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Perceived Risks Contra Benefits of Using Biosimilar Drugs in Ulcerative Colitis: Discrete Choice Experiment among Gastroenterologists

Petra Baji, PhD[1,2], László Gulácsi, PhD[1,], Petra A. Golovics, MD[3], Barbara D. Lovász, MD[3], Márta Péntek, PhD[1,4], Valentin Brodszky, PhD[1], Fanni Rencz, MD[1,5], Péter L. Lakatos, DSc[3]*

[1]*Department of Health Economics, Corvinus University of Budapest, Budapest, Hungary;* [2]*CERGE-EI, Nové Město, The Czech Republic;* [3]*First Department of Medicine, Semmelweis University, Budapest, Hungary;* [4]*Department of Rheumatology, Flór Ferenc County Hospital, Kistarcsa, Hungary;* [5]*Semmelweis University Doctoral School of Clinical Medicine, Budapest, Hungary*

ABSTRACT

Background: In middle-income countries, access to biological therapy is limited in ulcerative colitis in terms of the number of patients and the length of therapy. Because of their cost advantages, biosimilars have the potential to improve access to therapy, but physicians have concerns toward their use because of the lack of evidence from randomized clinical trials. **Objectives:** To explore the preferences of gastroenterologists for biosimilar drugs in ulcerative colitis as well as to compare our results with results of previous studies on gastroenterologists' preferences toward biosimilars. **Methods:** A discrete choice experiment was carried out involving 51 Hungarian gastroenterologists treating patients with inflammatory bowel disease in May 2014 with the following attributes: type of treatment (biosimilar/originator), severity of disease, availability of continuous medicine supply, and the stopping rule (whether the treatment is covered after 12 months). A conditional logit model was used to estimate the probabilities of choosing a given profile. **Results:** According to the results, the stopping rule was the most important attribute. The type of treatment mattered only for patients already on biologicals. The probabilities of choosing the biosimilar option with all the benefits offered in the discrete choice experiment over the originator option under the present reimbursement conditions are 85% for new patients and 63% for patients already treated. **Conclusions:** Most gastroenterologists have concerns about using biosimilars. They, however, are willing to consider the use of biosimilars if they could reallocate the potential savings to provide their patients better access to biological treatment.

Keywords: biologicals, biosimilars, discrete choice experiment, preferences, ulcerative colitis.

Introduction

Biological drugs (such as adalimumab, infliximab, golimumab, and vedolizumab) are indicated for moderately to severely active ulcerative colitis (UC) in adult patients who show inadequate response to conventional therapy (including corticosteroids and 6-mercaptopurine or azathioprine) or who are intolerant to or have medical contraindications for such therapies [1,2]. Both induction therapy and maintenance therapy with biological drugs are highly effective in UC [1–3]. These treatments, however, are rather costly, and access is rather limited to middle-income countries. Our previous study shows that in Poland and Bulgaria biological drugs cover five chronic inflammatory conditions including Crohn disease (CD) but not for patients with UC [3]. Compared with CD, lower biological treatment rates were found for UC in many countries such as the United States (16.8% vs. 3.5%) and most Central and Eastern European countries (0.2%–19.1% vs. 0%–6.4%) [3,4]. In Hungary, only patients with severe disease activity conditions (with a Mayo score of > 9) not responding to conventional therapy including high-dose intravenous steroids are eligible for biological treatment. Furthermore, only 1 year of consecutive therapy is covered by the National Health Insurance Fund Administration in patients with a clinical response at week 12 [5], although the literature suggests that the continuation of treatment after this period would be beneficial [6,7]. Since 2013, biosimilar infliximab has appeared on the market, providing a substantially cheaper treatment option for patients with UC. The biosimilar infliximab drugs (Remsima and Inflectra) are the first biosimilar monoclonal antibody medicines for chronic inflammatory conditions approved by the European Medicines Agency (EMA) in 2013. These drugs were registered under the same conditions as for the originator infliximab for the treatment of six adult conditions and in two pediatric indications [8,9]. Biosimilars offer cost savings and consequently

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* *Address correspondence to:* László Gulácsi, Department of Health Economics, Corvinus University of Budapest, Fővám tér 8. Budapest, H-1093, Hungary.

E-mail: laszlo.gulacsi@uni-corvinus.hu.

