

## Hemorrhoid Treatment in the Outpatient Gastroenterology Practice Using the O'Regan Disposable Hemorrhoid Banding System is Safe and Effective

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### Abstract

**Objectives:** Hemorrhoids are a common disorder and a major cause of rectal bleeding and perianal discomfort. Nonendoscopic rubber band ligation (RBL) is an effective treatment for hemorrhoids, but to date, this technique has not been widely employed by gastroenterologists. The purpose of this study was to evaluate the efficacy, complications, success rate, and recurrence rate at 3 months for the CRH-O'Regan Disposable Hemorrhoid Banding System in the outpatient gastroenterology setting. **Methods:** Eleven physicians at 7 locations, including offices and endoscopy centers, in a single-specialty gastroenterology practice employed the CRH-O'Regan Disposable Hemorrhoid Banding System after completing initial standardized inservice training. A total of 113 adult patients of all ages underwent hemorrhoid banding from June through November 2008. These included men (n = 62, 55%) and women (n = 51, 45%), with an average age of 54 years (range, 19–78). A total of 257 banding events were performed either in the office (n = 56, 50%) or in the endoscopy center (n = 57, 50%). Eight patients (7%) had prior hemorrhoid surgery. Indications for RBL included rectal bleeding alone (n = 62, 55%) or multiple symptoms (n = 51, 45%). External hemorrhoids were not treated in this study. Internal hemorrhoid grading included grade I (n = 8, 7%), grade II (n = 84, 74%), and grade III (n = 21, 19%). The data were abstracted retrospectively from the clinical chart. Safety data was abstracted for all 113 cases. Response data were abstracted for patients completing 2 or more RBL sessions (n = 76, 67%). A 3-month follow-up questionnaire was subsequently sent to each of these 76 patients. **Results:** Initial symptoms were resolved in 71 of 76 patients (94%). Rectal bleeding resolved in 90% of patients after at least 1 banding event. Complications included severe immediate discomfort (n = 1, 0.8%), thrombosis (n = 1, 0.8%), urinary hesitancy (n = 2, 1.8%), and near-syncope (n = 1, 0.8%). Severe bleeding occurred in 1 patient (0.8%). Severe pain occurred in 1 patient (0.8%). There were no cases of pelvic sepsis. No patient required time off because of the procedure. At the 3-month follow-up, symptom resolution or improvement, including rectal bleeding and discomfort, was noted in more than 80% of respondents. **Conclusion:** Outpatient treatment of hemorrhoids by gastroenterologists using the CRH-O'Regan Disposable Hemorrhoid Banding System is safe and effective. This is a novel, nonendoscopic approach to treating common symptoms of internal hemorrhoids, such as rectal bleeding, perianal discomfort, and other associated complaints. It can be employed in the office or endoscopy center, and patients do not require time off from work after the procedure.

Key Words: Hemorrhoids, banding, ligation, RBL

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### Introduction

Internal hemorrhoids are common and often symptomatic. Approximately 4% of the western population are affected annually.<sup>1</sup> Modern data suggest that 10.4 million Americans suffer from hemorrhoids, requiring 3.5 million physician visits per year with an estimated healthcare burden of \$500 million.<sup>2</sup> The most

common symptoms include bleeding, prolapse, pain, itching, and fecal soiling.<sup>3</sup> Symptoms of grade I and II hemorrhoids are usually treated conservatively, while those caused by grade III and IV may require intervention. Furthermore, patients presenting with grade III and IV hemorrhoids often complain of difficult evacuation or soiling.<sup>4</sup> Internal hemorrhoids are a common

cause of recurrent hematochezia as the dilated venous plexus enlarges and tends to protrude below the dentate line.<sup>2,3</sup>

The pathogenesis and etiology of hemorrhoids remain unclear. Theories include age-related destruction of perianal connective tissue, hormonal imbalance, hemodynamic changes, and bowel habits, namely straining and constipation.<sup>1,4</sup> While patients with hemorrhoids often complain of difficult evacuation that cannot be explained by the anatomic occurrence of enlarged and prolapsing anal cushions, it has been shown that constipation itself is not a primary risk factor for hemorrhoids.<sup>5,6</sup> Case control data suggest that hemorrhoid-like symptoms may simply reflect the prevalence of hemorrhoids in the general population, especially in those with constipation.<sup>4</sup> Interestingly, the most common symptom of hemorrhoids is rectal bleeding, followed by pain, soiling, and itching.<sup>4</sup> While between 35% and 55% of hemorrhoid patients report diffuse general bowel symptoms, including disturbed defecation, an exaggerated desire to strain, feeling of incomplete evacuation, flatulence, and bloating, it is in fact the more disturbing symptoms of rectal bleeding, pain, and pruritus that often lead patients to seek medical care.<sup>4</sup>

