

DDW 2022

Digestive Disease Week

**In this Edition
Extra Focus
on IBD**

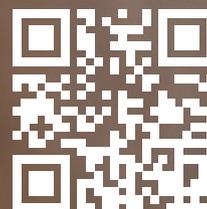
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Content

1. Antibiotic use elevates IBD risks in senior citizens
2. Too much hygiene: Crohn's disease in later life?
3. Biologic treatment decreases dementia risk in senior IBD patients
4. Crohn's disease: Induction treatment with upadacitinib successful in clinical and endoscopic ratings
5. IL-23 inhibition beneficial in maintenance treatment of ulcerative colitis
6. Positive outcomes for etrasimod in UC
7. Colonoscopy in UC: less pain and reduced recurrence with CO₂ insufflation
8. Substantial increase of oesophageal cancer prevalence in the middle-aged
9. Cannabis users need more sedation medication for gastroscopy
10. Preterm delivery and NICU admission are associated with the development of eosinophilic oesophagitis
11. Dupilumab promising as treatment for eosinophilic oesophagitis
12. AI-assisted colonoscopy improves adenoma detection
13. Faecal microbiota transplantation: a safe procedure to treat recurrent *Clostridium difficile* infections
14. Oral microbes effective for prevention of recurrent *Clostridium difficile* infections
15. Octreotide therapy beats standard of care in GIADs
16. Improvement in hepatic steatosis but worse lipid profile after alcohol cessation
17. Normal BMI in NAFLD patients is associated with a higher risk of cardiovascular disease
18. COVID-19 increases the mortality rates of patients with ALD

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1. Antibiotic use elevates IBD risks in senior citizens

An analysis including 2.3 million individuals older than 60 years showed that the use of antibiotics – independent of class – is associated with an increased risk of older-onset inflammatory bowel disease (IBD). Moreover, a positive dose-response was observed where multiple courses of antibiotics were associated with a higher risk.

In the real-world analysis presented by Prof. Adam S. Faye (NYU Langone Health, NY, USA), 2.3 million individuals aged 60 to 90 years were included and followed from 2000 to 2018 [1]. Prof. Faye and his colleagues used data from a nationwide registry in Denmark to assess the impact of cumulative antibiotic use, the timing of antibiotic use, and the association between specific antibiotic classes and the development of older-onset IBD.

From 2000 to 2018, 10,773 new cases of ulcerative colitis and 3,825 new cases of Crohn's disease were identified with diagnostic ICD-10 codes. Any antibiotic use was

associated with a 64% higher risk of developing IBD (incidence rate ratio [IRR] 1.64). All antibiotic classes elevated the risk for IBD development, including those not used to treat a gastrointestinal infection. However, the risk differed between classes and was highest when fluoroquinolones (IRR 2.27), nitroimidazoles (IRR 2.21), and macrolides (IRR 1.74) were used. Moreover, there was a clear dose-response observed: 1 course of antibiotics was associated with an IRR of 1.27, 2 courses with an IRR of 1.54, going up to ≥ 5 courses with a staggering IRR of 2.35. Effect estimates were slightly higher for Crohn's disease versus ulcerative colitis. The risk of developing late-onset IBD was

highest in the first 1–2 years after antibiotic use but remained elevated for 5 years.

"Inflammatory bowel disease often can be overlooked in older adults because there's a lot of different diagnoses you're thinking of," said Prof. Faye. "It should be considered, especially if you have a patient reporting that they had multiple courses of antibiotics within the past few years." Prof. Faye pointed out that, while antibiotic stewardship is essential, "avoiding antibiotics at all costs is not the right answer either. If patients are coming in with clear infections and they need antibiotics, they should not be withheld because of these findings," he concluded.

1. Faye AS, et al. Antibiotics as a risk factor for older-onset IBD: population-based cohort study. Lecture 400, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

2. Too much hygiene: CD in later life?

Different environmental factors influence inflammatory bowel disease (IBD) risk in first-degree relatives of patients with Crohn's disease (CD). Living with a dog and in a large family were both protective factors, adding to the existing evidence that too much hygiene might be responsible for an elevated risk for CD.

"Our study seems to add to others that have explored the 'hygiene hypothesis' which suggests that the lack of exposure to microbes early in life may lead to a lack of immune regulation towards environmental microbes," said Dr Williams Turpin (Mount Sinai Hospital and the University of Toronto, Canada). In the study, an environmental questionnaire was used to collect information from nearly 4,300 first-degree relatives of people with CD enrolled in the Crohn's and Colitis Canada Genetic, Environmental, and Microbial (CCC-GEM) project [1]. Using responses to the questionnaire and historical data collected at the time of recruitment, Dr Turpin and his team analysed several environmental factors, including family size, the presence of dogs or cats as household pets, the number of bathrooms in the house, living on a farm, drinking unpasteurised milk, and drinking well water. The analysis also included age at the time of exposure.

As a secondary analysis, regression models were used to identify the relationship of exposures with biological factors associated with CD risk: intestinal permeability using urinary fractional excretion of lactulose to mannitol ratio (LMR), with LMR ≥ 0.025 defined as abnormal; subclinical inflammation using faecal calprotectin (FCP), with FCP ≥ 100 $\mu\text{g/g}$; and faecal microbiome composition and diversity using 16S rDNA sequencing.

After a 5.6-year median follow-up time, 86 first-degree relatives developed CD. Living with a dog between ages 2–4 (HR 0.63; 95% CI 0.44–0.99) and large family size (>3) in the first year (HR 0.36; 95% CI 0.18–0.72) were significantly associated with lower risk of CD onset. Family size in the first year was not associated with changes in parameters assessed in the secondary analysis. In contrast, owning a dog between the ages of 2–4 was

significantly associated with normal LMR. Similar effects were observed with exposure to dogs across all age groups.

"We did not see the same results with cats as pets, though we are still trying to determine why," Dr Turpin said. "It could potentially be because dog owners get outside more often with their pets or live in areas with more green space, which has been shown previously to protect against CD."