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the potential to treat more patients in the same budget [10,11]. Nevertheless, randomized clinical trials on its efficacy and safety have been carried out in only two adult rheumatic disorders [12,13]. Hence, physicians have concerns about the extension of indication to inflammatory bowel diseases (IBDs) [14,15]. Physicians (as well as payers and patients) therefore face tradeoff between perceived risks and potential benefits when making decisions about the use of biosimilar medicines in this indication. In this case, perceived risk means uncertainty regarding the outcome of the treatment, also called ambiguity aversion (uncertainty aversion) in unknown.

In our study, we have carried out a discrete choice experiment (DCE) among gastroenterologists to reveal clinicians' preferences for originator versus biosimilar treatment in UC. The choice task described hypothetical scenarios, in which some benefits with regard to access to biological treatment (e.g., to start the treatment in less severe conditions, the availability of continuous medicine supply, and to continue treatment after 12 months) are offered when using the biosimilar treatment option. We are particularly interested whether these preferences are different in UC and in other conditions such as CD. The study aimed to provide important evidence on clinicians' preferences, which might affect the penetration of biosimilars into clinical practice and therefore the potential benefits related to their use.

This research is a part of a study that focused on gastroenterologists' preferences for using biosimilars for IBD. Results for CD have already been published elsewhere [16]. This article presents the results for UC.

Methods

Questionnaire

The study design and the process of data collection have already been described in detail elsewhere [16], but we will provide a brief description here.

A DCE is a widely used stated-preference method to evaluate preferences [17–19]. In a DCE, respondents are faced with a hypothetical scenario and choice sets of treatment options (goods or services) described by different attributes. The profiles differ from each other in the levels of their attributes. In all the choice sets, the respondents are asked to choose the profile that they prefer the most.

In our DCE, gastroenterologists treating patients with IBD were asked to imagine a hypothetical scenario in which budget savings of biosimilars were spent to provide patients better access to biological treatment. Seven hypothetical choice sets of two treatment options were presented, and respondents were asked to choose the one they preferred. All the choice sets contained a base-case originator treatment option under the present reimbursement conditions as well as an alternative biosimilar option in which various benefits providing better access to treatment were offered.

The following attributes describing better access to biological treatment were selected on the basis of interviews with experts:

1. *Milder disease severity prerequisite for the initiation of biological treatment*: At present, patients with UC with a Mayo score of 9 or less are not entitled for reimbursed biological treatment. Experts argue that starting the biological treatment at a lower disease activity level would result in a potential benefit of less costly treatment options.
2. *Availability of continuous medicine supply*: Clinicians mentioned budget constraints as a problem for the present medicine supply, which can lead to delays in the treatment.
3. *Stopping rule*: According to the present reimbursement guideline, the treatment can be continued beyond 12 weeks only if patients show clinical response or reach clinical remission, and should be stopped after 12 months of consecutive biological therapy regardless of the response. After 1 year of treatment, patients have to be switched to the conventional therapy. Anti–tumor necrosis factor drugs can be restarted only in case of a flare-up.

Thus, the base scenario described the originator treatment under the present reimbursement conditions (i.e., can be applied if the Mayo score is 9 or more, treatment might be delayed by 3–4 weeks because of the lack in supply of medicines, and treatment cannot be continued after 12 months). The following alternative biosimilar scenarios described the seven possible combinations of potential benefits on access to treatment: 1) can already be applied for patients with a Mayo score of more than 6, 2) continuous medicine supply is available, and 3) the treatment does not have to be stopped after 12 months.

In the seven choice sets, clinicians were asked to choose the preferred treatment option for 1) biological-naive patients and 2) patients currently treated with the originator biological drug. Table 1 presents an example for a choice set. The questionnaire was piloted with five clinicians.

The questionnaire contained additional questions regarding sociodemographic and professional features of the gastroenterologists and their practices. A multiple-choice question regarding clinicians' attitude to biosimilar treatment was also included in the questionnaire with the following options: 1) have no concerns about the use of biosimilar medicines in UC, and these can be applied under the same conditions as the originator; 2) have some concerns about using biosimilars; and 3) biosimilar medicines should not be applied in UC at all. For those who indicated concerns, we wanted to get a better insight into the origin of their perceived risk, and therefore they were asked whether these concerns are related to efficacy, safety, both efficacy and safety, or any other reason.

