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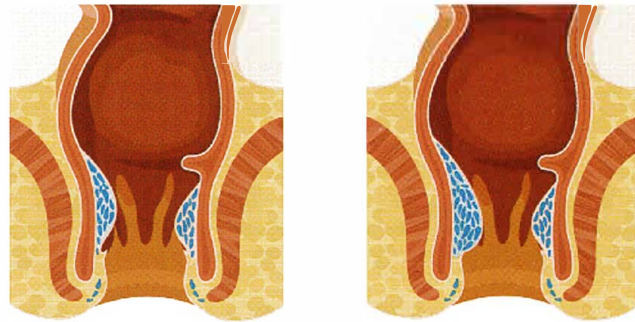
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Bipolar Energy System Improves Patient Experience In Treating Symptomatic Low-Grade Hemorrhoids

Due to the common nature of the condition, symptomatic low-grade (I and II) hemorrhoids are a patient complaint frequently encountered in GI practices—one with which most gastroenterology fellows will become familiar from the start of the fellowship.¹ Symptomatic hemorrhoids—engorged fibrovascular cushions lining the anal canal—affect more than 10 million Americans and approximately half of adults older than 50 years of age.^{2,4}

“Hemorrhoids are ubiquitous, affecting so many people with symptoms that are not debilitating, but are just very bothersome and aggravating,” said Jeffrey Hartford, MD, director of endoscopy at Advanced Gastroenterology & Nutrition, a hospital-based GI practice in Flemington, New Jersey.

The most common clinical symptom of low-grade hemorrhoids is painless rectal bleeding.^{3,5} Despite the high prevalence of symptomatic hemorrhoids in the most active age group in the United States, treatment options for many



years have remained limited to lifestyle modifications (eg, increasing daily fiber intake and avoiding the need to strain during bowel movements), or GI-administered procedures, such as rubber band ligation and infrared coagulation, which can often cause more pain for the patient than the hemorrhoid symptoms themselves.^{2,7}

► See **TREATMENT**, Page 2

Successful Endoscopic Treatment of Actively Bleeding Internal Hemorrhoids



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A 56-year-old man gradually developed shortness of breath and was not able to tolerate regular physical activity. He went to his primary care physician and blood tests revealed severe anemia. Upper endoscopy and

colonoscopy did not reveal the source of bleeding, and the patient was referred to Mercy Medical Center for double balloon enteroscopy (DBE) to evaluate the small bowel as a possible site of the GI bleeding.

During an outpatient visit, the patient described having several episodes of severe rectal bleeding with bright red blood in the toilet and on a toilet tissue. Rectal examination revealed grade II internal hemorrhoids (3 columns of enlarged hemorrhoids prolapsing out of the anus and

► See **BLEEDING**, Page 2

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TREATING LOW-GRADE HEMORRHOIDS

BLEEDING (Continued from page 1)

reduced spontaneously) with signs of recent bleeding (attached blood clots). Instead of performing DBE (a 3-hour-long, labor-intensive procedure under general anesthesia), the patient was offered endoscopic treatment of actively bleeding internal hemorrhoids.

The patient agreed, and unsedated treatment of internal hemorrhoids using the HET™ bipolar system was performed (Figure A and B). Total procedure time was 36 seconds (12 seconds to treat hemorrhoidal branch at 3 o'clock position, 14 seconds for hemorrhoidal branch at 7 o'clock position, and 10 seconds for hemorrhoidal branch at 10 o'clock position). The patient experienced only minor rectal discomfort during the procedure and did not report any pain during and after the treatment. He went home post procedure.

A repeat clinical visit a month later demonstrated absence of any rectal bleeding, reduction in hemorrhoidal size, and complete elimination of prolapse. Repeat complete blood cell count

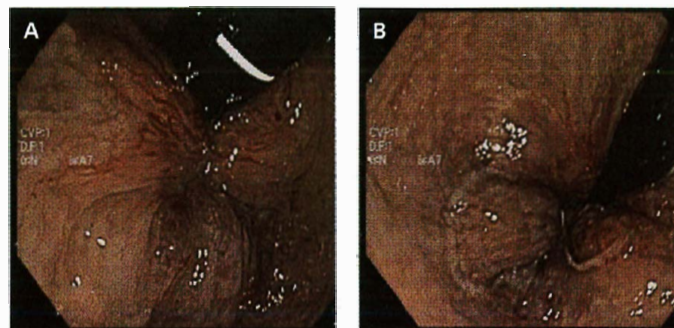


Figure. (A) Grade II internal hemorrhoids in retroflex view. (B) Internal hemorrhoids post treatment with HET™ bipolar system. White circular coagulation marks are visible at the sites of treatment with HET™ bipolar system.

showed normal hemoglobin and hematocrit. His presenting symptoms of shortness of breath disappeared and he was able to resume normal physical activity.

