ARTÍCULO ORIGINAL

Access barriers and ethical challenges of therapeutic decision-making in patients with inflammatory bowel disease and prior malignancy: a case series

Barreras de acceso y desafíos éticos de decisiones terapéuticas en pacientes con enfermedad inflamatoria intestinal y antecedentes de neoplasia: serie de casos

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Received: 16/09/2025
Peer-reviewed
Accepted: 27/02/2026
Online: 27/03/2026

Author contribution
LLM: conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration. TQS: data curation, formal analysis. MLCdF: project administration, resources, software, supervision. RJdF: conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing – original draft, writing – review & editing. ZBB: funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing – original draft, writing – review & editing. ACBL: supervision, validation, visualization, writing – original draft, writing – review & editing. BAAM: supervision, validation, visualization, writing – original draft, writing – review & editing. MVC: supervision, validation, visualization, writing – original draft, writing – review & editing. CCJ: supervision, validation, visualization, writing – original draft, writing – review & editing.

Conflict of interest
None.

Funding
None.

Cite as
Medeiros LL, Souza TQ, de Faria MLC, de Faria RJ, Bortoli ZB, Lopes ACB, *et al.* Access barriers and ethical challenges of therapeutic decision-making in patients with inflammatory bowel disease and prior malignancy: a case series. Rev Gastroenterol Peru. 2026;46(1):14-9. doi: 10.47892/rgp.2026.461.2047.

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ABSTRACT

Objectives: To report a case series of patients with inflammatory bowel diseases and a history of malignancy and to analyze how this condition influenced therapeutic decision-making presents a challenging scenario. **Materials and methods:** This was a retrospective observational study analyzing 11 patients with inflammatory bowel disease and malignant neoplasms followed at an inflammatory bowel disease outpatient clinic of a university hospital. Clinical, therapeutic, and oncologic findings are reported descriptively based on medical record review. **Results:** Seven patients (64%) had ulcerative colitis, and six (55%) were female, with a mean age of 47 years. Extra-intestinal neoplasms predominated. Six patients (55%) received advanced therapy near the time of cancer diagnosis; reintroduction was possible in four cases. Judicial action was required for two patients. **Conclusions:** Clinical decision-making in patients with inflammatory bowel disease and a history of malignancy is an individualized process, based on multidisciplinary discussion, bioethical considerations, and the most reliable available evidence, even in the face of state-imposed logistical obstacles. Continuous updating of Clinical Protocols and Therapeutic Guidelines is essential to ensure equitable access to the most appropriate and non-harmful treatment for this patient group.
Keywords: *Inflammatory Bowel Diseases; Neoplasms; Unified Health System; Bioethics (source: MeSH NLM).*

RESUMEN

Objetivos: Describir una serie de casos de personas con enfermedad inflamatoria intestinal y antecedentes oncológicos e investigar cómo esto influyó en su abordaje terapéutico. **Materiales y métodos:** Se trató de un estudio retrospectivo observacional que analizó 11 pacientes con enfermedad inflamatoria del intestino y neoplasias malignas, atendidos en el consultorio de enfermedad inflamatoria del intestino de un hospital universitario. Los hallazgos clínicos, terapéuticos y oncológicos se presentan de forma descriptiva a partir de la revisión de historias clínicas. **Resultados:** Siete pacientes (64%) tenían colitis ulcerosa, y seis (55%) eran mujeres, con una media de edad de 47 años. Predominaron las neoplasias no intestinales. Seis pacientes (55%) recibieron terapia avanzada cerca del diagnóstico oncológico; en cuatro de ellos fue posible la reintroducción. Dos pacientes requirieron judicialización. **Conclusiones:** La toma de decisiones clínicas en pacientes con enfermedades inflamatorias del intestino y antecedentes oncológico es un proceso individualizado, sustentado en discusión multidisciplinaria, consideraciones bioéticas y la mejor evidencia científica disponible, incluso frente a los obstáculos logísticos del sistema estatal. La actualización continua de los Protocolos Clínicos y Guías Terapéuticas es fundamental para garantizar la equidad en la provisión del tratamiento más adecuado y no maleficente para este grupo de pacientes.
Palabras clave: *Enfermedades Inflamatorias del Intestino; Neoplasias; Sistema Único de Salud; Bioética (fuente: DeCS Bireme).*

INTRODUCTION

Inflammatory bowel diseases (IBD), including ulcerative colitis (UC) and Crohn's disease (CD), are increasingly prevalent in Brazil, affecting 20 to 50 individuals per 100.000 population [1-3].

