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### **► To cite this version:**

Vincent Haghnejad, Catherine Le Berre, Yoann Dominique, Camille Zallot, Francis Guillemin, et al.. Impact of a medical interview on the decision to switch from originator infliximab to its biosimilar in patients with inflammatory bowel disease. Digestive and Liver Disease, 2020, 52, pp.281 - 288. <10.1016/j.dld.2019.09.012>. <hal-03490002>

**HAL Id: hal-03490002**

**<https://hal.science/hal-03490002v1>**

Submitted on 22 Aug 2022

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*Manuscript number: DLD-19-393*

## **Impact of a medical interview on the decision to switch from originator infliximab to its biosimilar in patients with inflammatory bowel disease**

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*Electronic word count: 2,942*

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***Funding:*** No funding was provided for this study.

***Author contributions:***

VH collected data, interpreted data and drafted the manuscript. CLB drafted and critically revised the manuscript. YD and FG performed statistical analysis, interpreted data and critically revised the manuscript. CZ collected data. LPB designed the study, interpreted data and critically revised the manuscript. All authors read and approved the final version of the manuscript.

## **Abstract**

### **Background**

To lighten the burden on health-care spending, switching from the infliximab originator to a biosimilar in patients with inflammatory bowel disease (IBD) is advocated. However, the uptake of biosimilars lacks initiatives aimed at educating patients.

### **Aims**

To explore the impact of a gastroenterologist's interview on IBD patients' acceptance for switching from infliximab bio-originator Remicade® to its biosimilar CT-P13 Inflectra®.

### **Methods**

After the interview of 138 included patients, 120 properly responded to a self-administered questionnaire to collect consent about the switch and relevant data. French national IBD patients' association (Association François Aupetit) provided an information sheet on biosimilars.

### **Results**

93 (67.0%) out of 138 and 82 (68.3%) out of 120 patients switched treatment. 114 (79.8%) had never heard about biosimilars. Paradoxically, having heard about biosimilars was associated with a poorer chance to switch (Odds Ratio OR [95% CI]=0.13 [0.02-0.72]). On the contrary, the more satisfied about generics, the more patients accepted the switch (OR [95% CI]=1.31 [1.01-1.69]). There were 1.47 (Relative Risk RR [95 % CI]=1.47 [1.07-2.01]) times more chance to agree to the switch if the interview modified the patient's opinion on biosimilars.

**Conclusion**

This study confirms that an organized information provided to the patient is a contributive way to enhance patient's acceptance of biosimilars in IBD.

**Key words:** Crohn's disease, ulcerative Colitis, CT-P13, patient education.

## Introduction

Both Crohn's disease (CD) and ulcerative colitis (UC) are chronic and disabling inflammatory bowel diseases (IBD).[1,2] The addition of anti-TNF agents, including infliximab (IFX), to the IBD therapeutic armamentarium has dramatically improved the outcome of both diseases.[3,4] Subsequently, IBD costs have shifted from inpatient acute care services (hospitalization, surgery) to outpatient pharmacy utilization, especially anti-TNF $\alpha$  therapy, currently exceeding costs for inpatient care.[5] A study led in the USA over a 9-year period (2007-2015) included more than 400,000 IBD patients and showed that the proportion of patients using biologics increased from 21.8% to 43.8% for CD and from 5.1% to 16.2% for UC, leading to an increase in the share of costs for biologics from 72.9% in 2007 to 85.7%.[6] By 2020, global spending on medicines will reach \$1.4 trillion with \$390 billion spent on biologics.[6,7] However, this spending growth should be offset by patent expiries allowing pharmaceutical companies to develop biosimilars. Over the past few years, particular emphasis was placed on the development of these biological products that are highly similar to reference products and should offer potential savings of more than 40 billion dollars across Europe and the USA.[7]

In the field of IBD, the infliximab biosimilar CT-P13 (Inflectra<sup>®</sup>, Remsima<sup>®</sup>) was the first biosimilar developed and thoroughly investigated *versus* Remicade<sup>®</sup>, leading to its approval by the European Medicines Agency (EMA) in September 2013, then by the US Food and Drug Administration (FDA) in April 2016.[8] The European Crohn's and Colitis Organization (ECCO) now supports switching from the IFX originator to a biosimilar in patients with IBD based on a recent meta-analysis of 11 published studies including 829 patients that showed the absence of new safety and efficacy concerns compared to originator.[9,10]

This marks a significant shift in physicians' attitude from the previous ECCO statement that highlighted a lack of confidence in biosimilars and the need for continued education.[11] In

2014, the first online ECCO survey showed that some IBD experts still had a misconception between generics and biosimilars.[12] Following a more extensive use of biosimilars, a 2016 update of this survey revealed more confidence among IBD specialists with only 19.5% of respondents having little or no confidence in their use, as compared with 63% in 2013.[13]

Furthermore, as active involvement of patients in treatment decisions is advocated, attitudes of patients regarding the use of biosimilars are also important to take into account.[14–18]

Strikingly, a survey led by the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) revealed that only 36.2% of patients had heard about biosimilars even though 45.0% of them were currently treated with biologics. Furthermore, 75.0% of respondents were concerned about biosimilars in terms of efficacy, safety and molecular basis.[18] Another study demonstrated that only 6% of the general population had heard about biosimilars but awareness was higher (20%–30%) in patients diagnosed with a disease for which one or more biologic therapy is available and who were members of a patient advocacy group.[19]

These results suggest that patient and physician communication is important for a proper uptake of biosimilars, but there is a lack of incentives aimed at educating patients.[20] The objectives of this study were to explore the impact of a medical interview on IBD patients' acceptance for switching from IFX bio-originator to its biosimilar, to inform and to understand patients' satisfaction and concerns regarding the use of biosimilars and to compare it with generics' perception.

