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Clinical Course and Predictors of Biologic Therapy, Hospitalisation and Surgery: A Five-Year Prospective Study in Newly Diagnosed Inflammatory Bowel Disease

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Abbreviations: CD, Crohn's disease; CI, confidence interval; EIM, extra intestinal manifestations; GETECCU, Spanish Working Group on Crohn's Disease and Ulcerative Colitis; HR, hazard ratio; IBD, inflammatory bowel disease; IBD-U, inflammatory bowel disease unclassified; IQR, interquartile range; JAKi, JAK inhibitors; UC, ulcerative colitis.

Javier P. Gisbert and María Chaparro share senior authorship.

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ABSTRACT

Aims: This study aimed to describe the characteristics of newly diagnosed inflammatory bowel disease (IBD) patients and to analyse their clinical course within the first 5 years after diagnosis, including the need for surgery, hospitalisations and treatments.

Methods: This prospective and large multicentre incident cohort registry in Spain enrolled adults diagnosed with Crohn's disease (CD), ulcerative colitis (UC) or unclassified IBD (IBD-U) in 2017 and followed them for 5 years.

Results: A total of 3301 patients were enrolled: 1526 with CD, 1633 with UC and 142 with IBD-U. Their median age at diagnosis was 43 years (interquartile range 31–56) and approximately 50% were male. Within 5 years post-diagnosis, 30% received biologics or JAK inhibitors (JAKi), 34% were hospitalised at least once and 9% underwent surgery. The cumulative incidence of biologic/JAKi treatment, hospitalisations and surgeries was higher among CD patients. Use of biologics/JAKi correlated with a more aggressive CD phenotype, greater UC extent and younger age at diagnosis. Biologics/JAKi treatment was associated with lower hospitalisation risk in both CD (Hazard ratio [HR] = 0.4, 95% confidence interval [CI] = 0.2–0.6) and UC patients (HR = 0.5, 95% CI = 0.2–0.9). However, it was not associated with the risk of abdominal surgery in CD but was linked to an increased risk of surgery in UC (HR = 11.9, 95% CI = 4.6–30.4).

Conclusions: This large multicentre cohort demonstrated a higher use of biologics/JAKi during the first 5 years after IBD diagnosis than previously reported. Treatment with biologics/JAKi was associated with reduced risk of hospitalisation. However, under current clinical practice patterns, this therapeutic approach did not translate into lower risk of abdominal surgery.

1 | Introduction

Inflammatory bowel disease (IBD), which includes Crohn's disease (CD), ulcerative colitis (UC) and inflammatory bowel disease unclassified (IBD-U), is a chronic disorder of unknown aetiology that involves an alteration of the immune system leading to chronic inflammation of the digestive tract. IBD is a relapsing–remitting disease characterised by alternating phases of remission and inflammatory activity; it is diagnosed mainly in young people [1], and exerts a significant effect on the quality of life of patients. As a result, patients affected by this condition frequently require immunomodulatory therapy (biologic agents or small molecules) and, in some cases, surgical intervention to induce and maintain remission.

Over the past several decades, the burden of IBD has steadily increased, driven by both a rising incidence of the disease [2, 3] and the growing economic impact associated with advanced pharmacological therapies and increasingly sophisticated diagnostic and therapeutic procedures [4–7]. In last decades, the therapeutic objective in the management of IBD has shifted from symptom control to mucosal healing [8], with the introduction of more effective but also more expensive therapeutic options [9–11].

In response to the growing clinical complexity and economic demands of IBD care, Integrated Care Units aim to standardise and optimise patient management through multidisciplinary collaboration. However, in hospitals without specialised IBD Units, patients are often treated by healthcare providers with limited expertise in this field, which may adversely affect treatment quality and clinical outcomes.

To effectively plan healthcare services for individuals with IBD and to ensure the appropriate allocation of economic and human resources, it is essential to conduct prospective longitudinal epidemiological studies. To date, most of the epidemiological studies in Europe have been conducted in Northern or Central European countries with relatively small populations and data from Southern Europe have rarely been included. Furthermore, these studies are typically retrospective in nature, with generally short follow-up periods [12–14]. A noteworthy European study, EpiCom, was initiated in 2010 and conducted in hospitals across several European countries; however, it included only a single Spanish centre [15]. In the case of Spain, epidemiological studies carried out prior to our investigation were conducted more than a decade ago, focused on very specific regions and involved a limited number of patients [16].

Several inception cohort studies have provided important insights into the natural history of IBD from diagnosis onwards, describing rates of surgery, hospitalisation and disease progression over time [17, 18]. For example, the IBSEN cohort and other European inception cohorts have shown that a substantial proportion of patients experience complicated disease courses despite advances in therapy [19–22], highlighting the need for better prognostic stratification at diagnosis.

Given these limitations, there is a clear need for new studies that not only provide more representative and updated data but also aim to characterise patients at the time of diagnosis and systematically evaluate their clinical trajectory over the initial years following diagnosis. To achieve these objectives, this study aimed to assess key outcomes including the need for surgical interventions, frequency of hospitalisations and patterns of pharmacological treatment throughout a 5-year follow-up period in a large, prospective, multicentre incident cohort registry in Spain.

2 | Methods

2.1 | Study Design and Study Population

We designed a prospective, observational, multicentre, incident cohort study that included cases diagnosed with IBD (CD, UC and IBD-U) in the adult population throughout 2017 in Spain. The diagnosis of IBD was based on the European Crohn's and Colitis Organisation criteria [23, 24]. Patients were eligible for inclusion if they belonged to the designated healthcare area of the participating centres. All aspects of the study protocol have been described in a prior publication [3, 16].

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The most appropriate case identification strategy was planned in collaboration with the coordinating investigator from each of the Autonomous Communities, taking into account the specific characteristics of each Community, province and healthcare area, with the aim of detecting all incident cases. The databases of Endoscopy Units, Radiology departments (optional depending on the specific characteristics of each centre) and Pathology departments of all participating centres in the study were reviewed throughout 2017 in order to detect possible incident IBD cases that had not been initially identified. The review of these databases was performed by the principal investigator at each centre.

