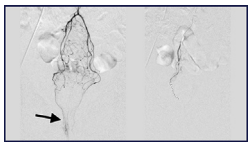
CLINICAL STUDY



Outcomes of Hemorrhoidal Artery Embolization from a Multidisciplinary Outpatient Interventional Center

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ABSTRACT

Purpose: To evaluate the safety and efficacy of outpatient transarterial embolization for symptomatic refractory internal hemorrhoids.

Materials and Methods: Retrospective analysis of 134 patients who underwent hemorrhoidal artery embolization (HAE) for symptomatic internal hemorrhoids between August 2021 and June 2022 (76 men and 58 women) was performed. The mean age was 54.9 years, with a mean Goligher hemorrhoid grade (HG) of 2.1. Branches of the superior rectal artery (SRA) or middle rectal artery supplying the corpus cavernosum recti were embolized with both spherical particles and microcoils. Standard-of-care evaluations were performed at baseline and the 1 month follow-up, which included hemorrhoid-related pain (HRP) (0–10), hemorrhoid symptoms score (HSS) (5–20), quality of life (QoL) (0–4), French bleeding score (FBS) (0–9), and HG (0–4). Clinical success was defined as improvement of symptoms without additional treatment.

Results: Embolization of at least 1 hemorrhoidal artery was achieved in 133 (99%) of the 134 patients. The mean number of SRA branches embolized per patient was 2.9 ± 1.0. Clinical success was seen in 93% (124 of 134) of patients at the 1-month follow-up, with 10 patients requiring repeat embolization. There were significant improvements in all mean outcomes at 1 month: HSS (11–7.8; $P < .01$), HRP (4.1–1.3; $P < .01$), QoL (2.2–0.8; $P < .01$), FBS (4.4–2.2; $P < .01$), and HG (2.3–1.2; $P < .05$). There were no severe adverse events.

Conclusions: HAE is a safe and effective outpatient treatment for refractory symptomatic internal hemorrhoids in the short term.

ABBREVIATIONS

AE = adverse event, CCR = corpus cavernosum recti, DG-HAL = Doppler-guided hemorrhoidal artery ligation, FBS = French bleeding score, HAE = hemorrhoidal artery embolization, HRP = hemorrhoid-related pain, HSS = hemorrhoid symptoms score, MRA = middle rectal artery, QoL = quality of life, RBL = rubber band ligation, SRA = superior rectal artery

Hemorrhoid disease is the fourth leading outpatient gastrointestinal diagnosis, with a prevalence rate of 4.4%, affecting more than 10 million Americans (1). Initial conservative treatments include dietary, lifestyle, and bowel habit modification; topical agents; and phlebotonics. To avoid the morbidity associated with surgical therapies, minimally invasive office-based therapies, such as rubber band ligation (RBL), sclerotherapy, infrared coagulation, radiofrequency ablation, Doppler-guided hemorrhoidal artery ligation (DG-HAL), and cryotherapy, have emerged as effective alternatives (2).

Vidal et al (3) first described hemorrhoidal artery embolization (HAE) as an effective procedure for patients with pain and bleeding secondary to internal hemorrhoids. Since then, there have been multiple publications (4–7) replicating this technique with clinical success and a high degree of safety. The purpose of this retrospective analysis was to report the safety and efficacy of transarterial embolization for symptomatic internal hemorrhoids in a large American cohort in the outpatient setting.

MATERIALS AND METHODS

This retrospective single-center study was approved by the Sterling institutional review board, and all study-related activities followed Health Insurance Portability and

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RESEARCH HIGHLIGHTS

- One hundred thirty-four patients with symptomatic bleeding internal hemorrhoids refractory to prior treatment were treated with HAE in an outpatient setting with mobile C-arm units.
- Significant improvements were noted in all outcomes at 1 month: hemorrhoid symptoms score (11–7.8; $P < .01$), hemorrhoid-related pain (4.1–1.3; $P < .01$), quality of life (2.2–0.8; $P < .01$), French bleeding score (4.4–2.2; $P < .01$), and hemorrhoid grade (2.3–1.2; $P < .05$).
- Clinical success, defined as improvement of hemorrhoid-related symptoms without additional therapy, was seen in 93% of patients at the 1-month follow-up, with 10 patients requiring repeat embolization.