These findings may assist physicians in assessing patients at high risk for developing IBD. A limitation of the study is that the early-life environmental factors were assessed by questionnaires, so caution is warranted in interpreting these results due to possible recall bias at recruitment.

1. Turpin W et al. Environmental factors associated with risk of Crohn's disease (CD) development in a prospective cohort of healthy first-degree relatives of CD patients. Lecture 793, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

3. Biologic treatment decreases dementia risk in senior IBD patients

A retrospective study on inflammatory bowel disease (IBD) in patients aged >65 years revealed that patients with IBD have a higher prevalence of dementia compared with the general population. Interestingly, in those treated with biologics, dementia was significantly less prevalent than in IBD patients not on biologic treatment.

Emerging evidence has identified the so-called gut-brain axis that includes metabolic, endocrine, and neural signalling as communication between the intestine and the central nervous system. Thus, a study point of interest is a possible difference in the prevalence of dementia in those with and without IBD. Healthcare information on over 7.5 million US patients served as a data source to investigate the presence of dementia in older patients with IBD [1].

Between 2016 and 2022, the study included patients who were over 65 years of age, of whom 41,860 had a diagnosis of Crohn's disease (CD) and 45,530 had ulcerative colitis (UC). These groups equalled 0.55% and 0.60%

of the total study cohort. The results showed a significantly higher prevalence of dementia in IBD patients than in the general population (5.4%): CD 10.8% and UC 7.8% ($P < 0.001$ for both comparisons).

Furthermore, the investigators strove to shed light on a possible difference in biologic- and non-biologic-treated IBD patients: 5,450 of the CD and 3,510 of UC patients received biologics. In terms of risk factor distribution in the groups with and without biologics, more than half of the CD and UC patients were women, 69%–88% had hypertension, and 27%–41% had diabetes. A history of smoking was present in 19%–27% of the IBD patients with and without biologic treatment.

Dementia was significantly less frequently found in the biologics group than in those not on biologics. The prevalence in CD was 4.2% with biologics and 11.7% without. The respective results for UC were 4.8% versus 8%, with a $P < 0.001$ for all comparisons.

Dr Ahmed Eltelbany (Cleveland Clinic, OH, USA) and his fellow researchers highlighted that this is the largest individual study investigating prevalence of dementia in senior patients with IBD with and without biological therapy. They concluded that IBD patients over 65 years treated with biologics were significantly less likely to be diagnosed with dementia than those never treated with biologics

1. Eltelbany A, et al. Impact Of Biologics Therapy On The Prevalence Of Dementia Among Older Patients With Inflammatory Bowel Disease: A Nationwide Population-Based Study. Poster Mo1545, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

4. CD: Induction treatment with upadacitinib successful in clinical and endoscopic ratings

Upadacitinib outperformed placebo in patients with moderate-to-severe Crohn's disease (CD). Besides clinical remission and endoscopic response rates, steroid-free and endoscopic remissions were significantly higher on treatment with the JAK inhibitor.

Upadacitinib showed promising results compared with placebo in the phase 2 CELEST trial ([NCT02365649](#)) and has thus advanced to double-blind, phase 3 testing [1]. Prof. Jean-Frederic Colombel (Mount Sinai Hospital, NY, USA) presented the results of U-EXCEED ([NCT03345836](#)), which investigated upadacitinib as induction therapy for patients with moderately-to-severely active CD who had a preceding inadequate response to biologics.

The study randomised 495 patients 2:1 to receive either daily 45 mg upadacitinib or placebo over 12 weeks. For those patients who were on corticosteroids (34%) at baseline, tapering was initiated after 4 study weeks. The co-primary endpoints at week 12 were

clinical remission and endoscopic response. Baseline measures included about 50% of men, mean age of around 38 years, and a median of 9–10 years of disease duration. In 60.8% of patients, the history showed the failure of at least 2 previous biologics, the majority of them TNF inhibitors.

The primary endpoints at week 12 were both met. Clinical remission measured by Crohn's Activity Index (CAI) <150 was achieved by 39% on upadacitinib compared with 21% on placebo ($P < 0.0001$). Also, significantly more patients had a $\geq 30\%$ decrease in stool frequency (SF)/average daily abdominal pain score (APS): 40% versus 14% ($P < 0.0001$ in favour of upadacitinib). Interestingly, about a third of patients in the upadacitinib group

experienced a ≥ 100 -point decrease in CDAI as early as week 2 and CDAI clinical remission at week 4. As for the endoscopic response, the threshold of a $\geq 50\%$ decrease in the Simple Endoscopic Score for Crohn's Disease (SES-CD) was present in 35% and 4% of the upadacitinib and placebo group, respectively ($P < 0.0001$).

Of the study participants previously taking corticosteroids, significantly more individuals in the upadacitinib group reached a clinical remission measured by CDAI (34% vs 12%; $P < 0.0001$) as well as SF/APS (37% vs 7%; $P < 0.0001$). Endoscopic remission was seen in more patients on upadacitinib with a difference of 17% between groups.

In terms of safety, treatment-emergent adverse events were observed in 65% in the placebo and 68% in the upadacitinib group. Concerning severe and serious treatment-emergent adverse events, the rates were

lower in the upadacitinib than in the placebo group (9% each, versus 12% and 10%). Most common were nasopharyngitis and headache (upadacitinib) or CD worsening and abdominal pain (placebo).

In summary, upadacitinib was found to be rapidly acting and overall superior to placebo in this study population, while being well-tolerated.

1. Colombel JF, et al. Efficacy and safety of upadacitinib induction therapy in patients with moderately to severely active Crohn's disease who failed prior biologics: results from a randomized phase 3 U-EXCEED study. Lecture 867f, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

5. IL-23 inhibition beneficial in maintenance treatment of UC

In the phase 3 LUCENT-2 trial, maintenance with mirikizumab demonstrated higher success rates in comparison with placebo in patients with moderately-to-severely active ulcerative colitis (UC). At week 40, the rate of achieving clinical remission with mirikizumab was almost double the percentage of that in the placebo group.

