

ABSTRACT

Background: Hemorrhoids are a common disorder and a major cause of rectal bleeding and perianal discomfort. Gastroenterologists often diagnose hemorrhoids, but treatment is generally conservative. Rubber band ligation is an effective treatment for hemorrhoids, but to date, this technique has not been widely employed by gastroenterologists.

Aims: To evaluate the safety and effectiveness of outpatient hemorrhoid ligation by gastroenterologists in the office or endoscopy center.

Methods: The O'Regan disposable bander was employed in the outpatient setting by eleven gastroenterologists at seven locations in a single-specialty practice. This rubber band applicator is a plastic plunger suction device resembling a syringe, which is applied to each hemorrhoid above the dentate line. Suction is induced causing the bulk of the hemorrhoid cushion to enter the nozzle. Releasing the band results in strangulation of the hemorrhoid. Bowel preparation and sedation/anesthesia are not required.

Results: A total of 113 patients underwent hemorrhoid banding from June to November 2008: male (n=62, 55%), female (n=51, 45%), average age 54 (range 19-78). A total of 257 banding events were performed. Procedures were performed in the office (n=56, 50%) and in outpatient endoscopy centers (n=57, 50%). Twenty-five patients (22%) underwent banding concurrent with sedated colonoscopy. Ninety-seven patients (86%) had undergone colonoscopy within the previous year; 32% had at least one polyp, none had colorectal cancer. Eight patients (7%) had prior hemorrhoid surgery. Indications included rectal bleeding (n=62, 55%) or multiple symptoms (n=51, 45%). Four patients (3.5%) had overt fecal seepage. Internal hemorrhoid grading included grade 1 (n=8, 7%), grade 2 (n=84, 74%) and grade 3 (n=21, 19%). Clinically significant external hemorrhoids (n=24, 21%), included acute thrombosed (n=4, 3.5%) and anal fissure (n=9, 8%). Complications included severe immediate discomfort (n=1, 0.8%), thrombosis (n=1, 0.8%), urinary hesitancy (n=2, 1.8%), rectal bleeding (n=1, 0.8%) and lightheadedness (n=1, 0.8%). There were no cases of pelvic sepsis. No patient required time off from work because of the procedure. Initial symptoms were resolved in 94% of patients. Rectal bleeding resolved in 90% after at least one banding event. Three month follow-up revealed a greater than 80% sustained improvement in initial symptoms.

Conclusion: Outpatient treatment of hemorrhoids by gastroenterologists using the O'Regan disposable bander is safe and effective. Initial symptoms are resolved in the majority of patients, and these results are sustained at three months. This is a novel approach to treating common conditions such as rectal bleeding, perianal discomfort and fecal seepage.

METHODS

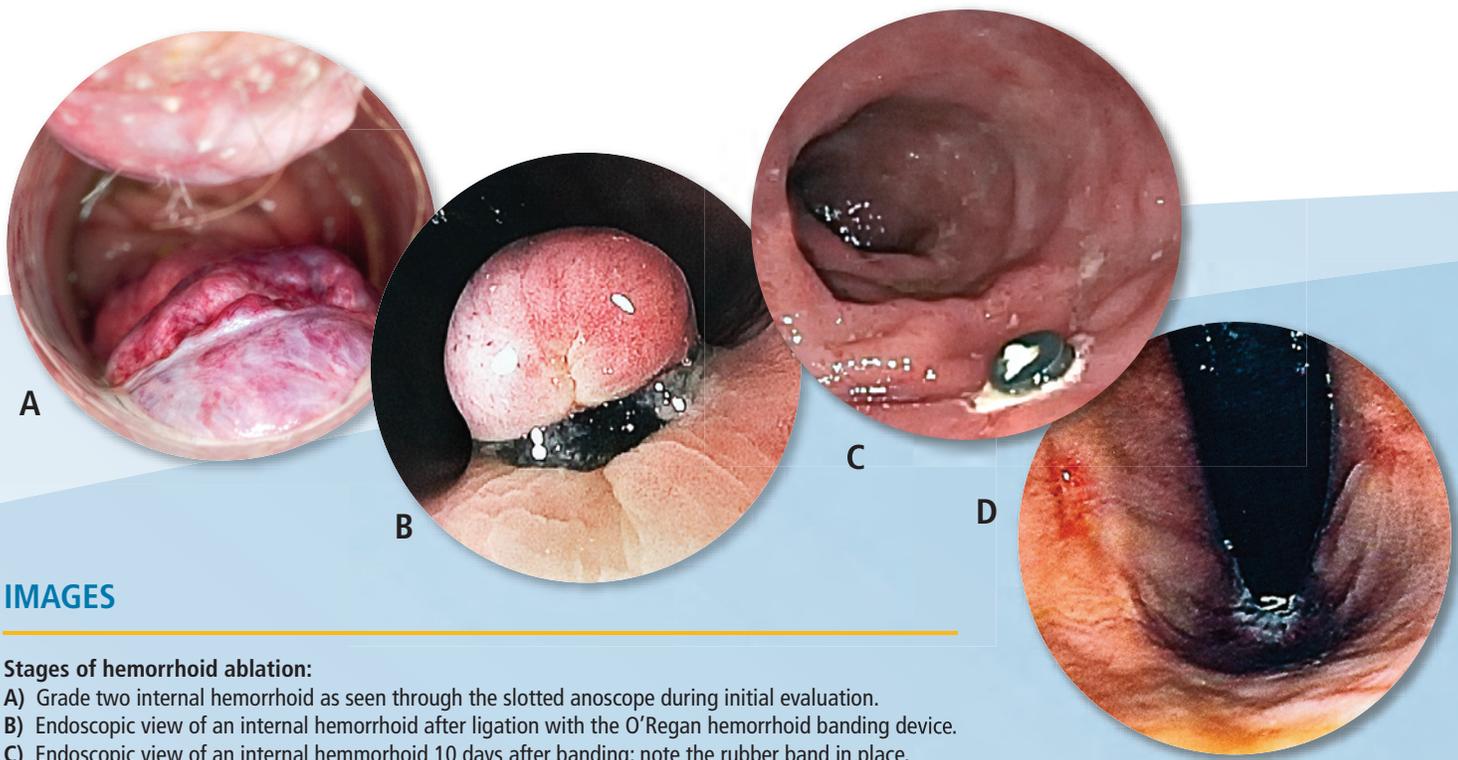
- All physicians received specialized training in the O'Regan banding procedure.
- The O'Regan disposable bander was employed in the outpatient setting (unsedated) or endoscopy center (after or during sedation).
- The rubber band applicator, a plastic plunger suction device resembling a syringe, is applied to each hemorrhoid above the dentate line.
- Suction is induced causing the bulk of the hemorrhoid cushion to enter the nozzle. Releasing the band results in strangulation of the hemorrhoid.
- Bowel cleansing and sedation/anesthesia are not required.