The patient was followed prospectively for 5 years after the HET™ procedure, and he did not have any recurrence of anemia or hemorrhoidal bleeding. He never required DBE.

TREATMENT (Continued from page 1)

Sergey Kantsevov, MD, PhD, director of the Center for Therapeutic Endoscopy at Mercy Medical Center in Baltimore, Maryland, noted how in his practice, these treatments have been effective yet undesirable due to pain and the necessary clinician commitment to multiple repeat procedures. "I started to use endoscopic banding, which is effective but extremely painful. A patient might have 3 branches, but you can only treat one branch at a time because the pain is incredible," he said. "So I tried doing a less painful treatment, infrared coagulation, but that has little effectiveness, so you need to do up to 5 or 10 therapeutic sessions. It's extremely time-consuming."

Drawbacks to conventional treatment options have led GIs to turn to the HET™ (Hemorrhoid Energy Therapy) bipolar system, a technology that coagulates the blood supply to grade I and II hemorrhoids, shrinking hemorrhoidal tissue.⁸ FDA-cleared since 2014, the HET™ bipolar system (acquired by Medtronic in 2014) was designed for outpatient treatment of low-grade

hemorrhoids in a single procedure with minimal discomfort.⁹⁻¹¹

"A major advantage of HET™ is that you can treat multiple—even all—hemorrhoid complexes at the same time," said Deepak Vadada, MD, associate director of the MIS/Flexible Endoscopy Fellowship at Richmond University Medical Center, New York.

The HET™ bipolar system consists of lubricated bipolar forceps used to reach the superior blood supply above the dentate line in the rectum. It features an atraumatic tissue-clamping window that provides accurate tissue targeting above the dentate line and controlled consistent compression that results in uniform delivery of bipolar electrical energy.^{8,12} "The device's transparent window allows a completely clear view of the circumferential treatment area, which makes it easier to identify which areas need to be treated," Dr Vadada said. The tissue thickness gauge gives visual confirmation that the optimal amount of tissue has been grasped and allows for consistent treatment of hemorrhoids.⁸

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Symptomatic hemorrhoids are either internal or external in nature. External hemorrhoids are more painful, particularly when complicated by thrombosis given its proximity to underlying tissues of the anus.¹³ Internal hemorrhoids are classified into 1 of 4 grades based on their degree of prolapse into the anal canal.⁵ Grade I hemorrhoids project into the anal canal and frequently bleed, but do not prolapse. Grade II hemorrhoids can protrude beyond the anal verge as a result of strain or defecation, but will spontaneously return to their starting point upon cessation of straining.⁵ Grade III hemorrhoids prolapse out of the anus and require manual reinsertion, and Grade IV hemorrhoids always protrude outside the anus and cannot be reduced back into the rectum, likely requiring surgical intervention.^{2,5,12}

Lifestyle changes used as first-line treatment include reducing time spent defecating and taking sitz baths.⁵ Also, various over-the-counter topical drugs are available, but these offer little benefit aside from some symptomatic relief, and some drugs—particularly steroids—may even be harmful long term.¹³ When lifestyle modifications fail to provide relief, patients typically present to clinicians who recommend rubber band ligation or infrared coagulation.^{2,7,12} Rubber band ligation is used in up to 80% of patients and causes the banded tissue to necrose and slough.^{3,7} With infrared coagulation, infrared energy is converted to heat and applied in pulses to the hemorrhoidal tissue causing protein necrosis in the hemorrhoid.^{2,12}

These techniques may cause tissue destruction, protein coagulation, and inflammation, which then lead to scarring and tissue fixation.¹² Both of these methods require multiple office visits, as they are too painful for patients to endure for treating more than one hemorrhoid at a time and, with rubber band ligation, may result in ongoing pain and discomfort.^{11,12} Banding ligation has a complication rate of up to 14% including even severe, life-threatening conditions.⁷ Other approaches include bipolar diathermy, requiring multiple applications; sclerotherapy, an older technique with a high incidence of complications; and cryotherapy, which has been found to be ineffective and is now very rarely used.^{5,7}

For Dr Hartford, the absence of more efficient, patient-friendly techniques led him to stop performing the procedures. "I always stayed away from banding because it seemed medical to me. I even stopped doing hemorrhoid procedures for a while because the available treatments were just so unsatisfactory," Dr Hartford said. Using bipolar energy, the HET™ bipolar

system uses a low treatment temperature to coagulate blood vessels feeding enlarged hemorrhoidal branches, resulting in minimal collateral tissue damage.^{11,12}

Additionally, the system's built-in LED-illuminated anoscope improves visualization, particularly in dark rooms, eliminating the need to purchase a separate anoscope and illumination system.⁸ Moreover, the HET™ bipolar system can be used with standard bipolar generators, obviating the need to purchase a generator specific to the device.⁸ For Dr Vadada, using the HET™ bipolar system has enabled treatment to be initiated very fast given its innovative features. "One of the benefits of having devices like HET™ is the fact that we can offer a therapeutic option—maybe even during the same visit as the diagnostic procedure," Dr Vadada said.