Once a patient was incorporated into the registry and signed the informed consent, two evaluations were carried out during the first year of follow-up, at 3 and 12 months, with the aim of confirming the initial diagnosis and updating clinical and evolutionary information. Subsequently, biannual follow-up visits were scheduled until a total observation period of 5 years was completed. The baseline visit, corresponding to the moment of diagnosis, was made in person, while the rest of the visits could be made by contacting the patient through telematics means and reviewing the episodes and evolution reflected in the clinical history.

The study protocol was evaluated and approved by the Research Ethics Committee of the coordinating hospital (Hospital Universitario de La Princesa, Madrid) prior to the start of the study.

2.2 | Participating Centres

The initial selection of centres was made from data from the 2016 health centres database of the Spanish Ministry of Health to obtain a representative sample. A total of 205 centres were selected to start the study, and those centres that did not adequately follow the study procedures or did not ensure the inclusion of all patients diagnosed with IBD in their healthcare area were excluded. Finally, 108 centres participated in the study (Table S1), covering a reference area with a population of 22,270,357 inhabitants (approximately 50% of the Spanish population, which was 46,659,302 as of June 28, 2018).

In addition, to carry out this project, an IBD specialist member of the Spanish Working Group on Crohn's Disease and Ulcerative Colitis (GETECCU) was selected from each Spanish region to act as study coordinator in his or her region.

2.3 | Data Collection

Demographic data (age, sex, smoking), family history of IBD, socioeconomic characteristics, type of IBD, pattern, location and presence of extraintestinal manifestations (EIM) at the time of diagnosis were collected for each patient. In addition, the occurrence of complications (fistulas, strictures and abscesses), changes in disease location, IBD treatments and IBD-related surgeries and hospitalisations during the first 5 years after diagnosis were recorded for those patients who signed the informed consent.

All study data were recorded in an electronic data collection notebook (e-CRD) created on the REDCap platform [25, 26].

2.4 | Monitoring

Throughout the study period, remote monitoring was conducted for all enrolled patients. Additionally, on-site monitoring was carried out in 50% of the participating centres, specifically, those in which the quality of the recorded data was deemed insufficient to rely solely on remote monitoring.

During the on-site monitoring visits, 100% of the collected data were systematically reviewed and cross-checked against the corresponding information documented in the patient's clinical histories. This process ensured the integrity and accuracy of the dataset, thereby enhancing the overall robustness and reliability of the study findings.

2.5 | Definitions

Disease location and phenotype were classified according to the Montreal classification [27]. Time to diagnosis was defined as the interval between the onset of symptoms and the confirmed diagnosis of IBD. Patients whose diagnosis was revised during follow-up were reclassified according to the updated diagnosis, which was applied retrospectively from the date of the original diagnosis. Phenotypic changes were defined as the development of disease manifestations not present at baseline; for these cases, the updated phenotype, the specific complication prompting reclassification and the date of onset were documented. Changes in disease extension were defined as the emergence of inflammation in previously unaffected intestinal segments. Importantly, disease behaviour was defined exclusively at the time of diagnosis (baseline) according to the Montreal classification and was not treated as a time-varying variable; subsequent changes in disease behaviour during follow-up were not considered in the present analyses.

Patients classified as 'symptom free' at diagnosis were those without typical gastrointestinal symptoms attributable to IBD at the time of diagnosis. In these cases, diagnosis was established following incidental findings during screening procedures, endoscopic or imaging studies or investigation of laboratory abnormalities.

Treatments administered for IBD during the 5-year follow-up period were documented. Only the initial prescription of each therapeutic class was recorded. Early initiation of therapy with immunosuppressants, biologic agents and JAK inhibitors was defined as treatment initiated within the first 6 months after diagnosis. This time window was selected as a pragmatic definition of early treatment initiation in routine clinical practice, allowing for referral to specialist care, completion of disease assessment, pre-biologic screening and treatment approval procedures.

All surgical interventions related to IBD performed after the diagnosis (as well as those conducted prior to diagnosis in which IBD was ultimately confirmed) were recorded, including the

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surgical indication and the date of the procedure. For the analysis of predictors, only abdominal surgeries were considered. All IBD-related hospital admissions occurring from diagnosis through the 5-year follow-up period were recorded. This included hospitalisations at the time of IBD diagnosis and any subsequent admissions during follow-up. Hospitalisations were considered IBD-related when the reason for admission was directly linked to IBD diagnosis or assessment, disease flare, intestinal or perianal complications, IBD-related surgery, treatment-related adverse events or other clinically relevant IBD-related events. Multiple hospitalisations per patient were recorded, and therefore a given patient could contribute more than one hospitalisation episode during follow-up. For time-to-event analyses, only the first IBD-related hospitalisation per patient was considered.

Hospitals were classified considering several variables such as infrastructure, services offered, activity and complexity or teaching, based on information obtained from the Spanish Ministry of Health. According to these variables, hospitals were classified into 5 categories (I to V), where I represented small hospitals with limited resources and V represented large general hospitals with extensive resources.

2.6 | Statistical Analysis

Qualitative variables are presented as percentages (with their 95% confidence intervals [CI]) and quantitative variables as arithmetic means and standard deviations. Variables that did not follow a normal distribution are presented as medians and interquartile ranges (IQR). Missing data were not imputed. Descriptive and univariate analyses were performed using all available observations for the variables involved in each analysis (available-case analysis). Multivariable Cox regression models were based on complete cases for the covariates included in each specific model. Consequently, the analytical sample could vary between models. In the univariate study, categorical variables were compared using the chi-square test (χ^2) and quantitative variables were compared using the appropriate test (ANOVA test or Kruskal-Wallis test, depending on whether their values followed a normal distribution or not). To study in detail the chronology of treatment use, hospital admissions and surgeries, the Kaplan–Meier method was used and the presence of differences between the curves was evaluated using the log-rank test. Multivariate analyses using Cox regression were performed to assess factors associated with the likelihood of treatment with biologics/JAKi, abdominal surgeries and hospitalisations. These analyses were conducted first in the overall IBD patient cohort, and subsequently, separately in patients with CD and UC. Before fitting the multivariable Cox regression models, the assumption of a linear relationship between age and the log hazard was assessed by comparing models with linear and quadratic specifications for age. Linearity was confirmed for all models except the model evaluating predictors of hospitalisation in patients with CD, in which the quadratic term for age was statistically significant ($p = 0.001$), indicating evidence of a non-linear association. Therefore, a quadratic term for age was included in this model, whereas age was retained as a continuous linear variable in the remaining models.

