

Efficacy and safety of bipolar energy-based therapy for hemorrhoids: a systematic review

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Abstract

Background Hemorrhoids arise from dilated vessels in the submucosal layer of the anorectal canal. Hemorrhoids are responsible for 4 million office and emergency visits annually in the US. Hemorrhoidal energy therapy (HET) is a novel nonsurgical, bipolar energy-based instrument for treating hemorrhoids. It has multiple benefits, such as requiring only a single session for resolution of symptoms, and minimizing heat-related collateral damage. However, there are limited data regarding the effectiveness and adverse events of HET. We performed the first systematic review to evaluate the efficacy and safety of HET in the treatment of internal hemorrhoids.

Methods A comprehensive search was performed from major databases to identify studies that investigated HET to treat hemorrhoids. The primary outcomes were technical success and clinical success. The secondary outcomes were total adverse events and individual adverse events, such as postprocedural bleeding and incontinence.

Results Eight studies with 512 patients were included in the meta-analysis. The average age was 55.6 years, and the majority of patients were female. Most patients presented with grade I and grade II hemorrhoids. The HET demonstrated technical and clinical success rates of 100% and 86.1%, respectively. All adverse events were determined to be mild, according to the ASGE lexicon, except for 1 case of perianal hematoma that required hospitalization.

Conclusion Our study demonstrates that HET is an effective and safe treatment for grade I and II internal hemorrhoids.

Keywords Bipolar energy-based therapy, hemorrhoidal energy therapy, internal hemorrhoids

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Introduction

Hemorrhoids are composed of dilated vessels and connective tissue in the submucosa of the anorectal canal. They are classified as internal and external, based on their presence above or below the dentate line. The most common causes of symptomatic hemorrhoids are constipation, aging, low-fiber diet, obesity, a sedentary lifestyle and pregnancy [1,2]. An estimated 4.4% of the population experience hemorrhoids each year in the United States [3]. Common symptoms of hemorrhoids include pain, bleeding, tissue prolapse or anal pruritus [4].

For low-grade internal hemorrhoids, conservative care is sufficient, via increased fluid and dietary fiber intake, stool softeners and sitz baths [5]. In patients with grade I to III internal hemorrhoids who do not respond to conservative care, additional measures, such as rubber band ligation (RBL), may be considered [6]. Surgical approaches are indicated for grade IV hemorrhoids and patients with a considerable degree of prolapse [7]. Complications such as abscess formation,

infection, urinary retention and anal strictures may arise from failed hemorrhoid therapy [8-10].

Hemorrhoidal energy therapy (HET) is a non-surgical, office-based procedure that involves the application of bipolar energy through a modified anoscope with constant tissue compression and temperature guidance for the treatment of internal hemorrhoids. With this bipolar energy-based instrument, the current passes between 2 electrodes and consequently affects only the tissue that is grasped between the tips of the device [11]. This approach minimizes heat-related collateral damage to the surrounding tissues and blood vessels, which could lead to fibrosis and thrombosis in the treated areas [12]. HET has been associated with less redundant tissue, and a lower risk of prolapse and recurrence [13].

However, there are limited data regarding the success and adverse events of HET in treating hemorrhoids. This is the first systematic review to assess the efficacy and safety of bipolar energy-based therapy in the treatment of hemorrhoids.

Materials and methods

Literature search strategy

The authors performed a thorough literature search from several databases (PubMed/Medline, Embase, CINAHL, Cochrane, Web of Science, and Google Scholar) using various keywords in the search engine, including “internal”, “external”, “mixed”, “hemorrhoid”, “bipolar therapy”, “hemorrhoid energy therapy (HET)”, “HET bipolar system”, “grade I hemorrhoid”, “grade II hemorrhoid”, “grade III hemorrhoid”, “grade IV hemorrhoid”, and “nonsurgical” in the search engine, from inception to July 18th, 2024. The initial literature search was independently performed by 2 authors (KMT and RV), who reviewed the title and abstract of each study. Any discrepancies in the article section were reviewed by other 2 authors (BSD and DA). Full texts of the remaining articles were retrieved for additional review. The “References” sections of these articles were also examined to identify additional articles that met the inclusion criteria. The literature search and study selection were conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA) criteria (Supplementary Fig. 1).

Eligibility criteria

Specific inclusion criteria were used in selecting articles. These included: 1) the use of bipolar energy therapy for the management of hemorrhoids; 2) patients 18 years of age or older; 3) a sample size of at least 10 patients; 4) patient demographic descriptions; and 5) articles and abstracts published in the English language. To avoid data duplication, included studies were also reviewed to ensure that the timeframe and location of the studies did not overlap. Exclusion criteria included: 1) case

reports, case series, and surveys; 2) studies that did not use bipolar energy therapy; 3) studies that used surgical techniques; 4) studies without pertinent patient data; 5) studies with non-human subjects; 6) subjects with participants <18 years old; 7) studies with sample size < 10; and 8) studies published in languages other than English.

