The aim our study was to analyze the impact of HSCT on the T cell repertoire in the inflamed intestinal mucosa.

Methods: Intestinal mucosal samples (ileal or colonic biopsies) were collected at baseline (pre-mobilization) and after HSCT (6 months and/or 1 year post transplant), in 16 CD patients recruited in the ASTIC trial or in the Barcelona Center. Endoscopic severity was evaluated by segment using SES-CD. T cell repertoire analysis was performed on DNA extracted from biopsies by next generation sequencing of the TCRβ locus (Adaptive Biotechnology Inc., Seattle, Washington, USA). TCR diversity of each sample was studied by quantification of the size taken in the repertoire by significantly expanded clones, and correlated with clinical outcome and endoscopic response (global and by segment) at one year. T cell clones were tracked and the repertoire similarities were quantified between different time points by the Morisita-Horn index (M-H; range 0–1).

Results: Monoclonal expansions in the T cell compartment were present at baseline in the mucosa of CD patients prior to HSCT procedure, expanded clones represented from 5 to 30 per cent of the total repertoire. The T cell repertoire appeared more polyclonal than previously anticipated (from 1000 to 20 000 unique TCR sequences, diversity index 0.02 to 0.1). Importantly, no shared public TCR sequences were found in the mucosa of different patients. After HSCT, TCR clonality was significantly increased in the mucosa of patients. Although around 20 per cent of specific TCR sequences persisted between baseline and after HSCT, the similarity index comparing the TCR repertoire was low (mean M-H=0.17), indicating a profound resetting of the TCR repertoire. In contrast, a high degree of similarity (mean M-H=0.7) was observed between mucosal samples collected at different time points after the procedure in the same patient.

Conclusions: Clonal expansions are present in the mucosa of refractory CD patients. HSCT induces dramatic changes and a significant resetting in the mucosal T cell repertoire.

OP005
The PROSIT cohort of infliximab biosimilar in IBD: a prolonged follow-up on the efficacy and safety across Italy

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Background: The Infliximab biosimilar CT-P13 has been used since March 2015 in Italy. We report here a prolonged follow-up of a prospective, nationwide, multicentre, observational cohort (PROSIT) evaluating the safety, and clinical/endoscopic efficacy.

Methods: A structured data base has been used to record relevant serious adverse events (SAEs), clinical efficacy (partial Mayo [PM] and Harvey-Bradshaw Index [HBI]), inflammatory markers (CRP and calprotectin [calpro]) and endoscopic findings (endoscopic Mayo [EM] and Simple Endoscopic Score for Crohn's Disease [SES-CD]).

Results: Results 680 consecutive patients (373 CD, 307 UC) have been included from academic (n=13) and non-academic (n=12) referral centers. Age at the disease onset was 30.5±13.9 years in CD and 33.7±13.3 years for UC. 400 patients were naïve to anti-TNFα (192 CD, 208 UC), 171 patients (115 CD, 56 UC) had a previous exposure to one or more biologics, whereas the remaining 109 patients (66 CD, 43 UC) were switched after a mean of 18±10 previous infusions of infliximab (range 3–72). All patients were included in the safety evaluation. A total number of over 4,000 infusions were recorded; 92 SAEs (13.5%) were reported, leading to stop biosimilar in 73 patients (10.7%). IRs were 46, leading to stop biosimilar in 38 subjects (5.6%), and were significantly more frequent in patients pre-exposed to anti-TNFα ($p<0.02$).

Primary failure was recorded in 55/680 patients (8.1%). The efficacy of therapy was calculated following the induction regimen or at least two infusions after switching in 601 patients with a mean follow-up of 32 weeks (range 8–83). As a whole 274 patients were in remission (45.6%), 186 were considered responders (30.9%) and 62 lost the response (10.3%). The remaining patients were failure or stopped the therapy. 377 patients (222 CD) and 150 patients (89 CD) completed the follow-up of 6 and 12 months, respectively. After 1 year of CT-P13 therapy, HBI, SES-CD, CRP, and Calpro significantly ($p<0.01$) dropped in CD patients (7.1±3.4 vs 3.2±2; 10.1±42 vs 3±2.6; 1.9±1.7 mg/dl vs 0.9±0.8; 565±485 mg/kg vs 126±133 respectively), compared to baseline. Similarly, in UC patients PM, EM, CRP, and Calpro (6.1±2.3 vs 1.9±1.8; 2.1±0.6 vs 1.3±0.8; 3±2 mg/dl vs 0.9±0.7; 759±516 mg/kg vs 72±65, respectively) were significantly reduced ($p<0.001$). A deep remission was achieved in 57% and 50% of CD and UC patients in whom all information were available, respectively.

Conclusions: This is one of the largest prospective cohort of patients with IBD treated with CT-P13. After a more prologed follow-up, no further signals of difference in safety and clinical efficacy has been observed.