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The University of Manchester

BIR
Biologics and Immunomodulators Register

2023

BADBIR
Annual Update

Monitoring the long-term safety of new treatments for psoriasis.

British Association of Dermatologists Biologics & Immunomodulators Register

Welcome

Welcome to the 2023 BADBIR Update. As I come to end of my first year as Chief Investigator, I can reflect on the huge achievement of the UK and Ireland dermatology community in building the Register.

Led by the British Association of Dermatologists and co-ordinated at the University of Manchester, since 2007 BADBIR has grown to be a leading source of real world data for researching psoriasis therapies. This has taken remarkable collective effort at dermatology departments from Inverness to Truro, Galway to Great Yarmouth and everywhere in between. All data recorded at sites contributes significantly to answering clinically important questions on safety and treatment selection, helping strengthen reassurance for patients and prescribers as we approach two decades of Biologics for psoriasis.

A Continued Success

Later in this update, we will report on some of the key statistics following 16 years of data collection. With over 21,000 participants now registered, BADBIR continues to grow each year not just in recruitment but also follow-up data adds to the available Person Years powering pharmacovigilance and other research objectives. The scope and scale of the Register has made it the largest such psoriasis project of its kind globally. The successful alliance of the BAD and the pharmaceutical industry in commissioning BADBIR has helped set a precedent for how real world data studies can be embedded in a clinic setting and ultimately inform practice. This model has influenced similar projects including ASTAR for atopic dermatitis and likely will lead to other Registers as new treatment interventions become available for an array of dermatological conditions.

High Quality Research

The dedicated contributions from research teams across the UK and Ireland have fuelled a growing number of publications using BADBIR data. At time of writing, there are 37 articles in scientific journals (listed in full on the final page of this update). Several areas of this research work are summarised in subsequent sections including a comparative analysis of effectiveness and persistence of methotrexate and adalimumab, a profile of biosimilar use of TNF-inhibitor products, how Artificial Intelligence methods can be used to predict treatment outcome and an interesting study on paradoxical eczema utilising additional data from partner-project BSTOP. The breadth of research topics demonstrates the power of the dataset accrued in addressing a wide range of questions. Data from BADBIR is constantly reaching greater maturity and there are still plenty of unexplored research questions. The data is available to access for this purpose and I encourage anyone with a research-interest in psoriasis to explore this further. Please visit www.badbir.org/Publications/DataAccess/ for full details.

Research into Practice

This research does not reside solely in academic journals. The impact of BADBIR data can be seen in clinics and has been influencing guidelines and how we practice. Over the years BADBIR has debunked theories such as etanercept carrying a lower infective risk vs adalimumab and continually been able to demonstrate which patients are most likely to stay on therapies in the long term as a surrogate marker of efficacy. Indeed, recent publications have demonstrated that there are important differences in persistence between bio-naive patients and those who have previously been biologic exposed where some drugs seem to suffer more than others (please see Yiu et al., JAMA Derm, 2022 for more details!). Critical work is currently being done looking at all types of cancer and risk on biologics and I hope to have broadly reassuring news on this front in future updates.

Looking Forwards

With data collection still ongoing, BADBIR continues to make changes to protocol to stay as contemporaneous as possible and relevant for clinical practice in 2023 and beyond. An example of this is the recently launched Patient Portal where participants can directly contribute their own data to the study. The study design was amended earlier this year to allow as many participants as possible to record questionnaires including the Dermatology Life Quality Index (DLQI). This amendment also added severity measures specific to Generalised Pustular Psoriasis to ensure the study can appropriately assess effectiveness in all diagnoses covered in BADBIR. As the available psoriasis therapies continue to expand, BADBIR will also aim to capture information on any new small molecule products and biosimilars as they reach the NHS in the coming year.

Thank you

To close we must thank the Principal Investigators and Research Teams who have dedicated so much time and effort to building such an impressive resource. Particular thanks go to the thousands of patients who have kindly agreed for their progress on new psoriasis treatments to be followed over the last 16 years. There is evident value in the outputs from BADBIR to date and we look forward to collaboratively adding further evidence for patients and clinicians for many years to come.