The majority of patients with grade I hemorrhoids and intermittent symptoms may be treated conservatively. Intervention is often required for effective treatment of symptomatic grade II and III internal hemorrhoids, and surgical hemorrhoidectomy is appropriate for rapid treatment of chronic advanced grade III and grade IV internal hemorrhoids.<sup>7</sup> While surgery is appropriate treatment for selected patients who fail medical and nonoperative therapy, it is associated with significantly more pain and complications versus nonoperative interventional techniques.<sup>8-10</sup> Up to 25% of patients with symptomatic internal hemorrhoids of any grade are currently treated surgically.<sup>10,11</sup> There is a role for an effective nonoperative treatment, which offers physicians a wider range of therapeutic options for patients failing conservative management.

The currently available nonsurgical treatment devices for hemorrhoids include sclerotherapy, rubber band ligation (RBL), infrared photocoagulation, direct current coagulation, bipolar electrocoagulation (BPEC), and heater probe thermocoagulation. Each is commercially available and may be employed in the outpatient setting. Complications are rarely encountered but may include pain, bleeding, urinary dysfunction, or infection. A meta-analysis comparing anoscopic, endoscopic, and surgical therapies for internal hemorrhoids reported that sclerotherapy was less effective than RBL or surgery.<sup>12</sup> Another meta-analysis comparing sclerotherapy, RBL, and infrared coagulation reported that RBL had greater long-term efficacy than other treatments.<sup>13</sup> Infrared coagulation was effective but required more treatment sessions.

Rubber band ligation is now more commonly used than either sclerotherapy or infrared photocoagulation. A recent study clear-

ly showed that RBL is superior to BPEC for the treatment of chronically bleeding grade II and III internal hemorrhoids, requires fewer sessions, and does not increase complications.<sup>14</sup> The effectiveness of RBL is generally greater than 80%.<sup>8,15,16</sup> Previous studies suggest that RBL is the most effective nonoperative treatment with the lowest symptom recurrence rate.<sup>12,17-20</sup> Both single- and multiple-ligation bandings have been studied.<sup>18,19</sup>

