team) in counterpart of which they undertook to use the application; b) the Freemium mode, a basic functionality that only gives the name of the study in the first selection phase; c) sites who were not interested to be equipped. The primary endpoint was the mean number of patients randomised per site per month. Patients screened and those finally randomised were compared in sites equipped (Premium or Freemium) and non-equipped using one-way ANOVA followed by post-hoc Tukey test.

Results: During the recruitment period from 4 to 36 months (mean 24.8 months), 221 and 130 patients were screened and randomised, respectively. The mean number of patients screened and randomised per site per month according to CT-SCOUT™ equipment is reported in the figure below.

Conclusion: This study shows that sites not equipped with CT-SCOUT™ recruit only a few patients. Among the equipped sites, those with Premium access have a significantly higher randomisation rate than those with limited functionality. Sites equipped with digital pre-screening support to facilitate patient recruitment and provide the sponsor visibility are the best candidates for trials.

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Polimedication in patients with inflammatory bowel disease: prevalence and outcomes in a retrospective unicentric series

F. Mesonero Gismero*[1], C. Fernández[1], E. Sánchez-Rodríguez[1], A. García-García de Paredes[1], A. Albillos[1], A. López-Sanromán[1]
[1]*Department of Gastroenterology, Hospital Universitario Ramón y Cajal, Madrid, Spain*

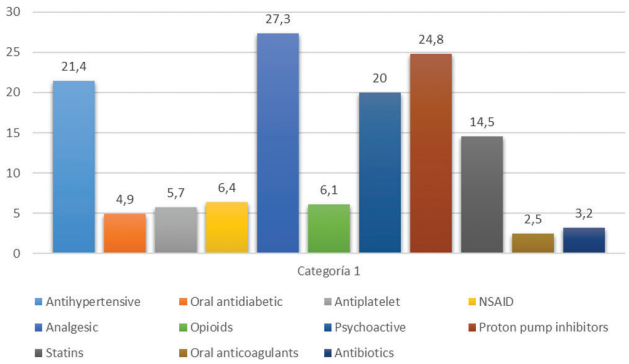
Background: Polymedication (PM) can complicate course and management of chronic diseases, and is currently a poorly explored issue in patients with inflammatory bowel disease (IBD).

Our aims were to determine the prevalences of PM, and of inappropriate and high-risk drugs use (APINCH) in a clinical series of IBD patients, describing epidemiological factors associated with PM, and evaluating a possible association of PM with poor disease outcomes.

Methods: A retrospective observational study of a unicentric series, including patients with IBD visited at our Unit (September-October 2018). Prescriptions, demographic data, and clinical features were collected reviewing clinical files and electronic drug prescriptions. PM was defined as the simultaneous use of more than 5 drugs (Gnjidic D, J Clin Epidemiol. 2012). APINCH drugs included insulin, antibiotics, anticoagulants, chemotherapies, narcotics, and potassium supplements (Clinical Excellence Australian Commission 2017). Disease outcomes (flares, hospitalisations, surgeries), non-adherence to treatment and undertreatment were evaluated 12 months after the index visit.

Results: We included 407 patients (56% males, median age 48 yo, range 17–92, 60.2% Crohn´s disease, 38.8% ulcerative colitis). Chronic comorbidity was present in 54% (29% metabolic, 25.5% cardiovascular, 12.8% psychiatric), and 27% presented multiple comorbidities (≥3). Median patient number of prescriptions was 3 (r 0–15); 14.3% were on more than three drugs, and 15.7% between four and five drugs. Most frequent prescriptions are represented in Figure 1. PM was identified in 18.4% of cases, inappropriate medication in 8.8%, and high-risk drugs in 6.1% (mainly opioids). In multivariate analysis, factors significantly associated with PM were chronic comorbidity (OR 11, CI 2.3-51,2, p<0.002), multiple comorbidities (OR 4.02, CI 1.93–8.38, p<0.001), and age >62 years (OR 3.66, CI 1.7–7.7, p<0.001). In univariate analysis, both undertreatment (54% vs. 16%, p<0.01) and non-adherence (26% vs. 12%, p<0.02) were associated with PM after 12 months. No association of PM with poor disease outcomes was found. In multivariate analysis, only undertreatment was significantly associated with PM (OR 5.9, CI 1.4–29.4, p<0.014).

Figure 1: Drug use, by class



Conclusion: PM occurs in around one of the five patients with IBD, mainly in the elderly and in those with comorbidity. This scenario could interfere with appropriate IBD treatment and therapeutic success.

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Efficacy of biosimilar infliximab CT-P13 among inpatients with severe steroid-refractory colitis

J. Ollech*[1], I. Normatov[2], S. Dwadasi[2], S. Dalal[2], D. Micic[2], A. Israel[2], J. Labas[2], P. Joel[2], R. Cohen[2], D. Rubin[2], S. Atsushi[2]
[1]*Gastroenterology, Rabin Medical Center- University of Chicago Medicine, Petach Tikva, Israel,* [2]*Gastroenterology, University of Chicago Medicine, Chicago, USA*

Background: The infliximab biosimilar CT-P13 has been reported to have similar clinical effect compared with its originator. In this study, we evaluated the efficacy and safety of CT-P13 in the treatment of inpatients with severe steroid-refractory colitis.

Methods: Adult colitis patients (UC or isolated Crohn's colitis; Montreal classification E2-3, or L3, respectively) admitted to the University of Chicago IBD inpatient service between January 2018 and December 2018 for management of severe colitis refractory to IV steroids who received CT-P13 were included in the study. Patients diagnosed with active small bowel Crohn's disease were excluded. CT-P13 was given as a single or several infusions of 5 to 10 mg/kg. For all patients, demographic, clinical, laboratory, and endoscopic data were attained by a comprehensive review of their electronic medical records. The primary endpoint was colectomy-free survival.

Results: Twenty-one patients, 14 with ulcerative colitis and seven with Crohn's colitis, were included. Fourteen (66%) of patients were female. The median age was 32.2 years (IQR 24.1–43.2). The median disease duration was 4.3 years (IQR 2–10.3), and the median follow-up time was 5.9 months (IQR 1.8–9.1). Patients had a median CRP of 23 (IQR 6–74). All patients had moderate to severe disease on flexible sigmoidoscopy. Three patients (14%) underwent colectomy during their index hospitalisation. Colectomy free survival was 76% at three months and 70% at six months (Figure 1). No severe adverse events were reported in this patient cohort.