Copyright © 2016 European Crohn's and Colitis Organisation (ECCO). Published by Oxford University Press. All rights reserved. For permissions, please email: journals.permissions@oup.com

Viewpoint

Patient Perspectives on Biosimilars: A Survey by the European Federation of Crohn's and Ulcerative Colitis Associations

Laurent Peyrin-Biroulet^a, Sanna Lönnfors^b, Xavier Roblin^c, Silvio Danese^d, Luisa Avedano^b

^aInserm U954 and Department of Gastroenterology, Nancy University Hospital, Université de Lorraine, Allée du Morvan, 54 511 Vandœuvre-lès-Nancy, France ^bEuropean Federation of Crohn's and Ulcerative Colitis Associations, Rue Des Chartreux, 33–35 Brussels B 1000 Belgium ^cDepartment of Gastroenterology and Hepatology, Saint-Etienne University Hospital, 25 Boulevard Pasteur, 42055 Saint-Etienne, France ^dIBD Center, Department of Gastroenterology, Humanitas University, Via Manzoni 56, 20089 Rozzano, Milan, Italy

Corresponding author: Prof. Laurent Peyrin-Biroulet, MD, PhD, Inserm U954 and Department of Gastroenterology, Nancy University Hospital, Université de Lorraine, Allée du Morvan, 54 511 Vandœuvre-lès-Nancy, France. Tel: 33-3-83-15-33-6; Fax: 33-3-83-15-36-33; Email: peyrinbiroulet@gmail.com

Abstract

Background and Aim: The aim of this survey was to find out the patients' perspectives concerning biosimilars.

Methods: An online survey consisting of 14 questions was made available between November 2014 and October 2015. Only respondents who had heard of biosimilars were asked to respond the final twelve questions.

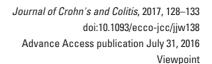
Results: A total of 1181 patients responded. Of these, 38% had heard of biosimilars. The respondents worried about biosimilars' safety profile [47.0%], efficacy [40.3%], and molecular basis [35.0%]. Only 25.2% of the respondents had no concerns about biosimilars. Just over half [55.9%] of the respondents thought that the lower cost of the biosimilars should not come before their safety and efficacy. Only 12.5% of respondents felt that extrapolation made sense. The survey showed that 39.9% felt that patients should be systematically informed, and 26.7% felt that patient associations should be informed and able to give their opinions. It also revealed that 20.9% of the respondents would be against the idea of interchangeability if the patient was not aware; 65.7% of the respondents would want to know whether they were receiving the reference drug or the biosimilar, and have all necessary information in writing before the drug was administered. Only 31.0% of the respondents would be fully confident about biosimilars, even if they were prescribed and explained by the treating physician.

Conclusions: Most patients were not familiar with biosimilars, and those who were had doubts and concerns about the biosimilars' safety and efficacy. The patients wished to be informed and involved in decision-making concerning biosimilars.

Key Words: Biosimilars; inflammatory bowel disease

1. Introduction

Inflammatory bowel disease [IBD] is a chronic and disabling condition.^{1,2} Anti-Tumour Necrosis Factor [TNF] therapy [infliximab, adalimumab, golimumab] has changed the treatment of IBD refractory to standard medications.³ Anti-TNF therapy is increasingly used to treat IBD in clinical practice. In a French referral centre,



OXFORD

the percentages of ulcerative colitis and Crohn's disease patients exposed to anti-TNF therapy were 29.0% for infliximab and 64.7% in total at 5 years from the time of diagnosis, respectively.^{4,5}

Interestingly, a Dutch study showed that health care costs caused by IBD have shifted from hospitalization and surgery-related costs to medication costs [most importantly, anti-TNF therapy].⁶

Biosimilars are now available in clinical practice to IBD patients in several countries around the world. Biosimilars are highly similar copies of previously approved original biologic medicines whose data patent protection has expired.⁷ Biosimilar infliximab was the first biosimilar monoclonal antibody approved by the European Medicines Agency.⁸

However, some concerns have been raised about the safety and efficacy of biosimilar medicines by both physicians and patients. In 2014, a first survey was published that evaluated awareness of biosimilar monoclonal antibodies among IBD specialists, and their readiness to use such therapies.⁹ The survey showed that most IBD experts had a good understanding of biosimilars; however, some still had a misconception of biosimilars being generic copies of the original biologic agents.⁹ A recent update of this survey showed that there were fewer concerns and more confidence among IBD specialists about using biosimilars in clinical practice.¹⁰ In contrast, the patients' perspectives concerning biosimilars has been unknown.

