Patterns of index biologic drug registrations to a pharmacovigilance register of psoriasis patients

Document Version
Final published version

Link to publication record in Manchester Research Explorer

Citation for published version (APA):

Citing this paper
Please note that where the full-text provided on Manchester Research Explorer is the Author Accepted Manuscript or Proof version this may differ from the final Published version. If citing, it is advised that you check and use the publisher's definitive version.

General rights
Copyright and moral rights for the publications made accessible in the Research Explorer are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Takedown policy
If you believe that this document breaches copyright please refer to the University of Manchester’s Takedown Procedures [http://man.ac.uk/04Y6Bo] or contact uml.scholarlycommunications@manchester.ac.uk providing relevant details, so we can investigate your claim.
Patterns of index biologic drug registrations to a pharmacovigilance register of psoriasis patients.


1. Division of Musculoskeletal and Dermatological Sciences, The University of Manchester, Manchester, United Kingdom;
2. British Association of Dermatologists, London, United Kingdom;
3. Dermatology Group, St Vincent’s University Hospital, Dublin, Republic of Ireland;
4. Department of Dermatology, Western Infirmary, Glasgow, United Kingdom;
5. Institute of Cellular Medicine, Newcastle University, Newcastle, United Kingdom.

BACKGROUND

- The introduction of biologic therapies revolutionised treatment of psoriasis and psoriatic arthritis (PsA).
- Recommendations for treatment of psoriasis (Figure 1 and Table 1) and PsA (Table 2) with biologics revised over time.

Figure 1: Timeline of biologic and biosimilar authorisation, and guideline publications

British Association of Dermatologists Biologics Intervention Register, BADBIR; British Association of Dermatologists, BAD; National Institute for Health and Care Excellence, NICE; technology appraisal guidance, TA; Scottish Intercollegiate Guidelines Network, SIGN; clinical guideline, CG; European Medicines Agency, EMA.

Table 1: Guidelines for treatment of psoriasis with biologics

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Recommendations (PASI≥10 &amp; DLQI≥10 unless specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAG</td>
<td>Smith et al. 20051 Enbrel first line; Remicade for rapid control; Rapiva for latent TB</td>
</tr>
<tr>
<td>Smith et al. 20052 Enbrel, Humira &amp; Remicade recommended; Stelara if anti-TNF failed</td>
<td></td>
</tr>
<tr>
<td>SIGN 121, 20101 Humira, Enbrel &amp; Stelara recommended; Remicade for rapid control (PASI≥20 &amp; DLQI=18)</td>
<td></td>
</tr>
<tr>
<td>NICE</td>
<td>TA103, 20081 Enbrel &amp; Rapiva recommended</td>
</tr>
<tr>
<td>CG153, 20121 Humira, Enbrel &amp; Stelara recommended; Remicade for rapid control (PASI≥20 &amp; DLQI=18)</td>
<td></td>
</tr>
</tbody>
</table>

Psoriasis Area Severity Index, PASI; Dermatology Quality of Life Index, DLQI; tuberculosis, TB; tumour necrosis factor, TNF.

Table 2: Guidelines for treatment of PsA with biologics

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>SIGN 121, 20101 Humira, Enbrel &amp; Stelara recommended</td>
<td></td>
</tr>
<tr>
<td>NICE</td>
<td>TA103, 20101 Humira, Enbrel &amp; Stelara recommended</td>
</tr>
<tr>
<td>TA340, 20151 Stelara recommended</td>
<td></td>
</tr>
</tbody>
</table>

- BADBIR is a prospective, observational, web-based pharmacovigilance cohort of psoriasis patients recruited from 153 dermatology centres in the UK and Republic of Ireland (ROI).
- The aim of the registry is to explore the long-term safety of biologic agents compared to conventional systemic agents.

OBJECTIVES

To describe patterns of index biologic registrations for biologic-naïve psoriasis patients in BADBIR by:

(i) country (England; Northern Ireland (NI); ROI; Scotland; Wales);
(ii) comorbid PsA.

METHODS

Figure 2: BADBIR study design

Inclusion: registration to biologic cohort before 01/01/2016 (n=7495);
Exclusion: prior biologic exposure (n=1345);
Outcomes: country of registration; prevalent PsA.

RESULTS

- 6140 biologic-naïve patients (82% biologic cohort); median age 45 years, inter-quartile range 36-54 years, 60% male.
- Registrations by country: England (n=4697; 76%); NI (n=299; 5%); ROI (n=289; 5%); Scotland (n=525; 5%); Wales (n=330; 5%).
- Humira (57%) was the most common index biologic (23% Enbrel; 18% Stelara; 2% Remicade).

Figure 3: Index biologic registrations for England (A), NI (B), ROI (C), Scotland (D) and Wales (E); 2010-2015

Future work will explore which baseline factors influence index biologic therapy prescribing practices.

CONCLUSION

- Registrations to BADBIR reflect index biologic prescribing practices in biologic-naive psoriasis patients.
- Humira was the most commonly prescribed index biologic drug across the UK and ROI.
- First line Enbrel prescribing decreased and Stelara increased over time in the UK; however, Enbrel use was common in ROI, with few index registrations of Stelara.
- Future work will explore which baseline factors influence index biologic therapy prescribing practices.

REFERENCES


ACKNOWLEDGEMENTS

The authors express their gratitude to all patients, centres, the BADBIR team, BAD, sponsors, and all current and/or former members of the BADBIR steering committee.

Disclosures: BADBIR is coordinated by the University of Manchester. BADBIR is funded by the British Association of Dermatologists (BAD). The BAD receives income from AbbVie, Janssen Cilag, Novartis, Samsung Bioepis and Pfizer for providing pharmacovigilance services. This income finances a separate contract between the BAD and the University of Manchester who coordinate BADBIR. All decisions concerning analysis, interpretation, and publication are made independently of any industrial contribution. KJM received lecture fees from Janssen Cilag (Dec. 2015) and Eli Lilly (May 2016).