Recent guidelines for the management of these conditions have emphasized not only symptom control but also the reduction of inflammatory markers and the achievement of endoscopic healing, as outlined in the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE II) study and the Selecting Endpoints for Disease-Modification Trials (SPIRIT) initiative [4,5]. Thus, the use of biologics and small molecules has become more liberal, showing a generally favorable safety profile, although their safety remains uncertain in IBD patients with a history of malignancy.

In Brazil, the supplementary health sector offers access to agents with diverse profiles, in contrast to the Clinical Protocol and Therapeutic Guidelines (Protocolos Clínicos e Diretrizes Terapêuticas, PCDT) of the Brazilian Unified Health System (SUS), which currently include only a limited selection of drugs. In this context, therapeutic decision-making represents a considerable challenge [6].

Decisions regarding whether to initiate or discontinue a given drug, along with the assessment of risks inherent to these agents, should be individualized - particularly considering that patients with a history of malignancy are not explicitly included in studies evaluating the safety profile of these medications. Therefore, from a bioethical perspective, this scenario subjects' principles such as nonmaleficence and justice to a new test in clinical practice [1,7].

The aim of the present study was to report a case series of patients with active or prior malignancy, followed at the IBD outpatient clinic of a university hospital within the SUS, and to examine how this condition influenced therapeutic decision-making.

MATERIALS AND METHODS

We conducted a retrospective, cross-sectional case series analyzing clinical data and disease course in patients from the IBD outpatient clinic at the University Hospital of Brasília.

Data collection was initiated following approval by the Research Ethics Committee (REC), CAEE number: 82870424.5.0000.0030. Written informed consent was obtained from all participants.

The study included patients with a history of malignant neoplasms and IBD who required treatment for disease control up to 2025, whereas those who discontinued outpatient follow-up were excluded.

Clinical and follow-up data were obtained from medical records.

Descriptive statistical analyses were performed, reporting absolute and relative frequencies of the identified neoplasms, as well as therapeutic decisions regarding the use of biologics as categorical variables. Continuous variables, such as age, were summarized using mean, median, and standard deviation (SD). All analyses were conducted using R version 4.3.

RESULTS

Sample characteristics

Of approximately 200 individuals with IBD, 11 (5.5%) with malignant neoplasms were identified. Of these, six (55%) were female, seven (64%) had UC, and four (36%) had CD. The mean age was 47 years, with a median of 54 years and an SD of ± 13. The mean follow-up duration was 38 months, with a median of 36 months and an SD of ± 18. Patient characteristics, tumor staging, decision and time to prescription for the reintroduction of biologic therapy, and types of neoplasms are described in Table 1.

Classification of neoplasms

The presentation of neoplasms was categorized as intestinal and extra-intestinal, with the latter predominating (n = 7), especially in patients with UC (n = 5), as shown in Figures 1 and 2. Figure 2 shows the distribution of neoplasms according to IBD diagnosis (UC or CD), and Table 2 summarizes the neoplasm types.

Use of biologicals

Six (55%) patients were on biologic therapy prior to or at the time of neoplasm diagnosis. All discontinued the medication. Three are awaiting the resumption of treatment. Two patients are awaiting the restart of a biologic not covered by the PCDT (ustekinumab [UST]) — via judicial action — and one is awaiting initiation of vedolizumab (VDZ) for refractory pouchitis.

Clinical outcomes

In one patient (case 7), a more conservative therapeutic approach was adopted, consisting of endoscopic resection for a gastric adenocarcinoma *in situ*.

Patients in cases 2, 5, and 8, with adenocarcinoma of the colon, colon and jejunum, and a grade II neuroendocrine tumor, respectively, presented locally advanced disease. In case 5, peritoneal carcinomatosis was subsequently identified.

The surgical procedure resulted in clinical improvement; however, case 2 presented with antibiotic-refractory pouchitis, with an indication for VDZ.

Among the extra-intestinal cases, case 3 presented with the most advanced staging. The patient had lymphoma

Table 1. Clinical cases of IBD and malignancy – main outcomes.