STUDY DETAILS

Study type: Retrospective, observational, descriptive study

Level of evidence: 4 (SIR-D)

Accountability Act (HIPAA) regulations. Between August 2021 and June 2022, a total of 134 consecutive patients who underwent HAE were included in the analysis. The mean age of this group was 54.9 years ± 14.5. Seventy-six men and 58 women were included. Of the 134 patients, 80 (59.7%) were overweight or obese (body mass index, >25 kg/m^2). Table 1 summarizes the baseline demographics and prior treatments, with almost half the patients (66 of 134, 49.3%) reporting prior RBL.

All patients had symptomatic internal hemorrhoids and were evaluated in a multidisciplinary clinic of gastroenterologists and interventional radiologists. The initial assessment involved a detailed history and examination, including a rectal examination, anoscopy, and/or colonoscopy. Patients with symptomatic internal hemorrhoids who failed to respond to conservative therapy and office-based procedures were referred for HAE.

Clinical assessment at baseline and follow up visits included 4 questionnaires: hemorrhoid-related pain (HRP) (range, 0–10), hemorrhoid symptoms score (HSS) (range 5–20) (8), quality of life (QoL) (range 0–10) (8), and French bleeding score (FBS) (range 0–9) (9). The Goligher hemorrhoid grade (I–IV) was also recorded at all visits (10). Because there are limited patient-reported symptoms scores to define success or failure, treatment was considered a "clinical failure" if the patients reported their symptoms as unchanged or worse or if they required additional therapy at any time point. This definition is consistent with a previously reported randomized controlled trial (11) of DG-HAL versus RBL. All patients were asked at all time points whether their symptoms had improved, unchanged, or worsened, and they were observed for the requirement of additional therapy.

Table 1. Population Demographics

Patient data	Values
No. of patients	134
Age (y)	54.9 ± 14.5
Sex	
Male	76
Female	58
BMI	
<25 kg/m^2	54/134 (40.3%)
>25 kg/m^2	80/134 (59.7%)
Symptoms	
<5 y	40/134 (30.0%)
5–10 y	34/134 (25.3%)
10–20 y	35/134 (25.4%)
>20 y	25/134 (18.7%)
Prior treatments	
Sitz bath and softener	89/134 (66.4%)
RBL	66/134 (49.3%)
Hemorrhoidectomy	10/134 (7.40%)
Infrared photocoagulation	5/134 (3.7%)
Baseline scores	
HRP	4.1 ± 2.1
HSS	11.0 ± 2.7
QoL	2.2 ± 0.8
FBS	4.4 ± 2.4
HG	2.3 ± 1.0

Note–Data are presented as n, n/N (%), or mean ± SD. Baseline scores: HRP, 0–10; HSS, 5–20; QoL, 0–4; FBS, 0–9, and HG, 0–4.
BMI = body mass index; FBS = French bleeding score; HG = hemorrhoid grade; HRP = hemorrhoid-related pain; HSS = hemorrhoid symptoms score; QoL = quality of life; RBL = rubber band ligation.

Embolization Procedure

The HAEs were performed by one of 3 interventional radiologists with 1 (A.P.), 3 (R.P.), and 13 (S.B.) years of experience performing embolization. During all procedures, patients received moderate sedation, and procedural imaging was performed with a mobile C-arm (Zenition 70; Philips Healthcare, Best, the Netherlands). Percutaneous arterial access was obtained from the femoral or radial artery, and selective angiography of the inferior mesenteric artery was performed as described in previous reports (12). A 2.4-F microcatheter (Progreat; Terumo, Somerset, New Jersey) was used in conjunction with a 0.016-inch (Asahi Meister; Asahi Intecc, Nagoya, Japan) or 0.018-inch wire (Double Angle GT; Terumo) to catheterize each branch of the superior rectal artery (SRA) and identify the vasculature supplying the corpus cavernosum recti (CCR) arteries (Fig 1). Before embolization, 600-μm spherical particles (Hydropearl; Terumo) were diluted to a ratio of 1:6 (particles-to-fluid ratio). Embolization was then performed distally in each SRA branch supplying the CCR by first administering 0.4 mL of particles, followed by 1 or 2 microcoils (Micronester; Cook Medical, Bloomington, Indiana), until stasis was achieved. (Fig 2). If middle

