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2025: The Inflammatory Bowel Disease (IBD) Year in Review

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Whole Food Diet Induces Remission in Children and Young Adults with Mild to Moderate Crohn's Disease and Is More Tolerable Than Exclusive Enteral Nutrition: A Randomized Controlled Trial. Aharoni-Frutkoff Y, et al. Gastroenterology. 2025;169(7):1462–1474.

Effective and well-tolerated dietary therapies for Crohn's disease have long been sought by both patients and providers. In pediatric inflammatory bowel disease (IBD), exclusive enteral nutrition (EEN) has gained traction and is recommended by treatment guidelines.[1,2] However, it has not been broadly implemented in adults due to poor tolerability, social constraints, and challenges with long-term adherence.[3,4] Consequently, there is a growing interest in dietary interventions that offer efficacy while imposing a lower burden on patients.

TASTI-MM is the first randomized controlled trial to provide evidence supporting an exclusive whole-food dietary strategy to treat active Crohn's disease.[5] Previous evidence for whole-food approaches was limited to observational cohorts.[6-9] This trial sought to determine whether a whole food diet could enhance compliance in comparison with EEN, improve disease activity, and modify the microbiome with the goal of sustained disease control.[10]

TASTI-MM employed an open-label design with blinded outcome assessment. Biologic-naive children and young adults (age 6–25 years) with mild-to-moderate Crohn's disease were randomized to either the Tasty & Healthy diet or EEN for an 8-week induction period. The Tasty & Health diet excludes gluten, animal fat (i.e. red meat and dairy, except plain yogourt) and processed foods. All participants received structured weekly dietary support to promote adherence and monitoring. The primary endpoint was tolerability, while secondary endpoints included symptoms, biochemical markers, and changes in the gut microbiome.

The key finding of the TASTI-MM trial was that the whole-food dietary intervention was significantly more tolerable than EEN, with tolerability rates of 88% versus 52%, respectively ($p<0.001$) with no significant differences in symptomatic remission rates or objective markers of inflammation. This suggests that improved tolerability was not accompanied by reduced clinical effectiveness. While EEN led to a reduction in microbiome alpha-diversity, the whole-food diet led to enrichment of commensal microbial taxa and a reduction in species associated with gut inflammation. Taken together, these observations suggest that whole-food dietary therapy may achieve remission as effectively as EEN, while improving adherence and creating a healthier gut microbiome environment.

Although TASTI-MM was generally well designed, several limitations warrant consideration. The trial did not assess endoscopic endpoints, enrolled only patients with mild-to-moderate uncomplicated disease, and evaluated induction rather than long-term maintenance of remission. Furthermore, successful implementation of any dietary regimen requires intense dietetic education and support, which can vary in feasibility across healthcare settings. Despite these concerns, TASTI-MM represents a significant advance in nutritional therapy for Crohn's disease, offers an alternative for patients who are either unwilling or unable to follow enteral feeding protocols, and should encourage multidisciplinary care with a renewed interest in nutritional stewardship.

Efficacy and Safety of Upadacitinib for Perianal Fistulizing Crohn's Disease: A Post Hoc Analysis of 3 Phase 3 Trials. Colombel JF, et al. Clinical Gastroenterology and Hepatology. 2025;23(6):1019–1029.

Fistulas are among the most challenging clinical manifestations of Crohn's disease, affecting up to half of patients throughout the course of their disease and exerting a substantial impact on their quality-of-life.[11-13] Current approaches combine medical therapy with surgical interventions such as seton placement or fistula repair.[14] Among medical therapies, only infliximab has demonstrated efficacy in controlled clinical trials for fistulizing disease.[15,16] Responses to treatment are often incomplete, creating a significant unmet need.[17,18]

Upadacitinib, a selective Janus kinase 1 (JAK1) inhibitor, has demonstrated efficacy across both clinical and endoscopic outcomes in moderate-to-severe luminal Crohn's disease.[19] Colombel et al conducted a post hoc analysis of the U-EXCEL and U-ENDURE trials, in which adults with moderately-to-severely active Crohn's disease were randomized to either receive once-daily upadacitinib 45 mg or placebo for a 12-week induction period.[20] Those who achieved a clinical response were subsequently re-randomized to either placebo, upadacitinib 15 mg, or upadacitinib 30 mg daily for 52 weeks of maintenance therapy. This post hoc analysis examined fistula-related outcomes among the subset of patients with penetrating disease at baseline.

