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Rethinking What We Know About Hemorrhoids

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Abstract

Although hemorrhoids are responsible for considerable economic cost and personal suffering, they have received surprisingly little research attention. In the United States, hemorrhoids are the third most common outpatient gastrointestinal diagnosis with nearly 4 million office and emergency department visits annually. The etiology of hemorrhoids is speculative. A low-fiber diet and constipation have historically been thought to increase the risk for hemorrhoids, but not proven. Symptoms commonly attributed to hemorrhoids include bleeding, pain, pruritus, fecal seepage, prolapse and mucus discharge. Research has found that these symptoms were equally reported by patients with and without hemorrhoids. Medical therapies for hemorrhoids have not been formally studied except for fiber where the results have been inconsistent. A number of office based interventions such as rubber band ligation and infrared coagulation are widely used and economically favorable for practitioners. Surgical procedures are effective at eliminating hemorrhoids but may be painful. Given the burden of disease and numerous gaps in our understanding, the time has come for targeted research to understand the cause, symptoms and best treatment for patients with symptomatic hemorrhoids.

Introduction

One in three Americans has hemorrhoids on screening colonoscopy.¹ Office-based treatment of hemorrhoids is a growing and lucrative business practice. Despite being prevalent and increasingly treated, symptomatic hemorrhoids are poorly understood with little evidence to guide treatment. To date, there has been no high quality study of hemorrhoids in the United States. Given the potential for overtreatment, hemorrhoids deserve more attention. The purpose of this perspective is to summarize what is known about hemorrhoids and to outline an agenda for future research.

Hemorrhoids are clusters of vascular tissue, smooth muscle, and connective tissue arranged in three columns along the anal canal.² They are present in healthy individuals as cushions

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that help to maintain continence.³ Although hemorrhoids are normal structures,⁴ the term hemorrhoid has come to refer to a pathologic or symptomatic process.² Internal hemorrhoids are located above the dentate line. [Figure 1]. They are covered by columnar epithelium innervated by visceral nerve fibers that are not associated with pain. Internal hemorrhoids are graded based on the extent of prolapse.

External hemorrhoids lie below the dentate line. They are covered with squamous epithelium and are innervated by somatic nerves that can produce pain. External hemorrhoids are generally asymptomatic unless they thrombose. Thrombosed hemorrhoids are acutely painful.⁵ When external hemorrhoids resolve, skin tags may persist that can become irritated or create problems with hygiene. The remainder of this article will focus on internal hemorrhoids.

The burden of hemorrhoids

There has only been one national survey of hemorrhoids in the US and that survey was conducted in 1989. In a digestive disease supplement to the National Health Interview Survey, participants were asked if a doctor had ever diagnosed them with hemorrhoids.⁶ The survey data were extrapolated to the US population. An estimated 23 million adults (13% US population) were diagnosed with hemorrhoids in the prior year. An estimated 36 million adults (20% US population) were ever diagnosed with hemorrhoids.⁶ Women were more likely to report hemorrhoids than men (24% vs 16%). Overall, 21% (7.7 million) reported having had surgery for their hemorrhoids. The number of US citizens with hemorrhoids in 2018 is not known.

Information on physician and hospital encounters for hemorrhoids can be found in published sources as a measure of burden. In 2004, there were 306,000 hospital discharges for hemorrhoids.¹ Demand for hemorrhoid therapy has been predicted to increase 23% over the next twenty years.⁷ Data from the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey from 2010 show that hemorrhoids were the third most common outpatient gastrointestinal diagnosis with nearly 4 million office and emergency department visits annually.⁸ Visits for hemorrhoids were more frequent than for colon cancer, diverticular disease, irritable bowel syndrome or inflammatory bowel disease.

Unfortunately, there are no recent published national data. Publicly available (but unpublished) data are provided by the Healthcare Cost and Utilization Project (HCUP). HCUP provides access to health statistics and information on hospital inpatient and emergency department utilization. Using the HCUP on-line query system we calculate that there were 25,292 ambulatory surgery center visits in 2013 for hemorrhoids and 203,552 ED visits in 2014 at centers in 29 states (about 2/3 of the US population. These are not national data.

