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Editorial Board Member of *World Journal of Clinical Cases*, Manabu Watanabe, MD, PhD, Full Professor, Division of Gastroenterology and Hepatology, Department of Internal Medicine, Toho University Medical Center, Ohashi Hospital, Tokyo 153-8515, Japan

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Effectiveness of vedolizumab treatment in two different anti-tumor necrosis factor alpha refractory pouchitis: A case report

Ozlem Ozer Cakir

ORCID number: Ozlem Ozer Cakir (0000-0002-5916-8049).

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Ozlem Ozer Cakir, Department of Gastroenterology and Hepatology, Alanya Alaaddin Keykubat University, School of Medicine, Antalya 07425, Turkey

Corresponding author: Ozlem Ozer Cakir, MD, Assistant Professor, Doctor, Department of Gastroenterology and Hepatology, Alanya Alaaddin Keykubat University, School of Medicine, Kestel yerleşkesi, Antalya 07425, Turkey. tansozlem@yahoo.com
Telephone: +90-532-1754014

Abstract

BACKGROUND

Refractory pouchitis is a common cause of pouch failure, which may require surgical excision of the pouch or permanent diversion. We aimed to show the effect of vedolizumab on treatment of the patient with refractory pouchitis.

CASE SUMMARY

A 32-year-old male with pancolonic ulcerative colitis since the age of 25 with primary failure of infliximab and mesalamine and intolerance of azathioprine, underwent a total proctocolectomy with ileal pouch-anal anastomosis in 2012. He developed chronic diarrhea in 2014, which was watery, 30 per day and accompanied with blood and mucus affecting his quality of life.

CONCLUSION

Vedolizumab is safe and effective in the management of anti-tumor necrosis factor alpha refractory pouchitis.

Key words: Anti-tumor necrosis factor alpha; Refractory pouchitis; Vedolizumab; Ulcerative colitis

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Core tip: Vedolizumab, a humanized immunoglobulin G1 monoclonal antibody to $\alpha 4\beta 7$ integrin, has been shown to moderate gut lymphocyte trafficking with an efficacy in treatment of both Crohn's disease and ulcerative colitis. In our patient who had two different anti-tumor necrosis factor refractory pouchitis, the gut-specific immune modulation mediated by vedolizumab treatment resulted in good responses. This case is important because vedolizumab is the novel therapy for refractory pouchitis. However, further large and prospective studies are needed for efficacy and the underlying mechanisms of efficacy of vedolizumab in treatment of refractory pouchitis.

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INTRODUCTION

Refractory pouchitis is a common cause of pouch failure, which may require surgical excision of the pouch or permanent diversion. Vedolizumab, a humanized immunoglobulin G1 monoclonal antibody to $\alpha 4\beta 7$ integrin, has been shown to moderate gut lymphocyte trafficking with an efficacy in treatment of both Crohn's disease and ulcerative colitis (UC)^[1,2]. Although tumor necrosis factor-alpha (TNF- α) inhibitors have been reported to be effective as treatment for pouchitis^[3], there is little data regarding the use of vedolizumab in refractory pouchitis^[4]. The effect of vedolizumab treatment on chronic antibiotic refractory pouchitis is very limited. Chronic antibiotic refractory pouchitis is a challenging complication in patients with UC who undergo proctocolectomy with ileal pouch-anal anastomosis. Chronic antibiotic refractory pouchitis occurs when patients do not respond to a 2-wk course of ciprofloxacin, metronidazole or rifaximin for pouchitis^[5].

CASE PRESENTATION

Chief complaints

We report on a 32-year-old male with pancolonic UC.

History of present illness

A 32-year-old male with pancolonic UC since the age of 25 with primary failure of infliximab and mesalamine and intolerance of azathioprine, underwent a total proctocolectomy with ileal pouch-anal anastomosis in 2012.

History of past illness

He developed chronic diarrhea in 2014, which was watery, 30 per day and accompanied with blood and mucus affecting his quality of life. He could not work. He lost a lot of weight. He had fallen from 55 kg to 43 kg during pouchitis. His body mass index was 15.2 kg/m². He used mesalamine 3 g orally, steroid intermittently, lavman and loperamide orally three times daily.

Personal and family history

His family history was unremarkable.

Physical examination upon admission

His abdominal physical examination was normal.