The purpose of the Biologics and Biosimilars survey was to assess patients' knowledge about biosimilars, to find out how aware patients are of the issues involving biosimilars, and to gain information to serve as a basis for a common European Federation of Crohn's and Ulcerative Colitis Association [EFCCA] position in order to effectively advocate for better patients' rights with the medicine licensing authorities and relevant government institutions. To our knowledge, this is the first such survey about patient perspectives concerning biosimilars.

2. The Survey

2.1. The questionnaire

The questionnaire [see Supplementary Data] was developed by EFCCA in collaboration with experts in the field [Laurent Peyrin-Biroulet, Xavier Roblin, Silvio Danese, and Luisa Avedano], and it consisted of 14 questions. A pilot questionnaire was first administered to 35 IBD patients. As a direct result of this pilot survey, minor modifications were made in order to improve understanding of the questions and to eliminate possible sources of confusion.

The final questionnaire was then available online from November 2014 to October 2015 on the website of EFCCA. The national patient associations were responsible for informing their members about the survey. After basic demographic questions, only those respondents who had previously heard of biosimilars continued to the biosimilar-specific questions. The questionnaire [see Supplementary Data] was made available in nine languages [English, French, Italian, German, Spanish, Russian, Greek, Turkish, and Hebrew].

2.2. The participants

The participants of the survey were members of EFCCA member associations as well as members of Agora [a platform of organizations of people with rheumatic diseases in southern Europe]. The recruitment was self-selective.

2.3. Statistical considerations

The response variables were categorical. Explanatory variables were integer age and binary disease. A binary logit model was used for the response variables that had only two possible values and a generalized logit model for the variables that had more than two possible values. In the case that the age or disease variable was not statistically significant, the variable with the greater *p*-value was removed from the model.

3. Patient views on biosimilars

3.1. Respondent demographics

By the closing of the survey in October 2015, a total of 1181 respondents had participated. Only those with IBD [n = 1059] were included in this analysis. Out of the 1059 respondents with IBD, 62% had Crohn's disease and 38% ulcerative colitis. Most respondents [52.7%] were 21–40 years old, and 3.6% had been diagnosed in 1980 or before, 8.7% between 1981 and 1990, 21.1% between 1991 and 2000, 40.2% between 2001 and 2010, and 26.0% in 2011 or later. The countries with the highest responses to the survey were Italy [22.8% of the respondents], Spain [12.0%], France [10.8%], Turkey [10.5%], Greece [6.8%], Poland [5.7%], Portugal [4.6%] and Switzerland [4.5%].

3.2. Exposure to biologics and biosimilars [Questions 1–2]

Question 1 was about current and previous exposure to anti-TNF therapy, while question 2 asked patients whether they had heard of biosimilars. Of the respondents, 52.9% of Crohn's disease [later referred to as CD] patients and 32.3% of ulcerative colitis [later referred to as UC] patients were currently treated with anti-TNF; 6.9% of all respondents had received anti-TNF in the past, but the therapy had been discontinued due to inefficacy, and 7.0% had received anti-TNF in the past, but the therapy was discontinued due to side effects.

Of the respondents, 36.6% of Crohn's disease patients and 35.5% of ulcerative colitis patients had heard of biosimilars. Only these respondents [n = 383] continued the survey to the biosimilar-specific questions.