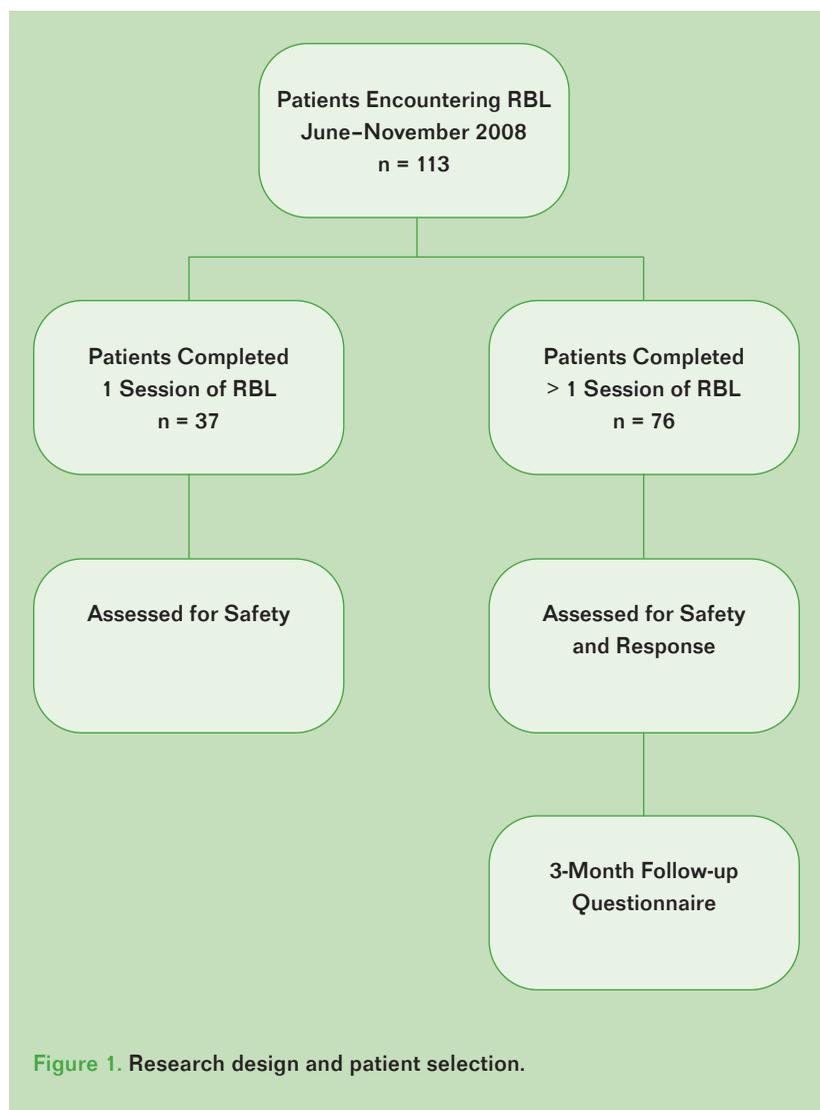
Rubber band ligation of hemorrhoids causes ischemic necrosis and eventual atrophy of the hemorrhoid tissue. Ulceration results in fibrosis and obliteration of the submucosal tissue. Older methods of RBL typically required 2 or more people to properly position the bands. Despite the shortcomings, these methods have proven to be highly effective with cure rates greater than 80%, recurrence rates lower than 20%, and clinically significant complication rates lower than 2%.<sup>12,13</sup> Common nonsurgical techniques for deploying the rubber band include rigid proctoscopy, flexible sigmoidoscopy, and colonoscopy. The advantages of endoscopic RBL for the gastroenterologist include ease of use and familiarity with the equipment. Multiple bands may be placed on the hemorrhoid tissue above the dentate line. Studies have shown that endoscopic banding is highly effective with up to 90% response and less than 10% relapse.<sup>12,14,21-24</sup>

Newer techniques for hemorrhoid banding are available and can be used by a single physician with improved band deployment and efficacy.<sup>25-27</sup> The CRH-O'Regan Disposable Hemorrhoid Banding System (CRH Medical Corporation, Vancouver, BC, Canada) for internal hemorrhoid ligation consists of a slotted anoscope, a syringe ligator, and rubber bands for ligation. The package includes all necessary equipment for a single operator ligation session and does not require equipment processing.

To the authors' knowledge, no studies of the safety or effectiveness of the CRH-O'Regan Disposable Banding System performed by gastroenterologists in the United States have been published. The purpose in this study was to assess the performance of the CRH-O'Regan Disposable Hemorrhoid Banding System in the outpatient setting for treatment of symptomatic hemorrhoids by gastroenterologists. Durability of treatments and recurrence of hemorrhoidal symptoms also were evaluated at 3 months.

## Methods

**Specific aims and inclusion/exclusion criteria.** This retrospective, non-randomized study was carried out at various practice locations within Atlanta Gastroenterology Associates, LLC, a large, single-specialty, gastroenterology practice in the metro Atlanta area. Western Institutional Review Board approved the study. The specific aims of the study were: (1) to evaluate the clinical performance of the single-use CRH-O'Regan Disposable Hemorrhoid Banding System within a gastroenterology practice; (2) to evaluate the safety and tolerability of the treatment; and (3) to evaluate the durability of treatment effect and recurrence of symptoms at 3 months. Traditionally, gastroenterologists have



**Figure 1.** Research design and patient selection.

not been trained to apply rubber bands via nonendoscopic approaches. The CRH-O'Regan hemorrhoid bander is easily incorporated into the general gastroenterology practice, and the procedure can be performed on an outpatient basis. The performance of this US Food and Drug Administration-approved device has not been studied by gastroenterologists to date but has been successfully used by surgeons. The rubber band applicator is a plastic plunger suction device resembling a syringe, which is applied to each hemorrhoid above the dentate line. One ligation is typically performed per session. Suction is induced to cause the bulk of the hemorrhoid cushion to enter the nozzle, and band release results in strangulation of the hemorrhoid. Bowel preparation and sedation/anesthesia are not required.

