

Management of Severe Watery Stools with Fecal Incontinence in Ileorectal Anastomosis Patient with Serum-Derived Bovine Immunoglobulin Therapy

Larry Good, MD: South Nassau Communities Hospital, Oceanside, NY; Raymond Panas, PhD: Entera Health, Medical Affairs, Cary, NC

Abstract

Introduction: For patients with various colonic diseases, an ileorectal anastomosis is a connection of the terminal ileum to rectum and has been used for over 50 years as an alternative for a proctocolectomy and permanent ileostomy. The ileorectal anastomosis provides significant benefit and allows most patients an improved quality of life and a reasonable management of their condition. A 79 year old, Caucasian female arrived at an ER with severe abdominal pain, sepsis, and severe ischemic colitis. Despite aggressive therapy, she required surgery and had total colectomy and ileostomy. Following surgery, she was plagued by ileostomy dysfunction and frequent hospitalization for rehydration and electrolyte correction. After nearly 10 months, of recurrent relapses she had surgery to create an ileorectal anastomosis but experienced severe refractory diarrhea. This consisted of 13-14 watery stools per day and fecal incontinence despite treatment with loperamide, diphenoxylate/atropine and anhydrous morphine.

Methods: After nearly 2 months of ongoing diarrhea and fecal incontinence, 5 g BID serum-derived bovine immunoglobulin/protein isolate (SBI) was added to her therapy. SBI, a prescription medical food, has been shown to help manage chronic loose and frequent stools in patients with Irritable Bowel Syndrome with Diarrhea (IBS-D) and refractory Inflammatory Bowel Disease (IBD). As such, it was considered for this patient due to a lack of response to conventional therapies. A chart review was used to gather this patient level data.

Results: Approximately 3 weeks following initiation of SBI therapy, the patient was having 3-4 formed stools daily and no fecal incontinence. Her serum albumin levels had increased from 3.4g/dl to 4.0g/dl and she had discontinued use of the anhydrous morphine.

Discussion: This is yet another case report of a patient benefiting from the use of this prescription medical food for the management of refractory chronic loose and frequent stools. SBI has been used as a safe rescue therapy in this elderly patient to achieve normal bowel function. Several case series and case histories have shown SBI to be a useful nutritional management tool in severe and intractable cases of chronic loose and frequent stools.

Management of Severe Watery Stools with Fecal Incontinence in Ileorectal Anastomosis Patient with Serum-Derived Bovine Immunoglobulin Therapy

Larry Good, MD¹ and Raymond Panas, PhD²

1. South Nassau Communities Hospital, Oceanside, NY, United States. 2. Entera Health, Inc., Medical Affairs, Cary, NC, United States.



INTRODUCTION

An ileorectal anastomosis (Figure 1) is a connection of the terminal ileum to rectum and has been used for over 50 years as an alternative for a proctocolectomy and permanent ileostomy for patients with various colonic diseases [1-2]. Although an ileal pouch-anal anastomosis is considered the gold-standard for surgical intervention, the ileorectal anastomosis (IRA) provides significant benefit by allowing most patients to have improvements in the management of their condition and quality of life [2-3].

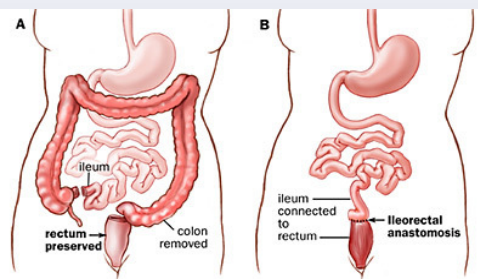


Figure 1. Ileorectal anastomosis. In this procedure, the whole colon is removed with only the rectum preserved. The ileum of the small intestine is attached to the upper portion of the rectum. A key advantage of this procedure is the preservation of fecal continence and tolerable bowel function [1]. Source: Johns Hopkins Medicine Gastroenterology & Hepatology.

