**Patients’ understanding and attitudes towards infliximab and etanercept biosimilars: Result of a UK web-based survey**

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**Running heading:** Patients’ perceptions of biosimilar medicines

**Abstract**

***Background*** Infliximab and etanercept biosimilars present significant potential cost savings to the NHS. Patients need to be involved in the decision to use these medicines but there is a limited published literature on their knowledge and attitudes about these biosimilars.

***Objectives*** To investigate ankylosing spondylitis and rheumatoid arthritis patients’ knowledge and attitudes towards infliximab and etanercept biosimilars in UK.

***Methods*** Aself-administered, web-survey conducted among the members of the National Rheumatoid Arthritis Society and the National Ankylosing Spondylitis Society in the UK between 2 March 2017 and 2 June 2017.

***Results*** A total of 182 patients participated in this survey. The majority of participants (73%) were on etanercept. 66%-80% of patients on originator biologic and biosimilars respectively understood what biosimilars were. Patients who were currently on biosimilars had greater confidence in their effectiveness and the doctor’s decision to initiate than those who were originally on originator biologics that doctors proposed to switch to biosimilars. The majority (82%) of participants on biosimilars thought that biosimilars help saving money for the NHS, while just over half (54%) of participants on the originator biologics thought the cost of treatment should not be considered when prescribing biosimilars.

***Conclusions*** Survey participants had a good knowledge and understanding of biosimilars. Participants on biosimilars were confident and positive about biosimilars’ safety, efficacy and switching, whereas participants on the originator biologics were more reluctant to switch to biosimilars. Those patients who expressed concerns felt that more clinical trials on switching biosimilars, better communication and reassurance by healthcare professional teams and further involvement in decision-making would increase their acceptance of biosimilars.

**Key points**

* Ankylosing spondylitis and rheumatoid arthritispatients on biosimilars were more well informed and confident in biosimilars than those on originator biologics.
* Both group of patients surveyed wanted clarity about reasons for switching.
* Those on biosimilars accepted that switching saved money for the NHS. Those on originator biologics thought that cost should not be an issue.
* Both patients’ groups felt the more clinical trials and better communications with healthcare professionals would increase reassurance.

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1. **Introduction**

Ankylosing spondylitis (AS) and rheumatoid arthritis (RA) are chronic and disabling conditions [1]. The management of AS and RA has improved with the introduction of anti-tumour necrosis factor (TNF) (infliximab, etanercept and adalimumab) [2]. Anti-TNFs are increasingly used to treat AS and RA in clinical practice due to their ability to reduce or reverse signs and symptoms, disability and progression of joint damage, improving patient’s quality of life, and functional capacity [3]. Anti-TNFs have a considerable impact on healthcare budgets. According to the Health and Social Care Information Centre report in 2015, the expenditure on infliximab, etanercept and adalimumab in England was £760 million which represents just under 5% of the total medicines expenditure [4].

Infliximab and etanercept were the first anti-TNFs to lose patent protection in Europe in 2013 and 2015 respectively, and have had competition from biosimilars [5]. Biosimilars for rituximab and adalimumab have recently been marketed and biosimilars for certolizumab pegol, golimumab and ustekinumab are in development [6]. The lower cost of biosimilars presents significant potential cost savings in a financially constrained health system such as the NHS [7]. Thus, in theory, a lower acquisition cost potentially removes one barrier to prescribing biologics and should lead to a better utilisation of anti-TNFs, freeing up resources for investment in new areas, bring relief to pressured healthcare budgets and enabling stakeholders (payers, physicians, and patients) to benefit from greater choice when it comes to treatment options [8].

Healthcare professionals (HCPs) have been surveyed on their knowledge, attitude and practice towards biosimilars in UK [9]. The results of that survey showed a high level of knowledge and awareness about biosimilars and that national as well as discipline specific guidance influenced their uptake of biosimilars. Rheumatologists were more concerned than other HCPs about switching patients to biosimilars.