Mirikizumab, an IgG4 antibody binding to the p19 subunit of interleukin (IL)-23, was assessed as maintenance therapy for patients with UC until week 40 [1]. Within the phase 3 LUCENT-2 trial ([NCT03524092](#)), 544 responders from the 12-week LUCENT-1 induction study ([NCT03518086](#)) were included and re-randomised to blinded treatment with either placebo or mirikizumab 200 mg every 4 weeks. The primary endpoint was the rate of clinical remission defined as stool frequency 0 or 1 (plus ≥ 1 -point reduction from baseline) and rectal bleeding 0 at the end of the study. Participants had a mean age of 42.7 years, 59% were men, and disease duration was 6.8 years. At baseline, 35.3% of the participants had a history of inadequate response to at least 1 biologic and 37.3% were on corticosteroids.

The results showed that nearly half of the participants on mirikizumab attained clinical remission (49.9% mirikizumab vs 25.1% placebo; $P < 0.001$) at week 40. A significant difference was measured in participants with steroid-free remission between the 2 study groups (44.9% mirikizumab vs 21.8% placebo; $P < 0.001$). Furthermore, mirikizumab led to superior results in all other secondary endpoints: endoscopic remission, histologic-endoscopic mucosal remission, bowel urgency improvement/remission, as well as maintenance of clinical remission ($P < 0.001$ for all comparisons in favour of mirikizumab). The proportion of participants attaining bowel urgency remission was 42.9% on mirikizumab versus 25.0% on placebo.

Looking at safety, the most frequent treatment-emergent (TE) adverse events (AE) were

nasopharyngitis (7.2%), arthralgia, and UC (6.7% each) in the study drug group. Those taking placebo most commonly experienced UC (20.8%). Overall, TEAE were similar in both cohorts with 68.8% on placebo and 64.5% on mirikizumab. Serious AEs were observed at a higher rate in the placebo group (7.8% vs 3.3%). There were 4 cases of depression on mirikizumab and 1 attempted suicide which was however not adjudicated to the study drug. The only death in the study happened in the placebo group and was due to COVID-19.

All in all, Prof. Marla C. Dubinsky (Icahn School of Medicine at Mount Sinai, NY, USA) and her fellow researchers emphasised that the results confirm mirikizumab's phase 2 efficacy data and build on the phase 3 induction efficacy, demonstrated in the LUCENT-1 trial.

1. Dubinsky MC, et al. Efficacy and safety of mirikizumab as maintenance therapy in patients with moderately to severely active ulcerative colitis: results from the phase 3 LUCENT-2 study. Lecture 867e, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

6. Positive outcomes for etrasimod in UC

The small molecule etrasimod was evaluated in 2 phase 3 trials with a duration of 12 and 52 weeks in patients with moderate-to-severe ulcerative colitis (UC). Significant better results were seen in the etrasimod groups which included about 4 times higher clinical remission rates at year 1.

Etrasimod is a selective sphingosine-1-phosphate-receptor modulator that is currently evaluated for various immuno-inflammatory indications. Newly reported was data on ELEVATE UC 52 ([NCT03945188](#)) and ELEVATE UC 12 ([NCT03996369](#)), 2 phase 3 trials on UC that were conducted by Prof. William J Sandborn (University of California San Diego, CA, USA) and colleagues [1].

Participating adults in both studies suffered from moderate-to-severe UC defined by activity measures of a modified Mayo Score of 4-9, plus a centrally read endoscopic subscore ≥ 2 beside a rectal bleeding subscore ≥ 1 . In line with the previous history at baseline, the assessment was stratified according to the type of prior treatments and corticosteroid medication. The 2 trials

randomised 354 (ELEVATE UC 12) and 433 (ELEVATE UC 52) patients 2:1 to the study drug groups with a regimen of 2 mg of etrasimod once daily or placebo. Between 61.8% and 62.9% of the patients in both studies had never received biologics or Janus kinase inhibitors before. While ELEVATE UC 12 involved a 12-week induction only setting, the design of ELEVATE UC 52 foresaw a 40-week period of therapy subsequent to induction over 12 weeks. Change to a currently still ongoing open-label extension trial (ELEVATE UC OLE; [NCT03950232](#)) was available for patients with treatment failure at week 12.

The presented results revealed that etrasimod met all its primary and secondary efficacy endpoints in both studies. The rate for the primary endpoint of clinical remission in ELEVATE UC 12 was 24.8% for etrasimod versus 15.2% for placebo (P=0.026). The respective outcomes in ELEVATE UC 52 were 27% versus 7.4% after 3 months and even higher after 1 year with 32.1% versus 6.7% (P<0.001 for both comparisons). The secondary endpoints included: mucosal

healing, endoscopic improvement, symptomatic remission, and sustained clinical remission. Steroid-free remission was achieved in >4-fold more patients on etrasimod than on placebo (32.1% vs 6.7%; P<0.001).

The researchers pointed out that in both studies, treatment-emergent adverse events (AE) and serious AEs were similarly reported between treatment groups. They also

highlighted that there were no serious AEs of bradycardia or atrioventricular block. The most common AEs in ELEVATE UC 52 were headache, nausea, and SARS-CoV-2 infection.

1. Sandborn WJ, et al. Etrasimod 2 mg once daily as treatment for moderately to severely active ulcerative colitis: results from the phase 3 ELEVATE UC 52 and ELEVATE UC 12 trials. Lecture 968a, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

7. Colonoscopy in UC: less pain and reduced recurrence with CO₂ insufflation

A Japanese study compared CO₂ with air as a means of insufflation during colonoscopies. The CO₂ cohort overall experienced less pain, and patients with baseline partial remission also suffered from fewer exacerbations of their ulcerative colitis (UC).

Patients with UC not only need to undergo colonoscopies for diagnostic indications, but for cancer screening as well. However, these procedures can also provoke disease flares. A prospective, randomised trial investigated if the use of carbon dioxide (CO₂) for intra-procedural insufflation may bear an advantage over the regularly used air insufflation in remissive UC patients (Partial Mayo Score [PMS] ≤2). The study enrolled 91 adults with a median age of 49 years; 66% were men. Overall, the baseline characteristics were evenly distributed among the 2 study groups, e.g. for disease location, Mayo Endoscopic Subscore (MES), clinical activity, and medication.