Data extraction and quality assessment

Data pertinent to outcomes of interest were extracted into a standardized form. The Newcastle–Ottawa Scale (NOS) was used to assess the methodological quality of the included cohort studies, with each study labeled as “low”, “moderate” or “high” quality [14]. For randomized controlled trials (RCTs), the Revised Cochrane risk-of-bias tool (RoB) was used: each individual domain was used to rate each RCT as high, low, or some concern [15]. Quality appraisal for each study was performed independently by multiple authors (KMT, KR, RV, DA). The NOS and RoB assessments are illustrated in Supplementary Tables 1 and 2, respectively.

Study outcomes and definitions

The primary endpoint of our systematic review was technical success and clinical success. Technical success was defined as successful administration of HET to the desired area, while clinical success consisted of complete resolution of symptoms directly related to hemorrhoids, such as rectal bleeding, pain and/or prolapse after HET at a 3-month follow up.

The secondary outcomes assessed were total adverse effects, as well as individual adverse effects such as bleeding and pain. Adverse effects were further stratified by severity, based on the American Society for Gastrointestinal Endoscopy (ASGE) lexicon [16].

Results

Our initial systematic search yielded 35 articles from Medline/PubMed, 100 from Embase, 12 from CINAHL, 17 from Cochrane, 36 from Web of Science, and 242 from Google Scholar, totaling 442 records. We removed 57 duplicate records from these, and 256 were marked as ineligible according to the inclusion criteria. Of the 40 remaining records, an additional 32 were excluded after screening and assessment for eligibility of the complete drafts.

Study selection and characteristics of included studies

Eight studies, including a total of 512 patients, were included in the final analysis [13,17-23]. These studies included 3 prospective cohort studies [17,20,22], 4 retrospective cohort

studies [13,19,21,23], and 1 randomized controlled trial [18]. All studies were single-center studies and were performed in the United States, except for the study by Filgate *et al* [18], which was conducted in New Zealand. In 7 of the studies, 54.22% (n=270) of patients were female and 45.78% (n=228) were male; Filgate *et al* [18] did not report the patients' sex (n=14). The mean patient age was 55.6 years (Table 1).

The most common presenting symptom was bleeding, which was reported in 460 (89.8%) cases, followed by pain, seen in 88 (17.2%) patients. Of the total cases, 48.6% (n=249) were classified as grade I hemorrhoids, while 42.4% (n=217) were grade II, and 3.5% (n=18) were grade III. In 28 (5.5%) cases, the grade of the hemorrhoids was not reported.

Quality assessment

As determined by the NOS, 2 cohort studies were of low quality [19,20] and 5 cohort studies were determined to be of moderate quality [13,17,21,22,23] (Supplementary Table 1). The study by Filgate *et al* [18] was determined by the Cochrane RoB tool to have a low risk of bias (Supplementary Table 2).

Outcomes

The outcomes of our analysis showed 100% technical success (412/412), while the clinical success rate was 86.1% (404/469). Most studies reported only the number of patients with complete resolution; only Kothari [17] reported the number of patients with a partial response (Table 2). Malik *et al* [19] did not report technical success or failure information, but 96 of 100 patients achieved clinical success in their cohort. Regarding clinical failures, 11/100 patients in the Peng *et al* [23] cohort, 4/100 in the study by Malik *et al* [19], and 8/27 in the Studniarek *et al* [22] group showed persistent symptoms without improvement; no such data were available from the other 5 studies. The recurrence rates were reported in 2 studies (Kantsevov *et al* [13] and Patel *et al* [21]), with an average of 19.3% (Table 2).

Adverse effects

Adverse events were reported in 71 (13.9%) patients, with bleeding seen in 43 patients (8.4%). Of those, 70 (98.6%) were

Table 1 Demographic data of included studies

Author/year [ref.]	Type of study	Mean age (years)	Total patients	Males	Females	Number of patients with respective hemorrhoid grades			
						Grade I	Grade II	Grade III	Grade IV
Kantsevov 2013 [13]	Retrospective cohort	64.3	23	10	13	11	12	0	0
Kothari 2021 [17]*	Prospective cohort	50.3	73	34	39	36	26	1	0
Filgate 2019 [18]	Randomized controlled trial	NR	14	NR	NR	NR	NR	NR	NR
Malik 2019 [19]	Retrospective cohort	59	100	39	61	37	63	0	0
Maharaja 2016 [20]*	Prospective cohort	51	60	32	28	25	24	7	0
Patel 2016 [21]	Retrospective cohort	58	107	52	55	73	34	0	0
Studniarek 2021 [22]	Prospective cohort	53	35	20	15	4	31	0	0
Peng 2022 [23]	Retrospective cohort	55	100	41	59	63	27	10	0