Despite the need for active involvement of patients in decisions about anti-TNFs [10], there have been limited publications on the views, opinions and the attitude of patients toward infliximab and etanercept biosimilars [11]. A survey of the literature revealed only three studies on patients’ attitudes towards anti-TNF biosimilars , only one was in rheumatology, and none involved UK patients only. Jacobs et al., (2016) study showed a low awareness of biosimilars with gaps in knowledge about biosimilars among US and European patients with ulcerative colitis, Crohn’s disease, rheumatoid arthritis and psoriasis [12]. Sullivan et al., (2017) and Waller et al., (2017) studies showed higher reluctance to receive biosimilars among ulcerative colitis and Crohn’s disease patients and AS and RA patients in Germany respectively, who were already on biologics than biologic naïve patients. Furthermore, both studies showed that quarter of the participants not knowing enough about their medications (biosimilar) as a concern [13-14].

Given the importance of biologic medicines in the UK NHS we aimed to address this gap in our knowledge of patients’ knowledge and attitudes to anti-TNF biosimilars. This study aimed to explore AS and RA patients’ understanding and attitude towards infliximab and etanercept biosimilars in UK.

1. **Methods**

This was an anonymised, self-administered web-based survey among AS and RA patients in UK. This survey was conducted between 2nd of March 2017 and 2nd of June 2017. The study was approved by the Ethics Review Panel at Keele University (Ref. ERP393).

A convenient sample of AS and RA patients who were registered members of the National Rheumatoid Arthritis Society and the National Ankylosing Spondylitis Society in the UK participated in this survey. The survey was an open survey. A request was sent to both societies to post the web survey advertisement and link to the survey on their Facebook page. A reminder post was sent via the society after four weeks of initial posting. The survey front page included information, describing the survey and asking for members voluntary participation. An electronic consent of voluntary participation was sought from the respondents by clicking an “agree” button. All the respondents were able to review and change their responses by scrolling up and down the page before submission. Cookies were used by the survey tool allowing only one response per computer. The survey tool was designed to allow only fully completed questionnaires to be submitted for analysis.

Survey themes were developed from emerging themes in the current literature on biosimilars. These themes were selected in such way that patients’ understanding and awareness about the biological nature of their medication and the concept of biosimilarity (questions 1-7), patients’ attitude toward biosimilars (questions 8-11), and concerns and questions to their HCPs in case of switching (question 12), could be successfully addressed.

A questionnaire comprising 12 questions was designed using an electronic website (Survey Monkey). All the questions were closed multiple choice questions (MCQ) with the exception of question 12 which was an open question. Questions were developed to explore knowledge, understanding and opinions towards biosimilars. The survey was piloted on a small number of lay individuals (the Primary Care user group at Keele University) and revised appropriately to eliminate redundancy and difficult or ambiguous questions. The questionnaire did not ask for any personal identifying information.

The survey responses to closed MCQs (1-11) were collated and summarised as number and percentage of responding patients using Survey Monkey and Microsoft Excel 2013. The open question (12) was analysed by thematic analysis. t-test analysis used to test the difference in the percentages between participants on originator biologics and participants on biosimilars.

1. **Results**
   1. Participants

A total 182 patients participated in this survey and responses were evenly distributed (50%:50%) between AS patients and RA patients. The majority of AS and RA patients (71%) and (73%) respectively were on etanercept. A significantly higher percentage of participants (41%) (p< 0.05) were on etanercept biosimilar (Benepali®) compared to (24%) on infliximab biosimilars (Remsima® and Inflectra®) (Table 1).

Table 1 Participants distribution

|  |  |  |
| --- | --- | --- |
|  | Ankylosing spondylitis patients (N=91) | Rheumatoid arthritis patients (N=91) |
| Infliximab   * Remicade® * Remsima® and Inflectra® | 26 (28.6%) | 24 (26.4%) |
| 21 (81%)  5 (19%) | 17 (71%)  7 (29%) |
| Etanercept   * Enbrel® * Benepali® | 65 (71.4%) | 67 (73.6%) |
| 40 (61.5%)  25(38.5%) | 39 (57%)  29 (43%) |

All survey participants (patients on originator biological and biosimilars) were aware that the medicine they used (infliximab or etanercept) was a biological medicine. The percentage of participants who knew that biosimilar versions of their branded biological medication existed was significantly higher among participants on biosimilars (83%) than in participants on originator biologics (60%) (p< 0.001). The majority of participants on biosimilars (80%), thought biosimilars were similar copies of biological medicines, 15% thought they were an identical copy of a biological medicine, and 5% thought they were a new brand of a biological medicine (Table 2).