Millions of over-the-counter prescriptions are purchased every year for the treatment of hemorrhoids. For example, worldwide sales of Preparation H, one of many over-the-counter medication, was \$136 million in 2017.⁹ Unfortunately there are no published figures about the aggregate costs for hemorrhoid medications in the US.

The prevalence of hemorrhoids is not known for certain, and prevalence figures vary widely based on the source of information. Self-report data from the National Health Interview Survey from 1983–1986 indicate that 4.4% of the population report a diagnosis of hemorrhoids. ¹⁰ Colonoscopy reports identify hemorrhoids in 38–39% ^{1, 11}

The estimates of health care utilization for hemorrhoids are outdated and there are no contemporary estimates of prevalence or health care costs.

Etiology

The etiology of hemorrhoids is uncertain. Ever since work by Burkitt in the 1970's, hemorrhoids have been considered to be caused by a low-fiber diet and constipation.^{12–14} The current belief is that constipation leads to chronic straining and hard stools resulting in degeneration of the supportive tissue in the anal canal and distal displacement of anal cushions.¹⁵ However, hemorrhoids and constipation have different epidemiologic features including age, sex, ethnicity and socioeconomic status, casting doubt on constipation as a risk factor.¹⁶ A study from the Milwaukee VA Medical Center found that diarrhea rather than constipation was associated with hemorrhoids.¹⁷ In a study using national VA data, the comorbid diseases that were linked with hemorrhoids were all conditions associated with diarrhea (colitis, malabsorption, intestinal bypass, chronic pancreatitis), not constipation.¹⁸

The most commonly demonstrated physiological abnormality is an increased resting anal pressure, but the evidence suggests that this is a secondary phenomenon and not causal.¹⁹ Hemorrhoids have been reported in Ehlers-Danlos syndrome suggesting a possible role for collagen.²⁰ Abnormalities in the quality and quantity of collagen in hemorrhoid cases could lead to reduced mechanical stability that could be etiologic.^{21, 22} Matrix metalloproteinases, which regulate extracellular proteins and tissue remodeling, have been found elevated in patients with hemorrhoids.²³

Hemorrhoids are thought to be more common in developed countries.¹³ In addition to differences in fiber consumption and constipation, the posture during defecation is another factor that distinguishes developed from developing countries. In societies that have adopted western toilets, people sit during defection as opposed to squatting. The belief that squatting is a more natural position for defecation, and one less likely to contribute to constipation and hemorrhoids, has led to the promotion of toilet accessories such as the Squatty Potty[®]. Promotional material for Squatty Potty® states "Hemorrhoids can heal without relapse when the squat posture is adopted for bowel movements." A proposed mechanism is straightening the anorectal angle during squatting. While there is some evidence of straightening of the anorectal angle on squatting, the studies were done in normal volunteers.^{24, 25} The effect of squatting on hemorrhoids is not known. People are likely to spend more time on a seated toilet than a squat toilet. A study of 100 patients presenting for proctoscopically determined hemorrhoids found they spent more time during defecation and reading on the toilet than a selected group of controls. ²⁶ Beliefs about the importance of time on the toilet have led to the recommendation to limit the time spent defecating to no more than 3-5 minutes once a day. 27

Instructions to patients published in JAMA state: "anything that puts pressure on the veins in the lower body can lead to hemorrhoids, including straining during a bowel movement; sitting on the toilet for long periods; constipation or diarrhea; being overweight; pregnancy; and age, which causes tissues to become weaker."²⁸ Overweight and pregnancy were not associated with current hemorrhoids.¹¹ Others have found an association with BMI but not with age or pregnancy.²⁹

Simply stated, commonly believed risk factors for hemorrhoids have not been adequately studied. Additional research is necessary to make evidence-based recommendations to patients.