## **Materials and Methods**

### **Study design and setting**

Patients were prospectively recruited between November 2017 and April 2018 during their infusion of Remicade® in the Medical Day Hospital of Nancy University Hospital. Patients went through an interview with the same gastroenterologist prior to every drug administration according to a structured baseline guaranteeing that the same information was given to all patients. This structured baseline was discussed prior to the beginning of the study by agreement with two other gastroenterologists responsible for the patients treated by infliximab and one pharmacist in order to make sure that it was in accordance with actual statements. During this interview, all patients eligible for inclusion were offered the possibility of switching from Remicade® to its biosimilar Inflectra®. Patients were provided with all relevant information regarding this therapeutic agent, and the potential consequences expected from the switch in terms of efficacy, safety, biosimilarity and costs. Patients were allowed time to ask any questions. At the end of the interview, all included patients received an information sheet (see Supplementary data 1) provided by the French national IBD patients' association (Association François Aupetit (AFA)), as a support measure to summarize relevant data discussed during the interview about biosimilars. After having received this information sheet, all patients responded to a self-administered questionnaire.

The questionnaire (see Supplementary data 2) consisted of four distinct parts: (i) the first part collected socio-demographic data, (ii) the second part aimed to collect clinical data regarding patient's disease, (iii) the third part assessed patient's knowledge regarding biosimilars, collected their opinion about the switch and the influence the medical interview might have had on their choice, (iv) the last part evaluated their experience in the use of generic drugs, with a satisfaction score based on a visual analog scale ranging from 0 to 10, assessing



efficacy, adverse effects, administration frequency and discomfort, impact on daily routine and global satisfaction with generic drugs.

### **Study population**

Patients of both sexes aged over 18, with an established diagnosis of IBD (Crohn's disease, ulcerative colitis or IBD unclassified), may be included in this study if they were currently treated and received at least one infusion of Remicade® as a maintenance therapy. No limits were set about prior or concomitant therapies. Non-inclusion criteria included insufficient command of French language and relevant psychiatric comorbidities, both of them making the patient unwilling to answer the self-questionnaire and give consent.

### **Data collection**

The information collected was strictly limited to the purpose of this study. Data were provided by patients themselves or extracted from their electronic medical record. The management of the electronic dataset was realized under conditions guaranteeing the confidentiality of data and the anonymity of patients.

### **Statistical analysis**

#### *Descriptive statistics*

Patients' characteristics were described overall and stratified by acceptance of the switch, by using mean and standard deviation (SD) or median and interquartile range (IQR) for quantitative variables, depending on the normality of their distribution, and numbers and percentages for categorical variables.

#### *Analytical statistics*

Acceptance of the switch was compared using ANOVA or Kruskal-Wallis test for quantitative variables, and Chi-square or Fisher's exact test for qualitative variables, according to conditions of use. Relative risks evaluated the effect of the interview on the decision to switch from the bio-originator to its biosimilar with the modification of opinion about biosimilars following the interview as the exposition variable. Patients having agreed to switch will later be referred to as S+, and patients who refused the switch will be called S-.

We used SAS 9.4 software (SAS Institute, Inc., Cary, NC) for the analyses, with a significance level set at 0.05. The multivariate logistic regression was performed with a threshold for entrance set at  $p=0.1$  and a threshold for exclusion set at  $p=0.05$ . The following variables were retained into the model: influence of the interview on the decision to switch, having heard about biosimilars, satisfaction scores concerning generic drugs and the annual recourse to a general practitioner.

## Results

Figure 1 describes the flowchart of the study. One hundred and forty-three patients underwent an interview with a doctor, of whom 138 patients gave their opinion on the switch and 120 fully completed the questionnaire with interpretable data.

### Comparison of patients according to the type of inflammatory bowel disease

#### *Socio-demographic and clinical data (Table 1)*

The patient followed for microscopic colitis was excluded from this analysis. Patients with Crohn's disease (n=95) were significantly younger than patients with ulcerative colitis (n=24) at the time of inclusion (mean $\pm$ SD, 41.1 $\pm$ 14.1 vs. 47.8 $\pm$ 15.2 years old, p=0.042) and at diagnosis (26.6 $\pm$ 13.7 vs. 33.1 $\pm$ 15.5 years old, p=0.047). CD patients were logically less frequently exposed to 5-ASA (42.2% vs. 100%, p<0.001). Harvey Bradshaw Index for patients with CD was lower than 4 except for 2 patients out of 95 (mean value 1, IQR 0-2). In patients with UC, mean Mayo score was 0 (IQR: 0-0.5). Disease activity was not significantly associated with the decision to switch in both diseases.

#### *Regarding the use of generics and biosimilars (Table 2)*

Patients with CD switched to Inflectra<sup>®</sup> more often than patients with UC (72.6% vs. 50%, p=0.034). They were also more frequently influenced by the medical interview (65.3% vs. 41.7%, p=0.035) and they would have taken another decision without the interview more often than patients with UC (35.8% vs. 8.3%, p=0.011). Satisfaction scores concerning generic drugs were not significantly associated with the type of IBD (p>0.05).