*Kothari *et al* [17] and Maharaja *et al* [20] did not report the grades of hemorrhoids in 10 and 4 patients, respectively
NR, not reported

Table 2 Technical and clinical outcomes

Author/Year [ref.]	Technical success	Clinical success	Partial resolution (improvement of symptoms)	Therapy failure (persistence of symptoms without improvement)	Recurrence (after initial clinical success)
Kothari 2021 [17]	73/73	44/71	20/71	NR	NR
Studniarek 2021 [22]	35/35	19/27	NR	8/27	NR
Kantsevov 2013 [13]	23/23	23/23	NR	NR	0/23
Patel 2016 [21]	107/107	96/107	NR	NR	23/96
Filgate 2019 [18]	14/14	NR	NR	NR	NR
Maharaja 2016 [20]	60/60	37/41	NR	NR	NR
Malik 2019 [19]	NR	96/100	NR	4/100	NR
Peng 2022 [23]	100/100	89/100	NR	11/100	NR

NR, not reported

classified as mild adverse events based on the ASGE lexicon. In the study by Filgate *et al* [18], 1 patient had a severe adverse event, involving perianal thrombosis, which necessitated readmission and required 21 days of work. No deaths were reported during these procedures.

Discussion

Our study showed that the technical and clinical success rates with HET were 100% and 86.1%, respectively. The recurrence rate, as documented in 2 studies, was 19.3% [13,21]. According to Ding *et al*, the recurrence rates after RBL and infrared coagulation therapies were lower, at 12.3% and 17.3%, respectively [24]. In addition, a recent study performed by Jin *et al* reported a recurrence rate of 11.4% in 35 patients with grade II hemorrhoids who underwent RBL [25].

The rate for persistence of symptoms after HET was 10.1% in our study and 11% following RBL [26]. In the Hubble trial, the recurrence rate was 30% for hemorrhoidal artery ligations and 49% for RBL [27]. However, for a better understanding of the differences between these 3 different treatment modalities, further research is needed in order to compare patients with similar grades of hemorrhoids and comorbidities.

The overall adverse event rate after HET in our study was 13.9%. Per the ASGE lexicon, 98.6% of adverse events were mild. One patient suffered a severe adverse event, perianal thrombosis, that required readmission [18]. The most common adverse event was postprocedural bleeding, occurring in 8.4% of the patients. All reported bleeding events resolved spontaneously within 5 days [19,21,23].

The rate of postprocedural bleeding was lower with HET compared to RBL (12.5%) and coagulation (19.8%) [24]. Pain after HET was reported by 8.14% of the patients who responded to conservative treatment [19,21,23]. Filgate *et al* found lower pain scores with HET than with RBL, while Ding *et al* reported pain in 45.2% and 24.4% of patients after RBL and coagulation, respectively [18,24]. Kumar *et al* found pain and bleeding in 22% and 18% of RBL patients, respectively [26]. The lower pain incidence with HET is thought to be because it does not irritate the rectal mucosa: instead, it coagulates the hemorrhoids' feeder vessels [18].

HET is associated with clinical success in a single session [13]. It uses a lower temperature probe (50-55°C), reducing the risk of thermal injury compared to infrared coagulation, which uses a probe that reaches 149°C [12,13,17].

While HET may be effective in 1 session, multiple sessions may be necessary for patients with more severe symptoms, extensive hemorrhoids, or complex medical histories that require follow-up visits, making it inconvenient [17,28]. The use of HET for the treatment of Grade IV hemorrhoids has not been studied. The other side-effects include pain, bleeding, infection, or recurrence of hemorrhoids.

We acknowledge limitations in our analysis, mainly due to the nature of systematic reviews. We could not control for confounding variables, since the data were gathered from published studies. As HET is a novel treatment, the available

literature is limited. Only 2 studies [13,21], reported recurrence rates, preventing accurate conclusions, and only 1 study [23], provided clinical success rates based on hemorrhoid grades.

To conclude, our systematic review analyzed 8 studies, including 512 patients who underwent HET treatment. Our findings demonstrated technical and clinical efficacy, as well as the safety of HET in treating Grade I and II internal hemorrhoids.