Table 2 Participants’ knowledge and awareness

|  |  |  |  |
| --- | --- | --- | --- |
| Question | Answer | Participants on originator biologic | Participants on biosimilars |
| Did you know that etanercept or infliximab is a biological medicine? | Yes | 116 (100%) | 66 (100%) |
| No | 0 (0%) | 0 (0%) |
| Did you know there is a biosimilar etanercept or infliximab? | Yes | 70 (60%) | 55 (83%) |
| No | 46 (40%) | 11 (17%) |
| What do you think biosimilar is? | A new brand of a biological medicine | 15 (13%) | 3 (5%) |
| An identical copy of a biological medicine | 25 (21%) | 10 (15%) |
| A similar but not identical copy of a biological medicine | 76 (66%) | 53 (80%) |

* 1. Confidence in biosimilars and doctor’s decision

Participants on biosimilars had greater confidence in biosimilars to be as effective as the originator biologics and in their doctor’s decision to initiate and/or to switch to biosimilars than in participants on originator biologics (Fig. 1).

* 1. Biosimilars safety and efficacy

Most participants on biosimilars (72%) thought biosimilars were as safe and effective as the originator. In contrast, 45% of participants on the originator biologics thought that biosimilars were less safe and 60% of participants on the originator biologics thought that biosimilars were less effective than originator biologics (Fig. 2).

* 1. Switching to biosimilars

A significantly higher percentage of participants on biosimilars (74%) were comfortable and open to switching to other biosimilars than participants on originator biologics (28%) (p< 0.001) (Fig. 3).

* 1. Cost of biosimilars

58% of participants on biosimilars thought that using less expensive biosimilars would result in more patients being treated with biological medicines and 82% thought that biosimilars would help save money for the NHS. In contrast, 54% of participants on originator biologics thought that cost of treatment should not be considered when prescribing biological medicines (Fig. 4).

* 1. Patients concerns and queries

The open question of what would be your main question(s) if your healthcare professional wanted to switch you from branded infliximab/etanercept to biosimilar infliximab/etanercept, elicited some similarities in the groups but also some clear differences. More participants on biosimilars wanted to know about side effects and safety, whereas more participants on originator biologics wanted more evidence from trials. Similar proportions in both groups wanted to ask about the reasons for switching and if they could switch back. A small percentage of those on the originator biologic had been switched to a biosimilar, had a bad experience, after switching and were switched back. None of the participants currently on a biosimilar had a bad experience when switching and a small but significant proportion had switched without any concerns (Table 3).

Table 3 Responses to the questions “What would be your main question(s) if your healthcare professional wanted to switch you from originator biologic to a biosimilar?”