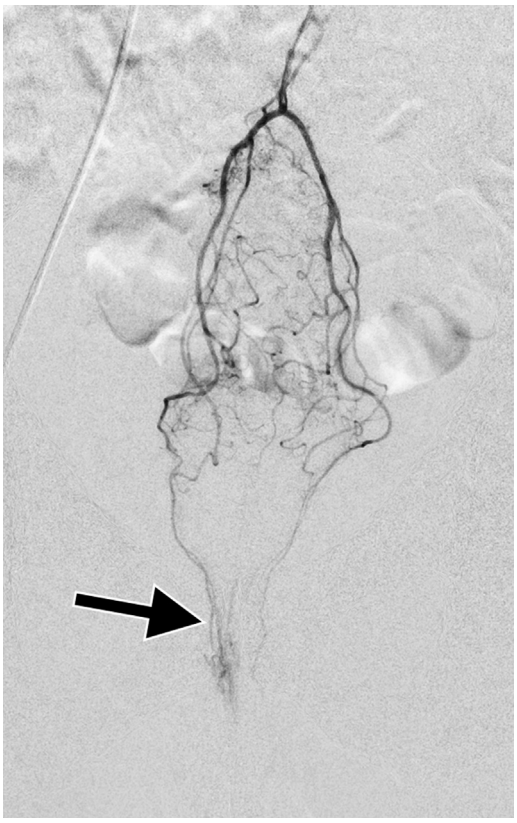

Figure 1. Digital subtraction angiography of the superior rectal artery. The right corpus cavernosum recti (arrow) demonstrated supply to the right hemorrhoidal cushion.

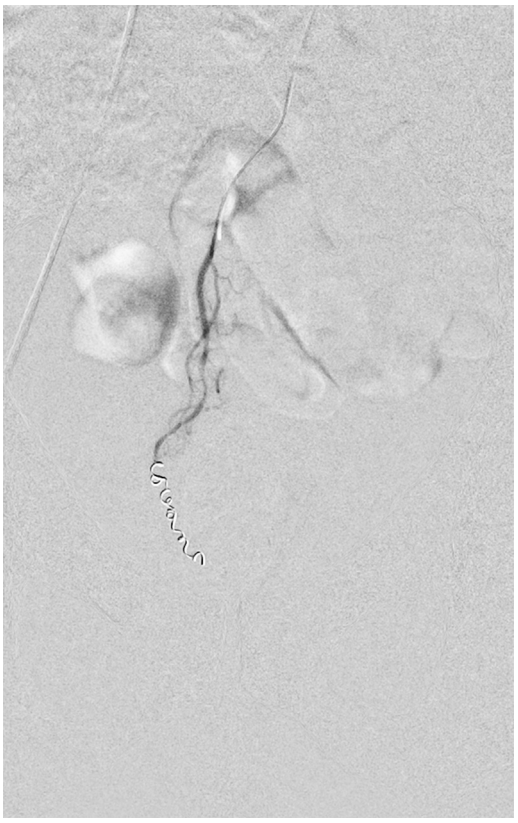

Figure 2. Digital subtraction angiography of the right superior rectal artery illustrated stasis after coil embolization.

rectal artery (MRA) inflow to the CCR was noted during SRA angiography, then the corresponding MRA was selected and embolized with a similar technique (**Fig 3a, b**). Inferior rectal arteries were not embolized to avoid cutaneous ischemia. Closure devices were used for arteriotomy hemostasis.

Patients underwent postprocedural evaluations in person and/or by telephone at 24 hours and clinical follow-up at 1 month. Data on all post-HAE adverse events (AE) were collected. AEs were reported according to the Society of Interventional Radiology (SIR) Adverse Event Classification System (13).

Statistical Analysis

Technical success was defined as embolization of at least 1 branch of the SRA or MRA. Clinical success was defined as improvement in hemorrhoid-related symptoms without additional therapy. This definition has been used in prior hemorrhoid treatment research (3,5–7,14,15). The baseline and 1-month outcomes for HRP, HSS, QoL, FBS, and hemorrhoid grade were compared using a paired 2-tailed *t* test. Data are expressed as mean ± SD, median (interquartile range), or n (%). *P* values of ≤.05 in 2-tailed tests were considered to indicate statistical significance.

RESULTS

Common femoral artery access was used in 129 (95.6%) patients, whereas left radial artery access was used in 5 (4.4 %) patients. The mean procedural time, defined as the time from arterial access to placement of a closure device, was 47.1 minutes ± 18.8. The mean number of SRA and/or MRA branches that were embolized per patient was 2.9 ± 1.0. Technical success was achieved in 133 (99%) of the 134 patients. All 134 patients were discharged the same day 2 hours after the procedure.