Professor Richard Warren,
BADBIR Chief Investigator

Meet the **Team**

Colleagues from the BADBIR co-ordinating centre based at The University of Manchester

Study Managers

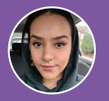
Kathy McElhone

Ian Evans

Pharmacovigilance Team

Shamila Irshad

Victoria Wilde



Saliha Tahir

Centre Support Team

Danielle Bowerbank

Aneisha Ahmed

Kerry Williams

Research Associate

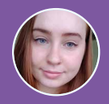
Oras Alabas

Finance Administrator

Adele Moores

Data Processing Team

Yoana Petrova



Rose Mennell

Sam Pacynko

Tegan Galbraith

Database Team

Ollie Steer

Hassan Ali

Colleagues based at The British Association of Dermatologists

Shehnaz Ahmed
Director of Research and Publishing

Joy Read
Research Coordinator

Zin Mon
Research Manager

Contents

Key statistics

21,318 total registrations

14,733
in Biologic Cohort

6,168
in the Conventional Comparison Cohort

417
in the Small molecule Cohort

141,167
Follow-up Visits recorded on BADBIR

194,967
PASIs collected

94,611
DLQIs completed

99,766
Adverse events entered

37 Journal Articles Published Using Data from BADBIR

Data held on **34** Different Systemic Treatments for Psoriasis

What the baseline characteristics of a BADBIR patient looks like...

They have had psoriasis for **19 years**

58% Are male

They were **44 years old** on Enrolment to BADBIR

19% Have Psoriatic Arthritis

90% have a white ethnicity

Their Body Mass Index is **30**

They were **21 years old** when they were diagnosed with psoriasis

Centre of the **Month**

Each month we shine the light on a BADBIR centre, we ask these centres to provide a statement on how they make BADBIR a success at their centre...

Royal Free London NHS Foundation Trust

Ruth Staunton, Richard Horne and Dr Sandy McBride

"The success of BADBIR at our site is down to teamwork. Our Consultants are very involved with BADBIR and ensure that all the information I need is documented in the hospital notes. Our Health Care Assistant in Clinic Margret Cummings is incredibly helpful when it comes to gathering the observations and ensuring correct questionnaires are given out to the BADBIR patients."

Richard Horne, Research Nurse

University Hospitals of North Midlands

Kelly Smith, Mia Marsden, Nenette Abano and Simone Locker

"We feel passionate about delivering an accurate account of the patient outcomes and ensuring that the suitable patients are successfully protected and cared for on their bespoke pathway. Successful delivery of the study would not be possible without clear and open communication not only between patients but the whole team."

Kelly Smith, Research Nursing Assistant

Wye Valley NHS Trust

"A system was devised whereby all the information that the Clinical Trials Team need is contained within the patient's clinic letter. Patients are tracked by the Clinical Trials Team on the BADBIR website so that they are aware of when patients' appointments should be. There is close liaison with our Lead Inflammatory Specialist nurse who sees many of the BADBIR follow up patients and also provides a link with the Clinical Team."

Dr Vicky Diba, Consultant Dermatologist

Liverpool University Hospitals NHS Foundation Trust (Aintree)

James Pratt, Kate Massey, Maureen Flinn, Michelle Linforth, Dr Arun Bharati

"The research nurses and practitioners have worked hard to complete all the outstanding visits and queries with the much-needed help of Kerry Williams, Clinical Pharmacovigilance Advisor, who is always happy to help and often at short notice. Maureen Flinn, Dermatology specialist nurse, who has worked on the study for 12 years, has been a great help to the research nurses with her knowledge and willingness to help when there are any queries."

Dr Arun Bharati, Principal Investigator

NHS Ayrshire & Arran

Alison Love, Julie Alexander, Yvonne Murray, Marie McLeod, and Dr Alex Waters

"Our team understands the importance of the BADBIR project, and we have strived to regularly update the database with accurate and complete information. This was particularly challenging with reduced staffing during the earlier part of the COVID pandemic, but that situation has thankfully improved. We have well-run nurse-led biologic monitoring clinics at which the necessary information is collected in a timely manner. Having clear and concise documentation is key and greatly facilitates the input of data. We are grateful to be selected as BADBIR centre of the month, and we appreciate the recognition of our work."

Dr Alex Waters, Consultant and Principal Investigator

Norfolk and Norwich University Hospital

Prof Nick Levell, Dr Priya Patel, Dr Aga Latin and Catherine Wright

"We are fortunate in having a cohesive team of doctors and nurses who support clinical research and all help with recruitment."

Prof Nick Levell, Consultant Dermatologist

Patient Portal

The BADBIR Patient Portal can help to reduce the workload of BADBIR.

Patients are able to complete their questionnaires online or via the App rather than completing them on paper in the clinic.

As we are unable to contact patients directly the Patient Portal will need to be promoted to the patients by a member of staff at your hospital. Once a patient is registered with the Portal they will get an email reminder from BADBIR when their next follow-up is due to complete their questionnaires.