|  |  |  |  |
| --- | --- | --- | --- |
| Category | Participants on originator biologic N=96  N (%) | Participants on biosimilars N= 59  N (%) | Examples |
| Side effect and effectiveness | 25 (26%) | 22 (37%) | * I would want to know about possible side effects, risks & known effectiveness * Is it as effective? Are there any different side effects? * Would it work and reduce my pain as well as the branded infliximab? |
| More evidence from clinical trials on biosimilars | 31 (32%) | 8 (13%) | * Results and evidence based feedback from patient trials. Without this, I'd be reluctant to switch * What is the difference in safety, side effects, has it been vigorously tested and with how many people, is it as effective, what if it stops working? * Does it work exactly the same, does it have the same side effects, how many people who swap find it doesn't work for them. |
| Reasons for switching | 19 (20%) | 9 (15%) | * Why when it is working perfectly well * Why change from one that works and has a long-trusted safety record. * Why? I would be angry, as I've been using etanercept for 12 years ...why change something that works just to save money? |
| Switching back to originator | 16 (13%) | 10 (17%) | * Can I switch back to a branded etanercept if at any stage in the future I feel the biosimilar is becoming or has become less effective? * Can I switch back if biosimilar had no effect on my condition, or a lesser effect? * Will I be able to swap back if I don't get the same result? |
| Switched without concerns | Not applicable | 10 (17%) | * I have switched and to date it somewhat works * My doctor switched me and I did not notice any difference * I have been switched to Remsima, my disease still controlled. |
| Bad experience with biosimilars after switching | 5 (5%) | 0 (0%) | * I have previously been switched from Enbrel to Benepali which resulted in nausea, fever and feeling dizzy after the first injection. After 8 weeks, I was switched back onto Enbrel and have had no further issues since. * I tried Benepali and it did not work for me, my symptoms came back worse than ever and in more joints, I have had to switch back. * When I switched to Benepali, side effects increased |

1. **Discussion**

Almost three quarters of the participants were on etanercept. This is not surprising due to the preferred method of administration of etanercept (self-administration by subcutaneous injections or pen injectors at home) compared to intravenous infusion of infliximab in a hospital setting. This finding was in line with other studies that showed etanercept and adalimumab were the market dominant anti-TNF biologics in rheumatology [ 9, 15]. The uptake of biosimilars was also higher among participants on etanercept (40%) in comparison with those on infliximab (24%) which may also be due to the greater experience of rheumatologists with etanercept than infliximab and is in line with our previous study on HCPs [9].. In April 2017, the NHS England Medicines Optimisation Dashboard report, indicated that the median use of infliximab biosimilars as a proportion of all infliximab by hospital Trusts was about 76%, and infliximab biosimilars use was more than 95% in 20 hospital Trusts. Similarly, the median use of etanercept biosimilar as a proportion of all etanercept is about 66%, and etanercept biosimilar use was more than 95% in 14 hospital Trusts [16].

All AS and RA patients on originator biologics and biosimilars were aware of the biological nature of their medicine. Similarly, the majority of participants on biosimilars were well informed that they were on a biosimilar version of the biological medicine and understood correctly what biosimilars were (Table 2). This reflects patient education by HCPs as an integral part of the management plan and the role of professional societies that provide further information about the disease and the treatment for patients [17]. Interestingly, the level of knowledge and awareness of AS and RA patients about biosimilars was higher than the level of knowledge and awareness of HCPs in our previous study [9]. This may be due to the diversity of specialities and types of HCPs who participated in that survey (consultants, nurses and pharmacists) in gastroenterology, rheumatology, dermatology and diabetology, where contact with biologics and biosimilars may have been less than AS and RA patients. Despite this high awareness and understanding of biosimilars among participants on biosimilars, more than one third of patients on the originator biologics were not aware of the availability of a biosimilar version of their medicine (Table 2). This may be due to the fact that patients stabilised on their originator biologic had not been offered a biosimilar. Our results also showed that UK AS and RA patients have a higher level of knowledge and awareness about biosimilars than US and European patients on biological medicine and Crohn’s and ulcerative patients in Europe, where up to 70% had not heard of a biosimilar [12, 18].

Patients on biosimilars were more confident in the efficacy and safety of biosimilars and their doctors’ decision to initiate or switch patients to biosimilars than patients on the originator biologic (Fig. 1 and 2). Participants on biosimilars were more comfortable switching to other biosimilar than participants on originator biologics (Fig. 3). This indicates healthcare professional teams have been successful in communicating with and educating patients starting biosimilars. The fact that no patients currently using biosimilars had a bad experience when switching (Table 3) may also be a reflection of this support. This result was in line with Waller et al study which assessed the acceptance of biosimilars among RA and AS patients in Germany [14].