The baseline HSS (range, 5–20) was 10.95, with a statistically significant 72% relative reduction in symptoms at 1 month to 7.8 ($P < .01$) (**Table 2**). The baseline HRP (range, 0–10) was 4.06, with a significant reduction at 1 month to 1.3 ($P < .01$). The baseline QoL (range, 0–4) was 2.2, with a significant improvement at 1 month to 0.8 ($P < .01$). The baseline FBS (range, 0–9) was 4.4, with a significant reduction at 1 month to 2.2 ($P < .01$). The baseline Goligher hemorrhoid grade (range, 0–4) was 2.3, with a significant reduction at 1 month to 1.2 ($P < .05$). Clinical success was achieved in 93% (125 of 134) of patients at the 1-month follow-up.

All 9 patients for whom the procedures were considered clinical failures returned for a second procedure in which additional SRA and/or MRA branches supplying the CCR were identified. After secondary embolization, 8

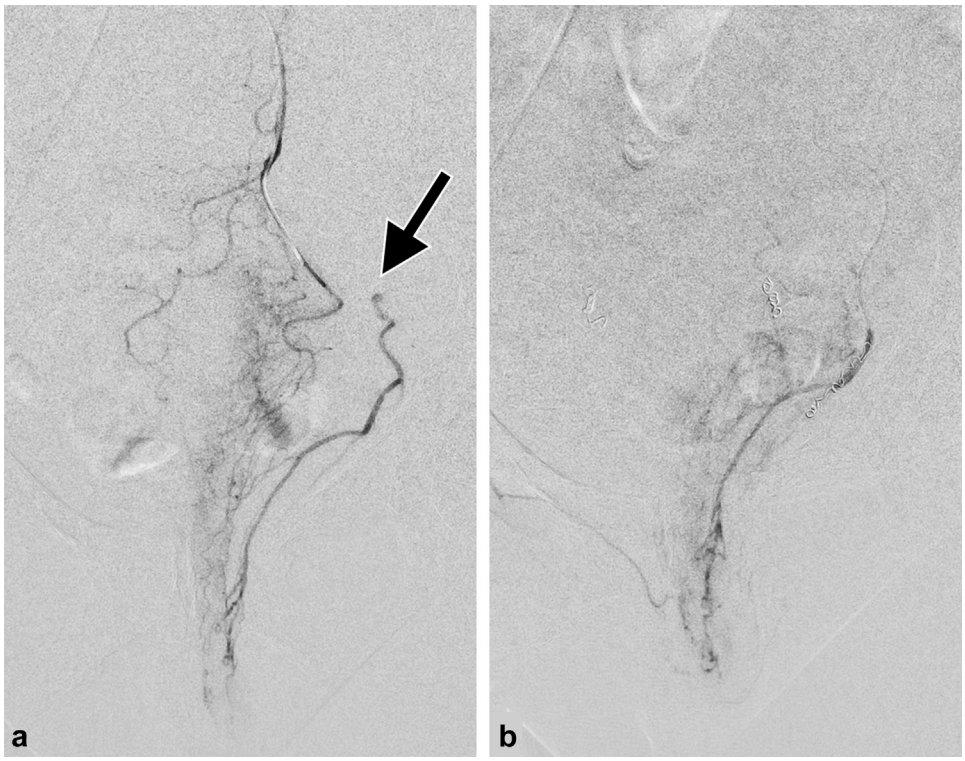

Figure 3. (a) Digital subtraction angiography after catheterization of the left superior rectal artery illustrated retrograde opacification of the left middle rectal artery (arrow) supplying the hemorrhoidal cushion, in addition to the superior rectal artery. **(b)** Selective catheterization of the left middle rectal artery originating from the left internal pudendal artery. One microcoil was placed in 1 of the 2 branches, and a second coil was placed after obtaining this image.