All consecutive cases of hemorrhoid banding by individual physicians between June 1, 2008, and November 30, 2008, were included in the study. Adult men and women of any age who had already consented and successfully completed at least 1 elective hemorrhoid banding in the clinic/office or endoscopy

center were included. Per standard protocol, grades I to III internal hemorrhoids are amenable to RBL based on physician discretion; grade IV internal hemorrhoids are excluded from RBL in the authors' practice. A total of 113 adult patients of all ages underwent hemorrhoid banding during this time. These included men (n = 62, 55%) and women (n = 51, 45%) with an average age of 54 years (range, 19–78). A total of 257 banding events were performed (1 band ligation per session). Procedures were performed in the office/clinic (n = 56, 50%) or endoscopy center (n = 57, 50%). Twenty-five patients (22%) underwent banding immediately after sedated colonoscopy once they were awakened and able to provide feedback to the physician on discomfort prior to rubber band deployment. Ninety-seven patients (86%) had undergone colonoscopy within the previous year; 32% had at least 1 polyp, and none had colorectal cancer. Eight patients (7%) had prior hemorrhoid surgery. Indications included rectal bleeding alone (n = 62, 55%), rectal discomfort (n = 39, 35%), or multiple symptoms (n = 12, 10%). Four patients (3.5%) complained of overt fecal soiling. Internal hemorrhoid grading included grade I (n = 8, 7%), grade II (n = 84, 74%), and grade III (n = 21, 19%). Clinically significant external hemorrhoids (n = 24, 21%), including acute thrombosed (n = 4, 3.5%) and anal fissures (n = 9, 8%), were encountered in addition to internal hemorrhoids but were treated conservatively.

Of the 113 patients, a total of 76 (67%) had completed 2 or more sessions of RBL, and 37 (33%) had completed only 1 session of RBL (typically

the first of 3 anticipated sessions) and were actively undergoing treatment (Figure 1). Background variables are shown in Table 1. Data abstraction in regard to procedure safety and adverse events was obtained from all cases. Data abstraction in regard to clinical response was obtained only from the 76 patients having completed 2 or more sessions of RBL. Eligible hemorrhoid grades including grades I to III were considered (grade IV hemorrhoids were excluded per standard protocol at the authors' facilities). Intervention included elective hemorrhoid banding that was performed either in a clinic/office or endoscopy center, depending on physician preference.

**General study design.** Data were retrospectively collected via a chart review query along with a questionnaire (Figure 2). Physician reporting determined clinical response. Patients did not participate in a "new device" trial. The authors aimed to collect outcomes data during a 6-month period of active procedures to evaluate the clinical response and potential adverse events associated with the use of the CRH-O'Regan Disposable

Hemorrhoid Banding System by gastroenterologists. To assess the durability of clinical response, a questionnaire was mailed to all patients (n = 76) having completed 2 or more sessions of RBL at the time of data abstraction.

**Endpoints.** The primary endpoint was the clinical response of hemorrhoid banding by treating physician. Patient satisfaction, resolution or improvement of rectal bleeding, clinical improvement, and management of anal/rectal discomfort were abstracted from the clinical chart. Adverse events were evaluated as secondary endpoints. Additional endpoints included evaluation of fecal soiling and perianal disease management.

**Physician training.** Beginning in 2008, all gastroenterologists in the authors' practice were offered the potential to become trained in the CRH-O'Regan Disposable Hemorrhoid Banding System. At the time of the study, a total of 11 physicians at 7 separate practice locations had completed training and subsequently performed the procedure in their respective practice locations. The initial training included a detailed review of hemorrhoid and perianal pathophysiology and multiple sessions of directly observing a board-certified surgeon performing the procedure at a local CRH facility (The Center for Colorectal Health, Atlanta, Georgia). After successfully completing the initial observation period, each physician individually completed a series of RBL using the CRH-O'Regan bander under direct observation by a CRH surgeon.

