4. A Clinical Series: Post-infectious IBS-D Patients

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Post-infectious irritable bowel syndrome with functional diarrhea following *C difficile* infections: Case studies of responses using serum-derived bovine immunoglobulin

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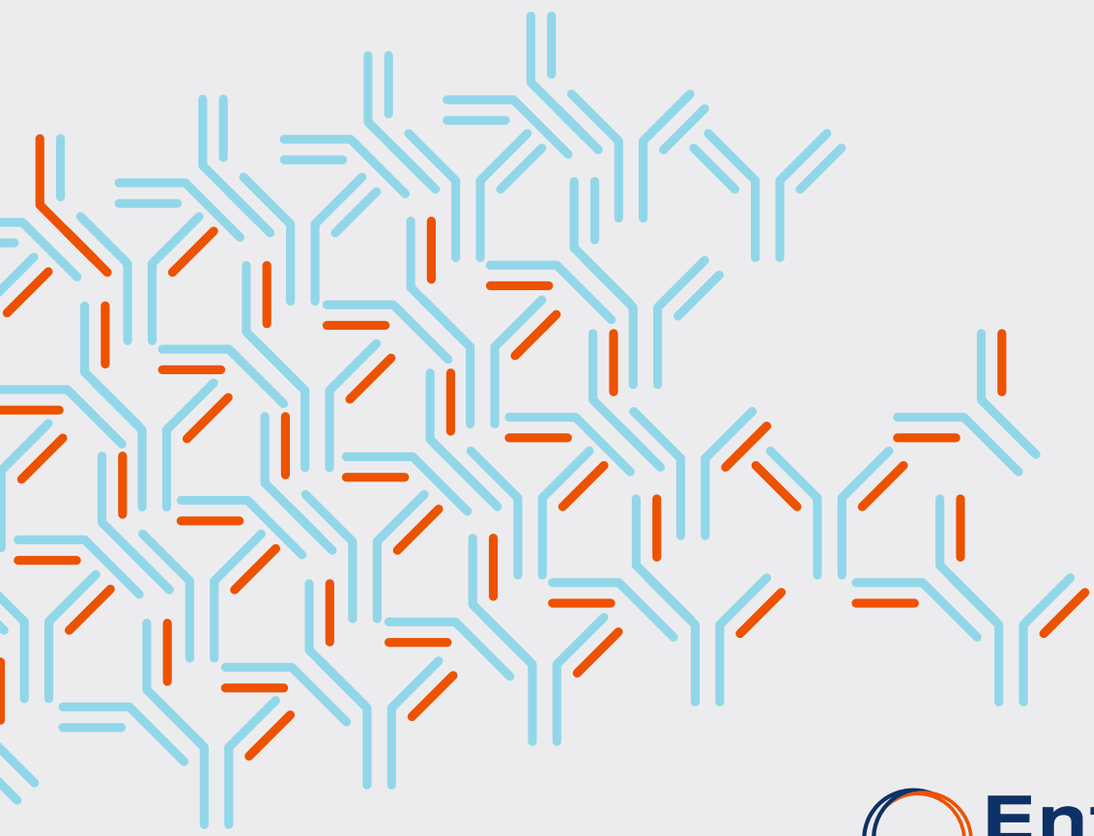
Introduction: Two patients who presented with persistent diarrhea following treatment for relapsing *Clostridium difficile* infection (CDI) utilized EnteraGam® daily (5 g BID and/or QID), a medical food containing serum-derived bovine immunoglobulin/protein isolate (SBI). Both patients had negative polymerase chain reaction tests for CDI prior to starting EnteraGam® and both responded to therapy.



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

Therapy with EnteraGam® resulted in management of frequent loose stools and abdominal discomfort[1]

Case #1

39-Year-Old Caucasian Female: Summary of Case Presentation

Abbreviated medical history:
Antiphospholipid antibody syndrome, methylenetetrahydrofolate reductase homozygous, and HSV-1.

Initial symptoms:
Abdominal discomfort, multiple bloody diarrhea episodes.

Initial treatments:
Fidaxomicin and vancomycin.

Cholecystectomy for acute cholecystitis.
Fidaxomicin for diarrhea and recurrent CDI.

Still symptomatic. Negative for CDI. Could not tolerate cholestyramine or antidiarrheals. No clinical change with low-fat diet.

Diagnosed with post-infectious irritable bowel syndrome (PI-IBS). Unable to work.

EnteraGam® 5 g QID therapy initiated.

Frequent loose stools managed within 48 hours.

~1 week after stopping EnteraGam® diarrhea returns. Negative for CDI.

EnteraGam® resumed, resulting in management of frequent loose stools and abdominal discomfort.

Patient continued with EnteraGam® 5 g BID. Patient able to return to work.

One month later, EnteraGam® reduced to 5 g QD. No further *C difficile* relapses.

EnteraGam® improved the patient's quality of life and allowed her to return to work.[1]

EnteraGam® managed the patient's PI-IBS symptoms[1]

Case #2

57-Year-Old Caucasian Female: Summary of Case Presentation

Abbreviated medical history:
Hypothyroidism, hypercholesterolemia, angioplasty for coronary artery disease (x3), neuropathy, and idiopathic gastroparesis.

Concurrent medications:
Levothyroxine, furosemide, duloxetine, pravastatin, and aspirin.

Initial treatments:
Antibiotics for flu-like symptoms, wheezing, and possible pneumonia.

Diarrhea (7 watery bowel movements/day) with mucus and blood for 2 months. Treated with ciprofloxacin and metronidazole.

Hospitalized for 5 days. Treated with metronidazole and vancomycin for positive CDI. Readmitted for dehydration. Continued vancomycin for positive CDI postdischarge.

Developed nausea and bloody diarrhea. Started fidaxomicin. Blood in stool resolved. Moderate diarrhea improvement.

Developed alternating diarrhea/constipation. No difference with dietary changes. Could not tolerate low FODMAP diet.

EnteraGam® 5 g BID therapy initiated.

Patient noticed better management of her condition within a few days.

Treated with metronidazole one month later for urinary tract infection. Patient reported some constipation.

EnteraGam® reduced to 5 g QD to avoid potential for constipation.

Patient continues to report normal regulation of bowel habits.

EnteraGam® therapy continues at 5 g QD for ongoing maintenance of patient's PI-IBS.[1]

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Discussion[1]

- "In both cases, the use of SBI [EnteraGam®] was able to…manage the patient's PI-IBS symptoms which included chronic and frequent loose stools as well as abdominal discomfort, allowing the patients to have normal bowel habits and improved quality of life."
- "Because SBI [EnteraGam®] is intended for use to manage IBS-D and has the added ability to bind to *C difficile* toxins, it may have a valuable role in both the management of PI-IBS as well as binding of *C difficile* toxins A and B if reinfection occurs. This may help normalize the gut environment to allow normal flora to outgrow *C difficile.*"
- "The outcomes of both cases reported in this manuscript suggest that there is a distinctive nutritional requirement for SBI [EnteraGam®] unique to patients with PI-IBS."

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

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. Crawford C, Panas R. Post-infectious irritable bowel syndrome with functional diarrhea following C difficile infections: case studies of responses using serum-derived bovine immunoglobulin. *J Gastroenterol Hepatol Res.* 2015;4(4):1577-1581.

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