**~~Ankylosing spondylitis and rheumatoid arthritis~~ Patients’ understanding and attitudes towards**

**infliximab and etanercept biosimilars in the UK**

**Abstract**

***Background*** The introduction of infliximab and etanercept biosimilars present ~~a~~ significant potential cost savings to the NHS. ~~Limited publications on~~ Patients need to be involved in the decision to use these medicines but there is a paucity of published literature on their knowledge and attitudes about these biosimilars. ~~has been identified~~.

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

***Methods*** Aself-administered, one-time web-based survey conducted among the members of the national rheumatoid arthritis society ~~in UK~~ and the national ankylosing spondylitis society in the U.K. between 2nd of March 2017 to 2nd of June 2017.

**Results** A total 182 patients participated in this survey. The majority of ankylosing spondylitis and rheumatoid arthritis patients (71%) and (73%) respectively were on etanercept. The majority of biosimilars users (80%), thought biosimilars were similar copies of biological medicines. ~~Higher~~ Greater confidence in biosimilars ~~efficacy~~ to be as effective as the originator biological and in the doctor’s decision to initiate and/or to switch to biosimilars was seen among biosimilar~~s~~ users than in originator users. The majority (82%) of biosimilars users thought that biosimilars help saving money to the NHS while just over half (54%) of originator users thought that the cost of treatment should not be considered when prescribing biosimilars.

***Conclusions*** UK Ankylosing spondylitis and rheumatoid arthritis have a good knowledge and understanding of biosimilars. Biosimilars users were more confident and positive about biosimilars safety, efficacy and switching whereas originator users were more reluctant to switching to biosimilars. More clinical trials on switching biosimilars and communication and reassurance of the patient by ~~HCPs~~ healthcare professional teams and further involvement in the decision-making concerning biosimilars were required to increase biosimilars acceptance.

**Key points**

**1**

**2**

**3**

1. **Introduction**

Ankylosing spondylitis (AS) and rheumatoid arthritis (RA) are chronic and disabling conditions [1]. The management of AS and RA have improved with the introduction of tumour necrosis factor (TNF) inhibitors (infliximab, etanercept and adalimumab) [2]. TNF inhibitors 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]. TNF inhibitors 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 TNF inhibitors to lose patent protection in 2013 and have had competition from biosimilars in Europe [5]. A biosimilar for rituximab has recently been marketed and biosimilars for adalibumab, certolizumab pegol, golimumab and ustekinumab are in development (9). The lower cost of biosimilars presents ~~a~~ significant potential cost savings in a financially constrained health system such as the NHS [6]. Thus, in theory, a lower acquisition cost potentially removes one barrier to prescribing biologics and should lead to a greater utilisation of ~~biosimilar~~ TNF inhibitors [7].

Healthcare professionals (HCPs) ~~had~~ have been surveyed ~~for~~ on their knowledge, attitude and practice towards biosimilars in UK [8]. 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 biosimilar. Furthermore, ~~HCPs~~ the survey showed that rheumatologists were more concerned than other HCPs about switching patients to biosimilars

Despite the need for active involvement of patients in ~~the management~~ decisions about disease modifying anti-rheumatic drugs (DMARDs) (ref 15 from Sullivan et al paper), and the decision to initiate or switch ~~of initiating and/or switching~~ to biosimilars ~~(or to originator) is~~ a multidisciplinary process involving the clinician, patient, specialist nurse and pharmacist, there has been a paucity of publications on the views, opinions and the attitude of patients toward infliximab and etanercept biosimilars [9]. Mo I could not see the paragraph about multidisciplinary process in ref 9 but could have missed it please check. Furthermore, whilst there has been three studies of patients attitudes to anti TNF biosimilars in Europe and only one in Rheumatology, there has been none involving U.K. patients only. Given the importance of biologic medicines in the U.K. 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 to 2nd of June 2017. This study approved by the Ethics Review Panel at Keele University (Ref. ERP393).

Participants were AS and RA patients who were registered members of the national rheumatoid arthritis society in ~~UK~~ and the national ankylosing spondylitis society in the U.K.