Among 1,021 patients enrolled in the induction trials, 143 had active fistulas at baseline, the majority of which were perianal. Over the 12-week induction period, cessation of perianal fistula drainage was achieved in 44.7% of patients with upadacitinib versus 5.6% with placebo (p=0.003). Similarly, closure of external fistula orifices in 22.1% of patients in the upadacitinib group versus 4.8% of those receiving placebo (p=0.013). These efficacy signals were similar across fistula locations. Maintenance therapy with upadacitinib showed a sustained effect through week 52 with respect to drainage resolution and fistula closure. The safety profile of upadacitinib was consistent with prior trials, with comparable rates of serious adverse events and no new safety signals identified.

Of note, the effect sizes for fistula outcomes in the induction phase of this trial are broadly comparable to those reported in the original infliximab trials.[15,16] The maintenance outcomes are more difficult to assess, as re-randomization was driven by luminal rather than fistula response. Nonetheless, these data support upadacitinib as an effective option for patients with perianal fistulizing Crohn's disease, particularly those who fail or do not tolerate anti-tumour necrosis factor (TNF) therapies.

Efficacy and Safety of Guselkumab Subcutaneous Induction and Maintenance in Participants with Moderately to Severely Active Crohn's Disease: Results from the Phase 3 GRAVITI Study. Hart A, et al. Gastroenterology. 2025;169(2):308–325.

The GALAXI trials established the efficacy of the interleukin (IL)-23 inhibitor guselkumab for the treatment of moderate-to-severe Crohn's disease.[21,22] The study protocol employed a regimen of intravenous induction dosing followed by subcutaneous maintenance dosing. While intravenous induction dosing of advanced therapy has long been popular among clinicians for its perceived potency, some patients prefer subcutaneous delivery, and access to infusion services can be limited in certain healthcare settings.

GRAVITI was a randomized, double-blind, placebo-controlled, multicentre trial designed to evaluate the efficacy and safety of subcutaneous guselkumab for both induction and maintenance therapy in moderately-to-severely active Crohn's disease. The study used a treat-through design, which has been argued to more closely reflect real-life clinical decision-making. Participants were randomized in a 1:1:1 ratio to receive one of two guselkumab dosing regimens or placebo. The guselkumab regimens were 400 mg administered every 4 weeks for a 12-week induction period, followed by maintenance dosing of either 100 mg every 8 weeks or 200 mg every 4 weeks. Corticosteroid tapering was permitted after week 12. The two co-primary endpoints were clinical remission and endoscopic response at week 12, in alignment with the STRIDE consensus.[23] Multiplicity-controlled secondary endpoints included clinical remission and endoscopic response at week 48.

Subcutaneous guselkumab achieved clinical remission in 56.1% of patients, versus 21.4% on placebo (p<0.001), as well as superior endoscopic response in 41.3% versus 21.4% on placebo (p<0.001). These efficacy benefits extended through week 48, with clinical remission achieved in 60.0% of patients receiving 100 mg every 8 weeks and 66.1% of those receiving 200 mg every 4 weeks, versus 17.1% on placebo (both p<0.001). Endoscopic response at week 48 was achieved by 44.3% in the lower maintenance dose group and 51.3% in the higher dose group, versus 6.8% with placebo (both p<0.001). Efficacy was maintained across subgroups stratified by prior biologic exposure; however, those with prior biologic exposure were more likely to achieve endoscopic outcomes at week 48 with the higher maintenance dose. The overall safety profile was excellent, with no meaningful differences in adverse outcomes between guselkumab treatment and placebo, consistent with the established safety profile of IL-23 inhibitors across all indications.