Immediately following colonoscopy, the abdominal pain score for patients in the CO₂ group was significantly lower compared with the air group, as was the score for abdominal fullness (P=0.0003 for both comparisons). At 30 minutes following procedure termination, these 2 measures were still significantly lower in patients in the CO₂ group (P<0.001 for both comparisons).

The assessment of clinical recurrence (PMS ≥3) was performed at week 1 and week 8 after the colonoscopy. At week 1, no significant disparity was observed between the groups receiving air or CO₂ for insufflation, both in patients with complete remission

(MES0 or PMS0) nor those in partial remission (MES 1–3 or PMS 1/2). However, at week 8, the group of UC patients with partial remission who had been insufflated with CO₂ instead of air had a significantly lower proportion of clinical recurrence: CO₂ 0% versus air 24% (P=0.048) for MES 1–3 and 0% versus 30% (P=0.022) for PMS 1/2.

The authors summarised that CO₂ insufflation can reduce abdominal discomfort after colonoscopy and decrease clinical recurrence in those UC patients who do not have complete remission.

1. Otake Y, et al. Efficacy of carbon dioxide insufflation during colonoscopy for patients with ulcerative colitis in clinical remission- a randomised trial. Poster EP1277, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

8. Substantial increase of oesophageal cancer prevalence in the middle-aged

Data on the prevalence of oesophageal adenocarcinoma and Barrett's oesophagus (BE) in people between 45 and 64 years of age is concerning. From 2012 to 2019, the prevalence of oesophageal cancer almost doubled in this age group.

"While the prevalence of oesophageal cancer (EC) and Barrett's oesophagus is thought to have plateaued in recent years, our team wondered whether this apparent trend could be age-dependent," explained Prof. Bashar J. Qumseya (University of Florida, FL, USA) [1]. He and his team analysed changes in the prevalence of EC and BE from 2012 to 2019, based on the OneFlorida Clinical Data

Network with records of over 5 million patients. The findings were reported for 3 age groups: young (18–44), middle-aged (45–64), and elderly patients (>65).

While the prevalence of oesophageal adenocarcinoma was highest in the elderly, it was quite stable over time. In contrast, the prevalence of EC rose from 49/100,000 in 2012

to 94/100,000 in 2019 in the middle-aged. It was paralleled by an also logarithmic increase in the prevalence of BE, a primary precursor of oesophageal adenocarcinoma, from 304/100,000 to 466/100,000 over the same time in those aged between 45–64 years. Assessing this augmented BE prevalence for the middle-aged in subgroups, the highest increase was found in those aged between 51–60 years.

"Whenever we see an increase in any type of cancer, we always have to ask if this could

be due to better screening, or more frequent screening, but unfortunately this was not the case here," commented Prof. Qumseya. His group explored this possible explanation for the rise and found stable rates for the utilisation of gastroscopy in the same population.

"This should be of great concern to physicians and patients, and maybe we should

consider screening for BE and EC in middle-aged patients or at younger ages," Prof. Qumseya said in his concluding remarks. "Our data from the same cohort shows that many people who have 4 or more risk factors for this disease have never had an endoscopy – we can definitely do better!" He suggested that, for example, conducting a gastroscopy at the same time as a

screening colonoscopy could be helpful to find more cases of BE and EC, and hopefully prevent this disease from progressing.

1. Qumseya BJ, et al. Alarming increase in prevalence of esophageal cancer and Barrett's esophagus in middle-aged patients: findings from a statewide database of over five million patients. Lecture 671, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

9. Cannabis users need more sedation medication for gastroscopy

Patients who reported using some sort of cannabinoids had a marked higher likelihood of needing higher doses of midazolam or any diphenhydramine while undergoing a diagnostic esophagogastroduodenoscopy (EGD). For those receiving colonoscopies, no significant difference in dosing requirement was established.

Endoscopist-directed conscious sedation (EDCS) is widely used for endoscopic procedures such as gastroscopy and colonoscopy. While efficient and cost-effective, EDCS can be limited by failure to achieve sufficient levels of sedation that enable safe endoscopy. "It is important to be able to predict which patients require higher doses of EDCS or are at a high likelihood of sedation failure," Prof. Yasmin Nasser (University of Calgary, Canada) explained the motivation for the presented study [1]. In light of the rising number of states/countries that legalise some sort of cannabis, with a resulting larger population of users, Prof. Nasser pointed out that medical practitioners will increasingly encounter patients with baseline cannabis use. In these patients, the possibility of drug interactions between cannabinoids and medications routinely used for sedation during endoscopy might be expected, but there is a lack of data on this matter.

A total of 419 adults who underwent either colonoscopy or gastroscopy (EGD) were included in the study. The participating outpatients gave information on topics like cannabis use, alcohol, and comorbidities prior to the diagnostic procedure. Also, a questionnaire to assess their endoscopy tolerability experience (PRO-STEP) was filled in before going home after endoscopy. By multiple logistic regression, differences between cannabis users and non-users were evaluated with variables including age, sex, alcohol use, anxiety, and depression.

The results demonstrated that participants undergoing EGD who had stated use of cannabinoids were nearly 3 times more likely to need ≥ 5 mg of midazolam (adjusted odds ratio [aOR] 2.89) and require diphenhydramine (aOR 3.04). For colonoscopies, these 2 outcomes were not significant.

Furthermore, cannabis use was not an independent risk factor for intra-procedural adverse events nor fentanyl use.

The need for high sedation with a combination of midazolam ≥ 5 mg, fentanyl ≥ 100 μ g, or any diphenhydramine during EGD was also significantly more likely in cannabis users (aOR 3.72). In terms of intra-procedural awareness, pain, or discomfort, there were no significant differences for cannabis users for either procedure.

"Overall, our findings could suggest the following: first, that baseline cannabis users undergoing endoscopic procedures require increased doses of benzodiazepines relative to opioids; and second, that the overall tolerability of outpatient endoscopy is similar between cannabis users and non-users," Prof. Nasser concluded.