The survey was an open survey. A request was sent to both societies to post the web survey advertisement ~~with~~ and link to the survey on ~~both societies~~ 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 ~~their~~ members voluntary participation. An electronic consent of voluntary participation was sought from the respondents by clicking “agree” button. The survey questionnaires were designed in such a way that it could not be submitted until all questions had been answered. 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.

A ~~12-question~~ questionnaire comprising 12 questions was developed from emerging themes in the current literature on biosimilars and designed using an electronic website (Survey Monkey). All the questions were closed ~~ended~~ multiple choice questions (MCQ) with the exception of question 12 which was an open ~~ended~~ question. Questions were developed to explore knowledge, understanding and opinions towards biosimilars. The survey was piloted on a small number of lay individuals and revised appropriately to eliminate redundancy and difficult or ambiguous questions. ~~Questionnaires were not asking any~~ The questionnaire did not ask for any personally identifying information.

The survey responses to closed MCQs ~~ended~~ ~~questions~~ (1-11) were ~~collected~~ collated and summarised as number and percentage of responding ~~HCPs~~ patients using Survey Monkey and Microsoft Excel 2013. The open ~~ended~~ question (12) was analysed by thematic analysis.

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 Higher percentage of participants (40%) were on etanercept biosimilar (Benepali) ~~utilisation (38.5%) and (42%) than~~ compared to infliximab biosimilars (Remsima and Inflectra) (24%)~~19% and 29% in AS and RA patients respectively~~ (Table 1).

Mo just simplified the narrative as readers can see the detail in the table

Table 1 Participants distribution

|  |  |  |
| --- | --- | --- |
|  | Ankylosing spondylitis patients (N=91) | Rheumatoid arthritis patients (N=91) |
| Etanercept* Enbrel
* Benepali
 | 65 (71.4%) | 67 (73.6%) |
| 40 (61.5%)25(38.5%) | 39 (58%)28 (42%) |
| Infliximab* Remicade
* Remsima and Inflectra
 | 26 (28.6%) | 24 (26.4%) |
| 21 (81%)5 (19%) | 17 (71%)7 (29%) |

All survey participants (patients on originator biological and biosimilars ~~users~~) were aware that the medicine they use (etanercept or infliximab) is biological medicine. Although the majority of participants on biosimilars ~~users~~ (83%) stated that they were aware that biosimilar version of their biological medicine was available, a small but significant number (17%) did not. The majority of participants on biosimilars ~~users~~ (80%), thought biosimilars were similar copies of biological medicines, 15% thought they were an identical copy of a biological medicine, and 5% ~~had~~ thought they were new brand of a biological medicine (Table 2). Mo I have changed the narrative slightly as I did not like the term ‘user’

Table 2 participants’ knowledge and awareness

|  |  |  |  |
| --- | --- | --- | --- |
| Question | Answer | Originator users | Biosimilars users |
| 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 ~~Higher~~ greater confidence in biosimilars ~~efficacy~~ to be as effective as the originator and in their doctor’s decision to initiate and/or to switch to biosimilars ~~seen among biosimilars users~~ than in participants on originator biological ~~users~~ (Figure 1).

Figure 1 Respondents were asked about their confidence in biosimilar efficacy and in doctor’s decision on initiating and/or switching to biosimilar

* 1. Biosimilars safety and efficacy

Most ~~of~~ participants on biosimilars ~~users~~ (79%) thought biosimilars were as safe and effective as originator. In contrast, moderate to high percentage of participants on originator ~~users~~ biologic thought that biosimilars were less safe and effective than originator (Figure 2).

Figure 2 ~~Respondents were~~ Participants responses when asked about their understanding with regard to biosimilar safety and efficacy

* 1. Switching to biosimilars

Most ~~of~~ participants on biosimilars ~~users~~ (74%) were comfortable and open to switching to other biosimilars, while only 28% of participants on originator biologic ~~users~~ were comfortable to switching to biosimilars (Figure 3).

Figure 3 ~~Respondents were~~ Participants responses when asked “How would you feel about being switched to a less expensive infliximab biosimilar?” Mo was it just Infliximab?