The GRAVITI trial further confirms the efficacy of guselkumab for the treatment of Crohn's disease with clinically meaningful gains in both clinical and endoscopic outcomes compared with placebo. Although cross-trial comparisons should be interpreted with caution, the outcome rates observed in GRAVITI are broadly comparable to those reported using intravenous guselkumab induction in the GALAXI trial.[21,22] Avoidance of intravenous dosing may better align with some patients' preferences and may facilitate access in many healthcare settings. GRAVITI also demonstrated efficacy of two maintenance dosing strategies, with one providing four-fold higher drug exposure. How clinicians and patients will decide between intravenous and subcutaneous induction, and between two doses for maintenance therapy, remains an important question for real-world practice.

Collectively, the GRAVITI and GALAXI trials provide helpful insights into the use of guselkumab in the treatment of Crohn's disease; however, results from other trials of this agent are eagerly awaited. These include DUET-CD, which evaluates the efficacy and safety of guselkumab in combination with the TNF antagonist golimumab,[24] and a planned head-to-head comparison of guselkumab and risankizumab, another inhibitor of IL-23.

Vedolizumab to Prevent Postoperative Recurrence of Crohn's Disease (REPREVIO): A Multicentre, Double-Blind, Randomised, Placebo-Controlled Trial. D'Haens G, et al. Lancet Gastroenterology and Hepatology. 2025;10(1):26–33.

Although overall rates of surgery for Crohn's disease have declined over time,[25] resection is still required for patients with refractory or complicated disease. Furthermore, emerging data support early ileocolic resection as an effective first-line strategy for patients with limited ileal disease.[26,27] A major and persisting challenge after resection and reanastomosis is the high rate of disease recurrence. Without therapy, approximately 80% of patients experience endoscopic recurrence, 50% experience symptomatic recurrence, and up to 20% will require a second surgery.[28] Consequently, both clinicians and patients must consider strategies to reduce these risks in the post-operative setting.

The REPREVIO trial assessed the efficacy and safety of vedolizumab, a monoclonal antibody targeting the α4β7 integrin, as secondary prophylaxis in patients undergoing ileocolic resection for Crohn's disease.[29] Adults at increased risk of recurrence (e.g., active smokers, penetrating disease phenotype, prior exposure to TNF antagonists, or more than one previous resection) were randomized within 4 weeks of ileocolonic resection to receive either intravenous vedolizumab (300 mg every 8 weeks without loading doses) or placebo. Ileocolonoscopy was performed after 26 weeks to assess endoscopic recurrence according to the modified Rutgeerts score. The primary endpoint compared the distribution of Rutgeerts scores between treatment groups using non-parametric analysis, while the first-ranked secondary endpoint was the proportion of patients with severe endoscopic recurrence, defined as a modified Rutgeerts score ≥i2b.

Both the primary endpoint and the first-ranked secondary endpoint significantly favoured vedolizumab. Importantly, severe endoscopic recurrence occurred in only 23.3% of patients receiving vedolizumab versus 62.2% assigned to placebo (p=0.0004). Interestingly, rates of clinical recurrence (defined as an increase in the Crohn's Disease Activity Index score of more than 70 points) were similar between the treatment arms, occurring

in 20.9% with vedolizumab versus 21.6% with placebo (p=0.94). No concerning safety signals were observed.

REPREVIO is the first major trial of biologic therapy for post-surgical prophylaxis in Crohn's disease to meet its primary endpoint, representing a major advance in this setting. However, it is worth noting that its findings align well with those of the PREVENT trial.[30] Although PREVENT did not demonstrate improvement in clinical outcomes (its primary endpoint) it did show a clinically and statistically significant reduction in endoscopic recurrence.