TABLE 1: Patient Characteristics

Study Duration June through November 2008	6 months	Percent
Physicians	11	
Site Locations	7	
Total Banding Events	257	
Total Patients	113	
Male	62	55%
Female	51	45%
Cases Fully Completed	76	67%
Office-Based Procedure	56	50%
Endoscopy-Lab-Based Procedure	57	50%
Banding Performed Same Day as Colonoscopy	25	22%
Colonoscopies Previously Performed	97	86%
Prior Hemorrhoid Surgery	8	7%
Prior Colectomy	5	4%
Fissure	9	8%
External Hemorrhoids - Clinically Significant	24	21%
External Hemorrhoids - Acute Thrombosis	4	3.5%
Internal Hemorrhoids - Grade 1	8	7%
Internal Hemorrhoids - Grade 2	84	74%
Internal Hemorrhoids - Grade 3	21	19%
Internal Hemorrhoids - Grade 4	0	0%

TABLE 2: Presenting Symptoms

Symptom	Total (N)	Percent (%)
Chief Complaint Rectal Bleeding Alone	62	55%
Chief Complaint Multiple Symptoms	51	45%
Constipation	21	19%
Diarrhea	6	5.3%
Rectal Bleeding	70	62%
Rectal Pain	49	43%
Perianal Burning/Itching	28	25%
Rectal Bleed from Coumadin® or Plavix®	3	2.5%
Fecal Seepage	4	3.5%



IMAGES

Stages of hemorrhoid ablation:

- A) Grade two internal hemorrhoid as seen through the slotted anoscope during initial evaluation.
 B) Endoscopic view of an internal hemorrhoid after ligation with the O'Regan hemorrhoid banding device.
 C) Endoscopic view of an internal hemorrhoid 10 days after banding; note the rubber band in place.
 D) Endoscopic view of an internal hemorrhoid 6 weeks after last banding; note the significant atrophy in the right anterior and right posterior hemorrhoid plexus.

TABLE 3: Complications

Complication	Total (N)	Percent (%)
Severe Discomfort	1	0.8%
Post-Band 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%

TABLE 4: Results After Banding

Results	Total (N)	Percent (%)
Presenting Symptom Improved	71 (of 76 cases)	94%
Rectal Bleed Resolved	46 (of 51 cases)	90%
Coumadin®/Plavix®-Associated Bleeding Resolved	3 (of 3 cases)	100%
Fecal Seepage Resolved	4 (of 4 cases)	100%

TABLE 5: Symptom Response 3 Months Post Procedure

Questionnaire data, 16 of 113 patients (15% response).

Symptom	Total * (%)	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 Seepage	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 one symptom)

** all patients had a total of 3 hemorrhoid bands

CONCLUSIONS

- Outpatient treatment of hemorrhoids by gastroenterologists using the O'Regan disposable bander is safe and effective.
- The procedure can be performed in the outpatient setting or following colonoscopy.
- Response rates are high with greater than 90% improvement in rectal bleeding, burning/itching, discomfort and fecal seepage.
- Symptom improvement is sustained at three months.
- This is a novel approach to treating common conditions such as rectal bleeding, perianal discomfort and fecal seepage.
- Patients do not require time off from work after the procedure.
- There is a sustained response in symptom improvement at 3 months.
- Patient satisfaction is high. Overall, 81% were highly satisfied with their treatment and 75% said they would choose this therapy again over a surgical option and/or recommend it to a friend.