**The CRH-O'Regan procedure.** Rubber band ligation was carried out with the CRH-O'Regan Disposable Hemorrhoid Banding System kit. This consists of a slotted anoscope, a syringe ligator, and rubber bands for ligation. A maximum of 1 hemorrhoid plexus is ligated with a maximum of 1 band per session. Patients typically return to clinic at 2-week intervals (3 separate treatment sessions) to complete subsequent single-hemorrhoid-single-band ligations in the left lateral, right anterior, and right posterior locations, in no particular order. Cases completed without a concomitant procedure (ie, office- or endoscopy center-based without same-day colonoscopy) require no additional observation, and patients generally leave within a few minutes after the procedure. However, cases completed the same day as colonoscopy require patients to be awakened after the procedure once the effects of sedations have resolved. This is essential to ensure the patient is able to provide immediate feedback during RBL. A brief period of observation is then employed prior to discharge.

## Results

**Baseline and initial results.** From June 1, 2008, to November 30, 2008, 113 patients with chronic hemorrhoid symptoms underwent at least 1 session of RBL with the CRH-O'Regan Disposable

**Table 1**  
**Background Variables**

Total patients	113
Male	62 (55%)
Female	51 (45%)
Physicians	11
Site locations	7
Total banding events	257
Office-based procedure	56 (50%)
Endoscopy-lab-based procedure	57 (50%)
Banding performed same day as colonoscopy	25 (22%)
Colonoscopies performed	97 (86%)
Prior hemorrhoid surgery	8 (7%)
Prior colectomy	5 (4%)
Fissure	9 (8%)
History of recent symptomatic external hemorrhoids	24 (21%)
Internal hemorrhoids - grade I	8 (7%)
Internal hemorrhoids - grade II	84 (74%)
Internal hemorrhoids - grade III	21 (19%)
Internal hemorrhoids - grade IV	0 (0%)

**Table 2**  
**Patient Symptoms at Presentation**

Symptom	Total, N (%)
Chief complaint rectal bleeding alone	62 (55%)
Chief complaint rectal pain or multiple symptoms (including minor rectal bleeding)	51 (45%)
Constipation	21 (19%)
Diarrhea	6 (5.3%)
Rectal bleeding at any time	70 (62%)
Rectal pain	49 (43%)
Peri-anal burning/itching	28 (25%)
Rectal bleed from warfarin or clopidogrel	3 (2.5%)
Fecal soiling	4 (3.5%)

Hemorrhoid Banding System. A total of 76 of these cases had 2 or more RBL sessions to support follow-up clinical response abstraction. A total of 257 bands were placed (ie, 257 RBL sessions) with 1 band placed per session, with at least 2 weeks between sessions. The most common presenting symptoms included rectal bleeding (62%), followed by rectal pain (43%) or burning/itching (25%); most patients had more than 1 symptom (Table 2). Interestingly, few patients complained of overt dysfunctional bowel habits (less than 20% constipation or diarrhea). Three patients required RBL for treatment of medication-associated bleeding (warfarin and clopidogrel); medication was held during treatment (5 days prior to and after each banding session) in all cases. Fecal soiling was noted in 3.5% of patients.

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HEMORRHOID BANDING SURVEY

Please check any of the symptoms below that you experienced prior to hemorrhoid banding procedure. Then check how those symptoms changed after your hemorrhoid banding procedure.

	Resolved	Improved	No Change	Worse
<input type="checkbox"/> Rectal bleeding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Anal burning/itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pain and discomfort	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Fecal/stool incontinence or smearing of stool with flatulence (passing gas)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Skin irritation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Prolapsing hemorrhoids (hemorrhoids that push out spontaneously with bowel movement) Have these returned inside? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

How would you describe your hemorrhoid treatment at Atlanta Gastroenterology? \_\_\_\_\_  
\_\_\_\_\_

Do you feel that your hemorrhoid procedure was helpful to your health?  Yes  No

Have you undergone hemorrhoid surgery in the past?  Yes  No

If yes, how would you compare this procedure to the previous procedure? \_\_\_\_\_  
\_\_\_\_\_

If you could go back in time, would you still consider this hemorrhoid treatment or would you consider other treatment options, such as surgery, instead?  Yes  No \_\_\_\_\_  
\_\_\_\_\_

How would you describe your bowel movements?  Loose  Normal  Hard  Variable

Do you frequently suffer from abdominal pain?  Yes  No

Do you frequently suffer from bloating?  Yes  No

Are you troubled by flatulence (passing gas)?  Yes  No  No answer

Do you have to strain hard to have bowel movements?  Yes  No

Do you have to spend a long time at the toilet to empty your bowels?  
 Yes, more than 5 min  Yes, about 20 min  More than 20 min  No

Thank you!