Case	Age	Sex	IBD diagnosis	Type of malignancy	TNM staging	Biologic therapy after cancer/ time interval from diagnosis to prescription (months)	Judicial action	Follow-up duration (months)	Neoplasm recurrence
1	64	M	Ulcerative colitis	Prostate cancer/nonmelanoma skin cancer	T1N0M0 (prostate)	No/NA	No	60	No
2	24	M	Ulcerative colitis	Colon adenocarcinoma	T3N2M0	VDZ/28	No	36	No
3	66	F	Ulcerative colitis	Non-Hodgkin lymphoma	Estimated: relapsed IVb	No/NA	No	60	Yes
4	48	F	Crohn's disease	Melanoma *in situ*	T1N0M0	UST*/36*	Yes	36	No
5	55	F	Crohn's disease	Synchronous adenocarcinoma of the colon and small bowel	T4N2M1 and T4N1M1	UST**/26**	Yes	36	Yes
6	54	M	Ulcerative colitis	Clear cell multilocular renal neoplasm	T1N0M0	VDZ/24	No	38	No
7	54	M	Crohn's disease	Gastric adenocarcinoma and intracholecystic papillary neoplasm	T1aN0M0 and TisN0M0	No/NA	No	18	No
8	34	F	Ulcerative colitis	Neuroendocrine tumor in the ascending colon	T3N0M0	No/NA	No	24	No
9	34	F	Ulcerative colitis	Papillary thyroid cancer	T1N0M0	No/NA	No	48	No
10	54	M	Ulcerative colitis	Hepatocarcinoma	T1N0M0	No/NA	No	60	No
11	38	F	Crohn's disease	Cervical adenocarcinoma	T1NxMx	No/NA	No	2	No

ADA = adalimumab; IBD = inflammatory bowel disease; VDZ = vedolizumab; UST = ustekinumab; NA = not applicable.
* Drug prescribed at 36 months awaiting the outcome of judicial proceedings.
** Drug prescribed at 26 months, but despite being available through legal action, the finding of carcinomatosis prevented the reintroduction of biologic therapy.

and underwent a bone marrow transplant; the disease was in remission, and the transplant did not alter UC activity.

Only in cases of nonmelanoma skin cancer, such as in case 1, there was a clear association with therapy – azathioprine [8].

Judicial action

Judicial action was required in two cases, both with CD, for whom the PCDT allowed only infliximab (IFX) and adalimumab (ADA) until June 2025. One patient had synchronous adenocarcinoma of the jejunum and colon, and the other had melanoma. Both successfully obtained UST.

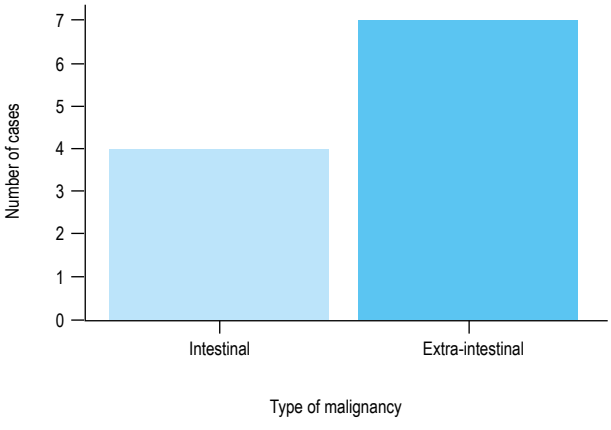
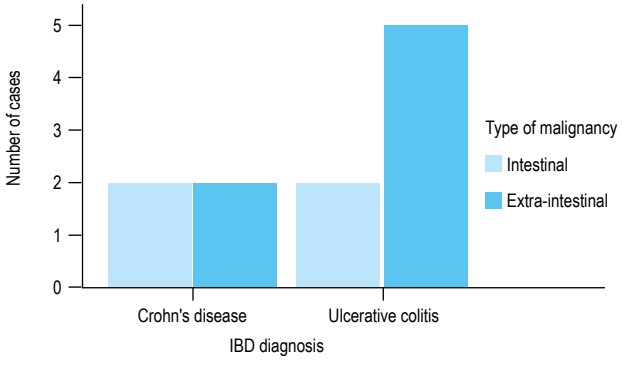


Figure 1. Distribution of intestinal and extra-intestinal neoplasms in patients with inflammatory bowel disease and a history of malignancy.



IBD = inflammatory bowel disease.