In patients who underwent the IRA, 90% noted that their health status had improved following surgery and 84% had a general improvement in quality of life [3]. At 5 years, 78-84% of the patients reported benefit from the IRA [2] and at 20 years these results were still 46-69% [3]. A review of various studies noted that the average stool frequency was 4-6 bowel movements per day without episodes of incontinence [2-4]. A common complaint following an IRA is frequent, loose stools that often require dietary modification, use of anti-diarrheal medications (25-35%), and/or use of topical or systemic steroids (33%) [3]. Pouchitis can also occur in patients without a prior history of inflammatory bowel disease as small section of the rectum remains and thus there is a risk of disease occurrence [2-4]. While there is no FDA approved treatment for pouchitis [4-5], conventional treatments currently applied include the use of antibiotics, systemic and topical steroids, budesonide, topical mesalamine, and VSL#3.

METHODOLOGY

This is a retrospective chart review of a patient with an IRA experiencing severe watery stools/fecal incontinence. Given the prior findings reported for serum-derived bovine immunoglobulin/protein isolate (SBI) therapy in patients with IBS-D and IBD [6-7], it was considered for this patient. The reported response to SBI in the therapeutic management of this patient's condition were assessed.

Serum-Derived Bovine Immunoglobulin/Protein Isolate: SBI, a prescription medical food, has been shown to manage chronic loose and frequent stools in patients with Irritable Bowel Syndrome (IBS), Inflammatory Bowel Disease (IBD), and HIV-enteropathy [6-8]. SBI has been shown to have a multifaceted mechanism of action [9] (Figure 2). SBI is produced from pooled USDA-approved, edible-grade bovine plasma and manufactured to maintain homogeneity and reproducibility per lot. SBI contains ~60% immunoglobulins (>50% IgG, 1% IgA, 5% IgM), albumin, and other proteins typically found in serum [10]. EnteraGam® contains 5g of SBI and 5g of dextrose with trace amounts of sunflower lecithin per packet and only 40 calories [10].

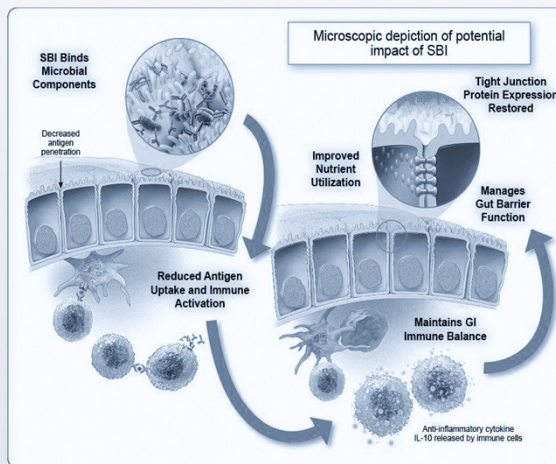


Figure 2. Mechanism of Action of Serum-derived Bovine Immunoglobulin. SBI binds to microbial components within the intestinal tract. This may sterically prevent the translocation of antigens through damaged epithelial cell tight junctions and help avoid immune activation. Subsequently, there is maintenance of GI immune balance and management of gut barrier function resulting in improved nutrient utilization. Used by permission from Entera Health.

CASE PRESENTATION

In April 2014, a 79 year old, Caucasian female arrived at an ER with severe abdominal pain, sepsis, and bowel infarction. Despite aggressive therapy with IV antibiotics, fluid resuscitation, and supportive care, she failed to improve and required surgery. A total colectomy with Hartmann procedure and ileostomy was performed. She recovered from surgery and returned home following a prolonged rehabilitation program. Following surgery and rehabilitation, she was plagued by ileostomy dysfunction and frequent hospitalization for rehydration and electrolyte correction. Due to these recurrent relapses, in February 2015 she had surgery to create an IRA. Subsequent to this surgery, she experienced severe refractory diarrhea consisting of 13-14 watery stools per day and fecal incontinence. This was unsuccessfully treated with loperamide, diphenoxylate/atropine and anhydrous morphine. In April 2015, despite the use of these conventional therapies and nearly 2 months of these ongoing symptoms, SBI 5g BID was added to the therapeutic regimen to manage her condition which included symptoms of frequent, watery stools and incontinence episodes.

