# 5. A Clinical Series: IBD Patients

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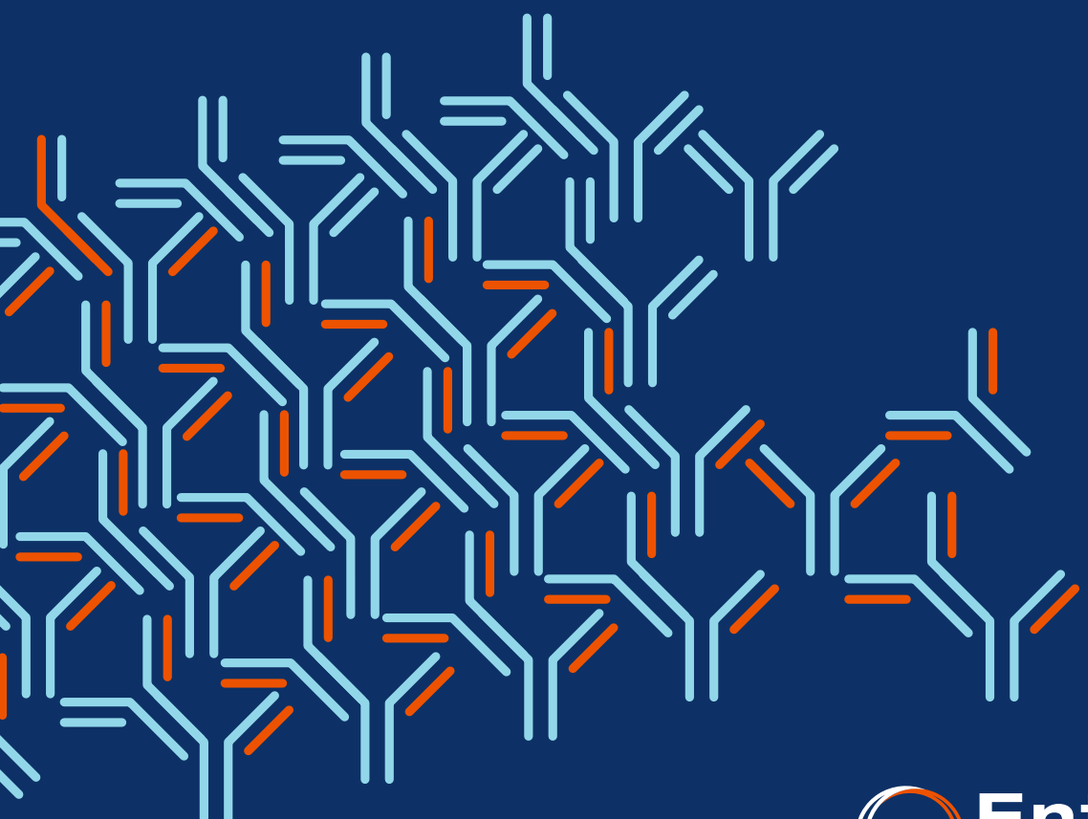
## Case series investigating the clinical practice experience of serum-derived bovine immunoglobulin/protein isolate (SBI) in the clinical management of patients with inflammatory bowel disease

Good L, Panas R.

**Methodology:** In a clinical practice setting, 7 ulcerative colitis (UC) and Crohn's disease (CD) patients who incorporated EnteraGam® into their therapeutic regimens were evaluated. All patients previously failed to adequately respond to conventional drug therapies. Response to EnteraGam® was assessed to determine its effect on further management in IBD patients. The addition of EnteraGam® for nutritional management resulted in improved IBD symptoms, including chronic loose and frequent stools.[1]



EnteraGam®
(serum-derived bovine immunoglobulin/protein isolate, SBI)

# In as little as 2 weeks, patients began to see a positive response after adding EnteraGam®[1]

## Summary of UC Cases and Response to EnteraGam®

| Patient | Primary GI Symptoms | Comorbidity | Previous Therapy | Current Therapy | Patient-reported Response |
|---|---|---|---|---|---|
| Female, age 66 | 10-12 watery bowel movements/ day for 6 weeks along with urgency, nocturnal diarrhea (loose/ watery stools), and some GI bleeding. | Hypertension, hyperlipidemia, and obesity. | Budesonide and mesalamine. | EnteraGam® (5 g QD) and mesalamine. | After 3 weeks, soft bowel movements were reduced to 3-6/day with no further rectal bleeding. After 4 weeks, bowel movements were further reduced to 3-4 formed stools/day with no associated symptoms. |
| Male, age 55 | 10-12 loose bowel movements/day along with urgency, bleeding, and mucous discharge. | Benign prostatic hyperplasia, Parkinson's disease, proctocolectomy and an ileoanal anastomosis, and chronic intermittent pouchitis (for 10 years). | Carbidopa/ levodopa *Saccharomyces boulardii* probiotic, tamsulosin, budesonide, and ciprofloxacin. | EnteraGam® (5 g QD). | After 6 weeks, no loose or watery stools, no urgency, and no blood or mucus in stools. After 6 months, patient had no exacerbations of pouchitis. |
| Male, age 24 | Loose/watery bowel movements and rectal bleeding. | N/A | N/A | EnteraGam® (5 g QD) and mesalamine. | After 2 weeks, no loose or watery stools and no rectal blood. After 3 months, patient remained asymptomatic. |

