Infliximab is Associated with an Increased Risk of Serious Infection in Patients with Psoriasis

Results from the British Association of Dermatologists Biologic Interventions Register (BADBIR)


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SUMMARY

Infliximab is associated with a higher risk of serious infection when compared to non-biologic systemic therapies in patients with psoriasis.

Patients with severe psoriasis who fulfill the criteria for the prescription of infliximab should be counselled for the associated risk of serious infection.

BACKGROUND

1. Adverse events (AEs) can lead to discontinuation of biologics for the treatment of psoriasis. Of these AEs, infection is the most common.
2. Randomised clinical trials are not powered to investigate AEs and have low external validity.
3. Risk of serious infection in patients with psoriasis on biologics is currently not well-understood.
4. Infliximab is prescribed to a select group of patients in the UK (PASI ≥ 20, DLQI > 18).

AIM

To determine whether infliximab is associated with a higher risk of serious infection as compared to non-biologic systemic therapies for psoriasis.

METHODS

British Association of Dermatologists Biologic Interventions Register (BADBIR) - prospective safety registry of patients with psoriasis established in 2007 in the UK and the Republic of Ireland.

Compares a cohort on biologic therapies with a cohort on non-biologic systemic therapies with the same disease severity entry criteria: Psoriasis Area and Severity Index (PASI) ≥10 and Dermatology Life Quality Index (DLQI) ≥ 10

Data collected 6 monthly for first 3 years, annually thereafter

Inclusion criteria:
- Data lock October 2016
- Biologic-naive
- Chronic plaque psoriasis
- Follow-up data available

RESULTS

<table>
<thead>
<tr>
<th>Infliximab (1st line)</th>
<th>105</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab (all)</td>
<td>442</td>
</tr>
</tbody>
</table>

3843 eligible patients in total

Figure 1: Number of patients and median follow-up in each cohort

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Total Persons (n=105)</th>
<th>Infections (1000 person-years)</th>
<th>Rate (/1000 person-years)</th>
<th>95% confidence interval (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-biologics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infliximab (1st line)</td>
<td>53.8</td>
<td>14</td>
<td>58.5 (47.98,69.0)</td>
<td></td>
</tr>
<tr>
<td>Infliximab (all)</td>
<td>53.2</td>
<td>45</td>
<td>47.8 (35.75,64.0)</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Total person-time, number of infections, and crude incidence rate in each cohort

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Crude HR (95% CI)</th>
<th>Adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab (1st line)</td>
<td>4.19 (2.42, 7.26)</td>
<td>3.97 (2.01, 7.76)</td>
</tr>
<tr>
<td>Infliximab (all)</td>
<td>1.51 (0.96, 2.39)</td>
<td>1.95 (1.01, 3.75)</td>
</tr>
</tbody>
</table>

Table 2: Crude and adjusted effect estimates for infliximab (1st and all-lines) against non-biologic therapies from the Cox regression models

DISCUSSION

1. Crude incidence rates of serious infections for infliximab are higher than reported figures.
2. Adjusted results similar to PSOLAR (US based psoriasis registry) (HR 2.51 mixed prevalent/incident population; HR 1.78 incident population) when compared to acitretin/phototherapy, and BIOBADADERM (Spanish psoriasis registry) (HR 2.52) when compared to methotrexate


ACKNOWLEDGEMENTS

Participants of BADBIR, principal investigators, research nurses, recruiting doctors, BADBIR office team, BADBIR biostatistics manager, BADBIR reviewing and data monitoring committee, BADBIR data analysis working group.

COSUR is an National Institute for Health Research (NIHR) Senior Investigator. ZZNY is funded by a NIHR Doctoral Research Fellowship (Ref: DRF-2015-08-095). This is a summary of independent research funded by the NIHR Doctoral Research Fellowship. The views expressed are those of the author and not necessarily those of the NHS, the NIHR, or the Department of Health.


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