If a patient doesn't wish to complete questionnaires please ask if patient would still be willing for their clinical data to be collected so that important safety data can continue to be collected.

How do Participants use the Portal?

Patients can access the Portal via the BADBIR website (**www.badbir.org**) and can create an account using details already known to them:

- NHS Number (or BADBIR Study ID Number)
- Date of Birth
- First and Last Initials

Newly registered patients can complete their baseline questionnaires through the Portal once they are entered onto the database by the clinical research team.

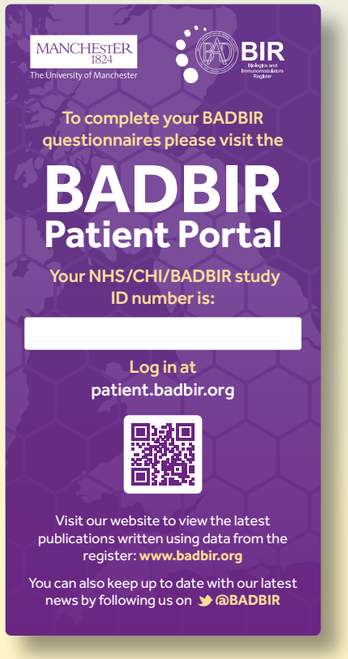
How do I inform patients of the Portal?

You are allowed to contact patients outside of their normal appointments to invite them to use the Portal. A BADBIR non-substantial amendment was approved on 15/07/2021 allowing you to make this contact.

You can contact patients however you wish (e.g. letter, phone, email, etc.) and advise them that more information is available on the BADBIR website on how to register and use the Portal.

We have a handout which can be given to the patient in clinic (picture 1). The BADBIR substantial amendment 13 which was approved on 19/01/2023 included an invitation letter for the Patient Portal which you can send to the patients in the post. The approval of this invitation letter allows reasonable changes to reflect your local practice.

Picture 1



Can all patients use the portal?

The amendment which was approved 19/01/2023 altered the study design to allow patient questionnaires to be completed at every follow-up.

Any data entered in the Patient Portal is automatically placed into the most appropriate follow-up based on the date it was completed.

Will Participants be Reminded When to Enter Questionnaire Data?

Patients who are set-up on the Portal will receive an email prompt when their next questionnaires are due and receive reminder emails if the questionnaires were not completed after the first prompt.

Where Can I Find More Information on the BADBIR Portal?

Further information about the Portal is available on the BADBIR website (**www.badbir.org**). The BADBIR team can also be contacted directly with any queries on **badbir@manchester.ac.uk** or **0161 306 1896**.

Save time in clinic by using the BADBIR Patient Portal

- **No need to print questionnaires for patients complete**
- **No data entry required – patient responses are saved directly into the BADBIR database**
- **Participants will be prompted automatically when questionnaires are due**
- **Time required to file, scan or archive questionnaires is not needed with the Portal**

Patient Follow-up

What is the importance of the BADBIR follow-up data?

Adverse Events

The primary purpose of BADBIR is to establish if there is an increased risk of serious adverse events following the exposure to biologic and small molecule treatments compared to patients treated with conventional treatments who have a comparable disease severity.

It is important we continue to capture adverse event data for these patients as often rare adverse event outcomes require many person years of follow-up to be identified.

Every follow-up entered helps BADBIR get closer to powering analysis and answering important research questions

Disease Severity

Long term follow-up of Psoriasis Assessment Score Index (PASI), Psoriasis Global Assessment Score (PGA) and Dermatology Life Quality Index (DLQI) scores are required for analysis to determine the long-term efficacy of anti-psoriatic treatments.

Current Anti-psoriatic Therapy

There has been a huge expansion of treatment options for psoriasis in the last decade, patients now have a cumulative exposure to many different products.

Accurate documentation of the drug the patient is taking is vital for analysis, if the wrong drug is reported at follow-up there will be an error in the safety reporting and analysis.

Since the introduction of biosimilars the brand name is crucial for correctly identifying and distinguishing between these and the originator products (e.g. Humira vs Amgevita).

Potential Confounders

We collect further data on potential confounders, these include:

- Concomitant therapies
- Phototherapy
- Weight
- Waist
- Smoking
- Alcohol Intake

All the potential confounders listed above need to be taken in consideration to understand how these factors affect the safety of these patients and the severity of their psoriasis.