3.3. Concerns about biosimilars [Question 3]

The most common biosimilar-related concerns among the respondents were safety and efficacy: 46.5% of the respondents worried about the safety profile of biosimilars [48.8% of respondents with CD, 42.7% of respondents with UC], and 38.6% worried that the biosimilar could be less effective than the reference drug [40.0% of respondents with CD, 36.4% of respondents with UC]. Furthermore, 32.9% of the respondents worried about the molecular basis of the biosimilar might be different than that of the reference drug [36.3% of respondents with CD, 27.3% of respondents with UC], and 31.9% worried about tolerability [32.1% of respondents with CD, 31.5% of respondents with UC]. Just over a quarter [26.4%] of the respondents [24.6% of respondents with CD, 29.4% of respondents with UC] had no specific concerns about biosimilars. Respondents were able to tick more than one option. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.4. Lower price of biosimilars [Question 4]

When asked about the possible lower price of biosimilars in comparison with the reference drug, 54.6% of the respondents were of the opinion that the cost of treatment should not come before the effectiveness or safety and tolerance of the medicine [56.3% of respondents with CD, 51.8% of respondents with UC]. Moreover, 31.3% of the respondents believed that more patients would be treated with biologics due to the lower price [30.0% of respondents with CD, 33.6% of respondents with UC]; 5.2% of the respondents

Table 1. Summary of main results.

		Overall IBD population $n = 383$ n [%]	Crohn's disease $n = 240$ n [%]	Ulcerative colitis $n = 143$ n [%]
3- (Concerning biosimilars, you worry [it is possible to choose more than one option]:			
a]	That the molecular basis of the biosimilar is different from that of the reference drug [the original drug].	126 [32.9]	87 [36.3]	39 [27.3]
b]	About safety profile [mainly infections and cancers].	178 [46.5]	117 [48.8]	61 [42.7]
c]	\About tolerability.	122 [31.9]	77 [32.1]	45 [31.5]
d]	That the biosimilar could be less effective than the reference drug.	148 [38.6]	96 [40.0]	52 [36.4]
e]	You have no specific concerns about biosimilars.	101 [26.4]	59 [24.6]	42 [29.4]
4- 7	The biosimilar will be less expensive than the reference drug. You think that:			
a]	This is good news because more patients will be treated with biologics.	120 [31.3]	72 [30.0]	48 [33.6]
b]	The cost of a treatment should not come before its effectiveness or safety/tolerance.	209 [54.6]	135 [56.3]	74 [51.8]
c]	This will help cost savings.	30 [7.8]	16 [6.7]	14 [9.8]
d]	You don't think that a lower cost will change anything.	20 [5.2]	13 [5.4]	7 [4.9]
trea ma	The biosimilar of REMICADE [infliximab] has been successfully developed and used for the atment of rheumatologic diseases. On June 27, 2013, the biosimilar of REMICADE [inflixib] received positive opinion from the European Medicines Agency [EMA] for the treatment inflammatory bowel disease by extrapolating data from rheumatoid arthritis.			
a]	You think that it makes sense, because its efficacy and safety profile has been established for chronic conditions other than IBD.	50 [13.1]	28 [11.7]	22 [15.4]
b]	You would prefer if it could be tested for inflammatory bowel diseases before extrapolat- ing data from rheumatologic disorders.	116 [30.3]	74 [30.8]	42 [29.4]
c]	You trust the decisions made by regulatory agencies and you are not waiting for data in IBD.	13 [3.4]	10 [4.2]	3 [2.1]
d]	You trust your treating physician, who would make the decision to use biosimilars in your treatment.	104 [27.2]	58 [24.2]	46 [32.2]
e]	You trust your pharmacist to make the decision to use biosimilars in your treatment.	3 [0.8]	3 [1.3]	0 [0.0]
f]	You are waiting for more data in IBD before accepting a biosimilar for either Crohn's disease or ulcerative colitis.	93 [24.3]	63 [26.3]	30 [21.0]
6-1	Now that biosimilars are coming onto the market, you think:			
a]	That patient associations should be informed and should be able to give their opinion.	96 [25.1]	62 [25.8]	34 [23.8]
b]	That patients should systematically be given information.	164 [42.8]	100 [41.7]	64 [44.8]
cl	That we should wait for many patients to receive biosimilars in a real-life setting before	87 [22.7]	57 [23.8]	30 [21.0]
. 1	recommending its use in a large population of IBD patients.			
d]	We should know in which country the drug has been tested/created before using it in our own country.	31 [8.1]	16 [6.7]	15 [10.5]
7-1	n the future, biosimilars could be interchangeable with the reference drug.			
a]	You are opposed to this idea if the patient is not aware of the decision.	76 [19.8]	51 [21.3]	25 [17.5]
b]	You think that this is acceptable, provided patients are systematically informed.	91 [23.8]	56 [23.3]	35 [24.5]
	You might accept this exchange if the drug is delivered by your usual pharmacist.	4 [1.0]	2 [0.8]	2 [1.4]
dl	You accept this exchange if your treating physician gives his approval.	115 [30.0]	75 [31.3]	40 [28.0]
e]	You accept this exchange if EBM [evidence-based medicine] data are available.	93 [24.3]	52 [21.7]	41 [28.7]
	The biosimilar will have the same pharmacological name as the reference drug; thus when scribed, there will be no way to distinguish it from the reference drug.			
a]	You wish to know whether you receive the biosimilar or the reference drug.	169 [44.1]	109 [45.4]	60 [42.0]
aj b]	You don't mind as long as the biosimilar has the same efficacy and safety profile as the	85 [22.2]	50 [20.8]	35 [24.5]
c]	reference drug. You would like to be informed about it, but you trust the pharmacist or your treating	45 [11.7]	27 [11.3]	18 [12.6]
	physician if he prescribes/delivers it.			
d]	You wish to have all the necessary information before the drug is administered and obtain written information [e.g. card] to be used for future care.	80 [20.9]	50 [20.8]	30 [21.0]
9-1	Do you think that the arrival of biosimilars will have an impact on the management of IBD?			
a]	Yes, completely.	46 [12.0]	22 [9.2]	24 [16.8]
b]	Probably.	139 [36.3]	81 [33.8]	58 [40.6]
c]	Maybe a little.	49 [12.8]	37 [15.4]	12 [8.4]
d]	Not at all.	27 [7.0]	16 [6.7]	11 [7.7]
el	Don't know.	118 [30.8]	80 [33.3]	38 [26.6]