3 | Results

3.1 | Patient Characteristics

A total of 3301 patients diagnosed with IBD during 2017 were included in the follow-up study. Of the 3301 patients, 1526 (46%) had CD, 1633 (50%) had UC and 142 (4%) had IBD-U. Table 1 shows the characteristics of the patients. Their median age was 43 years (46 in UC patients and 41 in CD patients) and 1734 (52.5%) were male. The median time to diagnosis was 3.5 months (IQR = 1.5–9.3 months), being longer in patients with CD (6 vs. 3 months, $p < 0.001$). A family history of IBD was reported in 498 patients (15%) and, at the time of diagnosis, 276 patients (8%) were symptom-free and 474 (14%) already had EIM. Of the patients included, 802 (24%) were smokers.

In patients with CD, the predominant location was ileal in 820 patients (54%) followed by ileocolonic in 415 (27%) and the most prevalent behaviour was inflammatory, in 1228 patients (80%) (Table 1). Perianal disease was present in 179 patients (12%) at diagnosis. Regarding UC patients, 511 (31%) exhibited extensive colitis and 511 (31%) left-sided colitis.

During the five years of follow-up, 33 patients (5.4%) initially diagnosed with proctitis progressed to left-sided colitis and 18 (3%) developed extensive colitis. Among those presenting with left-sided colitis at diagnosis, 22 patients (4.3%) progressed to extensive disease. Regarding patients diagnosed with inflammatory CD, 63 (5%) evolved to a stricturing phenotype and 39 (3.2%) to a fistulising phenotype. Of those with an initial stricturing behaviour, 12 (6.7%) developed fistulising disease. Finally, among CD patients, 36 (2.7%) developed perianal disease during follow-up.

3.2 | Long-Term Disease Course Without Need for Surgery or Advanced Therapy

Of the 3301 patients included in the cohort, 1795 (54%) did not require surgery or advanced therapy (biologics or immunosuppressive agents) during the 5-year follow-up (28% of the patients with CD and 72% of those with UC) (Figure 1).

3.3 | Treatment During the First 5 Years After Diagnosis

During the first five years after diagnosis, 2120 patients (approximately 65%) received corticosteroid therapy, 1217 (37%) were treated with immunomodulators and 976 (30%) received biologics/JAKi. Among those treated with biologics/JAKi, 917 (28%) received anti-TNF agents, 151 (4.6%) vedolizumab, 212 (6.4%) ustekinumab and 27 (0.8%) tofacitinib (Table 2). Most patients who started treatment with mesalazine, corticosteroids or immunomodulators began treatment within the first 2 years after diagnosis, whereas the use of biologics/JAKi steadily increased over time. When comparing patients according to diagnosis, we observed that while the cumulative incidence of mesalazine exposure was higher in patients with UC and IBD-U, the use of corticosteroids, immunomodulators and biologics/JAKi was higher in patients with CD (Figure 2). A total of 675 patients with CD (44%) were exposed to biologics/JAKi

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TABLE 1 | Sociodemographic and clinical characteristics of the study population. (A) Overall incident cohort. (B) Comparison between Crohn's disease (CD) and ulcerative colitis (UC) patients.

A.

Variables	*N* = 3301
Age at diagnosis (years), median (IQR)	43.6 (31.5–56.1)
Male sex, *n* (%)	1734 (52.5)
Diagnosis delay (months), median (IQR)	3.5 (1.5–9.3)
Symptoms at diagnosis, *n* (%)	3025 (91.6)
Family history of inflammatory bowel disease, *n* (%)	498 (15.1)
Extraintestinal manifestations, *n* (%)	474 (14.4)
Smoker, *n* (%)	802 (24.3)
Type of inflammatory bowel disease	
CD, *n* (%)	1526 (46.2)
Ileal, *n* (%)	820 (53.7)
Colonic, *n* (%)	288 (18.8)
Ileocolonic, *n* (%)	415 (27.2)
Upper gastrointestinal tract, *n* (%)	63 (4.1)
Inflammatory, *n* (%)	1228 (80.5)
Stricturing, *n* (%)	180 (11.8)
Fistulising, *n* (%)	116 (7.6)
Perianal disease, *n* (%)	179 (11.7)
UC, *n* (%)	1633 (49.5)
Pancolitis, *n* (%)	511 (31.3)
Left-sided colitis, *n* (%)	511 (31.3)
Proctitis, *n* (%)	611 (37.4)
IBD unclassified, *n* (%)	142 (4.3)

B.

	CD (*N* = 1526)	UC (*N* = 1633)	IBD-U (*N* = 142)	*p*
Age at diagnosis (years), median (IQR)	40.9 (28.4–54.4)	45.6 (34.5–57.1)	47.2 (33.5–58.8)	< 0.001
Diagnosis delay (months), median (IQR)	5.6 (1.8–15.2)	2.7 (1.3–5.8)	3.7 (1.5–8.8)	< 0.001
Male sex, *n* (%)	766 (50.2)	897 (54.9)	71 (50.0)	0.024
Symptoms at diagnosis, *n* (%)	1361 (89.2)	1538 (94.7)	126 (90.6)	< 0.001
Family history, *n* (%)	272 (17.8)	214 (13.1)	12 (8.5)	< 0.001
Extraintestinal manifestations, *n* (%)	294 (19.3)	157 (9.6)	23 (16.2)	< 0.001
Smoker, *n* (%)	589 (38.6)	186 (11.4)	27 (19.0)	< 0.001

Abbreviation: IQR, interquartile range.

within the first 5 years after diagnosis (Table 2). Regarding the type of hospital, the cumulative incidence of treatment with biologics/JAKi in patients with CD was higher in hospitals with higher resources, whereas mesalazine use was more common in hospitals with lower resources (Figure 3). In patients with UC, 281 (17%) were treated with biologics/JAKi and no differences were observed based on hospital type.