We are hugely grateful for the support we receive from the staff collecting the follow-up data at the 167 centres contributing to BADBIR across the UK and the Republic of Ireland.

Top Tips

- The Follow-up Summary is useful to check what psoriasis therapy the patient was on at their lastest BADBIR follow-up – this can be printed and taken to clinic.
- Speak to the Dermatology Team and Pharmacy as they may have a more accessible way to find out therapy brand name and start/stop dates as it can often not be clear from clinic letters.
- The most accurate adverse event data is obtained from checking hospital notes and speaking to the patient – The patients may not realise that an adverse event that happened some months ago would fall within the latest BADBIR follow-up.
- If you are struggling to catch-up, email us at **BADBIR@manchester.ac.uk** and a member of our team will contact you to arrange the appropriate support.

Portsmouth Hospitals University NHS Trust

Emily Rolfe, Dr Eleanor Clarke and Dr Alexa Shipman

"BADBIR is embedded into the clinical service. With potential new patients and follow-ups highlighted on clinic lists to our clinical colleagues and our psoriasis nurses, who see many of the patients. All of whom recruit patients. On a weekly basis we look at upcoming patients and review the follow ups and queries on the database so as to keep the data as up to date as possible. We have dedicated time from a clinical trials assistant purely for BADBIR data collection, a research fellow to assist and some research nurse time."

Jonathan Winter, Specialist Research Nurse

Aneurin Bevan Health Board

Rina Mardania, Clare Westacott

"We have created and maintained a collaborative relationship with all members of our dermatology team and this has been instrumental in making sure that all data is clearly documented at each patient follow up. This ensures that every follow-up conducted is completed accurately, and in a timely manner.

Rina Mardania, Clinical Research Officer

Incorporating **Research into Practice**

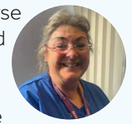
Teena Mackenzie, Research Nurse Royal Berkshire NHS Foundation Trust, Education and Development Lead for British Dermatological Nursing Group

Over the last few years, nurses have faced many challenges and nursing shortages is one of those which has added to the pressure of working within the NHS.

Worldwide 13 million more nurses are required over the next decade according to a recent report from the International Council of Nursing, which equates to almost half of the world's current 28 million workforce[1]. With staff shortages, nurses leaving the profession can add to the barriers of carrying out research in busy departments. However, we must remember research is vital in the NHS to provide the evidence we need to transform services and improve patient outcomes[2]. As nurses working in advanced practice, we incorporate the four pillars which comprise of Leadership, Education, Clinical Practice and Research[3]. Therefore, it's important for nurses to integrate research into their individual practice. Alas, this isn't easy with the pressures nurses are feeling with the increasing workload and time constraints.

However, the Chief Nursing Officer in NHS England developed a strategic plan for research to set out an ambition to "create a people-centred research environment that empowers nurses to lead, participate in and deliver research, where research is fully embedded in practice and professional decision -making for public benefit"[4].

In addition, part of the NIHR commitment is to enhance the nation's health and wealth through research and they work with the NHS to improve the environment for research in England. This includes funding and supporting research that is meaningful and practical[5]. I am fortunate to work alongside a Research Nurse Caroline Hayden (pictured right) at the Royal Berkshire, who is funded for Dermatology. Caroline is very passionate about research and joins me in clinic to actively recruit for BADBIR and other studies. Evidence shows that patients benefit from research and innovation, and this helps develop more effective treatments, better outcomes, and prevention of ill health[6]. Indeed, I have witnessed the benefits of patients seeing Caroline and how they feel cared for whilst taking part in research. Alas, not every department has allocated research teams and therefore its crucial more nurses become involved in research. Despite myself not being a research nurse, I am still a Principal Investigator for BADBIR. Indeed, working at advanced clinical practice a requirement under the four pillars is research. As I have mentioned we are under immense pressure with time constraints and increased workloads and need help in achieving this.



Therefore, the excellent BADBIR Team are here to help with organising Departmental meetings to help with the running of BADBIR. This includes ensuring all team members are aware of the importance of BADBIR, promoting the eligibility criteria, ensuring critical data is captured in notes to aid the research staff with their role. They also can provide one to one training for new staff and support with query and follow-up completion.

I would encourage nurses to contact the BADBIR Team, they are so helpful and supportive. It is possible to embed research into our busy Dermatology Departments. Please contact **badbir@manchester.ac.uk** if you need any further advice or support.

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Centre Profile: **Calderdale & Huddersfield NHS Trust**

Tonicha Nortcliffe, Clinical Trials Assistant

As a Clinical Trials Assistant, it is my role at Calderdale and Huddersfield NHS Trust (CHFT) to manage and complete BADBIR follow ups and data queries, with the support from the research nurse.