Clinical studies have found several advantages of the HET™ bipolar system.^{11,12} Using an in vivo porcine subject, Piskun and Tucker compared the histologic effects after treatment with the HET™ bipolar system and infrared coagulation at multiple treatment sites.¹² Results showed high variability in temperature with infrared coagulation, with temperatures being much higher than with the HET™ bipolar system. Consequently, tissue compression during infrared coagulation was inconsistent, resulting in some collateral tissue damage.¹² In contrast, the HET™ bipolar system enabled consistent compression that required less energy at a low standardized temperature to the respective treatment sites.¹²

Retrospective analysis of 23 patients with actively bleeding internal hemorrhoids demonstrated that the HET™ bipolar system was a well-tolerated and efficient non-surgical approach to treating grade I and II internal hemorrhoids.¹¹ Treatment with the system was performed with and without

conscious sedation (18 and 5 patients, respectively) and required only one therapeutic session.¹¹ Results showed that the total time to treat the hemorrhoids was 37.3±8.7 seconds.¹¹ All patients tolerated the procedure with minimal pain, discomfort, or other side effects.¹¹ Patients reported no bleeding at follow-up (average, 11.2±1.47 months).¹¹

Crawshaw and colleagues reinforced these findings with a prospective study of 20 patients with grade I and II symptomatic hemorrhoids who underwent treatment with the HET™ bipolar system after previous medical treatment or procedures (eg, laxatives, high-fiber diet, rubber band ligation) had failed.¹³ Treatment was performed in one session.¹⁰ Of the 20 patients, 17 (85%) underwent the procedure with light sedation,

► See **TREATMENT**, Page 4



The HET™ bipolar forceps.

TREATMENT (Continued from page 3)

whereas 3 (15%) were given general anesthesia.¹⁰ After the procedure, bleeding improved at 1-, 3-, and 6-month visits compared to baseline (88.2%, 81.8%, and 87.5%, respectively).¹³ The average visual analog pain score was 0.7±1.57 at 1 month. No unexpected adverse events were reported during the follow-up period.¹⁶

Dr Hartford described himself as an early adopter of the HET™ bipolar system, and he considers it to be a transformational procedure. "I've done hundreds of these procedures on patients with symptomatic hemorrhoids, whether it's with bleeding or some degree of prolapse," he said. "It's really taken a prominent role in our practice. I really want to make people aware that there's a much more efficient way to treat hemorrhoids."

Recently, Singh and colleagues presented the results of a retrospective chart review of patients who underwent treatment with the HET™ bipolar system at the 2017 Digestive Disease Week. In a cohort of 38 patients, 36 underwent the procedure under only mild sedation, with one patient given moderate sedation and one given general anesthesia. No patients reported pain or discomfort during the procedure, and 33 (87%) did not experience post-procedural pain. Rectal bleeding was resolved in 28 patients (74%).¹⁴ Dr Kantsevoy noted that the system fills a need in his practice, specifically for patients with hemorrhoids that are too small to refer for surgical resection, but nevertheless cause significant bleeding that could lead to anemia and require a blood transfusion.

As part of the armamentarium of approaches available for hemorrhoid treatment, the HET™ bipolar system offers a simple technique that does not require extensive training or referral to a colorectal surgeon, a benefit to gastroenterologists and GI fellows. "The HET™ bipolar system has a short learning curve," Dr Vadada said. Dr Kantsevoy agreed that the HET™ bipolar system is easy to use, noting that one could learn simply by watching a few procedures.

Using the HET™ bipolar system to treat grade I and II symptomatic internal hemorrhoids ensures improved visualization and consistent tissue compression using low energy, while minimizing pain and tissue damage to the patient and the need for further intervention.

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Indication/Contraindication/Risk Information

The HET™ bipolar forceps and temperature monitor are intended to be used for grasping, manipulating, and coagulating soft tissue during general surgery. The HET™ bipolar system may be used for the treatment of symptomatic grade I and grade II internal hemorrhoids. The bipolar forceps has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. The bipolar forceps is not intended for use to cut and seal vessels. Potential complications include anal discomfort, pain, bleeding, perforation, tissue damage, burns, and infection. Physician and Clinical staff must have adequate training and experience with electrosurgery to prevent serious injury, inadvertent tissue damage, or complications. Caution should be exercised in patients with an increased risk of bleeding, whether by medication or other disease states. See instruction manual for a complete list of risks.