Table 1 – Example for a choice set.

Attribute	Type of treatment	
	Originator	Biosimilar
Indication	Can be applied for patients with a Mayo score of >9	Can be applied for patients with a Mayo score of >9
Supply of medicines	Because of a shortage of medicines, the treatment can be delayed by 3–4 wk	Medicine supply is continuous
Stopping rule	The treatment has to be stopped after 12 mo	The treatment might be continued after the 12 mo if necessary
For new patients: 1. I start the therapy with the originator agent. 2. I start the therapy with the biosimilar treatment if I find the situation appropriate. For treated patients: 1. I continue to use the originator agent. 2. I change from the originator therapy to the biosimilar treatment if I find the situation appropriate.		

Data Collection

The study was carried out in Hungary where biosimilar infliximab has been covered by the National Health Insurance Fund for the treatment of UC since May 2014. Data were collected among gastroenterologists during a meeting of the Hungarian Gastroenterology Society in May 2014. Altogether 200 questionnaires were distributed. The participation was voluntary, and informed consent was taken. Ethical approval was obtained (Semmelweis University Regional and Institutional Committee of Science and Research Ethics, No. 103/2014). The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki (6th revision, 2008) as reflected in a priori approval by the institution's human research committee.

Data Analysis

A conditional logit model was used to analyze the DCE. The relative importance of the attributes was estimated. Odds ratios (ratio of the probability of choosing the alternative biosimilar profile over the probability of choosing the base originator option) are presented. A separate analysis was carried out for biological-naive patients and patients already treated with the originator.

Results

Fifty-one gastroenterologists filled in the survey (65% women) with the average age of 47.6 years (range 26–74 years). Other sociodemographic and professional characteristics of physicians are presented in Table 2. Regarding their attitudes toward biosimilar drugs, 10 clinicians (19.6%) indicated that they have absolutely no concerns regarding using biosimilars in UC, as the EMA registered them under the same conditions as the originators. Thirty-four (66.7%) clinicians indicated some concerns about using biosimilars in UC (2 had concerns about efficacy, 5 had concerns about safety, and 24 had concerns with both efficacy and safety). Six (11.8%) clinicians said they do not support the use of biosimilars in UC at all because of the lack of evidence from randomized controlled trials in this indication. One respondent did not answer this question.

In the DCE, 84% of the respondents chose the biosimilar option in at least one of the choice sets for biological-naive patients, and 61% for patients already treated with biologicals. Even among those who indicated concerns related to biosimilars, these shares were 80% and 53%, respectively.

The estimated coefficients of the conditional logit model are presented in Table 3. According to the results, the stopping rule (i.e., whether the continuation of treatment after 12 months is reimbursed) was found to be the most important treatment attribute driving the choices for both biological-naive patients and patients already treated with biologicals. For biological-naive patients, this was followed by the severity of the disease and the frequency of efficacy checkups. The type of treatment (biosimilar or originator) was found not to be a significant determinant of choice for biological-naive patients. For patients already treated with biologicals, the type of treatment (biosimilar or originator) was the second most important factor (preferring the originator treatment), followed by the continuity of the medicine supply. Severity had a positive but insignificant coefficient.

Predicted probabilities of choosing biosimilar medicines over the originator treatment under the present reimbursement conditions (i.e., can be applied when the Mayo score is >9, treatment might be delayed by 3–4 weeks because of the lack in supply of medicines, and the treatment cannot be continued after 12 months) were calculated (see Table 3). For new patients, the estimated probability of choosing the originator treatment over the biosimilars, when all the attributes describe the present reimbursement situation, is 48%. For patients already treated with biologicals, this probability is higher (71%). The probability of choosing the biosimilars with all the benefits offered over the originator treatment in the present situation is 85% versus 15% for new patients and 63% versus 37% for patients already treated with biologicals.

Discussion

A DCE was carried out to study the treatment preferences of gastroenterologists for biosimilar versus originator drugs in UC. We were particularly interested whether certain benefits with regard to access to biological treatment might compensate for the perceived risks of using biosimilars (e.g., uncertainty related to lack of experience). The study was part of a larger survey that assessed gastroenterologists' preferences regarding biosimilars in CD and UC [16].