3.4 | Hospitalisations and Surgeries

A total of 1121 patients (34%) were hospitalised during the first 5 years of follow-up (Table 2). The main reasons for hospital admission were IBD diagnosis ($n = 726$, 41%), IBD flare-up ($n = 516$, 29%) and surgical procedure ($n = 183$, 10%) (Table S2). When comparing patients according to diagnosis,

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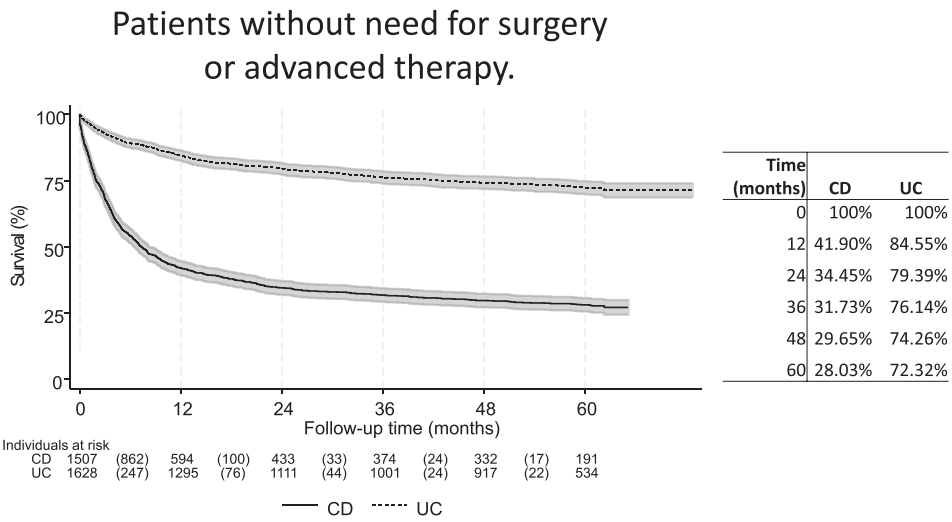


FIGURE 1 | Cumulative incidence of patients with Crohn's disease (CD) and ulcerative colitis (UC) who do not need surgeries or advanced therapy.

TABLE 2 | Treatments, surgeries and hospitalisations. (A) Incident cohort. (B) Comparison between Crohn's disease (CD) and ulcerative colitis (UC) patients.

A.	
Medications	***N*=3301**
Mesalazine, *n* (%)	2387 (72.1)
Steroids, *n* (%)	2120 (64.2)
Immunomodulators, *n* (%)	1217 (36.9)
Biologics/JAK inhibitors, *n* (%)	976 (29.6)
Anti-TNF	917 (27.8)
Vedolizumab	151 (4.6)
Ustekinumab	212 (6.4)
Tofacitinib	27 (0.8)
Hospitalisations, *n* (%)	1121 (34.0)
Surgeries, *n* (%)	292 (8.9)

B.				
	CD (*N*=1526)	**UC (*N*=1633)**	**IBD-U (*N*=142)**	***p***
Mesalazine, *n* (%)	665 (43.6)	1582 (96.9)	132 (93.0)	<0.001
Steroids, *n* (%)	1205 (79.0)	843 (51.6)	72 (50.7)	<0.001
Immunomodulators, *n* (%)	878 (57.5)	309 (18.9)	30 (21.1)	<0.001
Biologics/JAK inhibitors, *n* (%)	675 (44.2)	281 (17.2)	20 (14.1)	<0.001
Hospitalisations, *n* (%)	657 (43.1)	430 (26.3)	34 (23.9)	<0.001
Surgeries, *n* (%)	247 (16.2)	40 (2.5)	5 (3.5)	<0.001

we observed that the cumulative incidence of hospitalisations was higher in patients with CD than in those with UC or IBD-U (Figure 2).

Regarding surgical interventions, 292 patients (9%) underwent at least one surgery (Table 2), of which 264 (60%) were abdominal surgeries and 182 (40%) were perianal surgeries. The cumulative incidence of surgery was higher in patients with CD than in those with UC or IBD-U. In UC, most surgeries were performed within the first 2 years after diagnosis (Figure 4).

Concerning the type of hospital, both the cumulative incidence of hospitalisations and surgeries were higher in hospitals with

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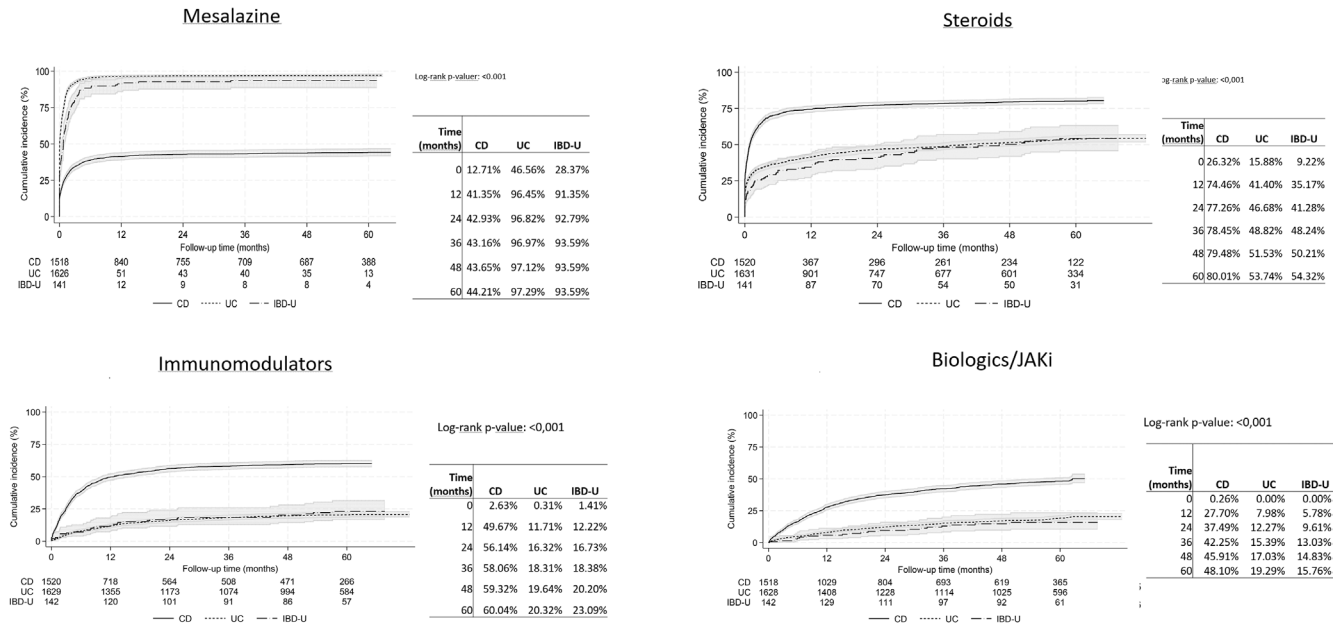


FIGURE 2 | Cumulative treatment exposure in Crohn's disease (CD), ulcerative colitis (UC) and inflammatory bowel disease unclassified (IBD-U) during the 5-year follow-up.