Patients on biosimilars appeared to better understand the reason for prescribing biosimilars, (i.e., cost saving to the NHS, from using less expensive biologics) (Fig. 4), while, participants on originator biologics thought that cost should not be taken into account when prescribing biological medicines (Fig. 4). A European study of Crohn’s and ulcerative colitis patients found a similar proportion felt that cost should not come before efficacy and safety, although this study did not differentiate between patients on originator biologics and biosimilars [18]. This may be due to the public misconception, previously found with generics that less expensive medicines would be less effective [19].

Patients on originator biologics and those on biosimilars had similar levels of questions about the side effects and effectiveness of biosimilars compared to the originator biologics, the reasons for switching, and the ability to switch back, whereas, a higher proportion of participants on originator biologic wanted more evidence from clinical trials on biosimilars (Table 3). Similar concerns had been reported by Crohn’s ulcerative patients, RA and AS patients in Europe [18, 14]. In the latter study which was in RA and AS patients similar to our cohort, 36-41% felt they did not know enough about biosimilars and a higher proportion of patients on originator biologic had similar concerns than those identified in our study. Both group of patients surveyed felt that more clinical trials on switching to biosimilars, pharmacovigilance studies and continuous education for HCPs would alleviate and answer patients concerns and queries. This has already been identified by the British Society of Rheumatology which has requested more clinical data before they will recommend switching and close monitoring of patients switched to biosimilars for non-clinical reasons to ensure efficacy and safety [20].

1. The strength of this study is that it is the first study in a UK cohort of patients on anti-TNFs to compare and contrast the attitudes of patients on originator biologics to those on biosimilars. Our study has some limitations, since it was not possible to calculate the response rate as the total number of members of the National Rheumatoid Arthritis Society and National Ankylosing Spondylitis Society are confidential. Despite the fact that web (Facebook) community is not a representative sample of the whole population, and results obtained with questionnaires on the web are biased towards self-selection, opinions surveyed were those of patients who were members of these specialised associations and on biological medicines (infliximab and etanercept) only which potentially could lead to bias, but we believe this unlikely as there are no advantage or disadvantages to the individual as a result of negative or positive results to the survey. Despite the fact that patients who have been switched to biosimilars had mentioned that in the open question, but it was not known the exact number of patients on biosimilars who were new users or have been switched from the originator. **Conclusion**

Within this survey of UK patients with AS and RA knowledge and understanding of biosimilars was good. Patients on biosimilars were more confident and positive about biosimilars safety, efficacy and switching, whereas, participants on originator biologics were more reluctant to switch to biosimilars. Evidence from clinical trials and information about the safety and efficacy and the possibility of switching back were the main questions participants had about biosimilars. More communication and reassurance of the patient by healthcare professional teams and further involvement in the decision-making concerning biosimilars were required to increase biosimilars acceptance. Our results are similar to other European patient studies but provide more detail on the attitudes of patients already on a biosimilar and those on originator biologic.

**Compliance with ethical standards**

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**Conflict of Interest:** Mohammed I Aladul, Raymond W Fitzpatrick, Stephen R Chapman declare that they have no conflict of interest.

**Informed consent:** Electronic informed consent was obtained from all individual participants included in the study.

**Ethical approval:** This study approved by the Ethics Review Panel at Keele University (Ref. ERP393).

**Contributors:** All authors have contributed to this study and all authors reviewed and approved the final version of the manuscript. MIA participated in the study design, data collection, and interpretation of results, prepared the manuscript draft, and performed all analytical testing and manuscript review. RWF participated in the study design, interpreted the results and reviewed the manuscript and corrected the final version of the manuscript. SRC designed the study, interpreted the results and reviewed the manuscript and corrected the final version of the manuscript.

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**Fig. 1** Participants responses when asked about their confidence in biosimilar efficacy and in doctor’s decision on initiating and/or switching to biosimilar

**Fig. 2** Participants responses when asked about their understanding with regard to biosimilar safety and efficacy

**Fig. 3** Participants responses when asked “How would you feel about being switched to a less expensive biosimilar?”

**Fig. 4** Participants responses when asked about the impact of less expensive biosimilars