Laboratory examinations

Laboratory work-up revealed erythrocyte sedimentation rate of 56 mm/h and C-reactive protein of 3.6 mg/dL with no liver function abnormalities. Autoimmune markers including IgG4, anti-nuclear antibody and anti-mitochondrial antibody were negative. His blood tests for hepatitis B virus, hepatitis C virus, and human immunodeficiency virus antibodies were negative. Stool studies for *Clostridium difficile*, viruses and bacteria were negative. Blood tests for Epstein-Barr virus and cytomegalovirus antibodies were negative.

Imaging examinations

An ileoscopy and pouchoscopy were performed that demonstrated normal proximal ileal mucosa, but there were diffuse edema, erythema and nodularity and multiple superficial and deep ulcers in the pouch. His pouchitis disease activity index score was 16. Biopsies obtained were negative for cytomegalovirus. An upper endoscopy was done at the same time to evaluate diarrhea, and it was normal. Duodenal biopsy was negative for the presence of celiac disease. Serum antibodies for celiac disease including anti-gliadin antibodies, endomysial antibodies and anti-transglutaminase antibodies were negative. Therefore, gluten restricted diet was not given to the patient. His chest X-ray was normal. Purified protein derivative skin test was 0 mm.

FINAL DIAGNOSIS

Chronic pouchitis.

TREATMENT

He was prescribed metronidazole 500 mg orally three times daily and ciprofloxacin 500 mg orally two times daily. But his symptoms did not improve. Then we added rifaximin 550 mg orally three times daily. We continued mesalamine 3000 mg orally two times rectally and loperamide three times daily. He also used probiotics. He continued to have diarrhea with blood and mucus 20 to 30 times per day. Then adalimumab was started at 160 mg, 80 mg and 40 mg subcutaneously at 0, 2, and every 2 wk, respectively. He reported improvement of diarrhea without blood 10 to 15 per day the first week of adalimumab treatment. However, this response decreased within 4 wk, and the diarrhea and weight loss increased. His pouchoscopy was the same as before treatment at 6 mo after the beginning of treatment. Therefore, we stopped adalimumab. We tested the patient again for other etiologies like infections that were negative. Finally, we decided to start vedolizumab. The patient was given 300 mg parenterally at 0, 2, and 6 wk then every 8 wk.

OUTCOME AND FOLLOW-UP

He reported improvement in clinical symptoms at 4 wk for frequency of diarrhea (six to eight per day) without blood and mucus. He did not have any abdominal complaints. A pouchoscopy at 6 wk and 15 wk after beginning vedolizumab demonstrated that there were less ulcers after 6 wk, and there was only one small superficial ulcer after 15 wk (Figure 1). A pouchoscopy before beginning vedolizumab treatment is shown in Figure 2. His laboratory tests including C-reactive protein, erythrocyte sedimentation rate and liver test were normal. He gained almost 9 kg during vedolizumab treatment, and his quality of life improved (he started to work again).

DISCUSSION

There is only one retrospective study on the efficacy of vedolizumab for refractory pouchitis of the ileo-anal pouch in the literature^[6]. This study suggested that vedolizumab is safe and effective for treatment of refractory pouchitis. The other studies found in the literature are case presentations and case series. These presentations showed us vedolizumab was a good choice for refractory pouchitis^[7-11]. The effects of vedolizumab for treatment of pouchitis is summarized in Table 1^[8-13]. We differentiated our case from other cases in the literature by taking an effective clinical and endoscopic response with vedolizumab treatment in two different anti-TNF alpha refractory pouchitis.

Vedolizumab, a monoclonal antibody, selectively blocks gut lymphocyte trafficking by interacting with $\alpha 4\beta 7$ heterodimer^[1]. There is severe infiltration of the mucosa by both innate and adaptive immune cells in active pouchitis. An increased proportion of mucosal dendritic cells expressing integrin $\beta 7$ in patients with pouch inflammation has been shown^[14]. The integrin signaling in the pathogenesis of this clinical condition of pouchitis may have a pathogenic role. Therefore, blockade of $\alpha 4\beta 7$ integrin with vedolizumab treatment might represent a promising therapeutic strategy for this clinical condition^[14].

Vedolizumab has been shown to be beneficial for the treatment of chronic antibiotic-refractory pouchitis^[15,16]. After 3mo of therapy with vedolizumab in patients with refractory pouchitis, the small case series of four patients had symptomatic and endoscopic improvements^[17].

Vedolizumab may be a new choice as a treatment option in patients with refractory pouchitis who showed no improvement with steroids and other biological therapies such as anti-TNFs. Future studies may show when to start vedolizumab and the advantages of vedolizumab therapy in patients with refractory pouchitis.