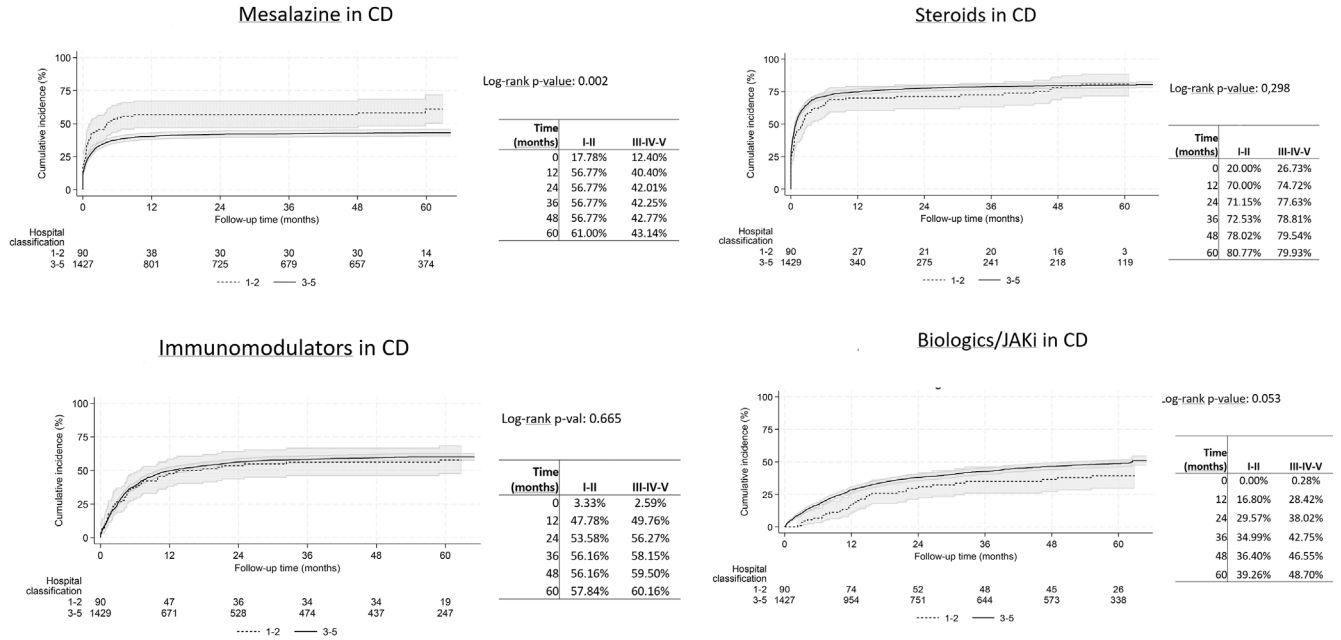


FIGURE 3 | Cumulative treatment exposure in Crohn's disease (CD) based on hospital categories: Lower resources (I and II) versus higher resources (III–V).

higher resources for patients with CD, whereas no differences were observed in patients with UC (Figure 5).

3.5 | Predictive Factors for the Use of Biologic Drugs and/or JAKi, Hospitalisations and Surgeries

Predictive factors for biologics/JAKi use, abdominal surgery and hospitalisation were analysed separately in patients with CD and UC (Tables 3 and 4). In patients with CD, younger age at diagnosis was associated with a higher likelihood of biologics/JAKi use (HR = 0.99, 95% CI = 0.98–1.00), as were family history of IBD (HR = 1.3, 95% CI = 1.1–1.6), smoking (HR = 1.3, 95% CI = 1.1–1.5), stricturing behaviour (HR = 1.9, 95% CI = 1.5–2.4), fistulising behaviour (HR = 2.3, 95% CI = 1.8–3.1) and perianal disease at diagnosis (HR = 1.9, 95% CI = 1.5–2.4). Regarding abdominal surgery in CD, stricturing and fistulising behaviour were strongly associated with increased risk compared with inflammatory behaviour (HR = 5.5, 95% CI = 3.6–8.4 and HR = 8.7, 95% CI = 5.6–13.6, respectively). Exposure to biologics/JAKi was not associated with a reduced risk of surgery, either when used later during follow-up (HR = 0.7, 95% CI = 0.5–1.8) or within the first 6 months after diagnosis (HR = 1.3, 95% CI = 0.8–2.0). In contrast, exposure to immunomodulators was associated

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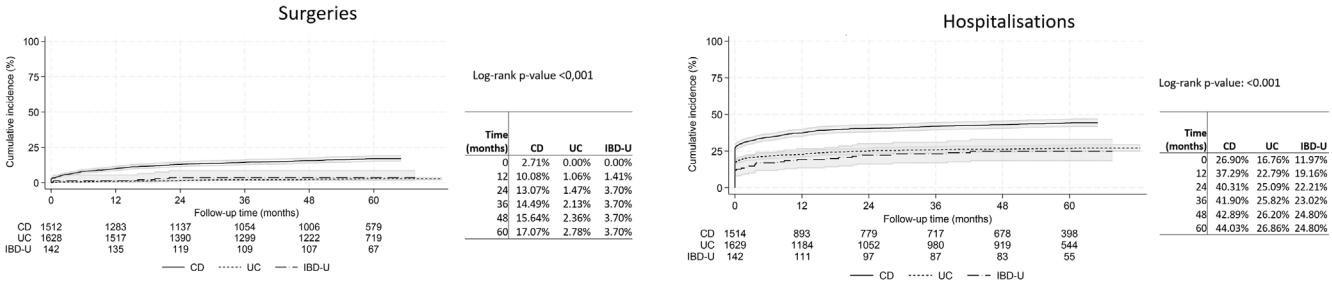


FIGURE 4 | Cumulative incidence of hospitalisations and surgeries in Crohn's disease (CD), ulcerative colitis (UC) and inflammatory bowel disease unclassified (IBD-U) during the 5-year follow-up.