### Factors associated with the decision to switch from infliximab originator to its biosimilar

#### *Socio-demographic and clinical data (Table 3)*

Socio-demographic and clinical data did not differ significantly between both groups except for the previous use of 5-ASA which was less frequent in S- patients than in S+ patients (46.9% vs. 70.6%,  $p=0.020$ ).

*Regarding the use of generics and biosimilars (Table 4)*

Paradoxically, S+ patients had less frequently heard about biosimilars than S- patients (14.6% vs. 32.4%,  $p=0.025$ ). S+ patients changed their opinion about biosimilars following the medical interview more frequently than S- patients (73.2% vs. 47.4%,  $p=0.006$ ). S+ patients also declared that their decision to switch had been influenced by the medical interview significantly more than S- patients (82.9% vs. 13.2%,  $p<0.001$ ) and that they would have taken another decision without the interview more often than S- patients (40.2% vs. 7.9%,  $p<0.001$ ).

Interestingly, S+ patients had been more frequently treated with generic drugs in the past (81.7% vs. 57.9%,  $p=0.006$ ) and tolerated them better than S- patients (89.6% vs. 63.6%,  $p=0.005$ ). The mean global satisfaction score related to generic drugs was significantly higher in S+ patients than in S- patients ( $p=0.006$ ).

Patients who had already heard about biosimilars less frequently changed their opinion after the interview (45.8% vs. 54.2%,  $p=0.03$ ). Patients declaring that the interview modified their opinion were more frequently influenced by the interview (78.2% vs. 21.8%,  $p<0.001$ ). They also would have taken another decision without the interview (39.7% vs. 60.3%,  $p=0.002$ ).

### **Relative risk**

Before the interview, 40 patients (33.3%) were ready to accept the switch. Following the interview with a doctor, 18 patients (15%) backed off while 60 patients (50%) were convinced to switch. There are 1.47 (Relative Risk RR [95 % CI]=1.47 [1.07-2.01]) times more chance to agree to the switch if the interview modified the patient's opinion on biosimilars.

**Multivariate analysis (Table 5)**

Age, type of IBD and other additional effects did not meet the 0.05 significance level for entry into the model. Acceptance of the switch was higher in patients having been influenced by the medical interview (Odds Ratio OR [95 % Confidence Interval CI]=60.74 [12.08-305.50]) as well as in patients satisfied about generics (OR [95% CI]=1.31 [1.01-1.69]). Having heard about biosimilars was associated with a poorer chance to switch (OR [95% CI]=0.13 [0.02-0.72]). The higher the annual attending to general practice was, the more patients tended to refuse the switch (OR [95% CI]=0.88 [0.78-1.00]). The chance to accept switching fell by 12% ( $1-0.88=0.12$ ) for every 1 consult increase in the annual attending to general practice.

## Discussion

This survey is the first study to show that a medical interview with a gastroenterologist prior to a switch from Remicade® to its biosimilar Inflectra® allows a better acceptance in two-thirds of patients diagnosed with inflammatory bowel disease.

A major result seems to be the change of opinion following the medical interview. Indeed, before the interview, only 33% of patients were ready to accept the switch, increasing to 50% following this interview, even though 15% of patients drew back after having received the information. This fact supports the concept of shared decision making to facilitate public health policies.[21,22] Until now, there has not been a proper European systematic effort at educating patients about biosimilars, and incentives to encourage the prescription of such products depend on country policies.[23] For example, in May 2015, the Danish Health Authority dictated a mandatory switch from originator IFX to its biosimilar CT-P13 in patients with inflammatory arthritis.[24] As a result, the uptake of biosimilars reached 97% prevalence[25] but this attitude has generated some fears amongst patients[25,26]. As a consequence, a national plan, launched in August 2015 and implemented throughout 2016 targeted both doctors and patients to address concerns over a potential ‘nocebo’ effect.[26] Hence, it seems that educating professionals and patients remains essential to avoid the pitfall observed for generic drugs a few decades earlier.[27] In England, the National Health Service (NHS) has established a sub-group of people focused on the development of education and communication materials about biosimilars for professionals and patients.[28] In France, education about biosimilars is regulated at hospital levels [23] and our study demonstrates that a proper information delivered at the hospital level considerably fastens the uptake of biosimilars.

Four-fifths (79.8%) of total respondents had never heard about biosimilars, confirming that there remains an urging need for education about biosimilars.[18,19] However, such levels of

awareness were attained before only in patients who were members of an advocacy group, while only 6 patients (5%) of our cohort were affiliated to the French patients' association AFA.(19) This might be related to a local decision to inform and educate IBD patients about biosimilars, reflected by the fact that, among patients who had heard about biosimilars, it was thanks to a gastroenterologist in 43% of cases. This fact is concordant with previous studies showing an increase in physicians' awareness regarding biosimilars and their sensitization to educate patients.[13,29]

Strikingly, having heard about biosimilars was paradoxically associated with a poorer chance to switch ( $OR=0.13$ ). Beyond gastroenterologist-patient dialogue, this suggests that physician's communication skills are a key in convincing patients, as illustrated in other studies,[17,30] since the majority of patients accepted the switch nonetheless. This is reinforced by the fact that the more patients had recourse to their general practitioner, the more they tended to refuse the switch ( $OR=0.88$ ). This might suggest that non-gastroenterological information sources are less reassuring and may potentially generate some worries and reservations as already evoked by Zelante *et al.*[31] This finding suggests that efforts have to be made with general practitioners since they are the frontline in communicating with patients. Different communication strategies could be implemented notably through IBD nurses to convey the concept of biosimilars. Indeed, the updated Nurses–European Crohn's and Colitis Organization statements recently acknowledge that IBD nurses are pivotal in managing the challenges associated with patients transitioning to biosimilars.[32,33]

