

**This case report is of a single patient.  
Patient results may vary.**

## Patient with 14-year history of ulcerative colitis: Successful outcome with balsalazide therapy



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### Introduction

This case report exemplifies a successful outcome with balsalazide therapy in a 46-year-old male patient with ulcerative colitis. In the 14 years since his diagnosis, his first 13 years of disease management included several frustrating experiences with treatment failures or intolerance during flares that occurred approximately once a year.

### Early course of disease and management: 1988 to 2001

In May 1988, the patient (then 32 years of age) noted the onset of bloody diarrhea, bilateral lower abdominal cramping, and malaise. He had no associated fever, visual changes, arthralgias, or skin lesions. The patient had no known personal or family history of liver disease, and no family history of inflammatory bowel disease. His primary care physician referred him to a gastroenterologist.

### Initial evaluation, diagnostic workup, and colonoscopy

The patient had a complete blood count performed: white blood cells 6600/ $\mu$ L, hemoglobin 13.8 g/dL, and platelets 184,000/ $\mu$ L. Serum chemistries and liver-associated laboratory studies were normal.

In July 1988, the patient underwent a colonoscopy that demonstrated inflammation of the distal colon with granular, friable, erythematous mucosa in a continuous fashion from the anal verge to 15 cm. The remainder of the colonoscopy to the cecum was normal. Biopsies were taken throughout the colon and demonstrated evidence of proctitis with histologic findings of crypt distortion and crypt abscesses in the area of inflammation. No granulomas were identified. Stool samples tested for ova and parasites, enteric pathogens, and *Clostridium difficile* toxin were unremarkable. These findings confirmed the diagnosis of ulcerative colitis.

### Treatment history: Sulfasalazine, prednisone, mesalamine

In July 1988, treatment was initiated with sulfasalazine 4 g daily and prednisone 40 mg daily. Following an 8-week taper, he was maintained

on 2 g sulfasalazine daily. Subsequently, the patient experienced flares approximately once a year, during which he increased his daily dose of sulfasalazine from 2 g to 4 g. He could tolerate this increased dose, however, for only one week because of headache. On three occasions, he added prednisone to his regimen for a maximum of 2 months, typically 40 mg daily and tapering off over the 2-month period.

In August 1989, the patient had 6 to 8 bloody bowel movements a day, and was admitted to the hospital for 4 days. He had been taking prednisone 60 mg daily for 2 weeks. While hospitalized, the patient required treatment with parenteral corticosteroids and intravenous methylprednisolone 30 mg bid. His colitis rapidly came under control and symptoms of this severity have not recurred.

By January 1991, the patient took daily acetaminophen to relieve headache pain caused by sulfasalazine (4 g daily). He required a minimum of one mesalamine enema (4 g nightly) because flares occurred when he tapered off the enemas. He had twice tried oral mesalamine 2.4 g daily, but each time he discontinued this therapy within one week because of abdominal cramping and diarrhea.

### Patient History (as of February 2002)

#### Family history

- \* Mother, age 76, alive and well, diabetes mellitus
- \* Father, age 76, alive and well
- \* 5 sisters, 3 brothers, alive and well
- \* Patient currently married with 10-year-old son
- \* No family history of cancer or disorders of the liver, intestine, or colon

#### Social/medical history

- \* Occupation: mechanical contractor
- \* No history of ethanol, tobacco, or illicit drug use
- \* Never received blood transfusions
- \* Medical history before diagnosis of colitis: unremarkable

#### Medications

- \* Multivitamin once daily

#### Allergies

- \* No known drug allergies

### Recent course of disease and management with balsalazide: 2001 to 2002

#### Evaluation and diagnostic workup

In February 2001, the patient was evaluated because of a continuous flare of symptoms lasting 4 to 5 weeks. He reported 6 to 8 liquid bowel movements per day, some including small blood clots, with no associated fever, chills, or arthralgias. This anorectic patient described his energy level as "low."

### Flexible sigmoidoscopy

Flexible sigmoidoscopy assessment (figure 1) showed evidence of chronic colitis extending from the anal verge to 25 cm. The colon more proximally was normal in appearance. The abnormal mucosa had evidence of spontaneous bleeding with no vasculature identifiable. Small internal hemorrhoids were also present.



**Figure 1.** Sigmoidoscopy of February 2001 (before balsalazide therapy) demonstrated normal appearance of proximal mucosa, but granular, friable mucosa circumferentially involving the bowel.

### Treatment decision: Balsalazide 6.75 g daily

Therapy with balsalazide at a dosage of three 750-mg capsules (2.25 g) tid, for a daily dose of 6.75 g (equivalent to 2.4 g of mesalamine), was initiated. Within 5 weeks, the patient's bowel movements had decreased to 2 to 3 times per day with well-formed stools and no hematochezia. He had not experienced fever, chills, headache, nausea, vomiting, or abdominal pain. The patient said his current state was the best he has felt in years.

### Follow-up evaluation 6 months after balsalazide therapy: Colonoscopy study

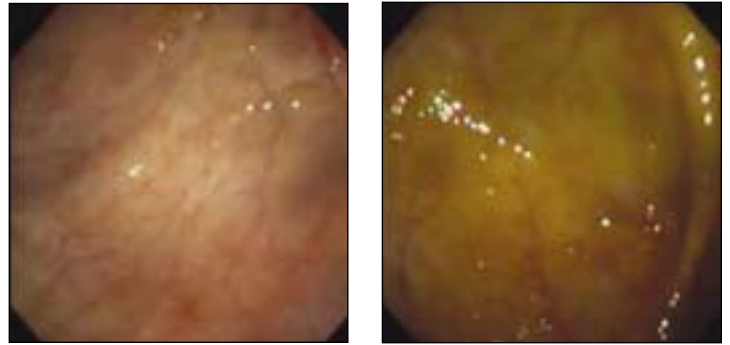
In August 2001, the patient underwent a surveillance colonoscopy for ulcerative colitis (figure 2), which was performed to the cecum. Loss of haustral folds was observed in the sigmoid and descending colon. Up to the level of the hepatic flexure, there was evidence for inactive colitis with scarring. The left colon showed evidence of small old pseudopolyps, which were not inflamed. Biopsy provided evidence of chronic ulcerative colitis with mild crypt distortion, but no evidence of dysplasia.

This single case report does not imply clinical superiority of COLAZAL over other medications.

COLAZAL is indicated for the treatment of mildly to moderately active ulcerative colitis. Safety and effectiveness of COLAZAL beyond 12 weeks has not been established. COLAZAL is contraindicated in patients with hypersensitivity to salicylates or to any of the components of COLAZAL capsules or balsalazide metabolites. In four well-controlled clinical trials, patients receiving a COLAZAL dose of 6.75 g/day most frequently reported the following events (reporting frequency  $\geq 3\%$ ): headache (8%), abdominal pain (6%), diarrhea (5%), nausea (5%), vomiting (4%), respiratory infection (4%), and arthralgia (4%). Withdrawal from therapy due to adverse events was comparable to placebo.

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**Figure 2.** Colonoscopy of August 2001 (after balsalazide therapy) demonstrated mucosal healing that paralleled the patient's clinical course. Throughout the colon, the vasculature was easy to identify, suggesting no evidence of active colitis.

### Conclusion

In February 2002, the patient reported no flares. In this case, a patient with a 14-year history of ulcerative colitis who had tried several therapeutic regimens was successfully controlled with balsalazide disodium 6.75 g daily.

**COLAZAL<sup>®</sup>** Capsules  
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