	Overall IBD population $n = 383$ n [%]	Crohn's disease $n = 240$ n [%]	Ulcerative colitis $n = 143$ n [%]
10- If a biosimilar is prescribed and explained to you by your treating physician:			
a] You will be fully confident.	123 [32.1]	76 [31.7]	47 [32.9]
b] You will be worried, but you will accept the treatment.	146 [38.1]	94 [39.2]	52 [36.4]
c] You will probably not accept it and express yourself on this matter.	48 [12.5]	33 [13.8]	15 [10.5]
d] You will ask another physician.	23 [6.0]	12 [5.0]	11 [7.7]
e] You don't know.	39 [10.2]	21 [8.8]	18 [12.6]
11- If the pharmacist hands out the biosimilar, changing the initial prescription without the consent of the prescribing physician:			
a] You will accept it because of the lower cost of the biosimilar.	13 [3.4]	8 [3.3]	5 [3.5]
b] You will accept it because of available scientific evidence.	72 [18.8]	40 [16.7]	32 [22.4]
c] You disagree, but you acknowledge that you will have to accept it.	52 [13.6]	30 [12.5]	22 [15.4]
d] You will try to obtain the reference drug.	239 [62.4]	156 [65.0]	83 [58.0]
12- After starting a treatment with biosimilar:			
a] You will carefully follow the treatment.	200 [52.2]	120 [50.0]	80 [55.9]
b] You will be worried and will probably stop the treatment at the first doubt or alternative event.	75 [19.6]	51 [21.3]	24 [16.8]
c] You will be worried, but the fact that the treatment has been approved by the European Medicines Agency is reassuring.	104 [27.2]	65 [27.1]	39 [27.3]
13- You believe that biosimilars:			
a] Are like generic* drugs.	116 [30.3]	70 [28.2]	46 [32.2]
b] Are close to generic* drugs.	127 [33.2]	85 [35.4]	42 [28.7]
c] Are not at all like generics*.	69 [18.0]	43 [17.9]	26 [18.2]
d] You don't know.	68 [17.8]	38 [15.8]	30 [21.0]
14- Regarding generic* treatments:			
a] You take them without worries.	126 [32.9]	80 [33.3]	46 [32.2]
b] You accept to take them, but you have some doubts.	128 [33.4]	84 [35.0]	44 [30.8]
c] You refuse them when you can.	78 [20.4]	44 [18.3]	34 [23.8]
d] You have never thought about this.	30 [7.8]	18 [7.5]	12 [8.4]
e] You don't know.	17 [4.4]	10 [4.2]	7 [4.9]

did not believe that a lower cost would change anything [5.4% of respondents with CD, 4.9% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.5. Extrapolating data [Question 5]