Symptoms

Symptoms attributed to hemorrhoids include bleeding, pain, pruritus, fecal seepage, prolapse and mucus discharge.³ However, it is not at all clear that hemorrhoids cause these symptoms as most complaints in the anal area are likely to be attributed to hemorrhoids.³⁰ In a large colonoscopy based study there was no significant association between hemorrhoid grade and hemorrhoid symptoms.²⁹ In a 2001 study from Germany, 458 consecutive patients referred with abdominal and/or anal symptoms were interviewed and examined. Of the 63% who believed they had hemorrhoids, only 18% were actually found to have hemorrhoids on proctoscopy, similar to the prevalence in the group who did not believe they had hemorrhoids (13%).³¹ Interestingly, symptoms were similar in both groups. The data suggest that the majority of people who believe they have hemorrhoids are mistaken. The study also supports the idea that symptoms linked to hemorrhoids may have other causes. There is no recent study of hemorrhoid symptoms in the US. Patients with hemorrhoids report bloating, abdominal pain, reduced well-being and disturbed social life which may be symptoms of irritable bowel syndrome.³²

Physical exam

The physical exam should include inspection of the anus at rest and during straining along with a rectal exam to detect anal pathology.³³ Hemorrhoids are graded based on degree of prolapse. Grade I do not prolapse below the dentate line and are visible on anoscopy or colonoscopy. Grade II prolapse below the dentate line but reduce spontaneously. Grade III prolapse and require manual reduction. Grade IV prolapse and remain below the dentate line. They are not reducible.

Treatment

Treatments for hemorrhoids include medical therapies, non-surgical office based treatments and surgery.⁵ First-line therapy typically involves dietary modification with adequate fluid and fiber intake, along with avoiding straining and limiting prolonged time on the toilet.³⁴ The data on fiber has been assessed in a systematic review and meta-analysis that identified seven treatment trials of moderate quality.³⁵ The trials investigated fiber supplements, generally isphaghula husk (not dietary fiber) in symptomatic patients, and found that hemorrhoid symptoms were improved over the short term with fiber supplements. Another

study did not find that a fiber supplement was more effective than placebo in controlling symptoms.³⁶ A case-control study found that hemorrhoid patients and control subjects reported similar stool consistency and rarely admitted to straining.³⁷ Evidence to support lifestyle modifications such as improved anal hygiene, sitz baths, and increased fluid are scarce.³⁸

There are more than 100 hemorrhoid remedies listed on Amazon.com, many with inflated claims of benefit or dubious ingredients. There is no evidence from well-designed studies to support the use of any of the over-the-counter preparations that contain low-dose anesthetics, steroids, keratolytics, protectants or antiseptics.³⁸ There is no literature about how often patients have used home remedies or whether those treatments improve symptoms.

Phlebotonics are a heterogeneous class of drugs of plant origin that are thought to improve venous tone, stabilize capillary permeability and increase lymphatic drainage. There are a number of different phlebotonics that are available in the US as dietary supplements including diosmin, troxerutin, hydroxyethylrutoside and calcium dobesilate. Evidence assembled in a Cochrane review suggests that there are benefits to using phlebotonics for symptomatic hemorrhoids.³⁹ Compared to control, phlebotonics improved bleeding (odds ratio (OR) 0.12, 95% CI 0.06–0.58), pruritus (OR 0.23, 95% CI 0.07–0.79) and discharge or leakage (OR 0.12, 95% CI 0.04–0.42). Adverse events were mild gastrointestinal disturbances. The Cochrane review identified a number of limitations. Not all of the pooled data was statistically significant and the methodological quality of the studies was moderate with risk of bias. Additionally there were wide confidence intervals on some estimates, statistical heterogeneity, and evidence of publication bias.³⁹

Outpatient interventions designed to obliterate hemorrhoids include rubber band ligation, infra-red coagulation, bipolar probe, heater probe, sclerotherapy, and cryotherapy. These forms of therapy are generally reserved for patients with grade I or II hemorrhoids.

Rubber band ligation

Rubber band ligation is considered the most popular nonsurgical intervention.⁴⁰ Placing small bands at the base of an internal hemorrhoid leads to ischemic necrosis, sloughing of tissue and ultimately fibrosis and obliteration of the submucosal tissue.⁴¹ Bands can be placed endoscopically, but are more often placed using single-use banding systems. A meta-analysis of 18 prospective studies from 1995 found that rubber band ligation was more effective than sclerotherapy and infra-red coagulation, but more painful.⁴² Complications occur in less than 10%.²⁷ The cure rate is high with low rates of recurrence.⁴³

The simplicity, speed, and favorable reimbursement for rubber band ligation have made this treatment attractive for the office setting. Reimbursement per minute by Medicare and one commercial payer was estimated to be higher for hemorrhoidal banding than for colonoscopy or endoscopy.⁴⁴ A testimonial for one office rubber band system notes: "The economics of banding are clearly positive for the physician, ASC and the GI practice."⁴⁵ Billboard advertisements for hemorrhoid treatment have appeared in a number of cities.

