Methods: We retrospectively compared disease course between children with IBD who stepped down to anti-TNF monotherapy (group 1) and children who continued combination therapy until the end of the study follow-up (group 2). In order to define risk factors for disease exacerbation after stepping down, we compared clinical data between children who exacerbated and children that kept disease remission.

Results: Sixty-four patients were included: 32 in group 1 and 32 in group 2, with median (IQR) age of 16 (13.4–17.5) years and mean (range) follow-up of 19.1 (6.5–24) months. The median (IQR) duration of combination therapy was 6 (6–10) months for children who stepped down. In a multivariate analysis, the risk for disease exacerbation and hospital admissions was significantly higher in group 1 compared with group 2 (OR 4.35, p = 0.01 and OR 3.13, p = 0.045, respectively). Penetrating phenotype, upper GI involvement, moderate–severe disease activity at diagnosis, treatment with Infliximab, sub-therapeutic anti-TNF levels and high stool calprotectin during combination therapy were associated with disease exacerbation and hospital admissions after stepping down to monotherapy.

Conclusions: Children with IBD are at higher risk of disease relapse after stepping down from combination to monotherapy. Several risk factors for disease relapse after cessation of combination therapy were identified.

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Machine learning (ML) in RCU-operated patients: Can we predict postoperative complications?
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Background: The study analyses short-term outcomes of laparoscopic and open total abdominal colectomy (TAC) for medically refractory ulcerative colitis (UC). A computer program based on Machine Learning (ML) was developed to predict postoperative complications.

Methods: 32 patients who underwent TAC either laparoscopic or laparotomic for UC between December 2010 and October 2017 were retrospectively identified from an hospital database. Biographical data, preoperative therapy (steroids and biological drugs), nutritional status, surgical technique, operative time, blood transfusion, hospital length of stay, morbidity and mortality were recorded. Univariate analysis by unpaired Student t-test and multivariate analysis were conducted. A feature selection was performed to use selected data as input of the ML algorithm.

Results: A total of 32 patients underwent TAC, 24 by laparoscopic (75%) and 8 (25%) by open approach. 17 patients presented an acute severe UC not responding to rescue therapy requiring urgent or semurgent colectomy: 70.5% treated by laparoscopic and 29.5% by open approach. 15 patients presented a chronic refractory UC in treatment with steroids: 86% treated by laparoscopic and 14% by open approach. Operative time was higher in the laparoscopic compared with open group (267.5 ± 27 vs. 193 ± 37.5 min, p < 0.01). Progressive decrease of operative time was observed in laparoscopic patients during recent years due to improvement of skills (220 min in last year). Infectious as well as no infectious complications observed in laparoscopic group were lower when compared with open group (respectively 10% vs. 50%, p < 0.05 and 15% vs. 58%, p < 0.05). Postoperative length of stay was shorter in laparoscopic than open group (11.25 ± 4.97 vs. 15.9 ± 7.69 days, p = NS). Progressive decrease of hospital length of stay was observed in laparoscopic group (7 days in last year). ML of evaluation analysing age, sex, surgical technique, nutritional status, preoperative therapy with steroids/biological drugs and blood transfusion has predicted infectious minor complications with high strike rate (84%), high sensitivity (87.5%), and high specificity (83%).

Conclusions: Data confirm that laparoscopic technique is a safe and valid approach in the surgical treatment of UC also in urgent setting with patient in critical conditions, reducing the global morbidity and hospital stay. ML has been proven to be useful in predicting rate of postoperative complications in patients operated for UC, despite of a small group of patients. ML used to wider samples or multi-centre experiences could became a valid help to choose the best treatment in order to avoid dangerous or simply annoying complications in RCU patients.

P681
Systematic review and meta-analysis of the safety and efficacy of intra-fistular injections of mesenchymal stem cells in clinical trials and observational cohort studies
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Background: Perianal fistulas in patients with Crohn’s disease (CD) is a stressful condition for both patients who suffer from pain, discharge and poor quality of life, and clinicians who face high rates of non-response and relapse with the available therapeutic armamentarium. Local injection of mesenchymal stem cells (MSC) has yielded promising results in this challenging condition. We conducted a systematic review and meta-analysis of all clinical trials and observational cohort studies to establish the safety and efficacy of local administration of MSCs for the treatment of perianal fistulas in CD patients.

Methods: The PRISMA (P) statement was used for both planning and reporting. MEDLINE, EMBASE, Web of Science, Cochrane, CINAHL, ClinicalTrials.gov and the ECCO 2017 proceedings were searched for observational cohort studies, one arm and randomised clinical trial (RCT) through May 15, 2017. Safety was assessed as acute local and systemic events (pain, bleeding, infusional toxicity, fever, thromboembolism), organ system complications, infection, and long-term events (death, malignancy). The efficacy endpoint was evaluated in terms of clinical and/or radiologic closure of fistula tracks. Rates and relative risks (RRs) were pooled for safety and efficacy endpoints according to the Der Simonian and Laird random effects models with 95% confidence intervals (CI) computed.

Results: A total of 345 citations were reviewed and 23 studies (3 sub-studies) met inclusion criteria. A total of 663 participants were evaluated. Four studies were RCTs and enrolled a total of 483 patients. At metaanalysis, clinical response occurred in 80% (95% CI 70–89) of MSC treated patients (18 studies). In RCTs, this rate was 64% (95% CI 57–70) in the MSC and 37% (95% CI 21–53) in the placebo arms, RR 1.54 (95% CI 1.03–2.29). Radiologic response occurred in 83% (95% CI 65–96) of MSC-treated patients (7 studies, of which only 1 RCT). The cumulative adverse event (AE) rate was 53% (95% CI 30–75) in MSC-treated patients (17 studies). In RCTs it was 71% (95% CI 35–96) in the MSC and 66% (95% CI 38–89) in the
control arm, RR=1.06 (95% CI 0.93–1.21). Treatment-related AEs occurred in 1% (95% CI 0–7) of MSC-treated patients (12 studies). In RCTs treatment-related AEs (e.g. anal abscess and pain) occurred in 13% (95% CI 5–24) in the MSC and 24% (95% CI 14–35) in the control arm, RR 0.65 (95% CI 0.44–0.98). No deaths occurred.

