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CASE REPORT | ENDOSCOPY

Impact of Using Self-Assembling Peptide (PuraStat) on Anastomotic Ulcers—A Multicenter Case Series

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ABSTRACT

Treatment of anastomotic ulcers, also known as marginal ulcers, is challenging, especially when established techniques have failed. PuraStat is a biocompatible synthetic peptide gel that is indicated for hemostasis of bleeding in the gastrointestinal tract and vascular anastomoses. We aim to evaluate the feasibility of PuraStat in the setting of nonhealing anastomotic ulcers when used alongside standard therapies. This is a multicenter case series of adult patients who had PuraStat applied with a follow-up repeat endoscopy. Nine out of 10 patients showed clinical improvement. We concluded that PuraStat is an effective agent to aid in healing of anastomotic ulcer.

KEYWORDS: PuraStat; gastrointestinal bleeding; anastomotic ulcer; endoscopy

INTRODUCTION

The incidence of upper gastrointestinal (GI) bleeding has been increasing in elderly patients with comorbidities that continue to have a major impact on healthcare system. The most common cause of acute nonvariceal upper GI bleeding has been peptic ulcer disease, accounting for 25%–65% of all the cases.[1] Treatment of this bleeding is challenging, especially when established techniques such as injection therapy have failed.[2] In the past decade, hemostatic powders have become common tools for managing GI bleed with few studies confirming its effectiveness.[3,4] However, visibility of the bleeding site and landmarks during esophagogastroduodenoscopy (EGD) can sometimes become obscure following application of the powders due to their opaque nature. Hence, techniques were necessary to better manage GI bleed if established techniques fail.

PuraStat (3-D Matrix), a hemostatic agent, is a transparent synthetic peptide gel that is indicated for hemostasis of bleeding in small blood vessels of the GI tract.[5,6] PuraStat was introduced for use in postadvanced resection techniques, for gastric tumor removal in 2014, but it became recognized for its application in cardiac and sinus surgery.[7-9] Despite Purastat's growing recognition, comprehensive data remain limited with multiple ongoing studies exploring its full potential. Notably, anastomotic ulcers are a significant cause for pain and bleeding, particularly in patients who have had bariatric surgery, and unfortunately, there are very few noninvasive medical remedies.

Anastomotic ulcers occur on the intestinal aspect of gastrojejunal anastomosis and are seen in up to 16% of patients, often within the first postoperative year. Patients present with abdominal pain, nausea, and sometimes, significant GI bleeding events leading to anemia.[10] These are typically managed with proton-pump inhibitor (PPI) and sometimes sucralfate. Here, we assess PuraStat for

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ulcer healing, and at the time of writing, there are no studies on effectiveness of PuraStat in wound/ulcer healing. This is the first analysis to evaluate the feasibility of PuraStat in the setting of anastomotic ulcers when used after failed maximal medical therapy.

CASE REPORT

We conducted a multicenter case series analysis of adult patients who underwent PuraStat application (3 mL) for anastomotic ulcers after failing multiple therapies. Patient characteristics and clinical symptoms such as age, gender, pain, nausea, and GI bleeding on the initial admission were recorded (Table 1). The study also included the location of the anastomotic ulcer. The data were also collected to assess the clinical and endoscopic improvement on follow-up endoscopy, typically done at 10–12 weeks. The clinical improvement was assessed by patients' symptoms, whereas the endoscopic improvement was assessed by improvement in size or complete healing of ulcer. Usage of PPI was noted. The small sample size precluded any advanced analysis.