1. Nasser Y. Baseline Cannabis Use is Associated with Increased Sedation Requirements for Outpatient Endoscopy. Poster Sa1022, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

10. Preterm delivery and NICU admission are associated with the development of eosinophilic oesophagitis

A nationwide, population, and registry-based case-control study showed that perinatal factors, specifically preterm delivery and neonatal intensive care unit (NICU) admission, are associated with an increased risk of eosinophilic oesophagitis. The strongest association was seen between the gestational age and the development of eosinophilic oesophagitis.

According to prior studies, early life exposure is a factor that increases the risk of developing

eosinophilic oesophagitis yet the results of most of these studies are limited by recall bias.

The current study was conducted to investigate the association between a selected number of perinatal factors with the development of eosinophilic oesophagitis, using registry-based data from the nationwide Denmark cohort [1].

In the large, case-control study presented by Dr Kurt Gencer (Aarhus University, Denmark),

393 cases of neonates with eosinophilic oesophagitis and 3,659 age- and sex-matched controls were included. The researchers collected data prospectively from the Danish health and administrative registries from 1997 to 2019. Dr Gencer and his colleagues defined pregnancy complications, mode of delivery, gestational age at delivery, birth weight, and NICU admission as the perinatal factors and assessed the association between these factors and the development of eosinophilic oesophagitis. They also performed an interaction analysis to see whether the association between the NICU admission and the development of eosinophilic oesophagitis is modified by the preterm status.

In all cases, diagnosis of eosinophilic oesophagitis was confirmed by biopsy and

other conditions associated with oesophageal eosinophilia were excluded. The strongest association was observed between the gestational age at delivery and eosinophilic oesophagitis (adjusted OR 3.2; 95% CI 1.6–6.3) and NICU admission and eosinophilic oesophagitis (adjusted OR 2.4; 95% CI 1.1–5.5). Moreover, a stronger association was observed between NICU admission and eosinophilic oesophagitis in term (adjusted OR 1.9; 95% CI 1.3–2.8) than in preterm infants (adjusted OR 0.6; 95% CI 0.3–1.3).

Therefore, the authors concluded that the association between NICU admission and eosinophilic oesophagitis is independent of the preterm status. Furthermore, pregnancy complications also elevated the risk of eosinophilic oesophagitis (adjusted OR 1.4;

95% CI 1.0–1.8) whereas weight for gestational age and caesarean delivery didn't have an influence.

When the gestational age at the delivery was considered, the risk of developing eosinophilic oesophagitis was highest when delivered at the 33rd week of gestation. Regarding the association with the NICU admission, the risk of developing eosinophilic oesophagitis was highest at 2–3 weeks of NICU admission.

The authors of the study suggest that there is a need for further research to elucidate the underlying pathway of the above associations.

1. Kurt G, et al. Perinatal factors and risk of eosinophilic esophagitis - a Nationwide population based case-control study. Poster Su1181, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

11. Dupilumab promising as treatment for eosinophilic oesophagitis

Dupilumab at a 300 mg dose was tested as a weekly or bi-weekly regimen for patients with eosinophilic oesophagitis in the phase 3 LIBERTY EOE TREET trial. Although only 1 of the 2 co-primary study endpoints was reached, most secondary endpoints were in favour of dupilumab.

Symptoms of oesophageal dysfunction and a mostly eosinophil inflammation in the tissue are typical for eosinophilic oesophagitis (EoE), a chronic and progressive condition [1]. As the inflammation is T2-driven, dupilumab was a candidate for treatment and it was thus evaluated in the 3-part phase 3 LIBERTY EOE TREET trial ([NCT03633617](https://clinicaltrials.gov/ct2/show/study/NCT03633617)) [2].

Prof. Evan S. Dellon (University of North Carolina School of Medicine, NC, USA) presented the 24-week results of study part B, in which 240 adults and adolescents with EoE were treated with placebo or weekly or bi-weekly dupilumab 300 mg. The primary endpoint consisted of 2 measures: the rate reaching an oesophageal intraepithelial eosinophil count (eosC) ≤ 6 /high-power field (hpf) on one hand, and the absolute change in dysphagia assessed by the self-reported Dysphagia Symptom Questionnaire (DSQ) score on the other. The percent change of DSQ was among the secondary endpoints.

At baseline the mean eosC/hpf ranged from 84.3 to 89.2 in the 3 study groups, reflecting severe inflammation. The mean DSQ score was 36.7. A prior history of dilative treatment was present in 35.4%, while 73.3% had already been treated with swallowed topical steroids.

Looking at the components of the primary endpoint at week 24, the ratios of achieving an eosC ≤ 6 /hpf were 58.8% with a weekly and 60.5% with a bi-weekly dose in the dupilumab groups compared with 6.3% for placebo ($P < 0.0001$ for both comparisons). Patients receiving weekly dupilumab also had better improvement in patient-reported DSQ scores. However, significance was not reached in the bi-weekly dupilumab group versus placebo for absolute nor percental difference: weekly dupilumab -23.78 and bi-weekly dupilumab -14.37 versus placebo -13.86 ($P < 0.0001$ and $P = 0.8$, respectively).

In terms of secondary outcomes, dupilumab demonstrated significant superiority over

placebo. Percentages for reaching a peak eosC < 15 were 82.5 (weekly dupilumab)/79.0% (bi-weekly dupilumab) versus 7.6% (placebo). Also, absolute LS means of Endoscopic Reference Score (ERFS), EoE Histologic Scoring System (HSS) grade, and EoE-HSS stage scores were significantly more ameliorated by the study drug ($P < 0.0001$ for all comparisons). In the assessment for gene signatures in type 2 inflammation and EoE diagnostic panel, a positive influence by dupilumab was also observed. There was overall good tolerability of the study drug.

In summary, Prof. Dellon expressed that weekly dupilumab 300 mg improved clinical, symptomatic, histologic, endoscopic, and molecular aspects of EoE and was well tolerated up to 24 weeks.