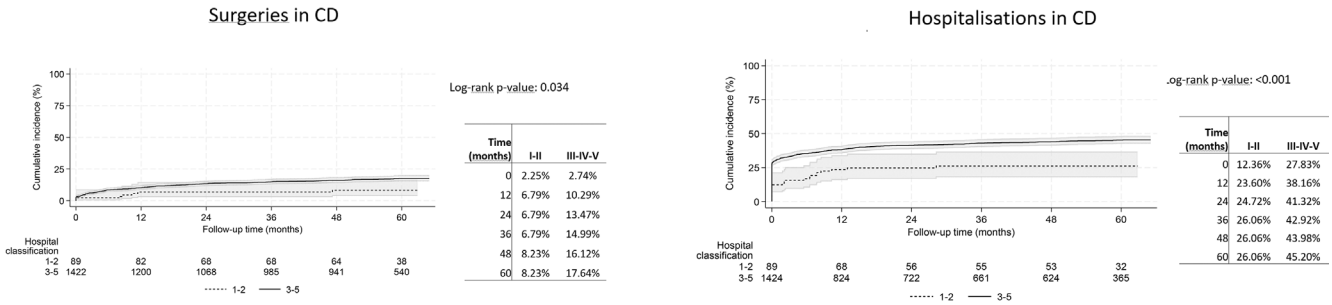


FIGURE 5 | Cumulative incidence of hospitalisations and surgeries in Crohn's disease (CD) according to hospital categories: Lower resources (I and II) versus higher resources (III–V).

TABLE 3 | Predictors associated with biologics/JAKi use (A), surgeries (B) and hospitalisations (C) in patients with Crohn's disease (CD).

A.

	Biologics/JAKi	
	***N*=1334**	
CD	**Hazard ratio (95% confidence interval)**	***p***
Age	0.99 (0.98–1.00)	<0.001
Family history of IBD	1.3 (1.1–1.6)	0.010
Smoker	1.3 (1.1–1.5)	0.002
Disease behaviour		
B1 (inflammatory)	Reference	
B2 (stricturing)	1.9 (1.5–2.4)	<0.001
B3 (fistulising)	2.3 (1.8–3.1)	<0.001
Perianal	1.9 (1.5–2.4)	<0.001

Variables included in the multivariable Cox regression model: age, sex, diagnostic delay, family history of IBD, smoking status, hospital complexity, disease behaviour, disease location at diagnosis, perianal disease and surgery at diagnosis. For clarity, only the most clinically relevant variables are presented in the table

B.

	Surgeries	
	***N*=1334**	
CD	**Hazard ratio (95% confidence interval)**	***p***
Disease behaviour		
B1 (inflammatory)	Reference	
B2 (stricturing)	5.5 (3.6–8.4)	<0.001
B3 (fistulising)	8.7 (5.6–13.6)	<0.001

(Continues)

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TABLE 3 | (Continued)

B.

CD	Surgeries *N* = 1334 Hazard ratio (95% confidence interval)	*p*
Exposure to biologics/JAKi before surgery		
No exposure to treatments	Reference	
Exposure to treatments	0.7 (0.5–1.8)	0.197
Early exposure to treatments	1.3 (0.8–2.0)	0.245
Exposure to immunomodulators before surgery		
No exposure to treatment	Reference	
Exposure to treatment	0.2 (0.1–0.5)	< 0.001
Early exposure to treatment	0.3 (0.2–0.5)	< 0.001

Variables included in the multivariable Cox regression model: age, sex, diagnostic delay, family history of IBD, smoking status, hospital complexity, disease behaviour, disease location, perianal disease, exposure to biologics/JAKi before surgery and exposure to immunomodulators before surgery. For clarity, only the most clinically relevant variables are presented in the table. Early exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment during the first 6 months after diagnosis. Exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment excluding those included in the early exposure group

C.

CD	Hospitalisations *N* = 1341 Hazard ratio (95% confidence interval)	*p*
Smoker	1.4 (1.1–1.6)	< 0.001
Disease behaviour		
B1 (inflammatory)	Reference	
B2 (stricturing)	1.7 (1.3–2.2)	< 0.001
B3 (fistulising)	1.6 (1.3–2.1)	< 0.001
Exposure to biologics/JAKi before hospitalisation		
No exposure to treatments	Reference	
Exposure to treatments	0.4 (0.2–0.6)	< 0.001
Early exposure to treatments	0.5 (0.3–0.7)	< 0.001
Exposure to immunomodulators before hospitalisation		
No exposure to treatment	Reference	
Exposure to treatment	0.4 (0.3–0.6)	< 0.001
Early exposure to treatment	0.6 (0.4–0.8)	< 0.001

Note: Variables included in the multivariable Cox regression model: age, sex, diagnostic delay, smoking status, hospital complexity, disease behaviour, disease location, perianal disease, exposure to biologics/JAKi before hospitalisation, exposure to immunomodulators before hospitalisation and exposure to corticosteroids before hospitalisation. For clarity, only the most clinically relevant variables are presented in the table. Early exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment during the first 6 months after diagnosis. Exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment excluding those included in the early exposure group.

with a lower risk of surgery, both when used later during follow-up (HR = 0.2, 95% CI = 0.1–0.5) and when initiated early (HR = 0.3, 95% CI = 0.2–0.5). For hospitalisation in CD, smoking (HR = 1.4, 95% CI = 1.1–1.6), stricturing behaviour (HR = 1.7, 95% CI = 1.3–2.2) and fistulising behaviour (HR = 1.6, 95% CI = 1.3–2.1) were associated with increased risk, whereas exposure to biologics/JAKi was associated with a lower risk of hospitalisation, both when used later during follow-up (HR = 0.4,

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TABLE 4 | Predictors associated with biologics/JAKi use (A), surgeries (B) and hospitalisations (C) in patients with ulcerative colitis (UC).

A.