Infrared coagulation (IRC)

IRC can be delivered using single-use flexible fiberoptic probes that are inserted through an endoscope channel. More commonly, IRC is performed using non-endoscopic systems that consist of a power unit with a tungsten-halogen lamp.⁴⁰ The infrared light probe is placed superior to the hemorrhoidal cushion and briefly activated converting the infrared light to heat. The heat leads to coagulation and necrosis with eventual fibrosis of the submucosa.⁴⁰

There are other techniques to achieve coagulation. A **bipolar probe** uses electrical current that passes between positive and negative electrodes at the tip of a probe to generate heat when current is applied.⁴¹A **heater probe** has a thermocouple inside the probe tip that delivers heat when current is applied to achieve coagulation. In a randomized trial, the heater probe had more pain, fewer failures and shorter time to symptom relief than the bipolar probe.⁴⁶

Sclerotherapy

Injection sclerotherapy is another approach to obliterating hemorrhoids. Sclerosants are injected at the base of the hemorrhoid which leads to an inflammatory response with eventual fibrosis. A variety of sclerosants have been used including ethanolamine, quinine, hypertonic saline, and 5% phenol in oil.⁴⁰ Sometimes serious side effects including impotence, urinary retention and abscess have been reported.⁵ The long term effects may not be superior than a bulk laxative.⁴⁷

Cryotherapy

Cryotherapy uses liquid nitrogen to cool hemorrhoids resulting in necrosis. A common side effect is profuse serous discharge.⁴⁸ This technique has been largely abandoned. A non-destructive form of cryotherapy uses cold therapy to produce vasoconstriction, analgesia and muscle relaxation and purportedly improves quality of life in patients with hemorrhoids.⁴⁹ This therapy is designed for self-administration and does not require a physician visit.

Surgery is reserved for patients who are refractory to or unable to tolerate office procedures, who have large external hemorrhoids, or combined internal and external hemorrhoids with prolapse.³⁴ There are hundreds of reports in the surgical literature reporting on or comparing various surgical approaches for prolapsing hemorrhoids including: open, closed, submucosal, stapled, transanal de-arterialization, laser, radiofrequency, and bipolar scissors. A systematic review and network meta-analysis of 98 trials with 7,827 participants and 11 surgical treatments suggested that open, closed and radiofrequency hemorrhoidectomies had more complications than transanal hemorrhoidal dearterialization, LigaSureTM and Harmonic® hemorrhoidectomies. Closed approaches had more postoperative complications but fewer recurrences.⁵⁰ Information was provided about postoperative bleeding, emergency reoperation, duration of surgery, operative blood loss, length of hospital say, pain, and recurrent symptoms. Followup time in many surgical series was limited. ⁵¹

It is difficult to compare therapies or to perform meta-analyses. Studies were done in different decades and geographic areas, in patients with a range of symptoms and hemorrhoid grades. Followup after interventions was variable. Randomization was

incompletely described or absent. Negative studies may not have been published. Surgical results depend on the experience and skill of the operator. Outcomes include both subjective (pain, pruritus) and objective (complication, bleeding) measures. A core outcome set is an agreed minimum set of outcomes to be measured and reported in clinical trials.²⁷ An international study has been launched to develop a core outcome set for hemorrhoids.⁵²

Who should treat hemorrhoids?