1. [Dellon ES, et al. Gastroenterology. 2018 Oct;155\(4\):1022–1033.e10.](https://doi.org/10.1093/gastro/ggab218)
2. Dellon ES, et al. Clinical and histological improvements with weekly dupilumab treatment in adult and adolescent patients with eosinophilic esophagitis at week 24: weekly and every 2 weeks' results from part B of 3-part LIBERTY EOE TREET study. Lecture 867a, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

12. AI-assisted colonoscopy improves adenoma detection

A study including more than 3,000 participants showed a significantly better adenoma detection rate when colonoscopy was assisted by a self-learning Artificial Intelligence (AI) system. The AI-assisted colonoscopy was superior, independent of the type or location of the adenoma – even in patients with inadequate preparation for the procedure.

Prof. Joseph Sung (Lee Kong Chian School of Medicine, Singapore) pointed out in his presentation that AI-assisted colonoscopy has been shown to improve polyp detection and characterisation in colonoscopy [1]. However, data from large-scale, multicentre, randomised-controlled trials (RCTs) are still missing. This was the rationale for a multicentre, single-blind RCT in China including Hong Kong.

Recruited participants were randomised (1:1) to receive either AI-assisted or conventional colonoscopy. Study participants were asymptomatic, 45–75 years old, and were undergoing colorectal carcinoma (CRC) screening either by direct screening colonoscopy or by a faecal immunochemical test (FIT)-based screening programme. IBD or a colonoscopy within 10 years were exclusion criteria. The AI system used was a deep convolution neural network trained

and validated by 112,199 still images and a separate dataset of 21 colonoscopy videos. According to an independent validation, the system achieved both sensitivity and specificity of >89% in recognising polyps. "This AI device has an ordinary desktop computer size and can fit in any endoscopy tower," said Prof. Sung. In the trial, high-definition colonoscopes, endoscopy processors, and monitors were used. However, neither electronic image enhancing function nor mucosal exposure devices were allowed.

The primary study outcome was the overall adenoma detection rate (ADR), the proportion of patients with at least one colorectal adenoma detected among all patients examined by an endoscopist. All adenomas (non-advanced adenomas, advanced adenoma, and CRC) were assessed.

Altogether, 3,059 participants were included in the intention-to-treat analysis. The ADR was significantly better in the AI group compared with the conventional colonoscopy (606 vs 499; $P < 0.001$). "Even those with inadequate preparation benefitted from the AI-assisted colonoscopy," Prof. Sung emphasised. A significant benefit was seen in both advanced and non-advanced, large and small adenoma, and proximal and distal adenoma. The only disadvantage was that the procedure itself took significantly longer with AI.

"AI should become standard of class in colonoscopy, because it does not only improve adenoma detection in general but also advanced adenoma, and thus can help in cancer prevention and will improve the outcome of patients," Prof. Sung concluded.

1. Sung JJ, et al. Artificial intelligence-assisted colonoscopy for colorectal cancer screening: a multicenter randomized controlled trial. Lecture 414, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

13. Faecal microbiota transplantation: a safe procedure to treat recurrent *Clostridium difficile* infections

A meta-analysis of patients receiving treatment for *Clostridium difficile* infection showed that faecal microbiota transplantation is generally a safe procedure, with the most significant adverse events being unrelated to the intervention. The majority of adverse events observed were minor and were commonly abdominal pain, constipation, nausea, and vomiting.

Despite the efficacy of faecal microbiota transplantation (FMT), the procedure is still highly underutilised, probably due to concerns over its safety. To shed light on this issue, Dr Eliot A. Rapoport (University of Illinois College of Medicine, IL, USA) and colleagues performed a meta-analysis including 61 unique original research studies on FMT for *Clostridium difficile* infections (CDI) [1].

The literature search was conducted using MEDLINE through PubMed, Ovid, Cochrane Library, and EMBASE from 2015 to 2021.

Published articles written in English or with English translation were eligible for inclusion if they reported the use and outcomes of FMT for the management of CDI in the non-paediatric population. They extracted data on rates of adverse events (AEs), the primary target of interest being the rate of significant adverse events (SAEs) related to FMT.

Of the 378 reference articles identified by the initial search, 61 studies met the inclusion criteria, with data from 5,099 patients

receiving 5,551 transplantations. An upper gastrointestinal route was specified in 30% of the cases and a lower gastrointestinal route in 56%. 4.8% of patients had IBD, and 8.0% were immunosuppressed.

Despite a significant proportion of patients being immunocompromised, the overall rate of SAEs related to FMT was only 0.65% (95% CI 0.45–0.89; $P < 0.01$). Harbord-Egger bias indicator showed that there was no publication bias. The most commonly reported SAEs were sepsis, aspiration pneumonia, and bowel perforation. The rate of SAEs deemed unrelated to FMT was higher at 2.9% (95% CI 2.47–3.39). This finding was to be expected because FMT was often reserved for extremely ill patients. However, minor adverse events were common but

were mostly self-limited gastrointestinal discomforts such as abdominal pain, constipation, nausea, and vomiting.

The meta-analysis demonstrated that FMT is generally a safe procedure for CDI with significant adverse events noted in less than 1% of the patients. Dr Rapoport stated, "our current knowledge of related SAEs and

unrelated SAEs indicates that FMT should be a therapy strongly considered for patients with recurrent CDI."

Further studies should evaluate the role played by route of administration and immunosuppression on FMT efficacy and safety to improve the present knowledge and to ascertain the improvements in the quality of

life of patients treated with FMT compared with those who have undergone standard antibiotic therapy.

1. Rapoport EA, et al. Adverse events in fecal microbiota transplantation: a systematic review and meta-analysis. Poster Su1602, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

14. Oral microbes effective for prevention of recurrent *Clostridium difficile* infections

An investigational oral microbiome therapeutic successfully prevented the recurrence of *Clostridium difficile* infections in the largest open-label study ever performed with an oral microbiome preparation. Moreover, a substantial treatment effect can still be expected with a second dose.