By contrast, in both Crohn's disease and ulcerative colitis, global satisfaction with generic drugs was found to be associated with the switch acceptance ( $OR=1.31$ ). However, it is important to note that patients with CD accepted to switch more often than patients with UC (72.6% vs. 50%). Interestingly, CD patients were significantly younger than UC patients but

whether a young age is predictive of a better acceptance for the switch is uncertain. Indeed, the type of IBD was not retained in our multivariate model, suggesting a selection bias. One study led on a total of 559 IBD patients showed that age (OR=2.0) and follow-up by a gastroenterologist (OR=3.0) were factors independently associated with greater adherence to medical therapy as opposed to young females followed-up by general practitioners.[31] Thus, further studies promoted by public health policies should investigate the impact of information sources on patients' health decision in order to promote evidence-based communication skills when discussing with a patient.

Our study has some limitations. First, even if the cohort is substantial, it might not be representative of the general population due to its monocentric nature led in a tertiary care center that may cause selection bias. Secondly, this study was performed in France, a country with an advanced healthcare system and broad access to biologic therapy, making our results difficult to extrapolate to other countries worldwide. Further, although our data were collected prospectively, this was an observational study and we cannot exclude confounding factors especially concerning the association between the type of IBD, the age and the decision to switch. In this study, being affiliated to a patient advocacy group was not associated with a better acceptance of the switch but this may be due to the low proportion (5%) of patients affiliated to the French IBD patients' association. Further studies are required with larger proportions of affiliated patients in order to explore the impact of this type of advocacy groups. Moreover, in addition to the medical interview, all included patients received an information sheet summarizing the most relevant data about biosimilars, but the impact of this information sheet on the switch has not been investigated in the questionnaire. This should also be investigated in further studies in order to determine if a written information could help in patient's decision-making process regarding the switch acceptance. Lastly, it is important



to note that this study focused on infliximab biosimilars and it seems difficult to extrapolate our results to adalimumab biosimilars.

In conclusion, this study confirms that an organized and structured information provided to the patient is a contributive tool to enhance patient's acceptance of biosimilars in IBD. It highlights that urging efforts of education remain to be made for the uptake of biosimilars in daily practice and confirms that patients are ready to be involved in decision making when starting a biosimilar. Informing general practitioner via educational program is advisable and this could be implemented with IBD nurses and local or national support. Further studies are required to assess physicians' and patients' understanding and concerns of using biosimilars, in order to adjust this educational program to every country across the world.

## **Acknowledgements**

Myriam Choukour.

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**Figure legends**

S+: patients having agreed to switch from infliximab originator Remicade® to its biosimilar Inflectra®.

S-: patients having refused the switch.

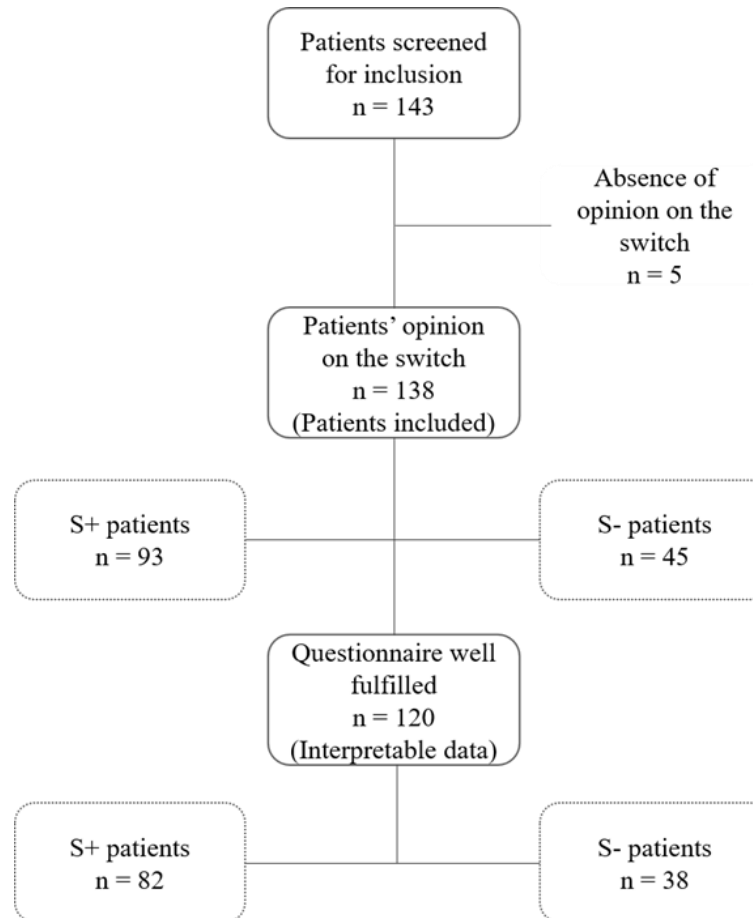




Table 1. Comparison of socio-demographic and clinical data between patients with Crohn's disease and patients with ulcerative colitis (n=119).