Table 2. Paired *t* Test Analysis

Score	Baseline (N = 134)	1 mo (N = 124)	*P* value
HRP			
Mean	4.1	1.3	<.01
Reduction (%)		68	
HSS			
Mean	11	7.8	<.01
Reduction (%)		29	
QoL			
Mean	2.2	0.8	<.01
Reduction (%)		64	
FBS			
Mean	4.4	2.2	<.01
Reduction (%)		50	
HG			
Mean	2.3	1.1	<.01
Reduction (%)		52	

Note–Outcomes over time at baseline and 1 month. Scores: HRP, 0–10; HSS, 5–20; QoL, 0–4; FBS, 0–9, and HG, 0–4.
FBS = French bleeding score; HG = hemorrhoid grade; HRP = hemorrhoid-related pain; HSS = hemorrhoid symptoms score; QoL = quality of life.

of the 9 patients experienced improvement in their symptoms. Secondary-assisted clinical success was 99% (133 of 134). The 1 patient who failed the secondary embolization subsequently underwent RBL with clinical success.

There were 2 AEs in this study. One patient reported severe perianal pain the day after HAE that resolved with a topical anesthetic agent within a few days (SIR grade 1 mild AE). In a second patient, there was a flow-limiting short-segment dissection that occurred during attempted inferior mesenteric artery catheterization. The procedure was aborted, the patient was prescribed antiplatelet medication, and he returned for repeat angiography several weeks later (SIR grade 2 moderate AE). At this time, angioplasty across the dissected segment was effective in restoring flow, and the hemorrhoid embolization was completed.

DISCUSSION

RBL is the most commonly recommended office-based treatment for hemorrhoids, with an efficacy rate of approximately 70% and almost half of the patients requiring additional banding within a 12-month period (16). In the largest randomized controlled study (11) comparing RBL with DG-HAL, lower recurrence rates were seen with the arterial ligation technique DG-HAL (30%) than with RBL (49%). However, DG-HAL was more costly and resulted in more early postoperative pain than RBL. Both procedures require a transanal approach and can result in periprocedural anal pain (11). HAE is analogous to DG-HAL in that both procedures aim to occlude the arterial inflow supplying the internal hemorrhoids. Therefore, it is likely that because the

mechanisms are similar, HAE may also demonstrate superior efficacy and have lower recurrence rates than those with RBL. Additionally, because the rectal mucosa and wall are not violated in HAE as it is in DG-HAL or RBL, there could be less postoperative pain and necrosis with HAE. In this cohort, there was only 1 patient with perianal pain after HAE.

The technique used for the procedures described in this report involved embolization with a combination of spherical particles and coils. The amount of particulate injected was very small (0.4 mL), and the solution was dilute. The purpose of this was to potentially occlude distal anastomoses before occluding proximally with coils. The size of these particles (600 μm) was chosen to prevent extremely distal embolization and potential rectal ischemia. Although this technique has not been proven clearly superior to coils alone in previous studies, there is some suggestion that it may be (17). In another study using only microspheres with no coils, larger microspheres (900–1200 μm) were favored (18). Given the safety of using 600-μm particles in small amounts, this has become the standard technique used by the operators who treated patients in this study.

This analysis differs from previously published reports on HAE in several ways. Early studies of HAE were focused on elderly patients with contraindications for more invasive treatments or anorectal manipulation (19). In this report, adults of all ages were included. Moreover, patients in the previous studies of HAE were often treated as inpatients, with Zakharchenko et al (20) reporting a mean length of hospitalization of 2.5 days. A recent meta-analysis (14) reported that only 40% of patients are discharged within 24 hours after HAE. In this analysis, all patients were discharged 2 hours after treatment, as is common practice with other elective embolization procedures. Furthermore, other studies (7,17,15) have described the use of cone-beam computed tomography for HAE, whereas, in this cohort, all procedures were performed with only 2-dimensional angiography on a mobile angiography system. The low rate of AEs reported suggests that with an adequate understanding of the involved anatomy, 3-dimensional imaging may not be necessary.

The main strength of this study is the large sample size. However, there are multiple limitations. First, the retrospective study design introduces selection bias and leads to underreporting of complications and a more heterogeneous study population. Second, there was no comparison arm, and the placebo effect of HAE is still unknown. Third, the follow-up period was short. However, multiple prior publications describing the results of HAE have shown that the 1-month outcomes persist through the midterm follow-up as well (7,14,15).

In conclusion, results from this large-cohort retrospective analysis indicate that HAE is a safe and effective outpatient procedure for patients with symptomatic hemorrhoids refractory to conservative management in the short term. Continued follow-up data from this study population will provide additional information about midterm and long-term results.

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