The PROSIT-BIO Cohort of the IG-IBD: A Prospective Observational Study of Patients With Inflammatory Bowel Disease Treated With Infliximab BioSimilars

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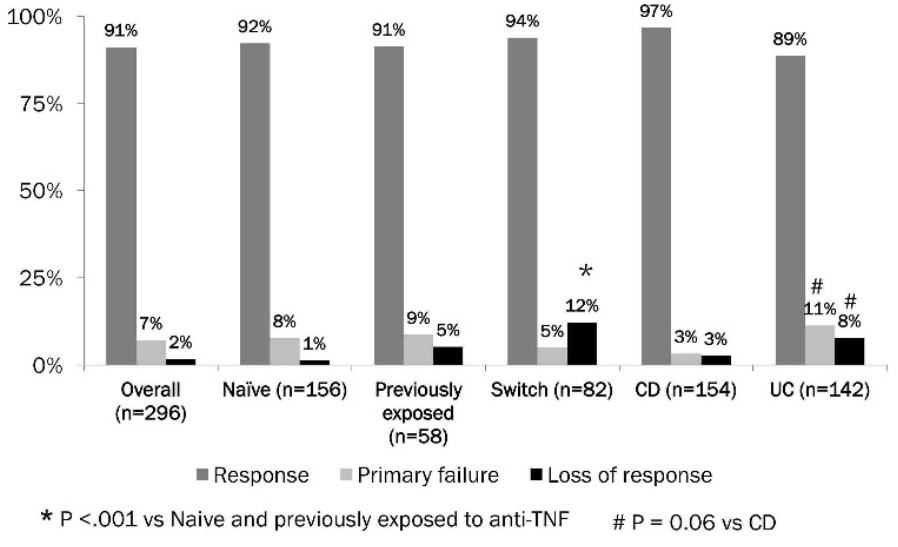
Background and Aim: Infliximab biosimilar (CT-P13) received EMA approval in June 2013 and entered the Italian market in April 2015. Few data are available on safety and efficacy in patients with ulcerative colitis (UC) and Crohn's disease (CD). Methods: this is a prospective, nationwide, multicentre, observational cohort with a structured data base including smoking status, duration of disease, previous anti-TNFα exposure and duration, indication for biologic therapy, use of combo therapy, response and remission at 6 and 12 months (Harvey-Bradshaw index and pMayo score), primary non-response and loss of response rates, infusion reactions, need for dose escalation, adverse events, and reasons for drug withdrawal. Results: 397 consecutive patients (223 CD, 174 UC) have been included from 30 academic (n=11) and non-academic (n=19) referral centers. Age at the disease onset was 30.6±14.4 years in CD and 38.9±14.3 years for UC. 217 patients were naïve to anti-TNF α (105 CD, 112 UC), 87 patients (67 CD and 20 UC) had a previous exposure to one or more biologics (26 infliximab, 59 adalimumab, 6 golimumab, 2 ustekinumab), whereas the remaining 93 patients (51 CD and 42 UC) were switched after a mean of 14±13 previous infusions of infliximab (rang 1-71). All patients were included in the safety evaluation. A total number of 1116 infusions were recorded; more specifically 166 patients received Inflectra™ (total number of infusions = 405) and the remaining 231 received Remsima™ (total number of infusions = 711). 33 adverse events (8.3%) were reported, leading to stop biosimilar in 19 patients (4.8%). 21 (5.3%) patients had infusion reactions leading to drug withdrawal in 16 (4%) cases (7 naïve, 8 previous exposed, 1 switch). The efficacy of therapy was calculated in 214 patients following the induction regimen and 82 patients receiving at least two infusions after switching. As whole, 144/156 naïve patients (69 CD), 49/58 previous exposed to ant-TNF (42 CD) and 77/82 (43 CD) switched were considered responders. Primary failure and loss of response were recorded in 21 (16 UC, 5 CD) and 15 patients (11 UC, 4 CD), respectively. 4 patients with UC underwent colectomy and 1 with CD had an ileo-cecal resection. The median follow-up was 6 months, while the total was 82.8 years/patient. Conclusions: No clear signal of difference in safety was reported, however, a 5-fold increase of loss of response after the switch (12.2% vs 2.3%, p=.001), and a trend towards more frequent primary failure and loss of response in UC compared to CD patients (11.3% vs 5.8%, 7.7% vs 2.6%, respectively; P=0.06) was recorded.These findings should be evaluated with caution due to the short follow-up.



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