The post-operative setting is arguably the best human model of early Crohn's disease, a setting in which most advanced therapies would likely show benefit. Although the strongest evidence now favours vedolizumab, selection of therapy should also consider patient preferences and prior treatment exposures. It should also be noted that REPREVIO enrolled only patients at increased risk of recurrence, and those at low-risk may reasonably elect not to start any therapy after surgery. Regardless of the initial management strategy, the POCER trial demonstrated the importance of scheduled endoscopic surveillance to assess for recurrence and inform treatment intensification.[31] These approaches are supported by recent clinical practice guidelines from the American College of Gastroenterology.[32]

Mucosal Healing with Vedolizumab in Patients with Chronic Pouchitis: EARNEST, a Randomized, Double-Blind, Placebo-Controlled Trial. Jairath V, et al. Clinical Gastroenterology and Hepatology. 2025;23(2):321–330.

Chronic pouchitis is one of the most difficult long-term complications following restorative proctocolectomy with ileal pouch-anal anastomosis among patients with ulcerative colitis. Although this procedure improves quality-of-life for many patients with medically refractory disease, most patients will experience at least one episode of pouchitis and a significant minority will develop chronic and disabling antibiotic-refractory or antibiotic-dependent pouchitis.[33] Historically, high-quality evidence to guide treatment for these patients has been lacking.[34]

EARNEST evaluated vedolizumab for the treatment of chronic pouchitis. Its primary efficacy results have shown that vedolizumab was more likely than placebo to induce remission according to the modified Pouchitis Disease Activity Index (mPDAI) (31.4% vs. 9.8%; p=0.01), with this benefit appearing to extend to week 34.[35] These findings led to the approval of vedolizumab for the treatment of pouchitis in many jurisdictions.

The additional analyses reported by Jairath et al examined the endoscopic and histologic outcomes in the EARNEST study cohort. All participants underwent pouchoscopy with biopsy at baseline and at weeks 14 and 34. In the absence of a validated endoscopic scoring for pouchitis, the authors used a modified version of the Simple Endoscopic Score for Crohn's Disease (SES-CD),[36] with endoscopic healing defined as a segmental score of 0. Histologic activity was assessed using the histologic component of the mPDAI,[37,38] with healing defined as a score of 0 or 1 (no or mild polymorphonuclear leukocyte infiltrate without ulceration). The outcome of mucosal healing required fulfillment of both endoscopic and histologic criteria.

The study population consisted of adults with a baseline mPDAI score of at least 5 and an endoscopic subscore of at least 2. Participants were randomized to receive either intravenous vedolizumab (300 mg at weeks 0, 2, and 6, followed by dosing every 8 weeks) or placebo. Both endoscopic and histologic outcomes were read centrally at weeks 14 and 34. Additional outcomes included patient-reported quality-of-life measured using the Inflammatory Bowel Disease Questionnaire, and biomarkers such as fecal calprotectin.

Both endoscopic and histologic outcomes favoured vedolizumab therapy over placebo. Remission according to the SES-CD was achieved in 23.8% of those receiving vedolizumab versus 7.5% with placebo, while mucosal healing was achieved in 16.7% versus 2.5%, respectively. A range of other endoscopic outcomes including the number of ulcers, absence of ulceration, and the proportion of mucosal surface with ulceration also favoured vedolizumab therapy. Of note, patients who achieved mucosal healing at week 14 had subsequently lower disease activity and improved quality-of-life scores compared with those who did not.

EARNEST is the only trial of advanced therapy to show benefit in the treatment of pouchitis and has established vedolizumab as the preferred treatment option for patients with antibiotic failure or antibiotic dependence. This trial addresses an important evidence gap in an

understudied population. An enduring challenge in the management of pouchitis is the frequent disconnect between symptoms, endoscopic findings, and histologic activity, with the natural history and long-term sequelae of endoscopic ulceration within the pouch remaining poorly understood. EARNEST makes an important contribution by demonstrating that both endoscopic and histologic activity can respond to medical therapy, and by showing that early endoscopic response predicts a more favourable subsequent clinical course. Nevertheless, further validation of endoscopic and histologic indices is still needed, and long-term data from this and other clinical cohorts will be essential to better define the long-term trajectory of refractory pouchitis.

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