The pandemic brought on new challenges to our site where patients were not being seen in clinics. Our clinicians and specialist nurses resorted to seeing patients remotely - as was the case at many other sites . This led to our follow up procedures changing including finding new ways to complete the follow ups remotely using the notes, highlighting the need for detailed documentation in the patients' record. .

Whilst conducting COVID-19 research the CHFT research team created pre-populated text for electronic patient records. These texts were made accessible to clinicians to enable them to document efficiently in the absence of the Research Team to include the source information we require for our studies.

This proved to be very successful in the COVID-19 studies which lead to our research team deciding to use this template for other studies such as BADBIR. The research nurse and I created a pre-populated text that reflected the 'BADBIR Clinical Follow-up Questionnaire'. I then spent some time with the Dermatology Specialist Nurses to set up their pre-populated templates and assist them in familiarising themselves with it.

It particularly works well for BADBIR as it makes sure all the source data required for the 'Clinical Follow-up Questionnaire' is collected by the Dermatology Specialist Nurses during the patient's routine appointment. For example, the brand of a drug may not routinely be documented in the patients notes or why a brand has been changed i.e., financial consideration. However, it is a requirement for the Clinical Follow-up Questionnaire, so having this as a prompt in the pre-populated text prompts the clinicians to document this information. This enables the Research Nurse and Clinical Trials Assistant to accurately complete BADBIR's Clinical Follow-up Questionnaires therefore reducing the number of queries received and improving the quality of data.

It is important to highlight our successes in these processes at our site and emphasise the importance of building good relationships with departments and teams by having good communication in this case with the Dermatology Specialist Nurses. There is a mutual understanding of the importance of using the pre-configured texts, as the Dermatology Specialist Nurses could see the benefits and willingness to add this additional step to their process.

I will log onto the BADBIR Database as often as possible to look out for any outstanding follow ups or data queries.

When a patient is due a BADBIR follow up, I will diarise the patient's clinic appointment within my own and the Research Nurse's outlook calendar. We will then decide who will attend clinic to complete the follow up depending on individual capacities.

Prior to attending clinic, I would pull up a patient's summary and transfer the data onto the paper Clinical Follow-up Questionnaire, then I use this to query outstanding information with the patient i.e., Stop dates for ongoing adverse events. I would also perform weight and waist measurements.

If it is not possible for myself or the Research Nurse to see the patient in clinic I will use the patients notes to complete the follow-up. This is where the pre-populated templates that are used by the Dermatology Specialist Nurses really help to collect all the data required.

As I am not from a clinical background there may be times that I need the Research Nurses support in answering certain Serious Adverse Events or completing the Event of Special Interest forms.

As part of my job role I process any amendments from a delivery team perspective i.e., localising documents and updating our local drives with the updated versions.

Application of artificial intelligence in **predicting biologic treatment outcomes in psoriasis**

Dr Amaani Hussain, NIHR Academic Clinical Fellow, Newcastle University
Dermatology Registrar in Newcastle upon Tyne

Applying for BADBIR data

The process of applying for access to the BADBIR dataset was simple and efficient. Our research group at Newcastle University (led by Principal Investigator Professor Nick Reynolds) submitted a collaborative application highlighting the aims of our project and our intended methodology. This was reviewed in a timely manner by the BADBIR Steering Committee and data access was granted and securely transferred. The BADBIR data management team guided us through the data structure and were available to answer queries regarding the data once the project commenced. Working external to Manchester University did not impact our ability to gain access to the data or prolong the process. We have been able to obtain subsequent data cuts and support as required.

Our research

Studies assessing how well biologics work outside of routine clinical trial settings, using BADBIR data, have shown that these are highly effective drugs for the treatment of moderate to severe psoriasis. However, these studies have also demonstrated that a proportion of patients do switch biologic therapy, due to lack of effectiveness or adverse events.[1] For clinicians, there is currently no good evidence-base to guide biologic treatment selection. As a result, much psoriasis research is being directed to personalising therapy selection, i.e., choosing the most safe and effective drug for an individual patient at baseline.

Artificial intelligence (AI) methodology has been applied to many clinical questions and is effective at analysing large, complex datasets such as that within BADBIR. A subset of deep learning AI known as recurrent neural networks (RNNs), are particularly effective at handling longitudinal healthcare data. Such models can highlight complex patterns within datasets that routine statistical methods cannot. At present, such models predicting treatment outcomes have not been applied to BADBIR data or other large psoriasis real-world datasets.

