

respectively (Table A). Both PMS response and PMS remission, at Wk 2, were significantly associated ($p < 0.0001$) with clinical endpoints at Wk 8 (Table B). Similar results were obtained in TNFi-naïve and -experienced subpopulations.

Conclusions: In pts with moderate to severe UC treated with tofacitinib 10 mg BID, tofacitinib demonstrated induction efficacy based on PMS as early as Wk 2, the first time point measured in this study. Efficacy at Wk 2 is a good predictor of efficacy at Wk 8, regardless of prior TNFi therapy. Pts who have not achieved remission or response at Wk 2 based on PMS may still achieve improvements in Mayo score at Wk 8.

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References:

[1] Sandborn WJ et al. *J Crohns Colitis* 2016;10(S1):S15

OC.06.2

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

A. Orlando^{*1}, W. Fries², A. Privitera²⁰, M. Cappello³, S. Siringo⁴, G. Inserra⁵, A. Magnano⁶, R. Di Mitri⁷, N. Belluardo⁸, G. Scarpulla⁹, G. Magri¹⁰, A. Trovatiello¹¹, A. Carroccio¹², S. Genova¹³, G. Calandrucchio¹⁴, R. Vassallo¹⁵, C. Romano¹⁶, G. Magazzù¹⁷, M. Citrano¹⁸, S. Accomando¹⁹, M. Ventimiglia¹, S. Renna¹, R. Orlando¹, G. Rizzuto¹, E. Vinci¹, F.S. Macaluso¹, M. Cottone¹

¹Division of Internal Medicine, "Villa Sofia-Cervello" Hospital, Palermo, Italy; ²Inflammatory bowel disease Unit, A.O.U. Policlinico "G. Martino", Messina, Italy; ³Gastroenterology and Hepatology Unit, A.O.U. Policlinico "G. Giaccone", Palermo, Italy; ⁴Gastroenterology Unit, A.R.N.A.S. "Garibaldi", Catania, Italy; ⁵Internal Medicine Unit, A.O.U. Policlinico "Vittorio Emanuele", Catania, Italy; ⁶Gastroenterology Unit, A.O.U. Policlinico "Vittorio Emanuele", Catania, Italy; ⁷Gastroenterology and endoscopy Unit, A.R.N.A.S. "Civico di Cristina Benfratelli", Palermo, Italy; ⁸Gastroenterology Unit, A.O. "Guzzardi", Vittoria, Italy; ⁹Gastroenterology Unit, A.O.O.R. "S. Elia- M. Raimondi", Caltanissetta, Italy; ¹⁰Gastroenterology Unit, A.O. "Santa Marta e S. Venera", Acireale, Italy; ¹¹Surgery Unit, A.O. "Umberto I", Siracusa, Italy; ¹²Internal Medicine Unit, A.O. "Giovanni Paolo II", Sciacca, Italy; ¹³Gastroenterology and Endoscopy Unit, A.O. "S. Antonio Abate", Trapani, Italy; ¹⁴Gastroenterology Unit, A.O.O.R. "Papardo Piemonte", Messina, Italy; ¹⁵Gastroenterology and Endoscopy Unit, A.O. "Buccheri La Ferla Fatebenefratelli", Palermo, Italy; ¹⁶Genetics and pediatric immunology Unit, A.O.U. Policlinico "G. Martino", Messina, Italy; ¹⁷Pediatric Gastroenterology Unit, A.O.U. Policlinico "G. Martino", Messina, Italy; ¹⁸Pediatric Unit, A.O.O.R. "Villa Sofia-Cervello", Palermo, Italy; ¹⁹Pediatric Unit, A.O.U. Policlinico "G. Giaccone", Palermo, Italy; ²⁰Gastroenterology Unit, A.O. "Cannizzaro", Catania, Italy

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.

OC.06.3

COMPARATIVE EFFICACY OF ANTI-TNFS IN INDUCING CLINICAL RESPONSE AND REMISSION IN ULCERATIVE COLITIS: A SINGLE CENTER REAL LIFE STUDY

M. Mendolaro^{*}, M.G. Cilluffo, V. Calvaruso, B. Scrivo, A. Vitello, S. Peralta, M. Cappello

Gastroenterology Section, DiBiMis, University of Palermo, Palermo, Italy

Background and aim: Anti-tumor necrosis factor (anti-TNF) agents, infliximab (IFX) and more recently adalimumab (ADA) and golimumab (GOL), have been shown effective and safe in the treatment of moderate-to-severe ulcerative colitis (UC). Lack of head-to-head RCTs makes the choice among the three anti-TNFs difficult and indirect comparisons lead to discrepant results. Our aim was to compare efficacy of IFX, ADA and GOL in inducing clinical response and remission in a prospective cohort of patients with moderate to severe UC.

Material and methods: From June 2015 to September 2016, 42 consecutive UC patients (25 male; mean age 42.1±16.9; mean duration of disease 6.9±5.1 years) were treated: 14 with IFX, 14 with ADA and 14 with GOL. Disease activity was assessed by Mayo Score. Clinical response and/or remission were evaluated at week 8 and at week 16. We also recorded: indications to biologic therapy, previous immunosuppressive or anti-TNF therapy and rate of anti-TNF discontinuation.

Results: 29 patients were thiopurine failure; 28 were naïve to anti-TNFs, most were treated with IFX ($p=0.001$). ADA and GOL were more often used as a second-line or third-line. IFX was started in 9 patients for steroid resistance and in 5 for steroid dependence; all patients on ADA and GOL were steroid dependent. No significant difference was observed between IFX and ADA both at week 8 (response $p=0.40$; remission $p=0.71$) and at week 16 (response $p=0.28$; remission $p=0.86$), though there was a trend towards a higher rate of response at week 8 with IFX (78.6% vs. 64.3%). Both IFX and ADA were more effective than GOL at week 8 (response: IFX vs. GOL $p=0.006$; ADA vs. GOL $p=0.045$; remission: IFX vs. GOL $p=0.010$; ADA vs. GOL $p=0.004$). At week 16 only IFX seems to be more effective