Table 1. Demographics, symptoms, and location of ulcer

Patient characteristics, N = 10	
Characteristic	**No. (%)**
Age, years, median (IQR)	55.5 (51–66)
Sex	
Female	1 (10)
Male	9 (90)
Smoking	
Yes	8 (80)
No	2 (20)
Primary clinical symptoms	
Abdominal pain	7 (70)
Nausea	4 (40)
GI bleed and anemia	4 (40)
Anastomotic ulcer present	10 (100)
Location of ulcer	
GJ anastamosis with gastric bypass surgery	6 (60)
GJ anastamosis without gastric bypass surgery	3 (30)
Duodenal bulb	1 (10)
PPI therapy BID pre-PuraStat application (8 wk min)	
Yes	10 (100)
No	0
PPI therapy BID post-PuraStat application	
Yes	6 (60)
No	4 (40)
PuraStat (3 mL)	10 (100)

BID, twice a day; GI, gastrointestinal; GJ, gastrojejunal; IQR, interquartile range; PPI, proton-pump inhibitor.

DISCUSSION

A total of 10 patients were included. Patients who initially presented with pain, nausea, anemia, and with confirmed anastomotic ulceration seen on endoscopy were included. Before making the decision to apply PuraStat, all patients were treated for at least 8 weeks on maximum medical therapy, which included PPI use as an open-capsule and use of cytoprotective agents such as carafate.[11] A total of 3 mL of PuraStat was applied on each of these patients' ulcers, and a repeat endoscopy was performed to evaluate ulcers at ~ 3 months. The median age was 55.5 years (51–66) with 9 male (90%) and 1 female (10%) (Table 1). The primary symptoms on the initial admission were abdominal pain (70%), nausea (40%), anemia (30%), and GI bleeding (30%) (Table 1). Our sample included 60% (6/10) patients with gastric bypass, and 40% of patients had anastomotic ulcers without gastric bypass (Table 1). Six patients used PPI while 4 patients did not *after* PuraStat application. These 4 patients opted to not use PPI because of failure of clinical improvement with PPI before PuraStat application. With the application of PuraStat, 9 of 10 patients showed healing of anastomotic ulcer on repeat endoscopy in 3 months, while one patient did not follow-up for repeat endoscopy. This patient opted to not undergo a repeat endoscopy as they had clinical improvement (Table 2). Nine out of 10 patients showed clinical improvement in their symptoms (90%), while one patient with anastomotic ulcer who presented with nausea and vomiting without GI bleeding and PPI therapy involvement did not show improvement in clinical symptoms (Table 2). This patient however did have endoscopic improvement.

In our small series, we found PuraStat to be a promising tool to help in healing of anastomotic ulcers. All patients in our sample showed clinical or endoscopic improvement, with 90% (9/10) of patients showing clinical improvement *and* endoscopic healing,

Table 2. Results post-PuraStat and its effectiveness

Post-PuraStat application results	
Surveillance EGD 3 mo post-PuraStat	**No. (%)**
Healing of anastomotic ulcer	
Yes	9 (90)
No	0 (00)
No follow-up EGD[a]	1 (10)
Improvement in clinical symptoms (abdominal pain, nausea, GI bleed)	
Yes	9 (90)
No	1 (10)

EGD, esophagogastroduodenoscopy; GI, gastrointestinal.
a Patient opted to NOT undergo an EGD because all symptoms had resolved.

whereas 1 of the patients had endoscopic healing only, of the anastomotic ulcer on repeat endoscopy at 3 months (Figures 1 and 2; Video 1, Video 2). To our knowledge, this is the first analysis to evaluate effectiveness of PuraStat in anastomotic ulcers in patients with gastrojejunal anastomosis. We discovered that application of PuraStat resulted in clinical and/or endoscopic improvement in 100% of our patient population.

The success of endoscopic treatments to achieve hemostasis is superior to most success rates observed for hemostatic powder application. A group previously reported a treatment success of 64% in upper GI bleeding with EndoClot.[12] A prospective trial found a primary hemostasis rate of 76% with hemospray.[13] Another analysis from Italy revealed successful hemostasis with PuraStat in 91% of the patients.[14] Despite a plethora of hemostatic agents, to date, no studies have been published on any such agent that helps with healing of an ulcer.