	Biologics/JAKi	
	***N*=1615**	
UC	**Hazard ratio (95% confidence interval)**	***p***
Age	0.99 (0.99–1.00)	0.047
Smoker	0.6 (0.4–0.9)	0.015
Extension		
Proctitis	Reference	
Left-side colitis	2.3 (1.6–3.4)	<0.001
Pancolitis	5.0 (3.6–7.0)	<0.001

Variables included in the multivariable Cox regression model: age, sex, symptoms at diagnosis, smoking status, hospital complexity, extent of ulcerative colitis and surgery at diagnosis. For clarity, only the most clinically relevant variables are presented in the table

B.

	Surgeries	
	***N*=1627**	
UC	**Hazard ratio (95% confidence interval)**	***p***
Extension		
Proctitis	Reference	
Left-side colitis	2.0 (0.5–7.5)	0.311
Pancolitis	2.3 (0.6–8.5)	0.199
Exposure to biologics/JAKi before surgery		
No exposure to treatment	Reference	
Exposure to treatment	2.7 (0.9–7.9)	0.068
Early exposure to treatment	11.9 (4.6–30.4)	<0.001
Exposure to immunomodulators before surgery		
No exposure to treatment	Reference	
Exposure to treatment	0.5 (0.2–1.6)	0.238
Early exposure to treatment	0.9 (0.4–2.2)	0.973

Variables included in the multivariable Cox regression model: age, sex, smoking status, extension, exposure to biologics/JAKi before surgery and exposure to immunomodulators before surgery. For clarity, only the most clinically relevant variables are presented in the table. Early exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment during the first 6 months after diagnosis. Exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment excluding those included in the early exposure group

C.

	Hospitalisations	
	***N*=1523**	
UC	**Hazard ratio (95% confidence interval)**	***p***
Extension		
Proctitis	Reference	
Left-side colitis	4.0 (2.8–5.7)	<0.001
Pancolitis	10.8 (7.8–14.9)	<0.001

(Continues)

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TABLE 4 | (Continued)

C.

	Hospitalisations	
	***N*=1523**	
UC	**Hazard ratio (95% confidence interval)**	***p***
Exposure to biologics/JAKi before hospitalisation		
No exposure to treatment	Reference	
Exposure to treatment	0.5 (0.2–0.9)	0.027
Early exposure to treatment	0.6 (0.2–2.1)	0.444
Exposure to immunomodulators before hospitalisation		
No exposure to treatment	Reference	
Exposure to treatment	0.7 (0.3–1.3)	0.245
Early exposure to treatment	0.8 (0.4–1.6)	0.475

Note: Variables included in the multivariable Cox regression model: age, sex, diagnostic delay, smoking status, hospital complexity, extension, exposure to biologics/JAKi before hospitalisation, exposure to immunomodulators before hospitalisation and exposure to corticosteroids before hospitalisation. For clarity, only the most clinically relevant variables are presented in the table. Early exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment during the first 6 months after diagnosis. Exposure to treatment: Patients who received immunosuppressive or biological/JAK inhibitor treatment excluding those included in the early exposure group.

95% CI=0.2–0.6) and when initiated early (HR=0.5, 95% CI=0.3–0.7).

In patients with UC, greater disease extent was associated with a higher likelihood of biologics/JAKi use, with left-sided colitis and pancolitis showing higher risks than proctitis (HR=2.3, 95% CI=1.6–3.4 and HR=5.0, 95% CI=3.6–7.0, respectively). Smoking was associated with a lower likelihood of biologics/JAKi use (HR=0.6, 95% CI=0.4–0.9). Disease extent was not significantly associated with abdominal surgery. However, early exposure to biologics/JAKi was associated with a higher risk of surgery (HR=11.9, 95% CI=4.6–30.4), whereas later exposure showed a non-significant trend in the same direction (HR=2.7, 95% CI=0.9–7.9). Regarding hospitalisation in UC, left-sided colitis and pancolitis were associated with a higher risk compared with proctitis (HR=4.0, 95% CI=2.8–5.7 and HR=10.8, 95% CI=7.8–14.9, respectively). Exposure to biologics/JAKi later during follow-up was associated with a lower risk of hospitalisation (HR=0.5, 95% CI=0.2–0.9), whereas early exposure was not significantly associated with this outcome (HR=0.6, 95% CI=0.2–2.1).

4 | Discussion

In this large multicentre incident cohort study, clinical characteristics, therapeutic interventions and predictive factors were assessed over a 5-year follow-up period in patients newly diagnosed with IBD in recent years.

One of the most significant findings in our study is the high proportion of patients who initiated biologics/JAKi therapy during the follow-up period, with rates exceeding those reported in previous studies [21, 22]. Previous evidence had already demonstrated a notable increase in the use of biological therapies over recent decades [21, 22, 28]; however, the results observed in our study showed significantly higher increases than those previously reported. For instance, in the EpiCom cohort, 33% of patients with CD from Western Europe received biological treatment during the first five years after diagnosis [21], whereas only 11% of those with UC were treated with biologics [22]. In our cohort, these rates were higher than previously reported, with approximately 50% of CD and 20% of UC patients initiating biologics/JAKi during the 5-year follow-up period. These findings indicate a clear shift in the management of IBD, characterised by increased utilisation of biologics/JAKi [29] and may therefore contribute to a more accurate understanding of the current treatment landscape for IBD.

Regarding hospitalisations and surgeries, the use of biologics/JAKi may be associated with a reduced need for hospital admissions and surgical interventions [30, 31]. However, long-term outcomes in real-world clinical practice remain controversial [9, 21, 22, 31–34]. In our cohort, 34% of patients required at least one hospitalisation within the first five years following diagnosis, with hospitalisation rates of 43% in patients with CD and 26% in those with UC. These values are slightly higher than those from previous studies reporting hospitalisation rates of 36% in patients with CD and 23% in those with UC within the first five years after diagnosis [21, 22]. In relation to surgeries, 9% of patients in our cohort underwent at least one surgical intervention during the first five years after diagnosis, including perianal and abdominal surgeries (16% in CD and 3% in UC). These numbers are lower than those reported in the aforementioned studies, in which the percentage of surgeries was 22% in CD and 6% in UC [21, 22]. The results also align with findings from more recent studies in patients with UC, which reported a decrease in the percentage of colectomies in recent years [35, 36].