Noninvasive treatments for hemorrhoids can be applied by primary care doctors, gastroenterologists or surgeons. For low grade hemorrhoids (grade I and II) the outcomes are likely to be similar. Surgeons might be better equipped to handle advanced grade hemorrhoids because they have more options available. Guidelines from the American College of Gastroenterology suggest surgical referral for patients who are refractory to or cannot tolerate office procedures, who have large external tags, or who have large grade three and four internal hemorrhoids.³³

Training for hemorrhoid therapy resembles training for other procedures - the apprentice system. The distributors of office-based treatment systems can arrange preceptorships where a surgeon visits a practice to teach the technique. In contrast to endoscopic procedures, there is no threshold number of procedures for trainees to demonstrate competence.

What is the best treatment for hemorrhoids?

Given the numerous options for hemorrhoid treatment, the obvious question is which option is best. Rubber band ligation has a lower rate of recurrence than competitors.^{53–55} Guidelines from the American College of Gastroenterology³³ and the American Society of Colon and Rectal Surgeons³⁴ conclude that rubber band ligation is the most effective office-based therapy. Surgery has the lowest rate of recurrence, but has more pain and complications.⁴² There are a number of shortcomings to the literature, however, making it challenging to determine the best treatment. Table 1.

Lack of head to head comparison

There are a number of treatment options available (banding, photocoagulation, sclerotherapy, cryotherapy, surgery) but there have been no head-to-head comparisons between each therapy. The strongest research design would be a randomized trial with each option as a treatment arm. That would be impossible. Alternatively, one could use the technique of network meta-analysis. Network meta-analysis relies on a number of assumptions the most important of which is that the trials being meta-analyzed are of good quality. There has been a network meta-analysis of 98 surgical studies.⁵⁰ There has been no network analysis comparing nonsurgical treatments.

Different grades of haemorrhoids

Published studies have included hemorrhoids of different grades. A technique that works well for grade I hemorrhoids may work less well for grade III hemorrhoids. 56

Different techniques for the same intervention

The same treatment can be delivered in different ways, with variable outcomes and success rates. Rubber bands can be applied using an endoscope or a hand held device. For non-endoscopic banding, the hemorrhoids can be grasped with suction or forceps.⁵⁷ Adverse events, e.g. pain, vary by technique.

Treatment success and complications are operator- and experience-dependent

Different operators bring different levels of skill and experience that will influence their success rate and complications.

Poor quality trials, e.g. lack of blinding, randomization, complete follow-up

The quality of published trials is generally low. In a Cochrane review, only 3 of the 26 trials were of sufficient quality to include in a systematic review, and each was judged to be of low quality.⁵⁸

Outcomes not measured in standard fashion

Outcomes for hemorrhoid treatment include symptoms and recurrence. Symptoms such as pain can be measured using visual analogue scales or a dichotomous measure. The outcomes can be measured at variable intervals, e.g. immediate, 24 hours, 72 hours, one year. Long term follow-up beyond 3 years is uncommon.⁴⁷ Recurrence can be defined as symptomatic recurrence or recurrence at anoscopy.

Absence of patient reported outcomes for range of symptoms

There are currently no accepted patient reported outcomes for hemorrhoids although some are in development.⁵² There is also a range of symptoms that patients care about – bleeding, itching, urgency, perianal leakage. Past studies have generally been limited to pain and bleeding.

Inadequate sample size

Prior studies may have been too small to detect a clinically important difference in treatments.

Short term and variable follow-up

In order to fully capture complications and outcomes, studies must be of long enough duration. The variable follow-up between studies makes it hard to draw comparisons or to conduct a meta-analysis.

Variable duration of symptoms prior to treatment

Patients may suffer for years before they seek treatment for hemorrhoids. Those patient may be more stoic than patients who present following the first episode of bleeding. The duration of symptoms prior to presentation could influence the outcomes of trials.

Perspective

Patients might prefer the treatment with the lowest complication and recurrence rate. Payers might prefer the cheapest therapy. Providers value low capital costs and efficiency.

Research agenda

Considering the large number of individuals affected by hemorrhoids and the number of available approaches to therapy, there have been surprisingly few rigorous studies. There are a number potentially important areas for future research.²⁹

Basic epidemiology

We lack even a rudimentary understanding of the distribution of hemorrhoids in the population. Inviting random members of the population for anoscopy is not likely to be popular or feasible. With the high penetration of colonoscopy in the over-50 population, however, we could determine prevalence in the screening population.⁵⁹ A colonoscopy-based study would provide a platform to obtain detailed information on diet (especially fiber), physical activity, straining, toileting habits and bowel movements.