RESULTS

In early May 2015, one month after initiation of SBI therapy to her therapeutic regimen, the patient was having 3-4 formed stools daily, no fecal incontinence, and minimal urgency. Her serum albumin levels had increased from 3.4g/dl to 4.2g/dl suggesting improved protein uptake and/or retention. The anhydrous morphine was discontinued and she is being maintained without symptoms on SBI 5g QD along with diphenoxylate/atropine and loperamide.

DISCUSSION

In an elderly IRA patient with refractory chronic loose and frequent stools, SBI was utilized to help manage her condition. It was not until the addition of SBI to conventional therapeutic efforts that the patient started having normal stool frequency and consistency without fecal incontinence. SBI as medical food is intended for the clinical dietary management of chronic and frequent loose stools. This patient's response with SBI is consistent with prior case series/case histories which have previously shown SBI to be a useful tool in the nutritional management of severe and intractable cases of chronic loose and frequent stools. This case report is yet another that demonstrates the potential benefit of providing for a distinctive nutritional requirement by administration of SBI in the clinical dietary management of these challenging refractory cases.

REFERENCES

1. Johns Hopkins Medicine, Department of Gastroenterology & Hepatology. Hereditary Nonpolyposis Colorectal Cancer: Therapy. 2015.
2. da Luz Moreira A, Kiran RP, Lavery I. Clinical outcomes of ileorectal anastomosis for ulcerative colitis. *British Journal of Surgery*. 2010;97:65-69.
3. Scoglio D, Ahmed Ali U, Fichera A. Surgical treatment of ulcerative colitis: ileorectal vs ileal pouch-anal anastomosis. *World Journal of Gastroenterology*. 2014;20(37):13211-13218.
4. Parry FQ, Wani ML, Malik AA, Wani SN, Bijji AH, Irshad I. Ulcerative colitis: a challenge to surgeons. *International Journal of Preventive Medicine*. 2012;3(11):749.
5. Meier J, Sturm A. Current treatment of ulcerative colitis. *World Journal of Gastroenterology*. 2011;17(27):3204-3212.
6. Wilson D, Evans M, Weaver E, Shaw AL, Klein GL. Evaluation of serum-derived bovine immunoglobulin protein isolate in subjects with diarrhea-predominant irritable bowel syndrome. *Clinical Medical Insights: Gastroenterology*. 2013;6:49-60.
7. Shafran I, Burgunder P, Wei D, Young HE, Klein GL, Burnett BP. Management of Inflammatory Bowel Disease with Serum-Derived Bovine Immunoglobulin. *Therapeutic Advances in Gastroenterology*. 2015.
8. Asmuth DM, Ma ZM, Albanese A, Sandler NG, Devaraj S, Knight TH, et al. Oral Serum-Derived Bovine Immunoglobulin Improves Duodenal Immune Reconstitution and Absorption Function in Patients with HIV Enteropathy. *AIDS*. 2013;27:2207-17.
9. Petschow BW, Burnett B, Shaw AL, Weaver EM, Klein GL. Serum-derived bovine immunoglobulin/protein isolate: postulated mechanism of action for management of enteropathy. *Clinical & Experimental Gastroenterology*. 2014;7:181-190.
10. EnteraGam Package Insert, February 2015.

DISCLOSURE & ACKNOWLEDGEMENT

Dr. Larry Good serves as a member of the Speaker's Bureau of Entera Health, Inc. Dr. Raymond Panas is an employee of Entera Health, Inc, Department of Medical Affairs.

We acknowledge the patient who consented for the use of their information. Preparation of this poster has been provided by Bruce Burnett, PhD, Hayley Young, PhD, and Bryon Petschow, PhD at Entera Health, Inc.

Poster Abstract #842 - 2015 ACG Annual Scientific Meeting, Honolulu, HI, October 19, 2015.