Figure 2. Questionnaire.

**Treatment results and follow-up.** Rubber band ligation effectively improved presenting symptoms in 71 of 76 cases (94%, Table 3). Of the 62 patients presenting with rectal bleeding alone, 51 had follow-up data at the time of abstraction; a total of 46 of 51 (90%) experienced resolution of rectal bleeding after at least 1 ligation. In 3 of 3 cases (100%), warfarin/clopidogrel-associated bleeding resolved. In 4 of 4 cases (100%), fecal soiling improved.

Photo documentation of treatment response at various stages is shown in Figure 3.

The complication rate was low for all cases of RBL (including data abstracted from all 113 patients, regardless of whether they had completed therapy) (Table 4). Four patients (3.5%) experienced immediate but minor discomfort, which resolved after manual loosening of the rubber band. One patient (0.8%) experienced severe discomfort requiring removal of the rubber band. Post-procedure bleeding was noted in 5 patients, with 4 (3.5%) being mild, not requiring physician notification, and 1 (0.8%) being severe, requiring hospital management. Two patients (1.8%) experienced urinary hesitancy that resolved spontaneously within 6 hours. Other complications including thrombosis, lightheadedness, and infection were less than 1%, respectively.

Patients having completed 2 or more RBL sessions were identified and received a mail questionnaire at 3 months following procedure completion (all patients completing the questionnaire had subsequently completed 3 RBL treatments by that time). Sixteen patients (21%) responded (Table 5). Symptoms were abstracted as either resolved (ie, sustained complete response to therapy) or improved (ie, minor symptom persistence) based on self-reporting. Rectal bleeding resolution or improvement was reported in 83%; burning/itching resolution or improvement was reported in 92%; pain/discomfort resolution or improvement was reported in 93%; fecal soiling resolution or improvement was reported in 75%; rash/irritation resolution or improvement was reported in 100%; and symptomatic hemorrhoid prolapse response or improvement was reported in 64%. Overall, 81% of respondents were highly satisfied with their treatment, and 75% said they would choose RBL therapy again over a surgical option. The majority (75%) said they would recommend this therapy to a friend.

## Discussion

Hemorrhoids are the most common anorectal disorder in the western world and are a major cause of rectal bleeding.<sup>1-4,28</sup> Conservative treatment is often sufficient for short-term relief of symptoms. However, many patients require interventional therapy or surgery to control chronic symptoms. The patients in this study provided a representative mixture of general hemorrhoid symptoms commonly encountered in a gastroenterology prac-

**Table 3**  
**Results after RBL**

Results	Total, N (%)
Presenting symptom improved	71 of 76 cases (94%)
Rectal bleed resolved	46 of 51 cases (90%)
Warfarin/clopidogrel-associated bleeding resolved	3 of 3 cases (100%)
Fecal soiling improved	4 of 4 cases (100%)

