Results:
The term outcomes in the two groups.

Methods:

The aim was to evaluate the short-term outcomes in the two groups. The dose-intensification regimen used achieved therapeutic levels in 50% and 100% at 6 and 12 months, and per-encounter remission rates increased by 27% (p = 0.031) and 21% (p = 0.125) for clinical, and 13% and 5% for biochemical (CRP) remission (p = 0.69 for both). Calprotectin did not change (p = 0.5). The rapid-test strategy saved AUD 214/patient/year compared with standard care.

Conclusions: The rapid test is accurate and its application in the setting of maintenance therapy led to dose adjustment in three of four patients and higher rates of therapeutic levels, implying standard weight-based dosing is inadequate. Dose-reduction did not carry risk of relapse. This rapid-test strategy has the potential to reduce patient risks and improve patient outcomes without negative costs implications.

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Robotic-assisted vs. laparoscopic proctectomy for inflammatory bowel disease: Results of the case-match comparison in single institution

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Background: Proctocolectomy with ileal pouch-anal anastomosis (IPAA) is considered a procedure of choice in the patients with ulcerative colitis (UC) resistant to medications as well as in selected patients with Crohn disease associated with remittent formation of perianal lesions. The robotic-assisted proctectomy can potentially provide several advantages including beneficial higher precision and less injury when working in the narrow spaces of the pelvis and, presumably, this technique may prevent trauma to the pelvic autonomic nerves providing better functional results

Methods: A case-match comparison of 16 robotic and 16 laparoscopic proctectomies for IBD performed between April 2014 and March 2017 was carried out. The aim was to evaluate the short-term outcomes in the two groups.

Results: Despite the longer surgery duration (298 vs. 264 min, p < 0.05) in the robotic cohort, the reduction of estimated blood loss (179 vs. 288 ml, p < 0.05) and conversion rate (0 vs. 12.5%, p = 0.15) were observed. The bowel movement recovery time (2.3 vs. 2.9 days, p < 0.05) and length of hospital stay (8.7 vs. 9.2 days p < 0.027) were similar in both arms. No readmissions were reported in the groups. At 1-year follow-up, no differences in the rate of postoperative complications (12.5% vs. 18.75%, p = 0.631) and the mean frequency of daily defaecation (3.8 vs. 4.1, p = 0.1) were observed in two arms. In 3 patients in laparoscopic group and 2 in robotic, the anastomotic leakage developed that was treated drainage placement under anaesthesia. In robotic patients, a higher sexual function score than laparoscopic was reported; however, the quality of life score did not differ (p = 0.78).

Conclusions: Although the costs for robotic proctectomy are high, the technique allows reducing the estimated blood loss and conversion rate overcoming some limitations of laparoscopic surgery both in ergonomic and accuracy aspects. Besides, the encouraging results regarding the positive impact on sexual function when performing robotic proctectomy were obtained.

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Distinct faecal bile acid profiles are associated with sustained remission following exclusive enteral nutrition (EEN) induction therapy in paediatric Crohn’s disease

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Background: Exclusive enteral nutrition (EEN) is a first-line therapy to induce remission in paediatric Crohn’s disease (CD). However, many patients will relapse upon resuming normal diet and there are no validated measures to determine subgroups of patients who will benefit most from EEN. We recently demonstrated that the certain compositional features of gut microbiome are associated with relapse following EEN. Microbiome composition can impact the balance of intestinal bile acids (BA), which have important antimicrobial and immune functions. The goal of this study was to analyse the relationship between intestinal BA composition and response to EEN in paediatric CD.

Methods: We performed faecal BA analysis on a biorepository of stool samples from 13 paediatric CD patients who were treated with EEN for 12 weeks and achieved remission as defined by wPCDAI <12.5. All patients received maintenance therapy with an immunomodulator. Of these 13 patients, 7 sustained remission (SR) and 6 relapsed within 3 months of EEN cessation (non-sustained remission (NSR)). Faecal BA quantification was performed by the Sick Kids Analytical Facility for Molecules (AFBM) by liquid chromatography tandem mass spectrometry (LC–MS-MS) using the Biocrates Life Sciences Bile Acids Kit according to the manufacturer’s instructions. For samples with BA abundance above the limit of detection, the missing data were imputed using area ratios relative to internal standards. BA concentrations were not normally distributed according to D’Agostino-Pearson test, so data are presented as median [range] and compared between groups using the Mann–Whitney U test.