The respondents were told that the biosimilar of Remicade® was approved for the treatment of IBD by extrapolating data from rheumatoid arthritis, and asked how they felt about this—30.3% of the respondents would prefer testing for IBD first [30.8% of respondents with CD, 29.4% of respondents with UC] and 24.3% would wait for more IBD-specific data before accepting a biosimilar for either Crohn's disease or ulcerative colitis [26.3% of respondents with CD, 21.0% of respondents with UC]; 3.4% of the respondents would trust the decisions made by regulatory agencies and would not wait for IBD-specific data [4.2% of respondents with CD, 2.1% of respondents with UC].

The survey also revealed that 27.2% of the respondents would trust their treating physician to make the decision to use biosimilars in their treatment [in terms of extrapolation] [24.2% of respondents with CD, 32.2% of respondents with UC], and 0.8% would trust their pharmacist to make the decision to use biosimilars in their treatment [1.3% of respondents with CD, 0.0% of respondents with UC]. Only 13.1% of the respondents thought extrapolation made sense [11.7% of respondents with CD, 15.4% of respondents with

UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.6. Biosimilars coming onto the market [Question 6]

Of the respondents, 42.8% thought that patients should systematically be given information about biosimilars [41.7% of respondents with CD, 44.8% of respondents with UC], and 25.1% thought that patient associations should be informed and able to give their opinion on biosimilar-related matters [25.8% of respondents with CD, 23.8% of respondents with UC]. Furthermore, 22.7% of the respondents thought that biosimilars should be given to many more patients in a real-life setting before recommending their use in large patient populations [23.8% of respondents with CD, 21.0% of respondents with UC], and 8.1% of the respondents thought that the country in which the biosimilar drug had been tested or created should be known before the biosimilar was used in their own country [6.7% of respondents with CD, 10.5% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.7. Interchangeability with reference drug [Question 7]

Respondents were told that in the future, biosimilars could be interchangeable with the reference drug. Of these respondents, 30.0% would accept the exchange if their treating physician approved it [31.3% of respondents with CD, 28.0% of respondents with UC], 24.3% if evidence-based data was available [21.7% of respondents with CD, 28.7% of respondents with UC], and 23.8% if the patient was systematically informed [23.3% of respondents with CD, 24.5% of respondents with UC]. Only 1.0% of the respondents might accept the exchange if the drug was delivered by their usual pharmacist [0.8% of respondents with CD, 1.4% of respondents with UC], and 19.8% of the respondents would be opposed to the idea if the patient was not aware of the exchange [21.3% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.8. Same pharmacological name [Question 8]

The respondents were told that the biosimilars would have the same pharmacological name as the reference drug, so that when prescribed, there would be no way to distinguish it from the reference drug. In response, 44.1% of the respondents said they would want to know whether they were receiving the biosimilar or the reference drug [45.4% of respondents with CD, 42.0% of respondents with UC], and 20.9% of the respondents would want to have all the necessary information before the drug was administered, and obtain written information, e.g. a card, to be used for future care [20.8% of respondents with CD, 21.0% of respondents with UC]; 22.2% would not mind not being able to distinguish use of the biosimilar from that of the reference drug as long as the biosimilar had the same efficacy and safety profile as the reference drug [20.8% of respondents with CD, 24.5% of respondents with UC], and 11.7% of the respondents would like to be informed, but would trust their pharmacist or treating physician [11.3% of respondents with CD, 12.6% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.9. Biosimilars' impact on the management of IBD [Question 9]

Of the respondents, 12.0% believed that biosimilars would completely impact the management of IBD [9.2% of respondents with CD, 16.8% of respondents with UC]; 36.3% believed that biosimilars would probably impact the management of IBD [33.8% of respondents with CD, 40.6% of respondents with UC]; 12.8% believed that biosimilars might impact the management of IBD a little [15.4% of respondents with CD, 8.4% of respondents with UC]; 7.0% of the respondents believed that biosimilars would not impact the management of IBD at all [6.7% of respondents with CD, 7.7% of respondents with UC]; and 30.8% did not know whether or not there would be any impact [33.3% of respondents with CD, 26.6% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.10. Biosimilar prescribed and explained by the treating physician [Question 10]

