

LONG-TERM OBSERVATION IN A LARGE GERMAN IBD REGISTRY

Stefanie Howaldt

Hamburgisches Forschungsinstitut für CED, Germany

Background: Inflammatory Bowel Disease (IBD) is diagnosed in approximately 350000 patients in Germany with increasing incidence and prevalence. Although on-going inflammation can result in irreversible damage to the GI tract, under-treatment and reluctance to use immunomodulatory therapies earlier in the course of disease are present. On the other hand, costs for therapies, surgeries and hospitalization are high, once damage has occurred. In 2015 we therefore implemented an independent national IBD registry (CEDUR) to methodically collect real life data of IBD patients with regard to the usefulness and comparability of immunomodulatory strategies.

Methods: CEDUR is a web-based, descriptive registry of large tertiary IBD centers throughout Germany, using time sparing documentation in an adapted medical charts-software via GDT interface. Patients with IBD who are willing to participate have visits every three months and fill in questionnaires that are later-on completed and controlled by their physicians. Since 2015 and for at least ten years, data on phenotypes, therapeutic effects including efficacy, safety and economy as well as hospitalizations, surgeries, comorbidities, day-off-work and quality of life are continuously collected in patients with Crohn's Disease (CD) and Ulcerative Colitis (UC).

Results: So far, 1856 IBD patients (UC: 859, CD: 992, indeterminate colitis 5) were enrolled, of whom 47% are men and 53% are women. In CD and UC, 24.3% were younger than 21 years, 38.6 between 21 and 30, 19.0% between 31 and 40, 10.5% between 41 and 50 and 7.5% older than 50 years. In CD, age at first diagnosis was younger than 21 in 29.8% and older than 50 years in 6.5%. In UC, age at first diagnosis was younger than 21 years in 17.6% and older than 50 years in 28.8%. In CD, biologics were used in 73.9% of patients, of those anti-integrins in 6.0% and IL-12/23 blockers in 5.6%. 31.4% of patients with TNF-blockers were treated for more than 4 years. 54.2 % of patients under infliximab received infusions every 7 to 9 weeks, 31.6% every 4 to 6 weeks. 49.5 % of patients under adalimumab received injections of 40mg every 2 weeks, and 38.4 % at least 80mg every 2 weeks. In UC, TNF-blockers or other biologics were used in 59.0% of patients, of those anti-integrins in 12.05% and IL-12/23 blockers in 0.2%. 24.8% of patients with TNF-blockers were treated longer than 4 years. 47.1 % of patients under infliximab received infusions every 7 to 9 weeks, 36.9% every 4 to 6 weeks. 52.7 % of patients under adalimumab received injections of 40mg every 2 weeks, and 37.9% at least 80mg every 2 weeks.

Conclusions: We successfully implemented a large national IBD registry for the collection of real life data by a contribution of patients and physicians from tertiary IBD centers throughout Germany. As a first result we can present the data on the use of biologic therapy in more than 1800 Crohn's disease and ulcerative colitis patients. IBD significantly affect patients in their young ages, biologic therapies seem to be necessary in much more patients than commonly assumed and standard treatment has to be adapted to higher doses in TNF-blockers in UC more than CD and in adalimumab more than infliximab. Our registry can serve as data base for a wide range of efficacy, safety and economy issues in IBD patients.