Currently, disruption of the microbiome is considered essential to the pathogenesis of recurrent *Clostridium difficile* infections (CDI). However, few trials have evaluated the efficacy and safety of orally administered microbiome therapeutics. Prof. Jessica Allegretti (Brigham and Women's Hospital, MA, USA) presented the results of the PRISM-EXT ([NCT03497806](https://clinicaltrials.gov/ct2/show/study/NCT03497806)) trial, where the safety and efficacy of open-label treatment with CP101 in adults with recurrent CDI was evaluated [1]. CP101 is an investigational, orally-administered, microbiome therapeutic designed to restore microbiome diversity and enable early intervention in recurrent CDI.

PRISM-EXT is the largest open-label study of an investigational oral microbiome therapeutic. As Prof. Allegretti pointed out in her

presentation, the 132 participants either rolled over from PRISM3 after experiencing a CDI recurrence (n=50) or directly enrolled after experiencing a CDI recurrence without previously participating in PRISM3 (n=82). The CDI episode was diagnosed prior to trial entry by PCR-based or toxin EIA-based testing in line with current guidelines. All participants received a one-time oral administration of CP101 without bowel preparation following standard-of-care (SOC) antibiotics.

The primary efficacy endpoint was sustained clinical cure, defined as an absence of CDI recurrence through week 8 following dosing.

80.3% of participants had no CDI recurrence through week 8 following administration of

SOC antibiotics and CP101 in PRISM-EXT. Efficacy was maintained with a sustained clinical cure rate of 78.8% through week 24. Of the 20 participants who had a recurrence in PRISM3 and received a 2nd CP101 dose in PRISM-EXT, 70% had no CDI recurrence through week 8 after the 2nd dose.

Microbiome diversity increased following administration of the oral microbiome therapeutic in all participants. Moreover, the results suggest that a significant proportion of patients that shows no response to a first dose of CP101 can be successfully treated with a second dose of the preparation. CP101 was well-tolerated with no treatment-related serious adverse events.

1. Allegretti JR, et al. CP101, an investigational orally administered microbiome therapeutic, was effective for prevention of recurrent *C. difficile* infection: Results from open-label prims-ext trial. Lecture Tu1519, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

15. Octreotide therapy beats standard of care in GIADs

The somatostatin analogue octreotide was investigated for the treatment of gastrointestinal angiodysplasias (GIADs) with anaemia. The results showed that therapy with octreotide led to a marked reduction of transfusions and the necessity of rescue treatment.

"GIADs are vascular malformations that frequently cause patients to suffer from symptomatic disease, ranging from mild anaemia to severe red blood cell transfusion dependency," explained Ms. Lia Goltstein (Radboud University Medical Center, the Netherlands),

who presented a trial that compared octreotide in GIAD treatment with standard of care (SoC) [1].

The study recruited 62 Dutch patients between 2015 and 2021. A prerequisite for inclusion

was a need for ≥ 4 transfusions of either red blood cells with or without 500 mg of iron intravenous in the year before the study. The 2 study groups received either 40 mg of intramuscular octreotide every 28 days or SoC. The primary endpoint was defined as the mean difference in the number of transfusion units among the groups. Throughout the study, endoscopic therapy was possible as a means of rescue treatment. The extent of these rescue endoscopies in the study groups was a secondary endpoint.

Mean baseline frequency data for patient requirements throughout the year before the trial was 20.3 for transfusion units and 2.4 for endoscopic treatments. Over the study period of 1 year, octreotide treatment led to a significant reduction in transfusions compared with SoC: 11.0 (95% CI 5.5–16.5) versus 21.2 (95% CI 15.7–26.7; $P=0.011$). Furthermore, endoscopic interventions were significantly decreased in the octreotide-treated study cohort ($P=0.005$).

The authors expressed that octreotide treatment effectively reduced the transfusion requirements and endoscopic procedures of patients with GIAD-related anaemia. These findings may be complemented by a result from an also presented meta-analysis of individual patient data on somatostatin analogues in GIADs, which demonstrated that patients with GIADs in the small intestine or colon have the greatest benefit from octreotide [2].

1. Goltstein L. Octreotide significantly reduces transfusion requirements compared to standard care in patients with angiodysplasia-related anemia: a multicenter randomized controlled trial. Lecture 876d, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.
2. Goltstein L, et al. Somatostatin analogs are highly effective and safe in patients with gastrointestinal angiodysplasias: An individual patient data meta-analysis. Abstract Sa109, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

16. Improvement in hepatic steatosis but worse lipid profile after alcohol cessation

A study conducted among patients with alcohol use disorder enrolled in an alcohol detoxification programme showed that hepatic steatosis improved rapidly after drinking was stopped. Unfortunately, this was accompanied by a significant change from an athero-protective profile (high HDL, low LDL) to an atherogenic one.

The study, including 93 patients, categorised lipoprotein (LP) changes and the association between LP-Insulin Resistance Index (LP-IR) and hepatic steatosis following alcohol detoxification [1]. Patients that were enrolled in a 4-week alcohol detoxification programme at the National Institute of Health and with the last drink within 3 days of admission were registered.

Laboratory values and NMR LipoProfile Testing® were collected upon admission and during the first and third weeks. Fibroscan® with controlled attenuation parameter (CAP) was performed during the first, second,

and fourth week. The Area Under Receiver Operator Characteristic (AUROC) was used to distinguish responders and non-responders, defined as a decrease or increase in liver CAP between week 1 and week 4.

A significant decrease was measured in CAP and aspartate aminotransferase over time. LP analysis showed a decrease in Apolipoprotein (Apo) A1 and an increase in ApoB and an initial decrease in LP-IR. A decrease in HDL particle number was detected, which was also seen in medium and large but not small HDL-P, as well as a decrease in HDL size. In comparison, an increase in LDL

particle number was detected, with an increase in small and a decrease in large LDL particles, as well as a decrease in LDL size. Lastly, an increase in total triglyceride-rich LP particle number was observed.

As the liver is a key producer of ApoA1 and ApoB100, the authors hypothesised that with alcohol, ApoA1 is upregulated resulting in increased HDL and ApoB is downregulated, resulting in decreased LDL and triglycerides with lipids unable to leave the liver. Initial LP-IR was found to predict CAP improvement. Further studies are needed to elucidate the mechanisms of hepatic influx and efflux of lipids and the interplay between insulin resistance and alcoholic steatosis.