Summary Box

What is already known:

- Hemorrhoids affect approximately 4.4% of the population in the United States; common symptoms include pain, rectal bleeding and tissue prolapse
- Patients with internal hemorrhoids who do not respond to conservative care may require surgical therapy, and complications such as abscess formation or anal strictures may arise
- Hemorrhoidal energy therapy (HET) is a novel, non-surgical bipolar energy-based instrument that typically requires only a single session and minimizes heat-related collateral damage to the surrounding tissues and blood vessels

What the new findings are:

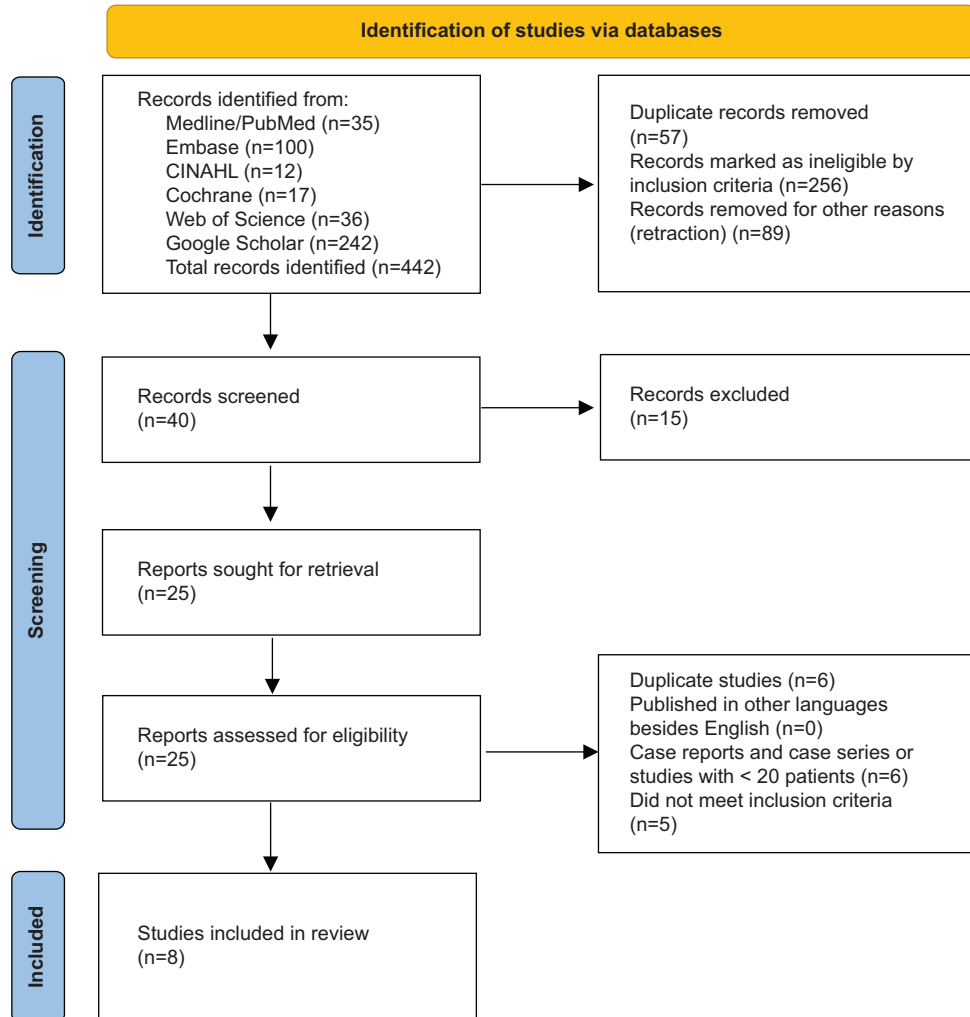
- HET demonstrated high technical success (100%) and clinical efficacy (86.1%) in treating grade I and II hemorrhoids, with clinical efficacy defined as complete resolution of symptoms directly related to hemorrhoids at 3-month follow up
- Although 13.9% of patients reported adverse events, 98.6% of those adverse events were mild and were managed conservatively, without requiring a visit to an emergency room or admission to a hospital

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Supplementary material



Supplementary Figure 1 Preferred reporting items for the systematic review and meta-analysis (PRISMA)

Supplementary Table 1 Quality assessment of the cohort studies with the Newcastle–Ottawa Scale

Author/year [ref.]	Newcastle-Ottawa Scale		
	Selection	Comparability	Outcome
Kantsevov 2013 [13]	*	*	**
Kothari 2021 [17]	**	*	**
Malik 2019 [19]	**		**
Maharaja 2016 [20]	**		**
Patel 2016 [21]	**	*	**
Studniarek 2021 [22]	**	*	**
Peng 2022 [23]	**	*	**

Supplementary Table 2 Quality assessment of the randomized controlled trial with Cochrane Risk of Bias tool

Author/year [ref.]	Randomization process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	Overall
Filgate 2019 [18]	+	+	+	+	+	+

+ represents low risk of bias