Figure 2. Distribution of intestinal and extra-intestinal neoplasms in IBD patients with a history of malignancy according to IBD diagnosis.

 https://doi.org/10.47892/rgp.2026.461.2047

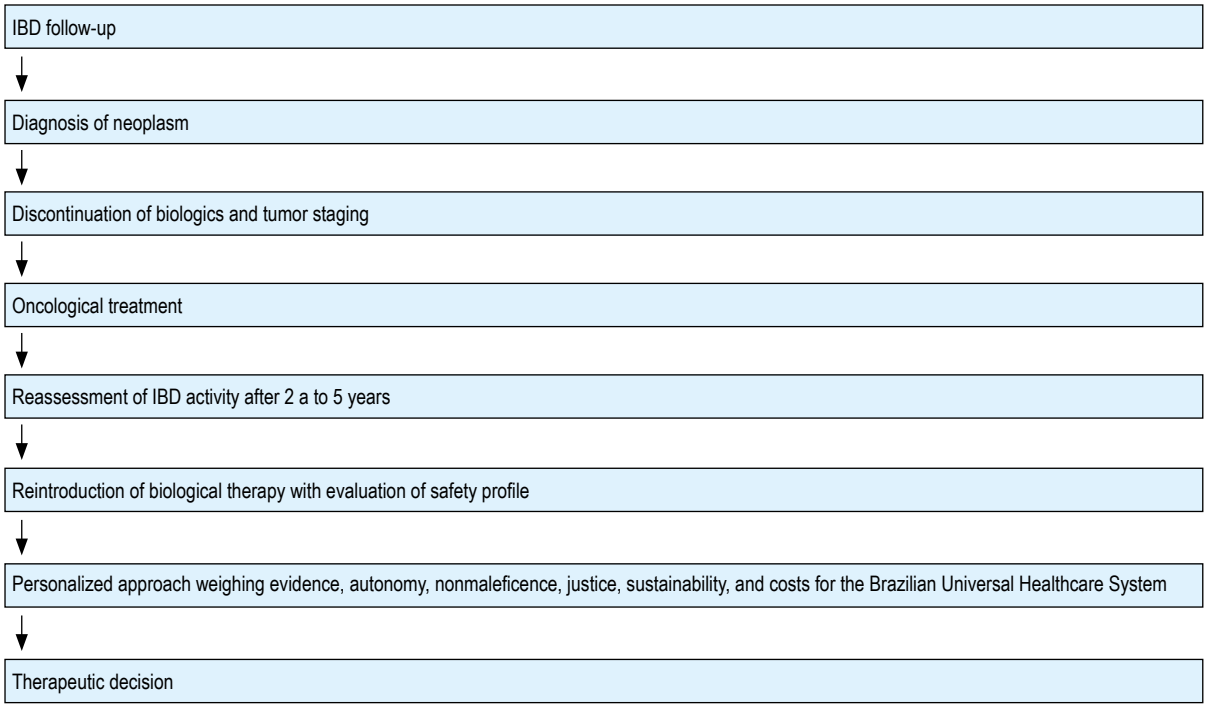
Table 2. Malignancy type and classification.

Type of malignancy	Classification
Moderately differentiated colon adenocarcinoma	Intestinal
Synchronous adenocarcinoma of the colon and small bowel	Intestinal
Gastric adenocarcinoma + intracholecystic papillary neoplasm	Intestinal
Low-grade neuroendocrine tumor in the colon	Intestinal
Prostate cancer (2014) / nonmelanoma skin cancer (2023)	Extra-intestinal
Large B-cell non-Hodgkin lymphoma	Extra-intestinal
Melanoma *in situ*	Extra-intestinal
Clear cell multilocular renal neoplasm	Extra-intestinal
Papillary thyroid cancer	Extra-intestinal
Hepatocarcinoma	Extra-intestinal
Cervical adenocarcinoma	Extra-intestinal

DISCUSSION

IBD, which includes CD and UC, is characterized by a chronic, immune-mediated inflammatory process. Management often requires the use of biologics and small molecules to achieve the therapeutic goals of remission established in studies such as STRIDE II [5]. However, the use of these drugs in patients with a recent history of neoplasm presents a clinical dilemma, as their administration may be associated with a potential risk of reactivating dormant micrometastases [9].

As a general recommendation, the interval between completion of oncologic therapy and resumption of biologic treatment should be at least of 2 years [6], with strict follow-up [10].



IBD = inflammatory bowel disease.

Figure 3. Therapeutic decision-making flowchart for the management of IBD patients with a history of malignancy.

In light of this still uncertain scenario, in which prudence must be exercised, it is worth noting that our sample is situated within the context of a public hospital. Thus, evidence-based approaches are adapted to the therapeutic arsenal available, which is constrained by logistic factors inherent to a system that must maintain sustainable strategies for its users [11].