	Total (n=119)	Crohn's disease (n=95)	Ulcerative colitis (n=24)	p*
<b>Socio-demographic data</b>				
Gender				0.252
▪ Male, n (%)	67 (56.3)	51 (53.7)	16 (66.7)	-
▪ Female, n (%)	52 (43.7)	44 (46.3)	8 (33.3)	-
Age (years), mean (SD)	42.4 (14.5)	41.1 (14.1)	47.8 (15.2)	<b>0.042</b>
Social category				0.144
▪ Craftsman, n (%)	3 (2.5)	3 (3.2)	0 (0.0)	-

▪ Worker, n (%)	16 (13.4)	14 (14.7)	2 (8.3)	-
▪ Employee, n (%)	51 (42.9)	42 (44.2)	9 (37.5)	-
▪ Senior manager, n (%)	12 (10.1)	6 (6.3)	6 (25.0)	-
▪ Retired, n (%)	15 (12.6)	10 (10.5)	5 (20.8)	-
▪ Student, n (%)	11 (9.2)	10 (10.5)	1 (4.2)	-
▪ Unemployed, n (%)	6 (5.0)	6 (6.3)	0 (0.0)	-
▪ Disabled, n (%)	5 (4.2)	4 (4.2)	1 (4.2)	-

#### Living area

1.000

▪ Major town (>100,000 inhabitants), n (%)	25 (21.0)	20 (21.1)	5 (20.8)	-
▪ Medium town (20,000-100,000 inhabitants), n (%)	13 (10.9)	11 (11.6)	2 (8.3)	-
▪ Small town (<20,000 inhabitants), n (%)	24 (20.2)	19 (20.0)	5 (20.8)	-
▪ Countryside, n (%)	57 (47.9)	45 (47.4)	12 (50.0)	-

Clinical data				
Date of diagnosis, mean (IQR)	2005 (1999-2010)	2005 (2000-2010)	2004 (1997-2008)	0.909
Age at diagnosis (years), mean (SD)	27.9 (14.3)	26.6 (13.7)	33.1 (15.5)	<b>0.047</b>
Affiliated to a patient advocacy group				0.599
▪ Yes, n (%)	6 (5.0)	4 (4.2)	2 (8.3)	-
▪ No, n (%)	113 (95.0)	91 (95.8)	22 (91.7)	-
Annual number of consultations with a GP, mean (SD)	4.3 (4.7)	4.5 (5.1)	3.5 (2.6)	0.860
Annual number of consultations with a gastroenterologist, mean (SD)	0.9 (0.7)	1.0 (0.8)	0.8 (0.6)	0.222
Smoking status				0.051
▪ Never smoker, n (%)	69 (59.0) <sup>a</sup>	52 (54.7)	17 (77.3) <sup>a</sup>	-
▪ Past smoker, n (%)	14 (12.0) <sup>a</sup>	11 (11.6)	3 (13.6) <sup>a</sup>	-
▪ Active smoker, n (%)	34 (29.1) <sup>a</sup>	32 (33.7)	2 (9.1) <sup>a</sup>	-

Previous IBD-related treatment				-
▪ Corticosteroids, n (%)	101 (88.6) <sup>b</sup>	77 (85.6) <sup>b</sup>	24 (100.0)	0.067
▪ 5-ASA, n (%)	62 (54.4) <sup>b</sup>	38 (42.2) <sup>b</sup>	24 (100.0)	<b>&lt;0.001</b>
▪ Azathioprine, n (%)	82 (71.3) <sup>c</sup>	64 (70.3) <sup>c</sup>	18 (75.0)	0.653
▪ Methotrexate, n (%)	24 (21.1) <sup>b</sup>	17 (18.9) <sup>b</sup>	7 (29.2)	0.273
▪ Anti-TNF alpha other than infliximab, n (%)	14 (12.3) <sup>b</sup>	10 (11.1) <sup>b</sup>	4 (16.7)	0.489
Start date of anti-TNF alpha, mean (IQR)	2010 (2006-2012)	2010 (2007-2012)	2009 (2005-2013)	0.641
Duration of anti-TNF exposure (years), mean (SD)	8.8 (4.1)	8.7 (4.2)	9.2 (3.8)	0.641
Duration between diagnosis and start of anti-TNF (years), mean (SD)	5.8 (6.8)	5.8 (7.1)	5.5 (5.6)	0.857
Clinical activity				-
▪ Harvey-Bradshaw Index, mean (IQR)	-	1 (0-2)	-	-
▪ Partial Mayo score, mean (IQR)	-	-	0 (0-0.5)	-

Hospitalization during the past 12 months, n (%)	10 (8.4)	10 (10.5)	0 (0.0)	0.209
Allergic reactions				
▪ History of allergic reactions	13 (10.9)	12 (12.6)	1 (4.2)	0.462
▪ Number of allergic reactions, mean (SD)	2.0 (1.7)	2.0 (1.7)	0.0 (0.0)	-
▪ Type of allergic reactions				1.000
○ Pruritus, erythema, n (%)	9 (75.0) <sup>d</sup>	8 (72.7) <sup>d</sup>	1 (100.0)	-
○ Dyspnea, n (%)	2 (16.7) <sup>d</sup>	2 (18.2) <sup>d</sup>	0.0 (0.0)	-
○ Other	1 (8.3) <sup>d</sup>	1 (9.1) <sup>d</sup>	0.0 (0.0)	-

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<sup>a</sup>: 2 missing data; <sup>b</sup>: 5 missing data; <sup>c</sup>: 4 missing data; <sup>d</sup>: 1 missing data.