Hemorrhoid symptoms

Patients and many health care providers attribute most symptoms in the anal area to hemorrhoids. However, many patients who thought that they had hemorrhoids had none identified by proctoscopy.³¹ Symptoms were similar in patients with and without hemorrhoids.³¹ It would be helpful to have additional information on symptoms in a group of patients carefully examined for the presence of hemorrhoids.

Patient reported outcomes

Patient reported outcomes (PROs) measure the effect of disease from the patient perspective. ⁶⁰ PROs concern symptoms, quality of life and functional status. In order to adequately study an intervention in a disease with a considerable symptom burden (like hemorrhoids), validated PROs are needed prior to a trial or cohort study. Such an instrument would then help in the conduct of comparative effectiveness studies. There are no published PROs for hemorrhoids or anorectal symptoms (beyond a handful of questions on fecal incontinence). Citius Pharmaceuticals, in an August 2016 press release, announced that they had developed a PRO to guide designing endpoints in a planned phase 2b study for hemorrhoids.⁵² No results have been published.

Comparative effectiveness

It is difficult to determine the best therapy for any given patient because there are few headto-head comparisons of individual therapies. Treatment decisions ought to be driven by formal effectiveness studies or by cost-effectiveness studies.

Economic costs and impact

There are specific ICD-9 (455) and ICD-10 (K64.9) codes for hemorrhoids. These codes could be used with large administrative, Medicare or VA databases to examine visits, costs,

comorbid illnesses and treatments. There are Common Procedure Terminology (CPT) codes for various interventions that are used to treat hemorrhoids. These codes could be used to estimate regional variation, time trends and costs.

Conclusions

Hemorrhoids are common, affecting between 20 and 50% of the population and resulting in four million office and emergency visits annually. Despite the extensive burden of disease, symptomatic hemorrhoids are either treated with over-the-counter remedies of uncertain benefit or with more invasive interventions that can be expensive, inconvenient and occasionally associated with complications. Common beliefs about risk factors such as constipation or straining are contradicted by research studies.¹¹ There is insufficient evidence about hemorrhoid risk factors, impact and therapy.

Enormous amounts of time and money are being spent by patients with hemorrhoid symptoms. We live in an era where patients and physicians value the application of evidence in making decisions about healthcare. Given the numerous gaps in our understanding of hemorrhoids, the time has come for research designed to expand the evidence base.

Abbreviations

OR	odds ratio
IRC	infrared coagulation
PRO	patient reported outcome
СРТ	Common Procedure Terminology

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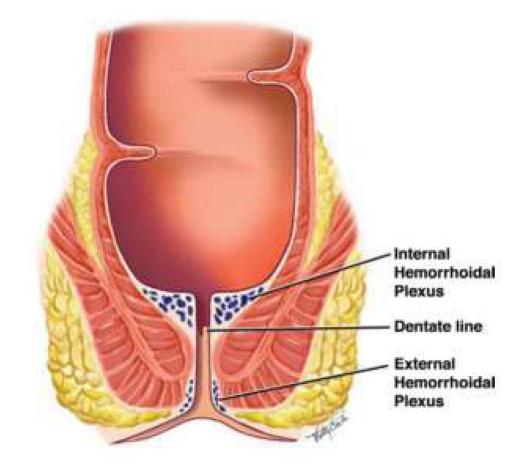


Figure 1. Anorectum with internal and external hemorrhoids.

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Table 1.

Why we don't know the best treatment for hemorrhoids

- Poor quality trials, e.g. lack of blinding, randomization, complete follow-up
- Lack of head to head comparison for each treatment (RBL, IRC, cryotherapy, surgery)
- Treatment success is operator- and experience-dependent
- Outcomes not measured in standard fashion
- Absence of patient reported outcomes for range of symptoms (itch, urgency, perianal leakage)
- Inadequate sample size
- Short term and variable follow-up
- Different techniques for the same intervention (forceps, suction for banding)
- Variable duration of symptoms prior to treatment
- Different grades of hemorrhoids (I, II, III)