fig. 1A), and this is consistent with recently reported multi-center data from Japan.[18] In JAK inhibitor-naïve patients, we found a significant difference in 24-week response rates between tofacitinib and upadacitinib (Supplementary Fig. 1B). Further studies are needed to see the comparative efficacy of tofacitinib and upadacitinib in patients with or without previous JAK inhibitor treatments. We analyzed time series changes to determine whether there were any predictive differences in efficacy and whether the speed of onset differed between the 2 drugs. However, in response cases, it was found that clinical and serological improvements occurred at similar time course. For treatment survival, 80% of the patients who received upadacitinib were able to continue the treatment for 24 weeks, compared with 50% of those who received tofacitinib.

As we described here, our results support the earlier real-world evidence showing that upadacitinib was more effective than tofacitinib for UC treatment.[16,17] Also, our results support the clinical trial data which show that both JAK inhibitors are effective in patients with previous advanced therapy exposures.[2,3] Our data showed that upadacitinib was more effective than tofacitinib in refractory UC patients. The comparative analysis of changes in pMS and laboratory data in the responders showed no significant differences in the parameters assessed in this study. This suggests that both JAK inhibitors, once effective, show almost equal improvement in clinical manifestations and biomarker levels over the same time course.

We also reported comparative data on adverse events of both JAK inhibitors in real-world practice. The incidence of adverse events with upadacitinib was twice as high as that with tofacitinib. In terms of details of adverse events, mild infections were most frequently observed with tofacitinib, while skin disorders (especially acne) were more frequently observed with upadacitinib. In fact, acne was the most frequently reported adverse event in upadacitinib-treated patients in our study. This was unexpectedly higher than that reported in a previous phase III study.[3] The main subjects of the phase III study were non-Asians, while our study were Japanese, which may be a reason for the difference in the incidence of acne. In our study, the severity of acne improved with upadacitinib dose reduction, and previous safety reports of upadacitinib in patients with atopic dermatitis revealed a dose-dependent trend of acne incidence, which supports our findings.[19,20] Since UC is relatively common in young patients, acne, despite posing a relatively low medical risk, can be a major obstacle in longer maintenance treatment as a cosmetic concern for patients, causing poor medication adherence. We had no cases of discontinuation due to acne at 24 weeks as we ensured prior explanation to patients before treatment initiation, and dermatological treatments and referrals were performed as appropriate. Accumulation of long-term analyses of upadaci-

tinib-related adverse events is required.

Our study has several limitations that should be acknowledged. The small number of cases in the distinct patient population from a single-center and the retrospective nature of the study constitute significant study limitations. In particular, criteria for selecting therapeutic agents and history of JAK inhibitor administration are potential confounding factors. Currently, there is still a paucity of real-world evidence of the efficacy and safety of upadacitinib in UC treatment, especially comparing upadacitinib to tofacitinib, as well as comparison by race. On this point, our report provides precious novel knowledge and we think our study is relevant for future clinical practice. How to use JAK inhibitors in different cases is an important question that is yet to be determined; therefore, studies with larger cohorts and longer-term data accumulation are required.

ADDITIONAL INFORMATION

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Data Availability Statement

All data in the study can be provided upon request.

Author Contributions

Conceptualization; Data curation; Formal analysis: Tamura A, Shimizu H. Investigator: Tamura A. Methodology: Tamura A, Shimizu H. Project administration: Fujii T, Shimizu H. Resources: Tamura A, Shimizu H. Supervision: Fujii T, Nagahori M, Ohtsuka K, Okamoto R. Validation: Morikawa R, Hibiya S, Takenaka K. Visualization: Tamura A, Shimizu H. Writing - original draft: Tamura A, Shimizu H. Writing - review & editing: Kawamoto A. Approval of final manuscript: all authors.

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Supplementary Material

Supplementary materials are available at the Intestinal Research website (https://www.irjournal.org).

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