ASA: Aminosalicylate; GP: General practitioner; IBD: Inflammatory bowel disease; IQR: Interquartile range; SD: Standard deviation; TNF: Tumour necrosis factor.

\*: Chi-square or Fisher's exact test for qualitative variables, Student's *t*-test or the Wilcoxon signed-rank test for quantitative variables, acceptance of the switch was compared using ANOVA or Kruskal-Wallis test for quantitative variables, and, according to conditions of use.

Table 2. Results of the questionnaire regarding the use of biosimilars and generic drugs and comparison according to the type of inflammatory bowel disease (n=119).

Items of the questionnaire	Total (n=119)	Crohn's disease (n=95)	Ulcerative colitis (n=24)	p*
<b>Biosimilars</b>				
<b>Have you ever heard about biosimilars?</b>				0.156
Yes, n (%)	24 (20.3)	22 (23.2)	2 (8.7) <sup>a</sup>	-
No, n (%)	94 (79.7)	73 (76.8)	21 (91.3) <sup>a</sup>	-
<b>If yes, from where?<sup>b</sup></b>				1.000
General practitioner, n (%)	1 (4.8)	1 (5.0)	0 (0.0)	-
Gastro-enterologist, n (%)	9 (42.9)	8 (40.0)	1 (100.0)	-
AFA, n (%)	2 (9.5)	2 (10.0)	0 (0.0)	-

Media, n (%)	1 (4.8)	1 (5.0)	0 (0.0)	-
Other, n (%)	8 (38.1)	8 (40.0)	0 (0.0)	-
<b>Are you ready to switch?</b>				<b>0.034</b>
Yes, n (%)	81 (68.1)	69 (72.6)	12 (50.0)	-
No, n (%)	38 (31.9)	26 (27.4)	12 (50.0)	-
<b>Has the medical interview changed your opinion about biosimilars?</b>				<b>0.092</b>
Yes, n (%)	77 (64.7)	65 (68.4)	12 (50.0)	-
No, n (%)	42 (35.3)	30 (31.6)	12 (50.0)	-
<b>Has the interview influenced your decision to switch?</b>				<b>0.035</b>
Yes, n (%)	72 (60.5)	62 (65.3)	10 (41.7)	-
No, n (%)	47 (39.5)	33 (34.7)	14 (58.3)	-
<b>Would you have taken another decision without the information provided by the doctor?</b>				<b>0.011</b>
Yes, n (%)	36 (30.3)	34 (35.8)	2 (8.3)	-
No, n (%)	83 (69.7)	61 (64.2)	22 (91.7)	-

## Generics

**Have you ever been treated with generics?** 0.153

Yes, n (%)	88 (73.9)	73 (76.8)	15 (62.5)	-
No, n (%)	31 (26.1)	22 (23.2)	9 (37.5)	-
<b>If yes, have you tolerated them well?<sup>c</sup></b>				1.000
Yes, n (%)	74 (84.1)	61 (83.6)	13 (86.7)	-
No, n (%)	14 (15.9)	12 (16.4)	2 (13.3)	-
<b>If no, why?<sup>d</sup></b>				0.683
Refusal, n (%)	11 (35.5)	7 (31.8)	4 (44.4)	-
Never prescribed, n (%)	20 (64.5)	15 (68.2)	5 (55.6)	-
<b>Satisfaction score for generics</b>				-
▪ Efficacy, mean (SD)	6.7 (2.6)	6.7 (2.7)	6.5 (2.2)	0.709
▪ Adverse effects, mean (SD)	6.6 (2.8)	6.7 (2.8)	6.0 (2.8)	0.240
▪ Administration frequency, mean (SD)	6.9 (2.6)	7.1 (2.6)	6.4 (2.7)	0.248
▪ Administration discomfort, mean (SD)	7.0 (2.8)	7.2 (2.7)	6.2 (2.9)	0.119
▪ Impact on your daily routine, mean (SD)	6.8 (2.8)	6.9 (2.9)	6.5 (2.4)	0.447
▪ Global satisfaction, mean (SD)	6.6 (2.9)	6.7 (2.9)	6.4 (2.5)	0.670

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<sup>a</sup>: 1 missing data; <sup>b</sup>: Based on the patients who have already heard about biosimilars, 4 missing data; <sup>c</sup>: Based on the patients who have already been treated with generic drugs; <sup>d</sup>: Based on the patients who have never been treated with generic drugs.

AFA: Association François Aupetit; SD: Standard deviation.

\*: Chi-square or Fisher's exact test for qualitative variables, Student's *t*-test or the Wilcoxon signed-rank test for quantitative variables, acceptance of the switch was compared using ANOVA or Kruskal-Wallis test for quantitative variables, and, according to conditions of use.

Table 3. Socio-demographic and clinical data of included patients (n=120) and comparison according to the decision to switch from Remicade® to Inflectra®.