CONCLUSION

In our patient who had anti-TNF refractory pouchitis, the gut-specific immune

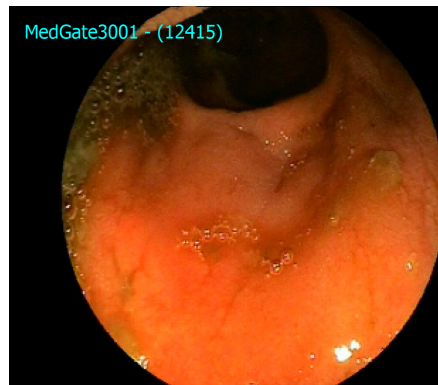


Figure 1 Fifteen weeks after vedolizumab treatment.

modulation mediated by vedolizumab treatment resulted in good responses. Further large and prospective studies are needed for the efficacy and the underlying mechanisms of efficacy of vedolizumab in treatment of refractory pouchitis.

Table 1 Effect of vedolizumab treatment of pouchitis in the literature

Country and reference	Number of patients	Age and gender	Features of inflammatory bowel disease	Outcomes
United States and reference 8	1	41-year-old female	She had pouchitis; 2 years later IPAA	Improvement in clinical symptoms and decreased frequency of bowel movements to four to six per day without blood or mucus were reported with 6 wk of vedolizumab treatment. There were no side effects
Italy and reference 9	1	33-year-old male	Anti-TNF-refractory chronic pouchitis and concomitant PSC	3 mo after ileostomy closure, chronic pouchitis occurred, refractory to antibiotics and anti-TNF. Thus, vedolizumab was started, leading to a marked improvement in clinical symptoms, which was maintained to the end of follow up (wk 34). There were no side effects
Germany and reference 10	20	12 male, 8 female; The median age was 22.5 years old	All of the patients were diagnosed with pouchitis	Improvement of clinical symptoms, the Oresland score and the PDAI score. There were no side effects
Greece and reference 11	1	22-year-old female	She was first diagnosed with pouchitis 1 year after surgery. Administered infliximab followed by adalimumab, both of which she discontinued after an early severe allergic reaction	Vedolizumab was subsequently initiated, together with a single course of antibiotics, and the patient experienced improvement in clinical symptoms and laboratory results with no documented relapse since then. A new pouchoscopy at wk 33 showed significant improvement
Greece and reference 11	1	22-year-old female	She was first diagnosed with pouchitis 1 year after surgery. Administered infliximab followed by adalimumab, both of which she discontinued after an early severe allergic reaction	Vedolizumab was subsequently initiated, together with a single course of antibiotics, and the patient experienced improvement in clinical symptoms and laboratory results with no documented relapse since then. A new pouchoscopy at wk 33 showed significant improvement
United States and reference 12	12	9 female, 3 male; The mean age was 41 years old	All of the patients had active pouchitis. Five patients (41.7%) used mesalamine, six (50.0%) took budesonide and four (33.3%) took prednisone prior to using vedolizumab. Eight (66.7%) had used anti-TNF agents prior to vedolizumab use	Eight (66.7%) patients demonstrated significant reduction in mPDAI symptom subscores before and after vedolizumab therapy
Portugal and reference 13	1	20-year-old female	She was diagnosed with pouchitis and a severe symptomatic autoimmune hemolytic anemia 1 year after IPAA	Patient reported symptom improvement at wk 12 and a pouchoscopy revealed only mucosal edema after 6 mo of therapy. Her inflammatory markers and hemoglobin normalized on repeat testing, allowing steroid withdrawal

IPAA: Ileal pouch-anal anastomosis; TNF: Tumor necrosis factor; PSC: Primary sclerosing cholangitis; PDAI: Pouchitis disease activity index; mPDAI: Modified pouchitis disease activity index.

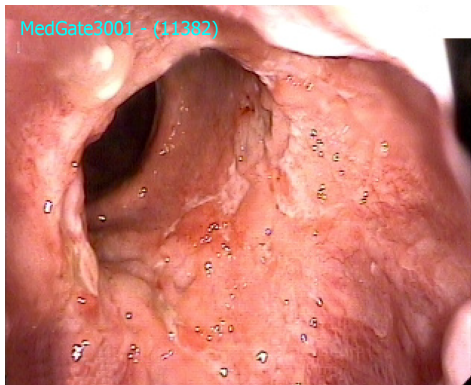


Figure 2 Before vedolizumab treatment.

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