3. A Clinical Series: IBS-D/IBS-U/IBS-M/IBS-C Patients

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New therapeutic option for irritable bowel syndrome: Serum-derived bovine immunoglobulin

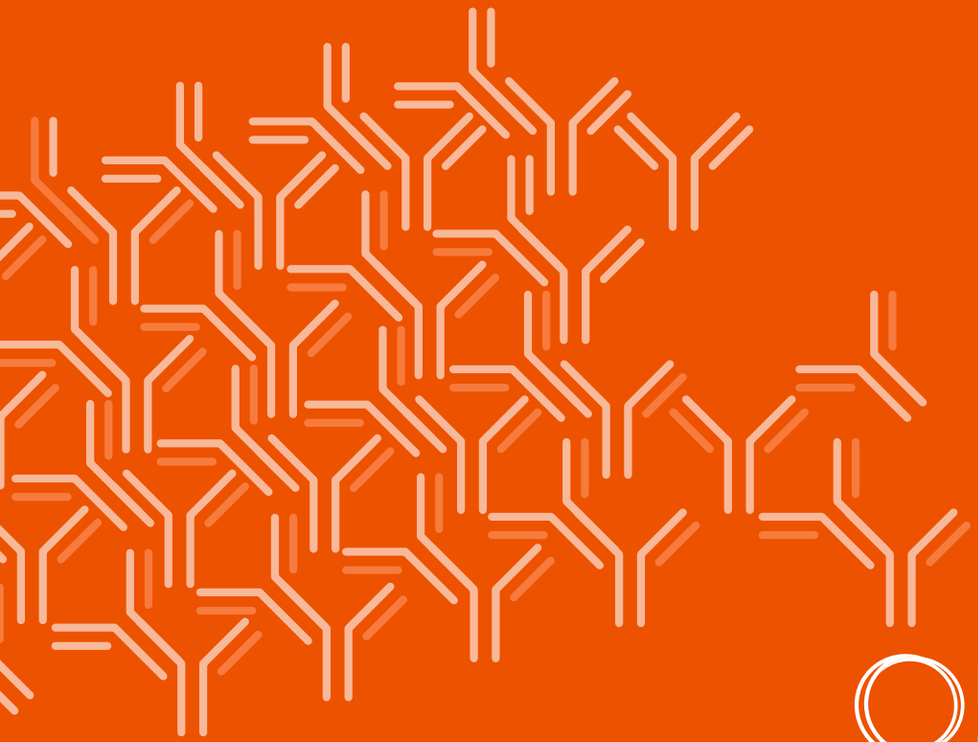
Good L, Rosario R, Panas R.

Methodology: 14 patients with differing forms of IBS, including:*

- IBS-D (n=7)
- IBS-M (n=2)
- IBS-U (n=3)
- IBS-C (n=2)

All patients utilized EnteraGam® daily (5g or 10g) in addition to standard of care. Patients were followed for up to 35 weeks to determine if symptoms were improved with EnteraGam® add-on therapy.[1]

*12 out of 14 patients responded to therapy



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

Summary of IBS-M/IBS-U/IBS-C* Cases and Outcomes with EnteraGam®

Patient	Primary Symptoms	Comorbidity	Other GI therapy	Duration of EnteraGam® Therapy (Weeks)	Clinician Evaluation
Female, age 66 (IBS-M)	Alternating diarrhea/ constipation, bloating, distension	Osteoporosis	Low FODMAP diet	14	Improved bowel movements, no bloating/distension
Female, age 33 (IBS-M)	Alternating diarrhea/ constipation, ABD pain, bloating, distension	Morbid obesity	Low FODMAP diet	15	Overall improvement, mild obstipation, reduced bloating
Female, age 62 (IBS-U)	ABD pain, bloating, distension, flatulence	Osteoporosis	Denosumab, rifaximin, Low FODMAP diet	8	Resolution of symptoms
Male, age 50 (IBS-U)	ABD pain, bloating, gas	GERD, osteoarthritis	Polycarbophil, saccharomyces boulardii lyo, polyethylene glycol 3350, prn	35	Resolution of symptoms
Female, age 82 (IBS-U)	Severe ABD pain, bloating, distension	Hypertension, atherosclerotic cardiovascular disease	Antidiarrheals	6	Unimproved
Female, age 55 (IBS-C)*	Obstipation, bloating, distension, nausea	Non-erosive reflux disease	Lubiprostone	14	Reduced bloating/ distension, unchanged obstipation
Female, age 22 (IBS-C)*	Constipation, bloating, distension	None	Low FODMAP diet, linaclotide, lubiprostone	11	Ineffective

Adapted from Good, Rosario and Panas 2015.[1]

"The 12 patients who continued on therapy reported an overall improvement in symptoms with better stool consistency, decreased frequency as well as reductions in abdominal pain, bloating, distention, and incontinence."

*EnteraGam® is not specifically indicated for IBS-C.

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In as little as 4 weeks, most patients reported therapeutic effects of EnteraGam®[1]

Summary of IBS-D Cases and Outcomes with EnteraGam®

Patient	Primary Symptoms	Comorbidity	Other GI therapy	Duration of EnteraGam® Therapy (Weeks)	Clinician Evaluation
Male, age 24	Diarrhea, frequency, urgency, abdominal (ABD) pain	Chronic urethritis, ulcerative proctitis	Low FODMAP diet, mesalamine	32	Complete resolution of symptoms
Male, age 63	Diarrhea, urgency, ABD cramps, flatulence	Eosinophilic esophagitis, RIH, BPH	Pantoprazole	27	Complete resolution of symptoms
Female, age 87	Diarrhea, urgency, ABD pain, distention	Osteoporosis, GERD, anxiety	Perphenazine/ amitriptyline, omeprazole	17	Dramatic reduction in symptoms
Female, age 36	Diarrhea, urgency, incontinence	Hypothyroidism, anxiety, depression	None	18	Marked improvement in chronic loose stools/urgency
Male, age 86	Loose stools, urgency, cramping	COPD, lung cancer	Domperidone	12	Marked improvement in chronic loose stools/urgency
Male, age 66	Diarrhea, urgency, ABD pain, incontinence	Hypertension, benign prostatic hyperplasia	Tramadol	16	Marked reduction in urgency/ABD discomfort; formed bowel movements
Female, age 36	Diarrhea, severe ABD pain	Ulcerative colitis	Low FODMAP diet, mesalamine	12	No ABD discomfort, improved chronic loose stools

Adapted from Good, Rosario and Panas 2015.[1]

86% of patients reported some level of improvement with EnteraGam®

Discussion

- "For patients with IBS-D observed in this physician's clinical practice, SBI [EnteraGam®] has been highly effective in managing chronic loose and frequent stools in IBS."
- "While the findings in patients with IBS-D were expected based upon prior clinical evidence, the elements of benefit for patients with other types of IBS, particularly for IBS-M and IBS-Bloating [IBS-U], merit more study."
- No adverse effects were noted in patients who took EnteraGam® for up to 35 weeks.

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

Please see full Prescribing Information including contraindications.

Reference: 1. Good L, Rosario, R, Panas R. New therapeutic option for irritable bowel syndrome: Serum-derived bovine immunoglobulin. *World J Gastroenterol.* 2015;21(11):3361-3366.

Entera Health®