Aim: Using BADBIR data, develop a subtype of RNNs, known as long short-term memory RNNs, to predict:

1) Discontinuation of biologic therapy (also known as drug survival) (model 1)
2) Absolute Psoriasis Area and Severity Index (PASI) ≤2 (equivalent to a 90% reduction in baseline PASI)[2] at 6 (model 2) and 12 months (model 3) after initiating biologic therapy

Results: Good predictive performance was achieved following training.

Model 1 (predicting drug survival, n= 10,932) performance: precision 0.90, recall 0.65, F1 score (a combined metric of precision and recall) 0.75, AUROC (area under receiver operator characteristic curve) 0.83 and AUPRC (area under precision-recall curve) 0.82. Model 2 predicted absolute PASI≤2 at 6 months: precision 0.59, recall 0.93, AUROC 0.71, AUPRC 0.78. Precision improved at 12 months (0.65, n=6,506).

Performance was superior to previously published models predicting treatment outcomes in psoriasis.[3,4]

Implications: This research demonstrated that AI can be successfully applied to BADBIR data and that such models could have potential clinical utility in the future.

This proof of concept study was presented at the International Society of Investigative Dermatology meeting held in Tokyo, Japan in May 2023.

Future work: There are several steps that are required to understand the potential clinical application of these models, which will form the next stage of this project.

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Biosimilars for Psoriasis Treatment: **Findings, Future Directions, and Challenges**

Duc Binh Phan, PhD Student, The University of Manchester

My name is Duc Binh Phan, a PhD Student at The University of Manchester. I have been granted a PhD studentship by The Psoriasis Association for my project titled "Evaluation of Tumour Necrosis Factor Inhibitor Biosimilar Use in the UK for psoriasis: a study from the British Association of Dermatologists Biologics and Immunomodulator Register."

My PhD Project

Tumour Necrosis Factor Inhibitors (TNFi) are effective but costly treatments for moderate to severe psoriasis. Biosimilars, products that are highly similar to licensed originator compounds, are much cheaper and therefore offer potential cost savings in healthcare. However, due to manufacturing complexities, it is almost impossible to produce a biosimilar that is an exact replica of the originator. Therefore, biosimilars are not identical to their originator product. Although clinical trials have not revealed any disparities between biosimilars and originators, the extent to which these findings translate into routine clinical practice is yet to be fully understood. My PhD project aims to assess TNFi biosimilars (adalimumab, etanercept, and infliximab) in psoriasis treatment in the UK and the Republic of Ireland (RoI). The 2 objectives include describing biosimilar distribution and uptake among new users and switchers, as well as comparing their effectiveness and safety to originator products.

Initial results of the project

In the first stage of our project, we looked at how biosimilars of TNFi drugs were being used in the UK and the RoI. We examined how many people were choosing to switch from the original drugs to the biosimilars in different geographical regions of England, Wales, Scotland, Northern Ireland, and the RoI. We also looked at how many patients who were new to TNFi drugs were starting with the biosimilars instead of the original ones. Additionally, we wanted to see if there were any factors about the patients that influenced their decision to switch or start with the biosimilars.

Our study found that over time, more patients using the original biologics switched to biosimilars. For example, in the first year, only 1% of patients using infliximab, 1% using etanercept, and 44% using adalimumab switched. By the third year after the introduction of biosimilars, these numbers increased to 15%, 24%, and 67%, respectively. However, the use of biosimilars varied in different regions of the UK and the RoI. For instance, the rates of switching from originators to infliximab biosimilars ranged from 0% to 44%, etanercept biosimilars ranged from 13% to 40%, and adalimumab biosimilars ranged from 13% to 84%. We also found that male patients were 1.2 times more likely to switch to biosimilars compared to female patients. Additionally, patients with a Psoriasis Area and Severity Index (PASI) of less than 4 were 0.6 times less likely to switch to biosimilars. These findings provide insights into how biosimilars are being used to treat psoriasis, and they can help guide future investigations into their cost-effectiveness in the UK and the RoI.

Work in process

Assessing biosimilars' long-term effectiveness and safety in real-world settings by looking at how likely people are to stop using these treatments can inform clinical decision-making and identify optimal treatment options. Evaluating the risk of adverse events associated with biosimilars in real-world settings is also crucial as it may differ from clinical trial estimates. These evaluations provide reassurance on biosimilar effectiveness and safety, enhance confidence in their use, or identify differences among available adalimumab products.