* 1. Cost of biosimilars

58% of participants on biosimilars ~~users~~ thought that using less expensive biosimilars would result in more patients to be treated with biologics and 82% thought that biosimilars help saving money to the NHS. In contrast, 54% of participants on originator ~~users~~ biologic thought that cost of treatment should not be considered when prescribing biosimilars (Figure 4).

Mo can you change the legend to participants on xxx. Vertical axis is Percentage of Respondants

Figure 4 ~~Respondents were asked “biosimilar is less expensive than originator. I think that:”~~ Participants responses when asked about the impact of less expensive biosimilars.

* 1. Patients concerns and queries

~~In response to~~ The open question of what would be your main question(s) if your healthcare professional wanted to switch you from branded etanercept/infliximab to biosimilar etanercept/infliximab, 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 reasons for switching and could they switch back. No participants on originator biologics had been switched without concerns and a small percentage had a bad experience after switching. In Contrast no participants on a biosimilar had a bad experience on switching and a small but significant proportion had switched without any concerns. ~~the most frequently asked questions by originator users were about the side effect and effectiveness of biosimilars compared to the originator, more evidence from clinical trials on biosimilars and switching and the reason of switching. While, the most frequently asked questions by biosimilars users were about the side effect and effectiveness of biosimilars compared to the originator, the possibility of switching back them to the originator if their biosimilars was less effective~~ (Table 3).

Table 3 ~~Respondents were asked~~ 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?”~~. N= 96 for originator users. N= 59 for biosimilars users~~.

|  |  |  |  |
| --- | --- | --- | --- |
| Category | Originator users’N=96 N (%) | Biosimilars users’ N= 59N (%) | 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 of 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 | 0 (0%) | 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

This survey indicates that ~~more than two-third~~ almost three quarters of the ~~patients~~ participants were on etanercept. This is not surprising ~~since rheumatologists are highest users of etanercept than infliximab,~~ 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 ~~at~~ 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 [7,8, 11]. ~~Similarly,~~ The ~~percent of~~ uptake of biosimilars was also higher among participants on etanercept ~~users~~ (40%) in comparison with infliximab users (24%) which may also be due to the greater experience of rheumatologists with etanercept than infliximab and is in line with our previous study of healthcare professional [8].

 ~~which~~ This usage of anti TNF biosimilars in U.K. patients is higher than reported biosimilar usage by German Rheumatologists (10%) and gastroenterologists (12-13%) (9, 14) ~~taking into account that gastroenterologists are higher users of infliximab [9, 8].~~

This survey indicates that all AS and RA patients using originator and biosimilars were aware of the biological nature of their medicine. Similarly, the majority of participants on biosimilars ~~users~~ 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 healthcare professionals 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 [11]. Interestingly, the level of knowledge and awareness of AS and RA patient were higher than the level of knowledge and awareness of HCPs in previous study [8]. 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, ~~which were in less~~ where contact with biologics and biosimilar than may have been less than AS and RA patients. Despite this high awareness and understanding of biosimilars among participants on biosimilars ~~users~~, more than one third of patients on the originator biologic ~~users~~ were not aware ~~about~~ of the availability of a biosimilar version of their ~~biological~~ medicine (Table 2) ~~and/or not familiar with the concept of biosimilarity~~ . This may be due to the fact that patients stabilised on their originator biologic and not been offered a biosimilar. Our result also show 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 [12, 13], where upto 70% had not heard of a biosimilar. ~~since patient with rheumatological disease are more prone to use biological medicine than other diseases.~~

Our survey results showed that patients using biosimilars were more confident in the efficacy and safety of biosimilars in addition to their doctors’ decision about initiating and or switching patients to biosimilars than patients on originator (Figure 1, 2). Furthermore, biosimilars users were more comfortable for switching to other biosimilar than originators users (Figures ~~1, 2 and~~ 3). This indicates the success of the ~~supportive plans of managing~~ support by healthcare professional teams for patients starting biosimilars particularly in education, and communication, and their experience in using biosimilars since none of the participants in this study had a bad experience on switching (Table 3)  ~~procurement, administration and monitoring patients who will start biosimilars by healthcare professionals team (consultants, nurses and pharmacists) by informing the patients about all they need about their new medication to remove any barrier or concerns~~. This result was in line with Waller et al study which assessed the acceptance of biosimilars among RA and AS patients in Germany [14]. ~~The reason of the less confidence of originator users in biosimilars was further discussed later~~. Mo I think we have explained in the revised paragraph above.

