

The effect of the Crohn's Disease Exclusion Diet (CDED) on pouch inflammation: an interventional pilot study

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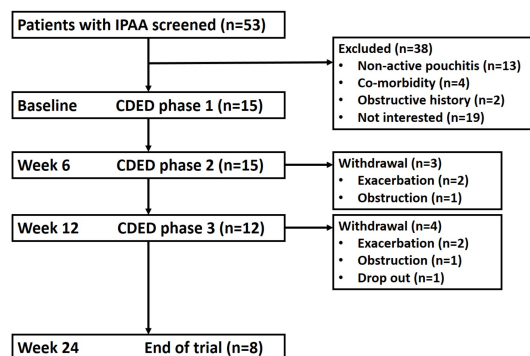
Background

- Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the surgical treatment of choice for patients with UC suffering from a medically uncontrolled disease or dysplasia
- Inflammation of the pouch (Pouchitis) is a common condition, reported in up to 72% of pouch patients
- Pouchitis pathogenesis has similarities to Crohn's disease (CD), given the de-novo inflammation of the small intestine and the microbial dysbiosis
- The Crohn's Disease Exclusion Diet (CDED) has demonstrated its efficacy in improving clinical and biochemical parameters of intestinal inflammation in CD. Therefore, **we aimed to examine whether the CDED may be effective for the treatment of active pouchitis**

Methods

- A non-controlled, open-label, interventional pilot trial
- Active pouchitis patients were recruited at the comprehensive pouch clinic of the Tel Aviv Medical Center (TLVMC), a tertiary center
- Patients were treated with the CDED (phases 1-3) for 24 weeks. Clinic visits (weeks 0, 6, 12 and 24, Figure 1), included physician assessment and monitoring (clinical PDAI sub score evaluation), dietary evaluation and guidance (**Figure 1**)
- Patients underwent three pouchoscopy procedures (baseline, end of phase 2 and end of phase 3) for assessment of endoscopic and histological disease activity (PDAI)
- The primary endpoint of the study was week-6 clinical remission (cPDAI subscore<2)

Figure 1. Flowchart of study population



Results

- Fifteen patients (mean age 41.9±11.3 years, 3 males, pouch age range 0.5-31 years) with pouchitis were recruited
- Clinical remission was achieved by 66.7% of the study population at week 6 and was maintained by 60% at week 12 and by 46.7% by week 24. Remission (clinical and endoscopic, mPDAI<5) was achieved by 40.0% of the patients by week 12, and by 46.7% of patients by week 24
- Modified PDAI (mPDAI) significantly decreased at week 12 of the study compared to baseline (8.0 vs. 4.5, P=0.007, **Figure 2**), with a significant improvement in the median number of defecations per day (24h) (13.0 vs. 8.0, P=0.007), and night (3.0 vs. 1.0, P=0.011, **Figure 3**)
- Compared to patients who demonstrated partial adherence to the diet at week 12 (n=4), patients who demonstrated perfect adherence (n=8) experienced a significant reduction in inflammatory markers CRP and Fcal (**Figure 4**).

Figure 2. Changes in mPDAI score (A), clinical PDAI score (B) and endoscopic PDAI score (C) between baseline and week 12

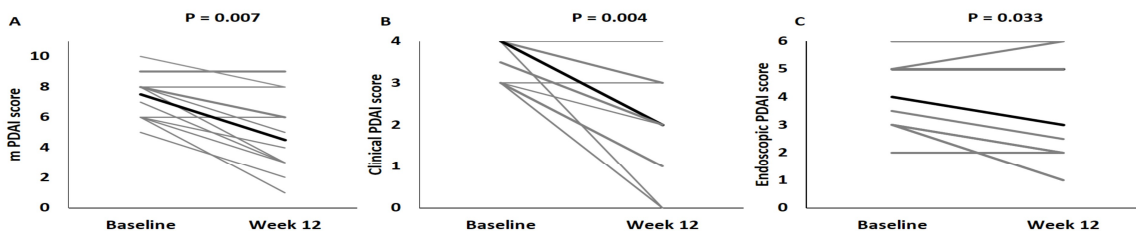


Figure 3. Clinical outcomes on the study visits (A) Day defecations (B) Night defecations (C) Urgency, (D) Pain

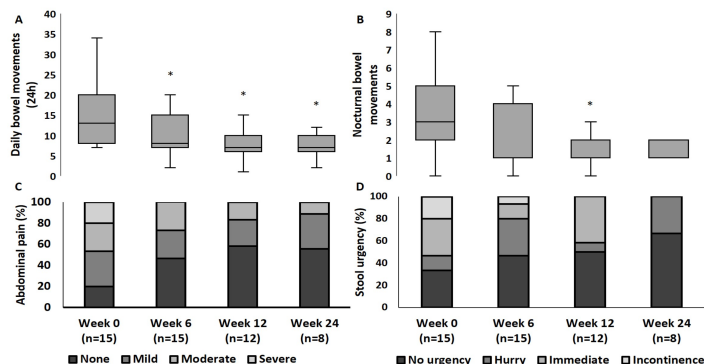
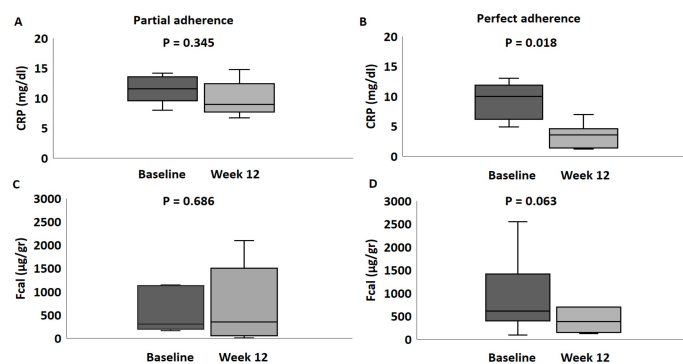


Figure 4. Distribution of CRP (A-B) and Calprotectin (C-D) levels by adherence to mCDED dietary instructions



Conclusions

This study is the first to report a positive effect of the CDED, a balanced, whole food diet, in pouchitis. Larger, controlled trials should further assess the effect of the CDED in pouchitis