	Total (n=120)	Switch acceptance (n=82)	Switch refusal (n=38)	p*
<b>Socio-demographic data</b>				
Gender				0.135
▪ Male, n (%)	67 (55.8)	42 (51.2)	25 (65.8)	-
▪ Female, n (%)	53 (44.2)	40 (48.8)	13 (34.2)	-
Age (years), mean (SD)	42.6 (14.6)	41.6 (13.9)	44.6 (15.8)	0.307
Social category				0.570

▪ Craftsman, n (%)	3 (2.5)	1 (1.2)	2 (5.3)	-
▪ Worker, n (%)	16 (13.3)	11 (13.4)	5 (13.2)	-
▪ Employee, n (%)	51 (42.5)	36 (43.9)	15 (39.5)	-
▪ Senior manager, n (%)	12 (10.0)	7 (8.5)	5 (13.2)	-
▪ Retired, n (%)	15 (12.5)	8 (9.8)	7 (18.4)	-
▪ Student, n (%)	11 (9.2)	9 (11.0)	2 (5.3)	-
▪ Unemployed, n (%)	6 (5.0)	5 (6.1)	1 (2.6)	-
▪ Disabled, n (%)	6 (5.0)	5 (6.1)	1 (2.6)	-
Living area				0.322
▪ Major town (>100,000 inhabitants), n (%)	25 (20.8)	14 (17.1)	11 (28.9)	-
▪ Medium town (20,000-100,000 inhabitants), n (%)	14 (11.7)	11 (13.4)	3 (7.9)	-
▪ Small town (<20,000 inhabitants), n (%)	24 (20.0)	15 (18.3)	9 (23.7)	-

▪ Countryside, n (%)	57 (47.5)	42 (51.2)	15 (39.5)	-
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## Clinical data

Type of IBD				0.077
▪ Crohn's disease, n (%)	95 (79.2)	69 (84.1)	26 (68.4)	-
▪ Ulcerative colitis, n (%)	24 (20.0)	12 (14.6)	12 (31.6)	-
▪ Microscopic colitis, n (%)	1 (0.8)	1 (1.2)	0 (0.0)	-
Date of diagnosis, mean (IQR)	2005 (1999-2010)	2005 (1998-2009)	2004 (2002-2010)	0.406
Age at diagnosis (years), mean (SD)	28.1 (14.4)	26.8 (13.1)	31.0 (16.6)	0.134
Affiliated to a patient advocacy group				1.000
▪ Yes, n (%)	6 (5.0)	4 (4.9)	2 (5.3)	-
▪ No, n (%)	114 (95.0)	78 (95.1)	36 (94.7)	-
Annual number of consultations with a GP, mean (SD)	4.3 (4.7)	3.8 (3.4)	5.2 (6.6)	0.551

Annual number of consultations with a gastroenterologist, mean (SD)	0.9 (0.7)	0.8 (0.7)	1.1 (0.8)	0.072
Smoking status				0.095
▪ Never smoker, n (%)	69 (58.5) <sup>a</sup>	42 (51.9) <sup>b</sup>	27 (73.0) <sup>b</sup>	-
▪ Past smoker, n (%)	15 (12.7) <sup>a</sup>	13 (16.0) <sup>b</sup>	2 (5.4) <sup>b</sup>	-
▪ Active smoker, n (%)	34 (28.8) <sup>a</sup>	26 (32.1) <sup>b</sup>	8 (21.6) <sup>b</sup>	-
Previous IBD-related treatment				-
▪ Corticosteroids, n (%)	102 (88.7) <sup>c</sup>	71 (87.7) <sup>b</sup>	31 (91.2) <sup>d</sup>	0.752
▪ 5-ASA, n (%)	62 (53.9) <sup>c</sup>	38 (46.9) <sup>b</sup>	24 (70.6) <sup>d</sup>	<b>0.020</b>
▪ Azathioprine, n (%)	83 (71.6) <sup>d</sup>	61 (75.3) <sup>b</sup>	22 (62.9) <sup>e</sup>	0.173
▪ Methotrexate, n (%)	24 (20.9) <sup>c</sup>	17 (21.0) <sup>b</sup>	7 (20.6) <sup>d</sup>	0.962
▪ Anti-TNF alpha other than infliximab, n (%)	14 (12.2) <sup>c</sup>	8 (9.9) <sup>b</sup>	6 (17.6) <sup>d</sup>	0.245
Start date of infliximab, mean (IQR)	2010 (2006-2012)	2011 (2007-2013)	2007 (2005-2012)	0.168

Duration of anti-TNF exposure (years), mean (SD)	8.8 (4.1)	8.4 (4.1)	9.6 (4.1)	0.168
Duration between diagnosis and start of anti-TNF (years), mean (SD)	5.8 (6.8)	6.5 (7.5)	4.2 (4.4)	0.093
Clinical activity				-
▪ Harvey-Bradshaw Index, mean (IQR)	1 (0-2)	1 (0-2)	1 (0-2)	0.859
▪ Mayo score, mean (IQR)	0 (0-0.5)	0 (0-0.5)	0 (0-0.5)	1.000
Hospitalization during the past 12 months, n (%)	10 (8.3)	6 (7.3)	4 (10.5)	0.724
Allergic reactions				
▪ History of allergic reactions	13 (10.8)	7 (8.5)	6 (15.8)	0.234
▪ Number of allergic reactions, mean (SD)	2.0 (1.7)	0 (0.0)	2.0 (1.7)	-
▪ Type of allergic reactions <sup>b</sup>				1.000
○ Pruritus, erythema, n (%)	9 (75.0)	5 (83.3)	4 (66.7)	-
○ Dyspnea, n (%)	2 (16.7)	1 (16.7)	1 (16.7)	-

○ Other	1 (8.3)	0 (0.0)	1 (16.7)	-
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<sup>a</sup>: 2 missing data; <sup>b</sup>: 1 missing data; <sup>c</sup>: 5 missing data; <sup>d</sup>: 4 missing data; <sup>e</sup>: 3 missing data.