In the upcoming phase of our project, we will conduct a multinational cohort study to compare the probability of discontinuing treatment and the risk of adverse events of adalimumab biosimilars and adalimumab originators for psoriasis treatment. Utilising routinely collected healthcare databases and pharmacovigilance registries from the UK, France, and Spain, this study is anticipated to be the largest real-world cohort study investigating the use of adalimumab biosimilars for psoriasis treatment.

Challenges

In this project, one of the main challenges we faced was maintaining the accuracy of the data, which relies heavily on the quality of information recorded at each research centre. Accurate documentation of the drug brand name was crucial for correctly identifying and distinguishing between biosimilars and originator products. When a biosimilar like Amgevita or Imraldi is mistakenly labelled as Humira, it becomes a serious problem for studying these drugs. This issue has important consequences because it can hide important differences in how the treatments work or any safety issues. As a result, the analysis results become biased and inaccurate from the true picture. This means that valuable information can get lost. Therefore, it is essential to accurately record the brand name of each biosimilar and the originator biologic to ensure unbiased results and valid comparisons.

PUBLICATION

Effectiveness and survival of methotrexate versus adalimumab in patients with moderate-to-severe psoriasis: A cohort study from the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR)

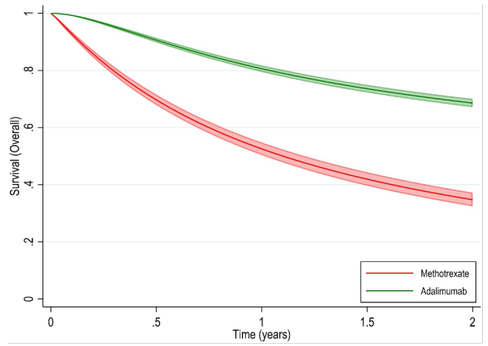
Dr Oras Alabas et al.
Br J Dermatol, 2023

Question: What is the effectiveness and persistence of methotrexate compared with adalimumab for the treatment of moderate-to-severe psoriasis in an everyday clinical setting?

Findings: We showed that patients prescribed adalimumab were twice as likely to be clear or nearly clear of psoriasis at any time during treatment as compared to patients on methotrexate [Risk Ratio (95% confidence intervals) 2.20 (1.98 - 2.45)]. We also showed that patients would stop methotrexate 0.53 years sooner than those on adalimumab.

Meaning: Our results confirmed previous findings from clinical trials and cohort studies that adalimumab is superior to methotrexate in both effectiveness and persistence. Nevertheless, non-biologic systemic agents are still offered before biologics to treat patients with moderate-to-severe psoriasis in the UK. This is undoubtedly related to cost of adalimumab prior to the introduction of far cheaper biosimilars of the originator (Humira). By considering these findings, we hope that the guidelines on the management of psoriasis could be updated to reinforce the argument for using biosimilars, a cheaper option to biologics, early in the treatment pathway for psoriasis as a more effective alternative to methotrexate.

Overall adjusted standardised drug survival with 95% confidence intervals (CI)



Results of effectiveness and survival

Effectiveness		Methotrexate	Adalimumab
	Total, n (%)	2,659 (40)	3,916 (60)
	Available PASI records, n (%)	975 (23)	3,297 (77)
	aPASI, n (%)	365 (37)	2,553 (77)
	PASI, median (IQR)	3 (1, 8)	0 (0, 2)
	Risk Ratio (95% CI)	2.20 (1.98, 2.45)	
Persistence		**Methotrexate**	**Adalimumab**
	Duration of exposure, mean (years) (SD)	0.7 (1.1)	2.9 (2.6)
6 months	Overall	69.7 (67.9, 71.5)	90.6 (89.8, 91.4)
	Ineffectiveness	79.6 (78.0, 81.3)	94.5 (93.9, 95.1)
	Adverse events	87.4 (86.0, 88.8)	96.1 (95.5, 96.6)
1 year	Overall	52.5 (50.4, 54.8)	80.6 (79.5, 81.8)
	Ineffectiveness	69.2 (67.1, 71.4)	87.2 (86.2, 88.2)
	Adverse events	76.6 (74.5, 78.6)	92.4 (91.6, 93.2)
2 years	Overall	34.8 (32.5, 37.2)	68.6 (67.2, 70.0)
	Ineffectiveness	56.9 (54.2, 59.7)	78.6 (77.3, 79.9)
	Adverse events	62.0 (59.0, 65.0)	87.1 (86.0, 88.2)
RMST (years)		**Methotrexate**	**Adalimumab**
2 years	Overall	0.53 (0.49, 0.58)	
	Ineffectiveness	0.37 (0.33, 0.42)	
	Adverse events	0.29 (0.25, 0.33)	