In our study, differences in the management of CD were observed depending on hospital resources. For example, a higher use of biologics/JAKi was observed in CD patients at high-resources centres. Conversely, mesalazine use was more frequent in lower-resources centres. This variability in prescribing patterns may be related to the degree of professional specialisation.

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Higher-resources centres typically have Integrated Care Units for IBD, which likely facilitate the prescription of more innovative therapies supported by scientific evidence regarding their efficacy in inducing remission and controlling disease activity. Similarly, we were able to observe a higher rate of hospitalisations in high-resources centres compared to lower-resources hospitals, despite more frequent use of biologics/JAKi therapies in high-resources centres. This difference was particularly pronounced at the time of diagnosis. The greater availability of resources at high-resources centres may explain this difference because it facilitates hospitalisation of a larger number of patients during early disease stages for more comprehensive clinical evaluation and earlier treatment initiation, potentially contributing to more rapid symptom control. These findings are aligned with the ECCO quality-of-care framework [37], which emphasises the relevance of structural and process standards, multidisciplinary IBD care and equitable access to specialised services. In this context, reducing variability between centres should be considered a priority to ensure that all patients with IBD can benefit from timely assessment and appropriate access to advanced therapies.

In the analysis of predictive factors, a more aggressive phenotype of CD, greater extent of UC and younger age at diagnosis were primarily associated with the use of biologics/JAKi. A significant association was also identified between CD behaviour and the extent of UC with the likelihood of requiring surgery. Specifically, patients with a stricturing phenotype of CD had an almost 5-fold increased risk of undergoing surgery, while those with a fistulising phenotype showed an 8-fold higher risk compared to patients with an inflammatory behaviour. A similar trend was observed with hospitalisations, as patients with extensive UC had a 10-fold higher probability of hospital admission compared to those diagnosed with proctitis. These factors reflect a clinical profile of higher complexity, in which a more intensive therapeutic strategy is prioritised from early stages.

With respect to hospitalisation, we observed that the current use of biologics/JAKi was associated with a lower risk of hospital admissions in patients with CD and UC. This finding is particularly relevant, as previous studies, such as the EpiCom cohort, did not demonstrate a statistically significant association between the use of biologics and hospitalisation rates [21, 22, 38]. In this context, considering the increasingly earlier and widespread adoption of these treatments, it is reasonable to expect that future cohorts may reveal a more evident reduction in hospitalisation rates related to IBD.

Similarly, analysis of predictors for surgery showed that the use of immunosuppressive therapy (mainly thiopurines or methotrexate) was associated with a lower risk of surgery in patients with CD. This finding may be explained by the fact that patients receiving this drug class probably show features of a less aggressive disease course and thus a lower likelihood of requiring surgical intervention. In contrast, in our cohort, the use of biologics/JAKi was not associated with a reduced need for surgical intervention, even when treatment was initiated early. Indeed, our results revealed that patients with UC who were early exposed to biologics/JAKi had an 11-fold higher risk of requiring surgery compared to those who did not receive these treatments. These drugs are often prescribed in advanced stages of the disease, when the prognosis is already poor and surgery cannot be avoided despite treatment. These findings highlight the current limitations of routine clinical practice in accurately selecting patients who will truly benefit from such therapies. In this context, the recently published PROFILE study demonstrated that early use of biologic agents improves patient prognosis; however, in that study, these treatments were administered to all patients, including those who might not have actually required them [39].

The median age at diagnosis in our cohort was slightly higher than that reported in some previous European inception cohorts [40]. This may be partly explained by the inclusion of adult patients only, as well as by the broad case ascertainment strategy, which aimed to capture all incident cases diagnosed within the participating healthcare areas, including milder or incidentally diagnosed cases. In addition, demographic differences and population ageing may have contributed to this finding. Of note, the age at diagnosis observed in our cohort is in line with recent Southern European data, including Spanish studies from the Vigo area, in which the median age at diagnosis ranged from 39 to 43 years [15].

The main limitation of our study is a potential selection bias related to the participating centres. In addition, multivariable analyses were performed using complete-case datasets, as no imputation of missing data was undertaken. Although comparisons between included and excluded patients showed negligible to moderate differences for most baseline characteristics, excluded patients differed in some relevant characteristics, particularly age (Table S3). Therefore, the complete-case samples may not be fully representative of the eligible cohorts and the possibility of selection bias cannot be excluded. Nevertheless, the broad representation of participating hospitals allowed for comparisons between different types of institutions based on their available resources. Additionally, because the registry was designed primarily for epidemiological purposes, treatment exposure was recorded as the first initiation of each therapeutic group or mechanism of action. Although exposure to different therapeutic targets over time could be identified, switches between individual drugs within the same therapeutic group were not systematically captured. Therefore, complete advanced-therapy sequences, treatment persistence and predictors of sequential therapy use could not be reliably assessed. On the other hand, the study has several strengths, including its multicentre design, large sample size, inclusion of updated and recent data subjected to rigorous monitoring and the application of standardised criteria in data collection and analysis.

In conclusion, this large, prospective, multicentre incident cohort study observed a significant increase in the use of biologics/JAKi therapies compared to previous cohorts. This rise in the use of these therapies seems to be associated with a reduction in the need for hospitalisation among these patients. However, our study did not show a decrease in surgeries in patients treated with biologics (compared with those who were not treated). This might be explained by the fact that the use of advanced drugs is a marker for severe disease. However, we cannot rule out that earlier and more extensive use of biologics in severe patients might have reduced surgical rates. This increase did not correlate with a decrease in the frequency of surgical interventions. Taken altogether, our results reinforce the need to improve patient stratification through clinical tools and biomarkers aiming

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to more accurately identify, at an early stage, those patients who will benefit from intensive therapies, with the goal of significantly altering the natural history of their IBD.

Author Contributions

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Conflicts of Interest

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Data Availability Statement

The data underlying this article cannot be shared publicly due to the privacy of individuals that participated in the study. The data will be shared on reasonable request to the corresponding author.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** List of participating centres and number of patients included per centre. **Table S2:** Reasons for hospitalisation within the first 5 years after diagnosis. **Table S3:** Comparison of baseline characteristics between patients included in and excluded from the multivariable Cox regression analyses due to missing covariate data. (A) Comparison between Crohn's disease (CD) patients and (B) comparison between ulcerative colitis (UC) patients.

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