Results: NSR patients had significantly lower levels of secondary BA (deoxycholic acid (DCA) and lithocholic acid (LCA) prior to starting EEN: median LCA 1 [1–4] pmol/mg vs. 1976 [19–3163] pmol/mg
(p < 0.05) and median DCA 2 [1–5] pmol/mg vs. 2605 [29–4288] pmol/mg (p < 0.05). NSR patients also exhibited higher levels of primary BA (cholic acid (CA) and chenodeoxycholic acid (CDCA)) at baseline and Week 12, although this was not significant. The ratio of primary to secondary BAs was profoundly increased in NSR patients compared with SR patients: median 318.4 [0.926–642.1] (p < 0.05) vs. median 0.005 [0.002–0.059]. Levels of primary and secondary BA did not change significantly over the course of EEN in either group, although secondary BA concentrations were slightly increased in NSR patients by Week 12 relative to baseline.

Conclusions: We demonstrate that primary and secondary BA compositions in stool differed between patients who sustained remission following EEN vs. those who relapsed. BA profiling may be a useful microbiome metabolic marker to identify patients who will sustain remission longer following EEN therapy.

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Golimumab dried blood spot analysis (GOUDA): A prospective trial to validate golimumab concentration analysis using the dried blood spot methodology

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Background: Therapeutic drug monitoring of golimumab (GLM) is performed by measuring trough concentrations, obtained by venous sampling. Sampling via dried blood spots (DBS) allows multiple determinations within a dosing interval and thereby gives a more complete insight in the total drug exposure (here expressed as area under the curve or AUC). We assessed the robustness and user-friendliness of the DBS method and the relation between GLM trough concentration (TC) and exposure during induction and maintenance regimens.

Methods: Ten patients with ulcerative colitis (UC) were recruited prospectively (NCT02910375). Finger and venepunctures were performed according to the sampling schedules depicted in Figure 1A and B in five patients initiating GLM and in five patients on ≥2 years GLM maintenance therapy. At the end of the study, user-friendliness was evaluated using a questionnaire. GLM and anti-GLM antibody concentrations were measured using in-house developed ELISAs. Non-compartmental pharmacokinetic evaluation was performed using the PKNCA R package. Mucosal healing (Mayo endoscopic sub-score ≤1) was evaluated at Week 14. Data are expressed as mean ± SD.

Results: A total of 79 matched pairs of serum and DBS sample GLM concentrations showed a very good correlation (Spearman r = 0.990, p < 0.0001). Nine out of 10 patients reported DBS sampling as user-friendly. For patients initiating therapy, TC were not measured using in-house developed ELISAs. Non-compartmental pharmacokinetic evaluation was performed using the PKNCA R package. Mucosal healing (Mayo endoscopic sub-score ≤1) was evaluated at Week 14. Data are expressed as mean ± SD.

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Figure 1. (A) GLM concentration vs. time profiles of patients who started GLM therapy. Patients 4 and 5 achieved mucosal healing (B) GLM concentration vs. time profiles of patients on ≥2 years GLM maintenance therapy. All patients had achieved mucosal healing.

Conclusions: The GOUDA study showed that DBS sampling is a robust and patient-friendly alternative to venous blood collection. DBS sampling provides also better insights into GLM exposure, as exposure was not captured well by the TC during induction. The GOUDA data are currently pooled with two other datasets to determine the GLM exposure-response relationships.

Reference

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Does medical acceleration improve long-term outcomes in ulcerative colitis patients who are in clinical remission but have endoscopic mucosal inflammation?

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Background: Discrepancies between clinical symptoms and mucosal inflammation have been reported in up to 50% of patients with ulcerative colitis (UC). However, there are no guidelines and only limited information for appropriate treatment manipulation in these patients. We aimed to evaluate long-term outcomes according to treatment strategies and determine predictive factors for disease relapse in UC patients who are in clinical remission (CR) but still have endoscopic inflammation.

Methods: A total of 204 patients who were confirmed as achieving CR but still had active mucosal lesions were included. CR was defined as ‘partial Mayo score ≤1’ with no changes in medications or use of any corticosteroids during the past 3 months. An active mucosal lesion was defined as “endoscopic Mayo subscore > 0.”

Results: The mean patient age was 43.5 years, and 53.9% of the included patients were male. The mean disease duration was 89.9 months. During a mean follow-up of 34 months, 90 patients (44%) experienced disease relapse. The cumulative relapse-free rate did not differ by treatment strategy (maintenance of current therapy vs. dose elevation or step-up strategy). Multivariate analysis revealed that left-side colitis or pancolitis at diagnosis (OR, 2.10; 95% CI 1.04–4.27; p = 0.040) and number of extraintestinal manifestations ≥ 2 (OR, 5.62; 95% CI 1.10–28.68; p = 0.038) were independent predictive factors for disease relapse.

Conclusions: The current medical acceleration treatment strategy did not have a significant influence on the long-term outcomes of UC patients in CR but with active mucosal inflammation. Disease extent