Adapted from Good and Panas 2015.[1]

"The initiation of SBI [EnteraGam®] at 5 g once or twice daily resulted in significant management of their conditions starting in about 2 weeks."

## Summary of CD Cases and Response to EnteraGam®

| Patient | Medical History | Primary GI Symptoms | Previous Therapy | Current Therapy | Patient-reported Response |
|---|---|---|---|---|---|
| Male, age 49 | CD and right hemicolectomy for nearly 20 years. Small bowel disease revealed by MR enterography. | Flares with abdominal pain, cramps, and diarrhea (loose/ watery stools). | Failed to respond to infliximab or adalimumab, resulting in intermittent steroid use. | EnteraGam® (5 g BID) was added. | After about 2 weeks, management of abdominal discomfort and cramps. After 3 months, successfully tapered off steroid therapy (replaced with vedolizumab for maintenance therapy) without return of symptoms. |
| Male, age 21 | CD for 7 years. CT abdominal scan revealed an ileitis and colonoscopy detected moderately active disease. | Intermittent exacerbations of CD (abdominal pain, anorexia, and weight loss). | Maintenance regimen of adalimumab and mesalamine. | EnteraGam® (5 g QD) was added. | No recurrent breakthrough symptoms and 10-pound weight gain after 9 months. |
| Male, age 54 | CD and right hemicolectomy performed 20 years ago. | Moderate-severe exacerbation of CD. CT scan revealed long segment rectosigmoid colitis, neoterminal ileum disease. | 6-mercaptopurine, tadalafil, and adalimumab injection once every other week. | EnteraGam® (5 g BID) added and adalimumab increased to weekly injections. | No symptoms after 3 months; adalimumab injection reduced to every other week. Patient remained stable with EnteraGam®, adalimumab, and 6-mercaptopurine for 9 months. |
| Male, age 53 | CD for 30+ years. Chronic dehydration, short bowel syndrome, nephrolithiasis, and hypomagnesemia, Brooke ileostomy (and subsequent small bowel resection), and peripheral neuropathy. | Concerns about chronic dehydration and high ileostomy output (5 liters/ day) led to a small bowel series, revealing minimal terminal ileitis. | 6-mercaptopurine, fentanyl patch, alprazolam, and omeprazole. | EnteraGam® (5 g QD) was added. | Response beginning after 4 weeks. After about 10 weeks, ileostomy output reduced from 3.5 to 1.2 liters/day. After 5 months, further improvement in creatinine levels from 3.2 to 2.9 mg/dL with further reduction to 2.6 mg/dL after 9 months. |

Adapted from Good and Panas 2015.[1]

"The ongoing use of SBI therapy has helped in the continued management of the patients' chronic condition for up to 15 months without reported side effects."

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# Conclusion

"…SBI [EnteraGam®] can have an impact on management of chronic loose and frequent stools associated with IBD."

"…the evidence suggests that SBI [EnteraGam®] provided further management of IBD patients who were not fully controlled on traditional therapies by providing for distinctive nutritional requirements in these patients."

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www.enteragam.com

**Important Safety Information:**
EnteraGam® contains beef protein; therefore, patients who have an allergy to beef or any component of EnteraGam® should not take this product. The most commonly reported adverse events in clinical studies (incidence of 2%-5%) include mild nausea, constipation, stomach cramps, headache, and increased urination. EnteraGam® has not been studied in pregnant or nursing women, so the choice to administer EnteraGam® for patients who are pregnant or nursing is at the clinical discretion of the prescribing physician. EnteraGam®, as a medical food, must be used under physician supervision.

EnteraGam® does not contain any milk products such as lactose, casein, or whey. It is gluten-free, dye-free, and soy-free. EnteraGam® contains 5 g of SBI and other ingredients such as dextrose (5 g) and trace amounts of sunflower lecithin.

**Please see full Prescribing Information including contraindications.**

**Reference: 1.** Good L, Panas R. Case series investigating the clinical practice experience of serum-derived bovine immunoglobulin/protein isolate (SBI) in the clinical management of patients with inflammatory bowel disease. *J Gastrointest Dig Syst.* 2015;5:2.

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