Long Term Observation of Biologics in Germany –
Which Patients Are Treated with Biologic Compounds?

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Introduction

The efficacy of etanercept, infliximab, anakinra and adalimumab has been proven in randomised clinical trials in patients with active rheumatoid arthritis (RA), in particular in patients not responding to conventional disease modifying antirheumatic drugs (DMARDs). Nevertheless, the percentage of patients with rheumatoid arthritis treated with biologic compounds is limited especially due to financial restrictions. Therefore, we used data from the German biologics register (RABBIT) to investigate which patients are likely to receive this kind of treatment.

Patients and Methods

Since May 2001, patients with RA and a new prescription of etanercept, infliximab, anakinra and adalimumab (since September 2003) as well as control patients have been consecutively enrolled into the German biologics register (RABBIT). For better comparability with the patients on biologics, the control group consists of patients with RA who had a change in their DMARD therapies (no first prescription). The patients will be followed-up for five years. 172 rheumatological units (private practices and outpatient departments of hospitals) from all parts of Germany participate. Data are shown for patients enrolled until March 2004.

Additional comparison data are available for more than 11,000 RA patients per year from the National Database of the German Arthritis Centres (NDB) that registers outpatients treated by German rheumatologists.

The results of the multivariate logistic regression analysis are shown as estimated likelihoods (propensity scores) of being treated with biologics.

Results

As of March 2004, 2084 patients with RA had been registered in the RABBIT database.

Table 1 shows the demographic and clinical characteristics of the cases, controls, and the patients in the National Database (NDB). In patients who had just started on the biologic therapy, the disease was more active and severe than in patients from the control group (p<0.01, in all parameters shown in tab. 1). However, in patients in the control group the disease was significantly more active than in the NDB.

Table 1: Patient characteristics in RABBIT and in the National Database (NDB)

<table>
<thead>
<tr>
<th></th>
<th>Etanercept</th>
<th>Infliximab</th>
<th>Anakinra</th>
<th>Adalimumab</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: Males (%)</td>
<td>n.a. 45.0</td>
<td>40.2</td>
<td>43.9</td>
<td>41.0</td>
<td>40.5</td>
</tr>
<tr>
<td>% Employed</td>
<td>n.a. 4.6</td>
<td>4.2</td>
<td>4.9</td>
<td>4.7</td>
<td>4.6</td>
</tr>
<tr>
<td>Disease activity score DAS28</td>
<td>n.a. 4.6</td>
<td>4.2</td>
<td>4.9</td>
<td>4.7</td>
<td>4.6</td>
</tr>
<tr>
<td>No. of previous DMARDs</td>
<td>n.a. 4.0</td>
<td>3.9</td>
<td>4.0</td>
<td>4.0</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

Values are means if not otherwise specified.

Before study entry 45% of the cases were treated with leflunomide (alone (20%), in combination with MTX (17%), other DMARDs (3%)), 57% with MTX, and 5% with biologics. In the control group these percentages are 10%, 57%, and 2%.

As expected, patients in Germany receiving biologics are more severely ill than patients receiving conventional DMARDs. A high disease activity, poor functional status and a high number of previous treatment failures with conventional DMARDs are highly predictive for treatment with biologics.

Conclusion:

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