Most of the gastroenterologists (78%) had concerns regarding the use of biosimilars in UC, but they were willing to consider biosimilar treatment options if certain benefits providing better access to biological therapy were offered in exchange. According to the results, one of the major benefits of biosimilars would be if the treatment of patients would not be discontinued after 12 months, but the continuity of the medical supply was also an important benefit. These could compensate for the perceived risk of using biosimilar treatment for both new patients (biological-naive) and patients already treated with biologicals.

In the other section of this study on CD, we also found that the same gastroenterologists had similar concerns with biosimilars in CD and UC, and in both studies they were more willing to consider the biosimilar treatment option for new patients than for patients already treated with biologicals [16]. In UC, however, physicians were more willing to use the biosimilar treatment than in CD for patients already treated with biologicals. The probability of choosing the biosimilar option with all the benefits offered over the originator treatment option with the present reimbursement guideline was 44% versus 56% for patients already treated with biologicals. In this study, this probability was 63% versus 37%. This difference is most probably because in CD the biological treatment is not to be discontinued after 12 months.

So far, only a few studies have reported about physicians' concerns toward biosimilars in IBD and in rheumatic conditions [14,15]. Our study offers a different methodology, namely, DCE, which is although hypothetical, but makes the clinicians "trade" between benefits and perceived risks of biosimilars. Regarding the questions on attitude in our study, 78% of the clinicians indicated concerns or were against the use of biosimilars in UC. In the DCE, however, 84% of the respondents chose the biosimilar option in at least one of the choice sets for new patients and 61% for patients already treated with biologicals. This suggests that benefits related to access are highly valued by clinicians and could be an effective tool to increase the attractiveness of biosimilars among clinicians. It should be highlighted that we examined a hypothetical scenario in which budget savings remained in the clinicians' praxis and were spent to provide their patients better access to treatment. In real life, however, it might not be the case. Thus, physicians might be less motivated to use biosimilars.

Perceived risk means some kind of uncertainty regarding the outcome of the treatment, often called ambiguity aversion (uncertainty aversion) in unknown. In this case, we can distinguish between individual patient-level and society-level outcome. In this survey, we asked gastroenterologists very directly about their fears regarding the outcome on the individual patient level (questions on efficacy and safety of biosimilars compared

Table 2 – Descriptive statistics of the sample.

Variable	n (%)	Mean ± SD	Range (min.–max.)
Clinicians' characteristics			
Age (y)	51 (100)	47.6 ± 11.4	26–74
Years of practice as a specialized gastroenterologist	48 (94.1)	19.0 ± 11.3	0*–45
Sex: female	33 (64.7)	–	–
Senior consultant	21 (41.2)	–	–
Scientific committee member	21 (41.2)	–	–
PhD	28 (54.9)	–	–
Practice			
Settlement of practice		–	–
Budapest	21 (41.2)		
County capital	23 (45.1)		
Other town/city	4 (7.8)		
Multiple	3 (5.9)		
Type of practice		–	–
Outpatient care	5 (9.8)		
Inpatient care	21 (41.2)		
Both	24 (47.1)		
Missing	1 (2.0)		
Practice: mainly hepatology	5 (9.8)	–	–
Practice: mainly gastroenterology	33 (64.7)	–	–
Practice: mainly IBD	19 (37.3)	–	–
IBD centrum	33 (64.7)	–	–
Number of patients with UC	50 (98.0)	23.5 ± 26.0	0–100
Number of patients with UC treated with biologicals	50 (98.0)	3.4 ± 5.3	0–20
Risk perception regarding the use of biosimilars in UC		–	–
No concerns	10 (19.6)		
Concerns regarding the safety or efficacy	34 (66.7)		
Should not be applied because of lack of RCTs in UC	6 (11.8)		
Missing	1 (2.0)		

IBD, inflammatory bowel disease; max., maximum; min., minimum; RCTs, randomized clinical trials; UC, ulcer colitis.
* During specialization training.

