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THE SICILIAN NETWORK OF BIOLOGICAL THERAPY IN INFLAMMATORY BOWEL DISEASE: PRELIMINARY DATA FROM A PROSPECTIVE STUDY ON EFFICACY AND SAFETY


Background and aim: The monitoring of appropriateness and costs of biological therapy in Inflammatory bowel disease (IBD) is a relevant need. We aimed to evaluate appropriateness, efficacy and safety of biological therapy in IBD in Sicily through a web based network of prescribing centers.

Material and methods: The Sicilian network for the monitoring of biological therapy in IBD is composed by a super Hub coordinator center and five Hub plus ten Spoke centers. From January 2013 all IBD patients starting a biological agent (incident cases) or already on treatment ( prevalent cases) were entered in a web based software. Herein we report data on remission and response after twelve weeks of biological therapy, and side effects until the end of follow-up of incident cases.

Results: From January 2013 to June 2016, 1475 patients were included. Complete data were available in 1338 cases (983 with Crohn’s disease [CD], 345 with ulcerative colitis [UC], and 10 with unclassified colitis). Incident cases were 956 (673 CD, 274 UC, and 9 unclassified colitis). Considering that 12% of patients experienced more than one line of therapy, a total of 1098 treatments were reported. Adalimumab was used in 543 CD patients, in 69 UC patients, and in 4 with unclassified colitis. Infliximab was prescribed in 221 CD patients (64 biosimilars), in 226 UC patients (41 biosimilars), and in 5 patients with unclassified colitis. Golimumab was prescribed in 29 UC patients, and in 1 patient with unclassified colitis. After twelve weeks, the rate of response with Adalimumab was 46% and the rate of remission was 38% in CD, while the rate of response with Infliximab originator was 48% and the rate of remission 42% (biosimilars: 37% and 50%, respectively). In UC the rate of response with Adalimumab was 46% and the rate of remission was 38%, the rate of response with Infliximab was 41% and the rate of remission 45% (biosimilars: 25% and 64%, respectively), while the rate of response with Golimumab was 47% and the rate of remission was 27%. Overall, the rate of side effects was 17% (9.2% with Adalimumab, 20% with Infliximab originator, 15% with biosimilars, and 17% with Golimumab).

Conclusions: In one of the largest series of IBD patients on biological therapy reported to date, the rates of remission and response after twelve weeks were comparable to data from literature, and similar between the different biologics. Efficacy and safety of biosimilars were analogous to those reported for infliximab originator.