1. Rapoport EA, et al. Adverse events in fecal microbiota transplantation: a systematic review and meta-analysis. Poster Su1602, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

17. Normal BMI in NAFLD patients is associated with a higher risk of cardiovascular disease

A retrospective cohort study including more than 10,000 adults with non-alcoholic fatty liver disease (NAFLD) showed that, surprisingly, lean people with NAFLD have a higher risk of cardiovascular disease than those who are overweight or obese. This held true despite lean patients having a lower prevalence of risk factors like hypertension and dyslipidaemia.

"It seems counterintuitive that those with a normal BMI would have a higher prevalence

of cardiovascular disease (CVD), but our research highlighted this connection," said

lead study author Dr Karn Wijarnpreecha (University of Michigan, MI, USA). "This finding could have significant implications on patient care and warrants further analysis." Although most NAFLD patients are overweight or obese, approximately 10–20% have a normal BMI.

The retrospective cohort study looked at 18,793 adults with NAFLD at the University of Michigan from 2012 to 2021. Patients were categorised into lean (BMI 18.5–24.9), overweight (BMI 25–29.9), class 1 obesity (BMI 30–34.9), or class 2–3 obesity (BMI 35–<40). Prevalence of cirrhosis, CVD (coronary artery disease, congestive heart failure, cerebrovascular diseases, and peripheral arterial diseases), metabolic diseases (diabetes, hypertension, dyslipidaemia), and chronic kidney disease were assessed in the various groups.

The results showed that, compared with NAFLD patients who were overweight or obese, lean NAFLD patients had a significantly higher rate of CVD even though they had a significantly lower prevalence of risk factors associated with CVD, such as diabetes, hypertension, and dyslipidaemia. "A logistic regression analysis of the association between BMI categories and prevalence

of CVD controlled for confounders showed a significantly lower prevalence of coronary artery disease and cerebrovascular disease in overweight and obese subjects," Dr Wijarnpreecha said during the presentation. Compared with lean NAFLD patients, overweight patients had an odds ratio (OR) of 0.8 and obese patients (both class 1 and class 2–3) an OR of 0.7.

Almost 6% of lean patients had peripheral arterial disease, compared with rates of approximately 4%–5% in overweight people and people with obesity. Similarly, more than 6% of the lean group experienced a stroke, compared with 5% or less of the other BMI groups. However, lean patients had a lower prevalence of cirrhosis, diabetes mellitus, hypertension, dyslipidaemia, and chronic kidney disease.

A limitation of the study is its retrospective design. "We cannot definitively state

that lean NAFLD patients have a higher risk of CVD. The only conclusion we can draw from this study is that there was a higher prevalence of CVD in the lean group than in the overweight or obese NAFLD groups. Whether lean NAFLD patients are going to develop CVD or have a higher risk requires additional research," said Dr Wijarnpreecha. Future prospective studies should further explore the risk and incidence of comorbid conditions in NAFLD patients and how it relates to BMI.

Due to these results, Dr Wijarnpreecha recommended that "NAFLD patients with a normal BMI should not be overlooked in clinical practice."

1. Wijarnpreecha K, et al. Higher prevalence of cardiovascular disease among lean versus non-lean patients with nonalcoholic fatty liver disease despite lower prevalence of atherogenic risk and metabolic diseases. Lecture 325, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.

18. COVID-19 increases the mortality rates of patients with ALD

An analysis of 25,721 patients with alcohol-related liver disease (ALD) including 16,813 patients before and 11,625 during the pandemic, showed a staggering rise in 60-day and 90-day mortality rates men. the pandemic. This was especially pronounced in younger patients and males.

Stress related to the COVID-19 pandemic could lead to excessive alcohol use, which can be further aggravated by isolation-related boredom, shifted medical resources, and limited access to mental health care. Hence, a proper analysis of whether the COVID-19 pandemic has had any effect on the rates of patients with ALD is a crucial aspect of further health planning.

In the analysis conducted by Dr Yee Hui Yeo (Cedars-Sinai Medical Center, CA, USA), Dr Biyao Zou and Dr Mindie H. Nguyen (Stanford University, CA, USA), a total of 25,721 patients with ALD admitted to the emergency department or as an inpatient, including 16,813 patients before and 11,625 during the pandemic, were identified through data obtained from the Optum Clinformatics DataMart database, a source of the Population Health Science Center at Stanford University [1].

During the pre-pandemic period, there were no significant trends in mortality. A downward trend was detected in both 60-day and 90-day mortality rates between the first quarter (Q1) and the third quarter (Q3) of 2019, however, this trend turned upwards during the last quarter (Q4) of 2019 and Q1 of 2020. The pandemic phase was considered to be between Q2 of 2020 to Q1 of 2021. During this time period, a consistent upward trend was present in both the 60-day and 90-day mortality rates. Moreover, by the end of 2020, at least 25% of patients with ALD died by 90 days and 20% died within 60 days after their diagnosis.

The odds of death for ALD surged (18.73; $P < 0.01$) during the pandemic onset in Q2 of 2020 compared with slightly declining rates (0.995; $P < 0.01$) during the pre-pandemic phase. A quarterly comparison between 2020 and 2019 showed that the prevalence

ratio in 60-day and 90-day mortality rates of ALD significantly increased for all quarters. For example, the 60-day mortality rate in Q2 of 2020 was 45% higher than in Q2 of 2019.

The increasing trend was more prominent in patients younger than 65 years. Men had a higher gradient of an increasing trend than women. Also, racial differences were observed: while there was no significant change in the prevalence of ALD among non-Hispanic Asians, the upward trend among non-Hispanic Whites and Blacks was significant.

The researchers concluded that during the pandemic an alarming rise was observed in mortality rates in patients with ALD and that more targeted interventions and resource allocation to curb the surging burden of ALD was necessary, with special emphasis on mental health services and alcohol treatment programs.

1. Yeo YH, et al. Prevalence and mortality of Alcohol-related Liver diseases during COVID-19 pandemic. Poster Mo1336, Digestive Disease Week 2022, 21–24 May, San Diego, CA, USA.