2. A Clinical Series: IBS-D/IBS-M Patients

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Serum-derived bovine immunoglobulin/ protein isolate therapy for patients with refractory irritable bowel syndrome

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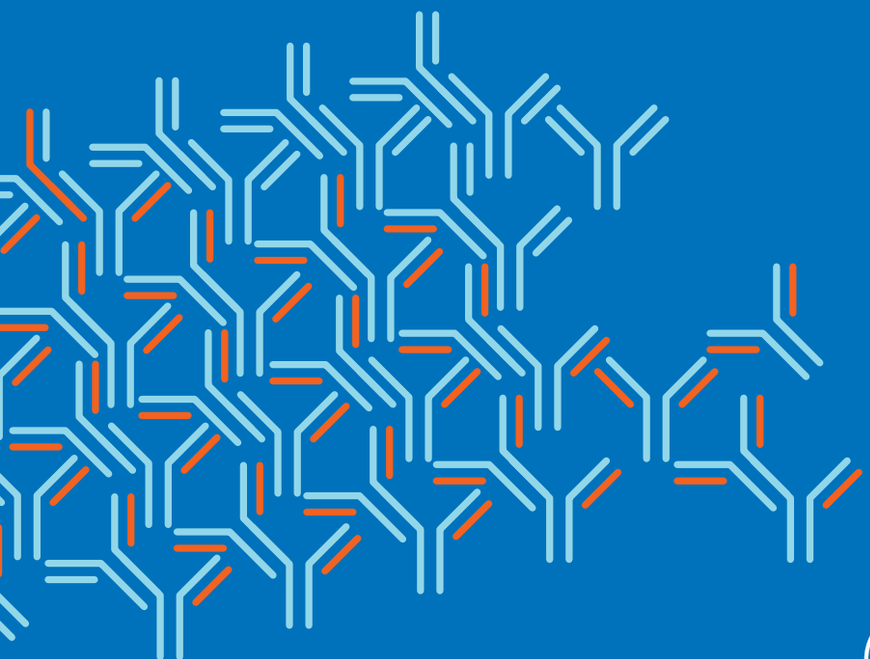
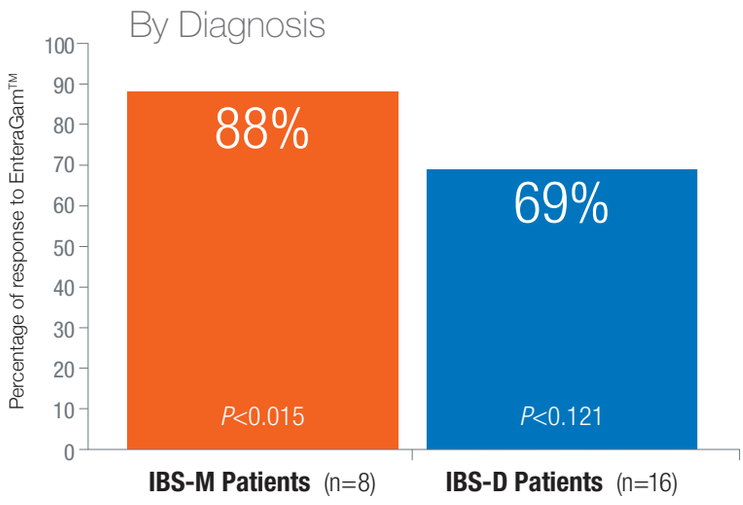
Methodology: Retrospective review of 35 patients with diarrhea-predominant irritable bowel syndrome (IBS-D) or mixed diarrhea/ constipation pattern (IBS-M). Patients were first screened for small intestinal bacterial overgrowth using the lactulose breath test (LBT). All positive LBT (+LBT) and negative LBT (-LBT) patients who met the study criteria (N=26) were refractory to treatment with common IBS therapies prior to receiving 5g/twice daily of EnteraGam™. After 4 weeks of therapy, clinical response was assessed in 24 patients (two patients were lost to follow-up) based on patient-reported satisfaction ("good response" or "no response"). The clinical response rate was calculated in three ways: 1) based on LBT status, 2) based on their IBS category (IBS-D or IBS-M), and 3) the entire patient group.[1]

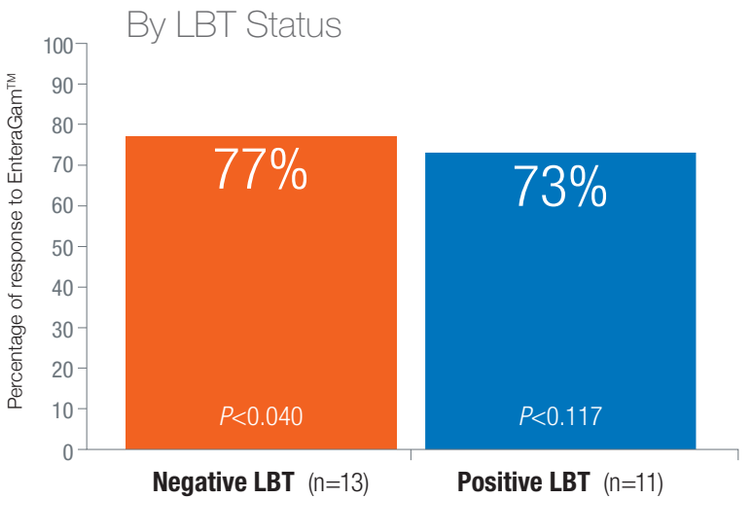


EnteraGam™
(serum-derived bovine immunoglobulin/protein isolate, SBI)

Clinical response to EnteraGam™ was high for all patients groups[1]

Clinical Response Rate By Group





Notable outcomes

While all patients were refractory to common IBS therapies, the response rate to EnteraGam™ was between 69% and 88%, whether patients were divided by LBT status, initial IBS diagnosis, or pooled together. Short-lived and self-limited adverse events included constipation, diarrhea, and nausea.

The response rate of 75% was significant when all patients were pooled (N=24, *P*=0.010)

Authors' note

"This retrospective chart review presents general clinical data that is supporting of the finding of the double-blind study of SBI [EnteraGam™] in IBS-D, which illustrates improvements in the number of days per week that patients reported loose stools, abdominal pain, flatulence, urgency and bloating."

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™ 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. Weinstock L, Jasion V. Serum-derived bovine immunoglobulin/protein isolate therapy for patients with refractory irritable bowel syndrome. *Open Journal of Gastroenterology.* 2014;4:329-334.

EnteraGam™ is manufactured and distributed by Entera Health, Inc.

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