The American Gastroenterological Association considers that anti-tumor necrosis factor (TNF) monotherapy may be regarded as safe, with no significant association with the occurrence of new tumors in patients with IBD and neoplasms [6]. The risk of developing melanoma-type skin cancer is almost twice as high among those using anti-TNFs compared to controls. Combination therapy with thiopurines appears to be consistently associated with an increased risk of developing lymphoma in young male patients not exposed to the Epstein-Barr virus (hepatosplenic T-cell lymphoma) [12]. Meanwhile, thiopurine monotherapy has been associated with a twofold increase in the risk of nonmelanoma skin cancer compared to controls [13].

Regarding VDZ and UST, evidence has not shown an increased risk of malignancies in patients treated with these agents [6], although patients with a history of neoplasm are not well represented in clinical trials [6].

The European Crohn's and Colitis Organization (ECCO) highlights the heterogeneity of the populations studied, the lack of detail regarding the type of cancer, and the observational nature of the studies, which limits the generalizability of these recommendations, particularly in relation to melanoma [9,14].

Recently, checkpoint inhibitors have been associated with severe colitis, for which IFX followed by VDZ has been proposed. Observational studies reinforce the perception of a more favorable safety profile for VDZ; however, further evidence is still needed [15].

Financial sustainability limits the broad availability of these medications, and policies for the incorporation of new therapies require rigorous cost-effective analyses, which may delay the inclusion of drugs in clinical protocols. Therefore, it is up to the specialist to adapt the options of the PCDT: until mid-2025, IFX, VDZ, and tofacitinib for UC, and IFX and ADA for CD. Such restrictions create a limited scenario for oncology patients.

Case 2 involved proctocolectomy with ileal pouch due to colon adenocarcinoma, and the patient developed refractory pouchitis. Thus, we opted to initiate VDZ. This decision was based on the drug's safety profile, stemming from its intestinal selectivity [16], and on the fact that a 2-year interval had already elapsed [10,17].

Case 4 consisted of perianal CD with failure to respond to ADA, which is currently discontinued. In fistulizing disease, anti-TNF-α drugs would be the first-line therapy. However, the patient developed melanoma, and the safety evidence for this drug remains uncertain [6]. Thus, we faced an obstacle in clinical management, with no immediately available and feasible therapeutic option in the public health network. The patient obtained UST through judicial action.

In case 5, the patient with ileocolonic, stenosing CD underwent surgery for acute obstructive abdomen, with the finding of synchronous adenocarcinoma of the colon and small intestine in 2022. Chemotherapy was initiated and remains ongoing due to peritoneal disease recurrence. In joint discussion with the oncology team, it was decided to withhold reintroduction of biologic therapy, with re-evaluations depending on the evolution of the oncologic context [9].

In case 7, a patient with CD associated with articular manifestations had recent diagnoses of gastric and gallbladder neoplasms, both *in situ*. Due to arthropathy and considering the risk-benefit of anti-TNF therapy, it was decided, in consultation with the rheumatology team, to discontinue ADA, with close monitoring of CD recurrence for 2 years.

In the follow-up of our patients, we applied the evidence while incorporating bioethical principles — nonmaleficence and autonomy — sharing risks and uncertainties with our patients. We are, however, limited by the low health literacy of our population [18], and when PCDT restrictions arise, judicial action — often lengthy and with uncertain outcomes — is required to ensure equity [6].

Figure 3 presents a summary of the therapeutic decision-making flow for the cases.

This report is limited by its retrospective, single-center design, small sample size, and short follow-up. Long-term follow-up studies and collaboration with other public centers may allow the development of more robust evidence on IBD management in the oncologic setting.

In conclusion, managing patients with IBD and a history of malignancy remains challenging. Studies supporting the safety of advanced therapy have important limitations, such as participant selection bias, sample heterogeneity favoring patients with better oncologic outcomes, and short follow-up. The restricted therapeutic options in our public health system — although intended to ensure a sustainable supply of medications — further complicate therapeutic decision-making.

Our series aimed to apply the best available evidence in the most personalized manner possible, guided by bioethical principles, allowing us to overcome the limitations imposed by our PCDTs and emphasizing that their updating is crucial to ensure equity [19,20].

Acknowledgements
This article is derived from the undergraduate thesis of Larissa Leandro Medeiros, defended in 2025 at

the conclusion of the Medical Residency Program in Gastroenterology at the Hospital Universitário de Brasília (University of Brasília – HUB-UnB).

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