PuraStat, on exposure to bodily fluids, triggers the peptide to self-assemble, forming a matrix. The actual sequence of amino acids and specifics of the above process is protected information. However, we hypothesize that it is this matrix formation of peptide molecules that allows the epithelial lining to heal more rapidly, perhaps by using this matrix as a scaffold.[15]

Our series possesses limitations. First, the absence of a comparative arm and randomized treatment assignment may introduce a selection bias. Second, the sample size is modest, underscoring the necessity for larger-scale investigations on this subject. Moreover, the assessment of PuraStat's efficacy may be challenging when it is administered concurrently with other established therapies. However, this also underscores the strength of the analysis, as it mirrors the routine clinical practice of using multiple therapeutic modalities to achieve favorable outcomes. Specifically, patients receiving PuraStat were already undergoing treatment with maximum medical therapies, including PPI and Carafate, and notably, demonstrated either clinical or endoscopic improvement irrespective of the continuation of these therapies.

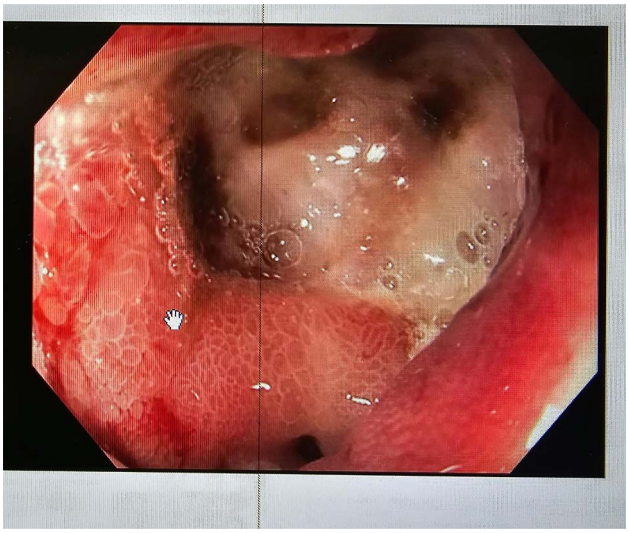

Figure 1. Anastomotic ulcer on one of the patients.

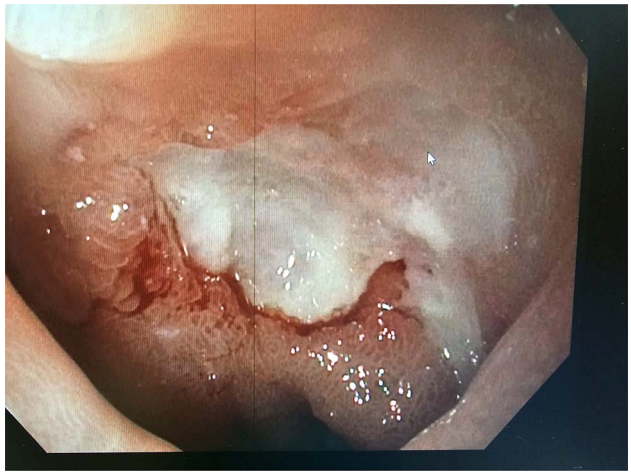

Figure 2. Improved anastomotic ulcer 3 months post-PuraStat application.

PuraStat is a viable primary option for anastomotic ulcers, both with and without bleeding. Our case series underscores the effectiveness of PuraStat in ameliorating patients' symptoms, with evidence of ulcer healing observed during follow-up endoscopy and improvement in clinical symptoms across all cases.

DISCLOSURES

Author contributions: TH Kothari and VM Oza: conceptualization. VM Oza and N. Mittal: writing-original draft preparation. All authors: data collection and writing-reviewing/editing. VM Oza and T. Kothari: supervision. All authors: data collection. TH Kothari is the article guarantor.

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Informed consent was obtained for this case report.

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