Abbreviation: IQR: 25, 75% Inter-quartile range; SD: standard deviation; BMI: Body Mass Index; PASI: the Psoriasis Area and Severity Index; aPASI: achieved PASI≤2 at any time during follow-up after 13 weeks of treatment; RMST: restricted mean survival time. 0. 53 (0.49, 0. 58),

PUBLICATION

Atopic polygenic risk score is associated with paradoxical eczema developing in patients with psoriasis treated with biologics

Dr Ali Al-Janabi et al.
J Invest Dermatol, 2023

Paradoxical eczema is an atopic eczema phenotype that develops in some patients receiving biologic therapies for psoriasis or other immune-mediated inflammatory diseases. This can lead to use of multiple immunomodulatory agents or cessation of biologic therapy, risking exacerbation of psoriasis. A range of paradoxical reactions, or cutaneous adverse events, to biologic therapies have been reported but the risk factors and mechanisms are poorly understood.

Questions: Are there genetic variants associated with paradoxical eczema? Is there an association between genetic burden for atopy (atopic eczema, asthma or hay fever) and paradoxical eczema?

Findings: In this study of 3212 genotyped psoriasis patients treated with biologics, of whom 88 developed paradoxical eczema during biologic exposure, we identified two non-coding loci associated with paradoxical eczema: lead variants rs192705221, near UNC5B, and rs72925168, within SLC1A2. The functional consequences of these variants are unknown. We additionally identified an association between paradoxical eczema and atopic genetic burden, as measured by polygenic risk scores, which are numerical values indicating the combined effect of multiple genetic variants for a disease or other trait. This association remained even after adjusting for known atopic comorbidities. A polygenic risk score containing variants influencing interleukin-12 signalling was also associated with paradoxical eczema.

Meaning: This is the first study to identify risk variants associated with paradoxical eczema. The polygenic risk score analyses indicate that patients with a higher genetic tendency to atopic diseases (atopic eczema, asthma or hay fever) are more likely to develop paradoxical eczema, even in those individuals who do not have a history of these conditions. Furthermore, in this study genetic variants influencing interleukin-12 signalling, an immune pathway which can impact the development T-helper 1 cells, increase the risk of paradoxical eczema. The significance of this study is that it advances our understanding of the mechanisms of paradoxical eczema. In combination with further studies examining the immunology of paradoxical eczema, this could provide a rationale for targeting type 2 inflammatory pathways, predominant in atopic eczema, in patients with or at risk of paradoxical eczema.

Association between atopic and pathway-specific polygenic risk scores and paradoxical eczema, before and after adjustment for known atopic comorbidities.

Polygenic risk score	Number of variants	Logistic regression		Logistic regression with atopic comorbidities	
		OR (95% CI)	*P*	OR (95% CI)	*P*
PRS_{AE}	81	1.89 (1.08-3.30)	0.026	1.90 (1.07-3.39)	0.029
PRS_{AT}	124	2.24 (1.20-4.17)	0.011	1.99 (1.06-3.76)	0.034
PRS_{CO}	170	1.83 (1.17-2.84)	0.0078	1.73 (1.09-2.73)	0.020
PRS_{IL4}	51	2.08 (0.70-6.06)	0.19	1.95 (0.65-5.91)	0.24
PRS_{IL12}	18	4.89 (1.03-23.29)	0.046	3.76 (0.77-18.24)	0.10
PRS_{IL17}	36	1.55 (0.47-5.14)	0.47	1.43 (0.42-4.91)	0.57

This study utilised data from both BADBIR and BSTOP (Biomarkers and Stratification To Optimise outcomes in Psoriasis). BSTOP is a UK, multi-centre, longitudinal observational study initiated in 2011, funded through the Psoriasis Association and NIHR. BSTOP aims to understand the causes and molecular mechanisms that drive psoriasis development, progression, and treatment response with over 7000 patients with psoriasis recruited and collected over 30,000 samples to date through a network of 81 UK Dermatology sites **www.kcl.ac.uk/research/bstop**

Principal Investigators

Thank you to the Principal Investigators and their teams at all the centres who contribute their time and effort to BADBIR. It is the ongoing hard work and commitment of these teams which helps continue the success of the Register.

Accurate on 05/06/2023. Note some centres do not have a current principal investigator listed.

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