with those of originators). Since the survey, there has been growing literature regarding real-world evidence for biosimilars [20,21]. We assume that this will prove the validity of the EMA's standpoint such that there is no difference between infliximab and biosimilar infliximab in terms of efficacy and safety, and thus physicians' ambiguity aversion in unknown is supposed to decrease. Societal outcomes are always more complex and difficult to assess and till date there is a lack of cost-effectiveness studies in the literature on biosimilars in UC that could inform clinicians about the expected changes in costs and outcomes on the societal level. Our DCE results, however, reflect that gastroenterologists take into consideration broader aspects than only the individual patient angle. Attributes that would close the gap between the clinical and financial guidelines were highly rated by physicians, because these could improve UC care, and as a consequence could benefit not only the individual patients but also the society. Reallocating budget savings, preferably among patients with IBD, provides additional benefit (health gain) at the societal level. Both types of information seem to reduce physicians' uncertainty regarding the outcome of the treatment.

In Hungary since May 2014, "newly initiated biological therapy with infliximab must be undertaken with a biosimilar drug" to be reimbursed by the social health insurance. The issue of interchangeability is not addressed in the financial guideline [3]. Thus, the present practice might have an influence on preferences as well. Nevertheless, we highlighted in the questionnaire that we examined hypothetical scenarios, and specifically asked clinicians to imagine that they had the authority to decide about the use of biosimilars. Furthermore, we have to account for the potential of sample selection bias. The relatively low sample size might limit the robustness of the statistical analysis. There are, however, only 16 IBD biological centers in Hungary [3], and the number of IBD specialists prescribing biologicals is approximately 50 to 60. In our study, most of the respondents (65%) were such specialists from IBD biological centers. At the national congress, we distributed the questionnaire to available gastrointestinal specialists, many of whom do not treat IBDs regularly and are interested in therapeutic endoscopy/hepatology. From the responses we received (65% working in IBD/biological centers), it was clear that responses were mainly obtained from the specialists who indeed prescribe and use the biologicals. Thus, the target group of specialists is well represented and we believe that the responses are representative for the doctors who are active in IBD care in the country.

Conclusions

Our study provides important evidence on the preferences of clinicians using biosimilars in UC. It is essential to study and be aware of these preferences, because these directly or indirectly influence treatment practices and choice of medication, and consequently the budget impact of biosimilars. We found that even though most gastroenterologists have concerns regarding the use of biosimilars, they are willing to consider treatment options with biosimilars if better access to biological treatment is provided in exchange.

Table 3 – Results of the conditional logit model and predicted probabilities of choosing biosimilar medicine over the originator treatment under the present reimbursement conditions.

Conditional logit model for the choice of treatment	Type: biosimilar	Benefit			No. of observations	Wald χ^2	Pseudo R^2
		Less severe condition	Secure supply	No stopping rule			
Regression results							
New patients, coefficient (SE)	0.0931 (0.305)	0.526* (2.958)	0.526* (2.875)	0.624* (3.457)	714	19.36 ($P < 0.001$)	0.184
Treated patients, coefficient (SE)	–0.899* (−3.292)	0.0903 (1.183)	0.260* (2.690)	1.062* (4.459)	714	26.01 ($P < 0.001$)	0.047

Estimated probabilities

Scenario	Type: biosimilar	Benefit			New patients		Treated patients	
		Less severe condition	Secure supply	No stopping rule	Pr† (%)	OR = Pr(alt)/Pr(base)	Pr† (%)	OR = Pr(alt)/Pr(base)
Base scenario	No	No	No	No				
Biosimilar scenario 1	Yes	No	No	No	52	1.10	29	0.35
Biosimilar scenario 2	Yes	Yes	No	No	65	1.86	31	0.39
Biosimilar scenario 3	Yes	No	Yes	No	65	1.86	35	0.74
Biosimilar scenario 4	Yes	No	No	Yes	67	2.05	54	0.35
Biosimilar scenario 5	Yes	Yes	Yes	No	76	3.14	37	0.82
Biosimilar scenario 6	Yes	Yes	No	Yes	78	3.47	60	0.73
Biosimilar scenario 7	Yes	No	Yes	Yes	78	3.47	56	0.38
Biosimilar scenario 8	Yes	Yes	Yes	Yes	85	5.87	63	0.80

OR, odds ratio; Pr, probability; SE, standard error.

* $P < 0.001$.

† Estimated probability of choosing the profile when the alternative biosimilar scenario is the base scenario (i.e., originator with no benefits).

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Supplemental Materials

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