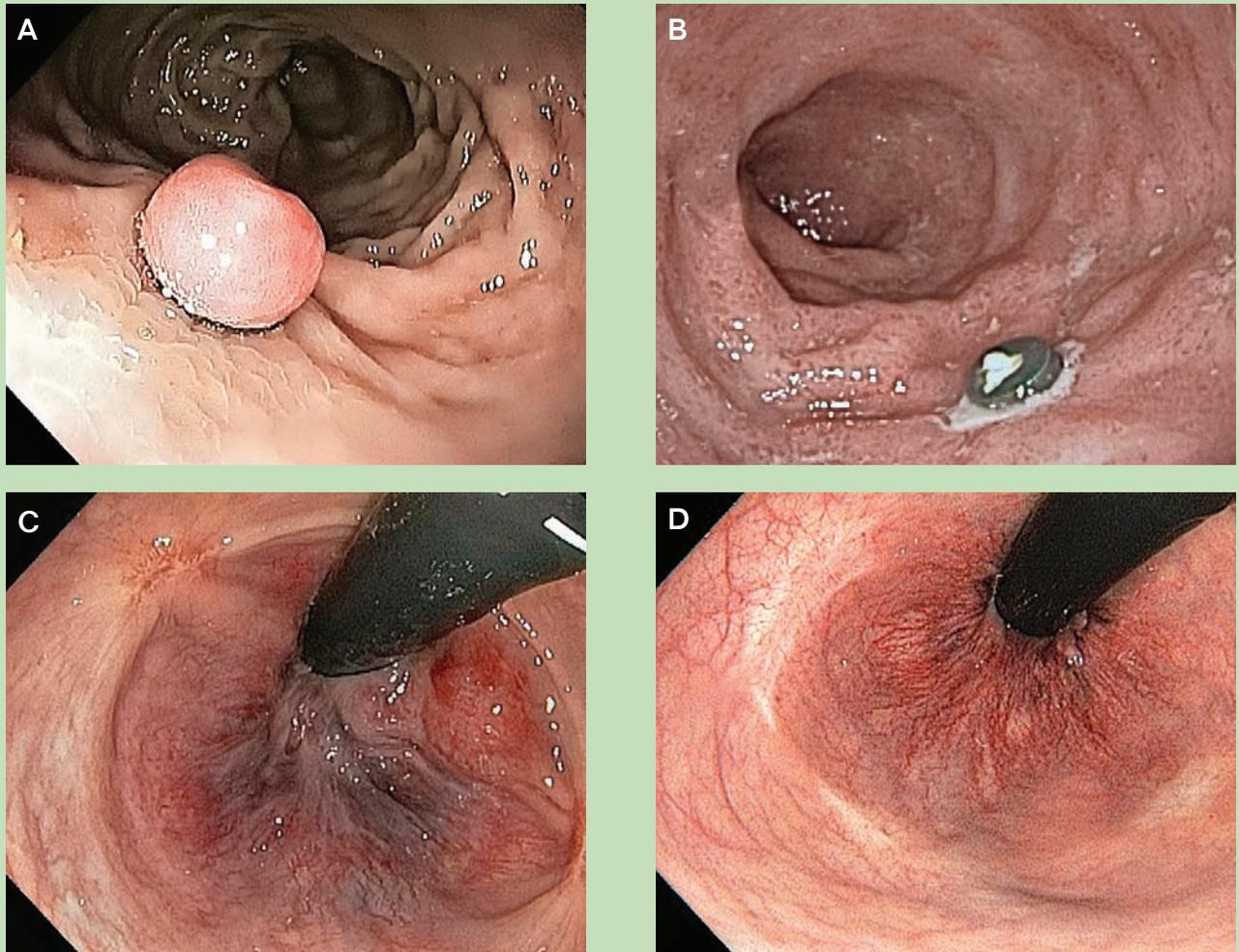
**Table 4**  
**Complications**

Complication	Total, N (%)
Severe discomfort	1 (0.8%)
Post-banding discomfort - resolved after band manually loosened	4 (3.5%)
Thrombosis	1 (0.8%)
Urinary hesitancy	2 (1.8%)
Lightheadedness	1 (0.8%)
Post-band bleeding (clinically significant)	1 (0.8%)
Post-band bleeding (mild, not requiring physician notification)	4 (3.5%)
Infection/sepsis	0 (0%)

tice and included rectal bleeding, pain, burning, itching, prolapse, and fecal soiling. By history, many of the patients had failed multiple courses of medical therapy without control of symptoms; a few had even undergone prior hemorrhoidectomy.

There is general consensus that RBL of hemorrhoids is safe and effective and that surgery should be reserved for those who have either failed less invasive treatments or have advanced internal hemorrhoids. Previous studies have shown that RBL is easy, efficient, and relatively inexpensive for control of rectal bleeding and is superior to bipolar coagulation for treatment of large internal hemorrhoids.<sup>14,29-31</sup> Furthermore, RBL is an alternative to surgical hemorrhoidectomy and has been shown to be highly economical.<sup>13,30,32</sup> The treatment benefits of RBL are sustained in two-thirds of patients at 5 years and more than half at 10 years.<sup>33</sup> The CRH-O'Regan kit offers all the advantages of standard surgical or endoscopic RBL with the added advantages of decreased cost, ease of physician use, patient convenience, and potential for fewer complications.<sup>26,27,34</sup>