If biosimilars were prescribed and explained by their treating physician, 32.1% of the respondents would be fully confident [31.7% of respondents with CD, 32.9% of respondents with UC]; 38.1% of the respondents would be worried, but would accept the treatment [39.2% of respondents with CD, 36.4% of respondents with UC]; 12.5% of the respondents would probably not accept the biosimilar [13.8% of respondents with CD, 10.5% of respondents with UC]; and 6.0% would ask another physician [5.0% of respondents with CD, 7.7% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.11. Pharmacist handing out the biosimilar [Question 11]

If the pharmacist handed out the biosimilar changed the initial prescription without the consent of the prescribing physician, 18.8% of the respondents would accept it because of the available scientific evidence [16.7% of respondents with CD, 22.4% of respondents with UC] and 3.4% because would accept it because of the lower cost [3.3% of respondents with CD, 3.5% of respondents with UC]; 13.6% would disagree, but acknowledge that they would have to accept it [12.5% of respondents with CD, 15.4% of respondents with UC]; and 62.4% would try to obtain the reference drug [65.0% of respondents with CD, 58.0% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.12. After starting biosimilar treatment [Question 12]

After starting a treatment with biosimilars, 52.2% of the respondents would carefully follow the treatment [50.0% of respondents with CD, 55.9% of respondents with UC], 19.6% would be worried and probably stop treatment at the first doubt or alternative event [21.3% of respondents with CD, 16.8% of respondents with UC], and 27.2% would be worried, but the fact that treatment was approved by the European Medicines Agency would reassure them [27.1% of respondents with CD, 27.3% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

3.13. Biosimilars and generic drugs [Questions 13–14]

After receiving a definition of what generic drugs are, 30.3% of the respondents believed that biosimilars are like generic drugs [29.2% of respondents with CD, 32.2% of respondents with UC]; 33.2% of the respondents believed that biosimilars are close to generic drugs [35.4% of respondents with CD, 28.7% of respondents with UC]; 18% of the respondents believed that biosimilars are not at all like generics [17.9% of respondents with CD, 18.2% of respondents with UC]; and 17.8% did not know [15.8% of respondents with CD, 21.0% of respondents with UC].

Finally, 32.9% of the respondents reported that they take generic drugs without worries [33.3% of respondents with CD, 32.2% of respondents with UC]; 33.4 of the respondents accept generic drugs, but have some doubts [35.0% of respondents with CD, 30.8% of respondents with UC]; and 20.4% of the respondents reported that they refuse generic treatments whenever they can [18.3% of respondents with CD, 23.8% of respondents with UC]. There were no statistically significant differences between illnesses or ages, and the results can be seen in Table 1.

4. Discussion

This is the first survey addressing patient perspectives on biosimilar medications. One of the most striking findings was the unfamiliarity of the respondents with biosimilars. Although 45.0% of the respondents were currently treated with biologic medications, only

36.2% had heard of biosimilars. This would mean that even some of the patients who were receiving biologic medications had not been told about biosimilars that might be considered as alternative treatments for them in the future.

As well as not being informed about biosimilars, the respondents seemed in general to be skeptical about various aspects of biosimilars. Only 26.4% of the respondents had no specific concerns about biosimilars. Respondents seemed especially skeptical when asked about extrapolation; only 13.1% of the respondents thought the concept of extrapolation made sense. Such concerns may be due to the extrapolation concept being rather difficult to grasp for a lay person with no scientific background. Proper patient education about the various issues concerning biosimilars would possibly decrease suspicions.

Respondents seemed to have more trust in their treating physician than in pharmacists or regulatory agencies. This highlights the importance of a good patient–doctor relationship. Furthermore, 25.1% of the respondents would like patient associations to be informed about matters involving biosimilars and to be able to give their opinions in discussions around biosimilars. Patient organizations could play a key role in informing their members and bring the patient perspective into the discussion concerning biosimilars.

Although there were no statistically significant differences between the responses from Crohn's disease and ulcerative colitis patients, Crohn's disease patients tended to be slightly more skeptical about biosimilars. Crohn's disease patients also tended to have more worries concerning biosimilars in comparison with ulcerative colitis patients.