Our results also indicate~~d~~ that patients using biosimilars were more open to the reason ~~behind the emergence of~~ for prescribing a biosimilar~~s~~, (i.e., cost saving to the NHS, from using less expensive biologics) (Figure 4) ~~which had been identified by the majority of the respondents~~ while participants on originator biologic ~~users~~ thought that cost should not be taken into account when prescribing biological (Figure 4). A European study of Crohns 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 (13).This may be due to the public misconception that less expensive medicines would be less effective which ~~was applied~~ has been found for generic medicine [15]. Whilst biosimilars are not the same as generic small molecule medicines they are in effect the same concept in biological medicines and cannot be claimed to be an identical copy as can generic small molecule medicines. ~~share the financial driver of introducing less expensive versions behind their emergence. Therefore, patients held similar views/expectations for generics and biosimilars.~~

This survey also identified patients concerns/questions ~~queries~~ ~~expressed~~ ~~when/in case of~~ if their clinician ~~want~~ were to switch them to a biosimilar version of their biological medicine. Patients on originator biologics and those on biosimilars had similar levels of questions ~~concerns were~~ about the side effects and effectiveness of biosimilars compared to the originator, the reasons for switching, and the ability to switch back, whereas a higher proportion of participants on originator biologics wanted more evidence from clinical trials on biosimilars (Table 3) ~~and switching and the reason of switching and some expressed their unpleasant experience with biosimilars after switching.~~ ~~Similarly, biosimilars users were also concerned about the side effect and effectiveness of biosimilars compared to the originator and switching back to originator if their symptoms recurred~~. Similar concerns had been reported by Crohn’s ~~and~~ ulcerative patients, ~~and~~ R.A. and A.S patients in Europe [1314]. In the latter study which was in R.A. and A.S patients similar to our cohort, 36-41% felt they did not know enough about biosimilars and a higher proportion of patients on originator biologics had concerns than those already on a biosimilar as we have found. These concerns suggest that more clinical trials on switching to biosimilars, pharmacovigilance studies and continuous education for HCPs are required to alleviate and answer patients concerns and queries. This ~~was~~ has already been identified by the British Society of Rheumatology which has requested more clinical data to recommend switching and ~~strong~~ and close monitoring of patients ~~with well response to switching~~ switched to biosimilars for non-clinical reasons to ensure efficacy and safety~~. And recommending switching back for those patients who failed to maintain the efficacy achieved with originator~~ [16]. ~~Furthermore, more communication between HCPs and patient, and incorporation of the patients in the decision-making concerning biosimilars are also required.~~ Mo not sure we need the last sentence as we have already said communication is good.

The strength of this study ~~was~~ is that it is the first study in a homogenous U.K cohort of patients on anti TNFs ~~we were able~~ to compare and contrast the attitudes of patients on originator biologics to those on biosimilars.~~users versus biosimilars users of infliximab and etanercept knowledge and attitude.~~ 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, although we would estimate it to be ~~that our response rate was low at~~ around 10%, which is a limitation.

**Conclusion**

UK AS and RA have a good knowledge and understanding of biosimilars. Patients on biosimilars users were more confident and positive about biosimilars safety, efficacy and switching. Patients on originator biologics ~~users~~ were more reluctant to switching to biosimilars. Evidence from clinical trials and information about the safety and efficacy and the possibility of switching back were the main ~~barrier for the acceptance~~ questions participants had about ~~of~~ biosimilars. ~~which require more clinical trials on switching biosimilars and communication and reassurance of the patient by HCPs team and further involvement in the decision-making concerning biosimilars.~~

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.

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