P635 Real-world treatment persistence and associated costs with biologic therapy in patients with inflammatory bowel disease: Results of a retrospective cohort analysis of 1,149 patients treated in Germany

A Groth1, T Wilke2, A Brandes3, B Ratsch4, A Fuchs4, B Deiters5, B Bokemeyer6

1IPAM e.V., Wismar, Germany, *Ingress-Health HWM GmbH, Wismar, Germany, 2Takeda Pharma Vertrieb GmbH & Co. KG, Berlin, Germany, 3AOK PLUS, Dresden, Germany, 4GWO ServicePlus AG, Düsseldorf, Germany, 5Gastroenterologische Gemeinschaftspraxis Minden, Germany

Background

- Inflammatory bowel diseases (IBD), represented by Ulcerative Colitis (UC) and Crohn’s disease (CD), are associated with significant morbidity, impact on quality of life and large therapeutic unmet medical need. The treatment options for IBD have improved significantly in the last twenty years due to, among others, the availability of new biological agents [1,2].
- Data on biologic treatment persistence and switching in German patients with IBD as well as disease specific cost data, especially in large population-based studies, are sparse.

Objective

- The main objectives of this interim analysis were to describe rates of biologic treatment switching and discontinuation for patients who initiated treatment on anti-TNFα antibodies (adalimumab, golimumab, infliximab) and vedolizumab (VDZ) in IBD patients and to report associated drug costs.

Results

- 1,149 IBD patients started an anti-TNFα or VDZ treatment within the inclusion period. Of these, 580 patients (50.7%) were followed up in this interim analysis for 12 months or until death (475 patients with anti-TNFα; 107 patients with VDZ).

Table 1: Patient baseline characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Patients treated with vedolizumab</th>
<th>Patients treated with anti-TNFα</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>475 (81.6%)</td>
<td>107 (18.4%)</td>
</tr>
<tr>
<td>Patients with CD</td>
<td>39 (86.6%)</td>
<td>13 (52.4%)</td>
</tr>
<tr>
<td>Patients with UC</td>
<td>30 (80.6%)</td>
<td>34 (70.2%)</td>
</tr>
<tr>
<td>Patients with unspecified IBD1)</td>
<td>17 (15.9%)</td>
<td>12 (13.1%)</td>
</tr>
<tr>
<td>Biologics-naive patients</td>
<td>23 (21.5%)</td>
<td>37 (34.7%)</td>
</tr>
<tr>
<td>Female gender</td>
<td>59 (55.1%)</td>
<td>56 (52.4%)</td>
</tr>
<tr>
<td>Age in years, mean</td>
<td>40.47 (SD: 12.07)</td>
<td>37.18 (SD: 13.45)</td>
</tr>
<tr>
<td>Charlson Comorbidity Index (CCI), mean (median/SD)</td>
<td>1.07 (1.14)</td>
<td>0.89 (0.01/45)</td>
</tr>
<tr>
<td>- Patients with at least one IBD complication1)</td>
<td>27 (25.2%)</td>
<td>10 (16.2%)</td>
</tr>
<tr>
<td>- with fistula</td>
<td>21 (19.6%)</td>
<td>9 (10.3%)</td>
</tr>
</tbody>
</table>

Methods

- This retrospective cohort analysis was based on claims data from several German sickness funds (in total approximately 7.5 M€ insured). Claims data are collected at statutory health insurance funds to remunerate health care services in Germany.
- The claims dataset comprises data of in and outpatient care, drug prescriptions, diagnoses and patient data.
- Adult patients (>18 years) who were continuously insured from 07/2013 06/2016, having a confirmed diagnosis of CD or UC (ICD-10 GM K50/K51) according to the MDQ criterion and initiated treatment with an anti-TNFα or VDZ between 07/2015-30/06/2016 were included.
- Patients were classified as having ‘unspecified IBD’, if they had confirmed diagnosis of CD and UC or confirmed diagnosis of CD or UC and indeterminate colitis (ICD-10 K52.3).
- A baseline period of 24 months and a minimum follow-up of 12 months was defined. Patients who died within the 12 months, were observed until death and were not excluded.

- Treatment groups were defined as follows:
  1. All IBD patients initiating treatment with VDZ (ATC-code L04AA33), either biologic treatment naïve or switching from another anti-TNFα.
  2. All IBD patients initiating treatment with an anti-TNFα (adalimumab, golimumab, infliximab; ATC codes L04AB04, L04AB06, L04AB07), either biologic treatment naïve or switching from another anti-TNFα.
- Observation started with the first prescription in this period. First observed treatment discontinuation and switching to another biologic were compared between anti-TNFα and VDZ patients, both unadjusted by means of log-rank tests and adjusted for age and gender by multivariable Cox proportional hazards models. A switch was assumed if at least one prescription of another biologic was observed; discontinuation was defined as no further prescription of any biologic agent >30 days after the last prescription.
- Drug costs, based on pharmacy retail prices (exclusive individual discounts; [3]), were reported per observed patient month for periods of continuous index treatment.

Strengths and Limitations

- The used claims data cover a patient population of 7.5 million insured persons, about 10.5% of the statistically insured population in Germany.
- Claims data in general are less prone to selection bias or cluster effects that may influence study results.
- Due to the fact that retrospective claims data were analyzed, specific patient parameters are not available (e.g. laboratory results or patient-reported-outcomes), since these data do not have any effect on the financial reimbursement for the sickness fund.
- As cases are not randomized to each cohort but follow a sequential treatment pathway, systematic baseline differences between the treatment cohorts are likely. Furthermore, treatments may be dictated by individual patient profile, which is characteristic for variables that cannot be observed in claims data.

Conclusions

- This is the first study reporting rates of treatment discontinuation and switching as well as drug related costs for German IBD patients treated with biologics based on a large, representative claims database.
- In contrast to previous observational evidence (>75%-80% [4-7]), less than 60% of all IBD patients continued treatment with a biologic agent after 12 months.
- Lower medication costs have been reported in the literature, as the share of biologic patients used to be lower in these studies and biologics are in general the main cost driver [8,9].
- There is a tendency towards a longer duration on therapy in VDZ patients, with comparable drug costs.
- Analysis of the full dataset including 1,149 patients will provide more detail, especially for subgroups (UC vs. CD and bio-naïve vs. bio-experienced).

Acknowledgements

This research was funded by Takeda Pharma Vertrieb GmbH.

References


Figure 1: Treatment course for 12 months observation

Figure 3: Results from the cox proportional hazards model

Figure 2: Kaplan-Meier-curve: Treatment continuation

Table 2: Drug costs

Table 3: Mean drug costs in \euro per patient month

Presented at ECCO 2018 • February 14-17, 2018 • Vienna, Austria