Conclusions: Based on the current state-of-the-art, local administration of MSCs appears safe and efficacious. Limited large-scale controlled studies exist; further clinical trials with rigorous reporting of endpoints are required to ensure the correct positioning of this new therapeutic tool in the management of perianal CD.

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**Role of laboratory markers in paediatric inflammatory bowel disease**

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**Background:** Non-invasive methods for objective assessment of disease activity are particularly valuable in paediatric patients with inflammatory bowel disease (IBD). The aim of this study was to evaluate the utility of 6 blood tests—white blood cell (WBC) and platelet (PLT) counts, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), fibrinogen and albumin, and 2 faecal markers—faecal alpha-1-antitrypsin (fA1AT) and faecal calprotectin (FC) to distinguish patients with endoscopic inflammation despite having no symptoms from patients in deep remission.

**Methods:** Thirty-one children with ulcerative colitis (UC) and 22 children with Crohn’s disease (CD) in clinical remission provided blood and faecal samples for evaluation of WBC, PLT, ESR, CRP, fibrinogen, albumin, fA1AT and FC. Endoscopic disease activity was assessed according to the Mayo endoscopic subscore (MES) and Simple Endoscopic Score for Crohn’s disease (SES-CD) in UC and CD patients, respectively.

**Results:** In UC children only FC and fA1AT were able to distinguish between patients with intestinal inflammation and endoscopic remission. Median levels for intestinal inflammation vs. endoscopic remission were (1000 µg/g vs. 100 µg/g, p < 0.001) for FC and (560 µg/g vs. 480 µg/g, p = 0.032) for fA1AT. In CD children only FC and fibrinogen were able to distinguish between patients with intestinal inflammation and endoscopic remission. Median levels for intestinal inflammation vs. endoscopic remission were (808 µg/g vs. 97 µg/g, p < 0.001) for FC and (435 mg/dl vs. 327 mg/dl, p = 0.032) for fibrinogen.

**Conclusions:** FC is a useful non-invasive marker of intestinal inflammation that may assist the follow-up of paediatric IBD patients.

**P683**

**Maintenance of deep remission in patients with ulcerative colitis treated with thiopurines after withdrawal of the drug: Perspective real-life experience of a single centre**

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**Background:** There are few data on long-term outcome of patients with ulcerative colitis after thiopurines withdrawal. Our aim was to analyse the outcome after thiopurines withdrawal for sustained remission and to identify predictors of relapse in a homogeneous cohort of patients with ulcerative colitis.

**Methods:** A Retrospective study was performed. A total of 59 patients with UC who discontinued thiopurines for stable clinical and endoscopic remission were included. For all patients were recorded both clinical and endoscopic data, the use of steroids at baseline, at the time of withdrawal of the drug, after 12 and 24 months from withdrawal and at the end of follow-up.

**Results:** The cumulative rate of recurrence was found to be 18.6% at follow-up. All patients who have relapsed during follow-up, had a recurrence after at least 12 months after discontinuation of therapy. The recurrence rate at 24 months was 6.7%. The early relapse was recorded at 15.9 months, the median time to relapse was 138.8 months (range 116.3–161.3). The duration of therapy with immunosuppressant in the study population was 61 months (IQR 47.5–73). On multivariate analysis predictors of relapse were: patients with chronically active disease at the beginning of the treatment [HR 16.64 (C.I. 2.21–125.1) p < 0.006] and patients with Mayo clinical score > 1 at the time of discontinuation of the drug [HR 3.48 (C.I. 1.54–7.89) p < 0.003].

**Conclusions:** If administered at correct dose and timing, thiopurine therapy is able to maintain remission long after withdrawal. Patients with chronically active UC have greater risk of relapse and should be treated early with biologic agents.

**P684**

**Sleep disturbances in IBD patients without sedative therapy**

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**Background:** Sleep disturbances are commonly reported in IBD patients, although it is unclear whether sleep fragmentation induces the debut of IBD or it is more likely a modifiable factor, potentially leading to disease exacerbation, consequently an effect of disease.

**Methods:** An observational study was performed to assess the correlation between the quality of sleep and disease activity in IBD patients without a sedative therapy. The study included 33 subjects with IBD, admitted consecutively in the Gastroenterology Department, and sleep quality was assessed by the same investigator using Pittsburgh Sleep Quality Index (PSQI), considering the upper normal value a PSQI score of 5. Disease activity was evaluated through MAYO score/CDAI and also by serological markers of inflammation, the assessment of endoscopic activity and histological degree of inflammation.

**Results:** Only 12.12% of the evaluated patients were in clinical remission, whereas the rest of the examined patients had mild to moderate disease activity. 88% of the patients with histological evidence or serological markers of inflammation on recent ileocolonoscopy also had abnormal PSQI scores (median PSQI score of 9), which were independent of their clinical disease activity status. There was no correlation between the PSQI score with the diseases type (Crohn’s disease, ulcerative colitis, proctitis) (p > 0.05). Most of the patients (66.67%) with clinically active disease declared sleep maintenance insomnia, whereas sleep quality was less influenced (21.2%) by digestive symptoms associated with IBD in this patient category.

**Conclusions:** There is a strong association between clinically active IBD and poor sleep quality, independent on sleeping disturbances.