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A QUASI-EXPERIMENTAL STUDY EVALUATING EFFECTIVENESS OF PARTIAL ENTERAL NUTRITION COMBINED WITH EXCLUSION DIET IN PATIENTS WITH MILD TO MODERATELY SEVERE ULCERATIVE COLITIS

Society: AGA**Track:** Obesity and Nutrition**Author(s) and Affiliation(s):**

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Introduction: We designed this trial to evaluate efficacy of partial enteral nutrition (PEN) combined with exclusion diet (ED) in patients with mild to moderately active ulcerative colitis (UC).

Methods: In this quasi-experimental study, patients with mild-to-moderate UC (SCCAI=3-11) were allowed to choose either PEN+ED along with standard of care (SOC) or SOC alone. Disease activity was measured using simple clinical colitis activity index (SCCAI). Primary outcome was clinical remission (SCCAI \leq 2) 4 weeks. In addition, fecal microbiota analysis was performed at baseline and after week 4 in ten responders and four non-responders in PEN+ED arm.

Results: Sixty UC patients were included (PEN+ED=30; SOC=30). In the intervention group, 23 patients completed 4 weeks of PEN, 3 took a lower than prescribed dose, and 4 stopped after one week but continued ED. At week 4, 66.7% (20/30) patients in the PEN+ED arm achieved clinical remission at week 4 compared to 83.3% (25/30) receiving SOC. The proportion of patients with stool frequency score \leq 1 was similar between the two arms (90% vs 93.3%, $p>0.99$), however proportion of patients with rectal bleeding score \leq 0 was lower in patients receiving PEN+ED (56.7% vs 86.7%, $p=0.01$) at week 4. A numerically higher number of patients required steroids in SOC arm compared to PEN+ED arm, but it was not significant (23.3% vs 16.7%, $p=0.748$). At the microbiome level, PEN+ED was associated with a significant enrichment of "healthy-gut" associated taxa (Figure 1) at week 4 compared to baseline and a concomitant- significant reduction in median Kendall distance to reference healthy Indian controls (p -value $\leq 1e-5$), indicating the treatment shifts the microbiomes of patients towards Controls.

Conclusion: Although PEN+ED does not appear to have additional clinical benefit to SOC at week 4, it was associated with significant improvement in gut microbiota. Long-term benefits of this therapy should be explored in future trials.

Keywords: Partial enteral nutrition; exclusion diet; ulcerative colitis;

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