This is the first study of the CRH-O'Regan Disposable Hemorrhoid Banding System employed by gastroenterologists in the United States. Ninety-four percent of patients experienced an improvement in symptoms, including rectal bleeding, discomfort, and associated complaints. Furthermore, it is 90% effective in treating patients with the chief complaint of rectal



**Figure 3.** Stages of rubber band ligation with the CRH-O'Regan Disposable Hemorrhoid Banding System. (A) Immediate post-procedure RBL, showing the loosely placed rubber band proximal to the dentate line. (B) One week post-RBL, showing the initial tissue necrosis ablation response with the rubber band still in place. (C) Six weeks post-RBL, showing scarring in the right anterior and right posterior locations with minimal residual internal hemorrhoid tissue. (D) Three months post-RBL, showing complete scarring in the right anterior, right posterior, and left lateral locations with complete ablation of the internal hemorrhoid plexus. Note: images were obtained with endoscopic capture, but the CRH procedure is a nonendoscopic RBL technique.

bleeding alone even after 1 RBL session. This includes patients requiring RBL for treatment of warfarin- or clopidogrel-associated bleeding (provided the medication is held during treatment). Interestingly, fecal soiling also appeared to respond to this treatment approach. The results were sustained at 3-month follow-up with resolution or improvement for rectal bleeding in 83% and for discomfort in 93%. The majority of patients (75%) were highly satisfied with the treatment, and those having undergone previous surgical hemorrhoidectomy preferred the CRH-O'Regan procedure.

The complication rate was low in this study. The most common adverse event of any RBL treatment method is immediate rectal discomfort, and here, it occurred in only 3.5% of cases but tended to resolve after manual loosening of the rubber band. Post-

procedure rectal bleeding was generally minor (3.5%) and did not require medical attention in most instances. The single case of significant rectal bleeding (0.8%) and single case of significant pain (0.8%) mirror previous reports from larger studies of RBL, either surgical or endoscopic. Urinary hesitancy was uncommon and transient (1.8%) and when encountered did not require medical intervention. There were no reports of pelvic sepsis or infectious complications.

On the basis of these results, the overall efficacy of RBL with the CRH-O'Regan Disposable Hemorrhoid Banding System is high with few complications. The results are sustained at 3 months. To the authors' knowledge, randomized studies comparing internal hemorrhoid ligation for standard/endoscopic RBL versus the CRH-O'Regan Disposable Hemorrhoid Banding System have

**Table 5**  
**Symptom Response 3 Months Post Procedure†**

Symptom	Total, n* (%)	3 Months After Hemorrhoid Banding**				
		Resolved (%)	Improved (%)	Resolved/Improved (%)	No Change (%)	Worse (%)
Rectal bleed	12 (75%)	6 (50%)	4 (33%)	10 (83%)	2 (17%)	0 (0%)
Burn/itch	13 (81%)	5 (38%)	7 (54%)	12 (92%)	1 (8%)	0 (0%)
Pain/discomfort	14 (88%)	5 (36%)	8 (57%)	13 (93%)	1 (7%)	0 (0%)
Fecal soiling	8 (50%)	3 (38%)	3 (38%)	6 (75%)	2 (25%)	0 (0%)
Rash/irritation	8 (50%)	5 (63%)	3 (38%)	8 (100%)	0 (0%)	0 (0%)
Hemorrhoid prolapse	11 (69%)	2 (18%)	5 (45%)	7 (64%)	1 (9%)	1 (9%)

\*n = number of patients with symptom at initial presentation out of 16 respondents (all patients had more than 1 symptom)

\*\* all patients had a total of 3 RBL sessions by time of questionnaire

†Patients completing 2 or more RBL sessions at the time of the initial study conclusion (n = 76) were selected for the follow-up portion of the study.

not been reported. This study reported the clinical experience of physicians early in their learning curve and highlights the fact that standard training is sufficient for providing the skills necessary to diagnose, treat, and manage multiple hemorrhoid symptoms in the outpatient setting with few adverse events. The economic benefits of nonendoscopy-based RBL are intriguing, since the need for additional resources, such as nursing staff, anesthesia services, and additional equipment, are unnecessary. Further studies of the CRH-O'Regan Disposable Hemorrhoid Banding System by gastroenterologists are indicated. ■

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