ASA: Aminosalicylate; GP: General practitioner; IBD: Inflammatory bowel disease; IQR: Interquartile range; SD: Standard deviation; TNF: Tumour necrosis factor.

\*: Chi-square or Fisher's exact test for qualitative variables, Student's *t*-test or the Wilcoxon signed-rank test for quantitative variables, acceptance of the switch was compared using ANOVA or Kruskal-Wallis test for quantitative variables, and, according to conditions of use.

Table 4. Results of the questionnaire regarding the use of biosimilars and generic drugs and comparison according to the decision to switch from Remicade® to Inflectra®.

Items of the questionnaire	Total (n=120)	Switch acceptance (n=82)	Switch refusal (n=38)	p*
<b>Biosimilars</b>				
<b>Have you ever heard about biosimilars?</b>				<b>0.025</b>
Yes, n (%)	24 (20.2) <sup>a</sup>	12 (14.6)	12 (32.4) <sup>a</sup>	-
No, n (%)	95 (79.8) <sup>a</sup>	70 (85.4)	25 (67.6) <sup>a</sup>	-
<b>If yes, from where?<sup>b</sup></b>				<b>0.577</b>
General practitioner, n (%)	1 (4.8)	1 (9.1)	0 (0.0)	-
Gastro-enterologist, n (%)	9 (42.9)	4 (36.4)	5 (50.0)	-
AFA, n (%)	2 (9.5)	2 (18.2)	0 (0.0)	-



Media, n (%)	1 (4.8)	0 (0.0)	1 (10.0)	-
Other, n (%)	8 (38.1)	4 (36.4)	4 (40.0)	-
<b>Are you ready to switch?</b>				
Yes, n (%)	82 (68.3)	-	-	-
No, n (%)	38 (31.7)	-	-	-
<b>Has the medical interview changed your opinion about biosimilars?</b>				<b>0.006</b>
Yes, n (%)	78 (65.0)	60 (73.2)	18 (47.4)	-
No, n (%)	42 (35.0)	22 (26.8)	20 (52.6)	-
<b>Has the interview influenced your decision to switch?</b>				<b>&lt;0.001</b>
Yes, n (%)	73 (60.8)	68 (82.9)	5 (13.2)	-
No, n (%)	47 (39.2)	14 (17.1)	33 (86.8)	-
<b>Would you have taken another decision without the information provided by the doctor?</b>				<b>&lt;0.001</b>
Yes, n (%)	36 (30.0)	33 (40.2)	3 (7.9)	-
No, n (%)	84 (70.0)	49 (59.8)	35 (92.1)	-
<b>Generics</b>				
<b>Have you ever been treated with generics?</b>				<b>0.006</b>

Yes, n (%)	89 (74.2)	67 (81.7)	22 (57.9)	-
No, n (%)	31 (25.8)	15 (18.3)	16 (42.1)	-
<b>If yes, have you tolerated them well?<sup>c</sup></b>				<b>0.005</b>
Yes, n (%)	74 (83.1)	60 (89.6)	14 (63.6)	-
No, n (%)	15 (16.9)	7 (10.4)	8 (36.4)	-
<b>If no, why?<sup>d</sup></b>				0.135
Refusal, n (%)	11 (35.5)	3 (20.0)	8 (50.0)	-
Never prescribed, n (%)	20 (64.5)	12 (80.0)	8 (50.0)	-
<b>Satisfaction score for generics</b>				-
▪ Efficacy, mean (SD)	6.6 (2.6)	7.1 (2.5)	5.6 (2.7)	<b>0.006</b>
▪ Adverse effects, mean (SD)	6.5 (2.8)	7.0 (2.7)	5.5 (3.0)	<b>0.007</b>
▪ Administration frequency, mean (SD)	6.9 (2.6)	7.3 (2.5)	5.9 (2.8)	<b>0.008</b>
▪ Administration discomfort, mean (SD)	6.9 (2.8)	7.4 (2.6)	5.9 (3.0)	<b>0.009</b>
▪ Impact on your daily routine, mean (SD)	6.8 (2.8)	7.2 (2.7)	5.9 (3.0)	<b>0.027</b>
▪ Global satisfaction, mean (SD)	6.6 (2.9)	7.1 (2.7)	5.5 (3.1)	<b>0.006</b>

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<sup>a</sup>: 1 missing data; <sup>b</sup>: Based on the patients who have already heard about biosimilars, 3 missing data; <sup>c</sup>: Based on the patients who have already been treated with generic drugs; <sup>d</sup>: Based on the patients who have never been treated with generic drugs.

AFA: Association François Aupetit; SD: Standard deviation.

\*: Chi-square or Fisher's exact test for qualitative variables, Student's *t*-test or the Wilcoxon signed-rank test for quantitative variables, acceptance of the switch was compared using ANOVA or Kruskal-Wallis test for quantitative variables, and, according to conditions of use.

Table 5. Multivariate logistic regression analyses of patients with switch acceptance as a dependent variable.

	<b>Odds Ratio estimates</b>	<b>95% Wald Confidence Limits</b>
Annual recourse to a General Practitioner	0.88	[0.78-1.00]
Having heard about biosimilars	0.13	[0.02-0.72]
Having been influenced by the interview	60.74	[12.08-305.50]
Being satisfied with generic drugs	1.31	[1.01-1.69]

Threshold for entrance:  $p < 0.1$ ; Threshold for exclusion :  $p > 0.05$ .