This survey had several limitations. The survey was self-selective, and because it was only available online and in nine languages, this may have affected the participant population. It may also be possible that some respondents found more than one applicable response option in some questions, but were only able to choose one, which may have affected the results.

In conclusion, our findings show that patients want to be informed and involved. They highlight the need to involve patients in decision-making when starting a biosimilar and in developing the management plan. Informing patients via therapeutic education programs is advisable, and this could be implemented with patient organization support.

Funding

This work was supported by an unrestricted grant from Abbvie for translations, technical tools and dissemination material to EFCCA.

Conflict of Interest

LPB has received consulting fees from Merck, Abbvie, Janssen, Genentech, Mitsubishi, Ferring, Norgine, Tillots, Vifor, Therakos, Pharmacosmos, Pilège, BMS, UCB-pharma, Hospira, Celltrion, Takeda, Biogaran, Boerhinger-Ingelheim, Lilly, Pfizer, HAC-Pharma, Index Pharmaceuticals, Amgen, Sandoz, Forward Pharma GmbH, Celgene, Biogen, Lycera and Samsung Bioepis; and lecture fees from Merck, Abbvie, Takeda, Janssen, Takeda, Ferring, Norgine, Tillots, Vifor, Therakos, Mitsubishi, and HAC-pharma.

XR has received lecture and consulting fees from Merck, Theradiag, Janssen, Takeda, Hospira, and Abbvie.

SD has served as a speaker, a consultant and an advisory board member for Abbvie, Ferring, Hospira, Johnson & Johnson, Merck, Millennium Takeda, Mundipharma, Pfizer Inc, Tigenix, UCB Pharma, and Vifor.

There are no further conflicts of interest to declare.

Acknowledgments

The authors would like to acknowledge Ms Johanna Ikonen for her support in the statistical analysis.

The main results of this work have been presented at the 11th Congress of ECCO [March 16–19, 2016, Amsterdam, The Netherlands].

References

- Gower-Rousseau C, Sarter H, Savoye G, *et al.* Validation of the Inflammatory Bowel Disease Disability Index in a population-based cohort. *Gut* 2015;Epub ahead of print. doi: 10.1136/gutjnl-2015-310151.
- Peyrin-Biroulet L, Loftus EVJ, Colombel JF, et al. The natural history of adult Crohn's disease in population-based cohorts. Am J Gastroenterol 2010;105:289–97.
- Danese S, Vuitton L, Peyrin-Biroulet L. Biologic agents for IBD: practical insights. Nat Rev Gastroenterol Hepatol 2015;12:537–45.
- Williet N, Pillot C, Oussalah A, et al. Incidence of and impact of medications on colectomy in newly diagnosed ulcerative colitis in the era of biologics. Inflamm Bowel Dis 2012;18:1641–6.
- Peyrin-Biroulet L, Oussalah A, Williet N, *et al*. Impact of azathioprine and tumour necrosis factor antagonists on the need for surgery in newly diagnosed Crohn's disease. *Gut* 2011;60:930–6.
- van der Valk ME, Mangen MJ, Leenders M, *et al.* Healthcare costs of inflammatory bowel disease have shifted from hospitalisation and surgery towards anti-TNFalpha therapy: results from the COIN study. *Gut* 2014;63:72–9.
- Rinaudo-Gaujous S, Paul S, Tedesco ED, et al. Review article: biosimilars are the next generation of drugs for liver and gastrointestinal diseases. Aliment Pharmacol Ther 2013;38:918–24.
- Schreiber S, Panés J, Kwon B, et al. Biosimilar infliximab for inflammatory bowel disease: from concepts to clinical practice. Case study illustrated with CT-P13. Expert Rev Gastroenterol Hepatol 2015;9 Suppl 1:5–15.
- Danese S, Fiorino G, Michetti P. Viewpoint: knowledge and viewpoints on biosimilar monoclonal antibodies among members of the European Crohn's and Colitis Organization. J Crohns Colitis 2014;8:1548–50.
- Danese S, Fiorino G, Michetti P. Changes in biosimilar knowledge among European Crohn's Colitis Organization [ECCO] members: an updated survey. J Crohns Colitis 2016;Epub ahead of print. doi: 10.1093/ecco-jcc/ jjw090.