



Transanal Hemorrhoidal Dearterialization

Effective: March 1, 2024

Next Review: December 2024

Last Review: January 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Transanal hemorrhoidal dearterialization (THD), also known as transanal hemorrhoidal artery ligation (HAL), is a minimally invasive procedure utilizing Doppler guidance to interrupt the blood supply by ligation of the hemorrhoidal arteries in the lower rectum.

MEDICAL POLICY CRITERIA

Transanal hemorrhoidal dearterialization is considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Hemorrhoids are amongst the most common anorectal complaints. It has been estimated that approximately 10-20% of individuals with symptomatic hemorrhoids require surgery. Hemorrhoidal symptoms vary and may include painless rectal bleeding, tissue protrusion, and

drainage of mucous. The traditional therapeutic strategies to treat hemorrhoids include surgical as well as nonsurgical treatment. Nonsurgical interventions may include ensuring adequate fluid intake, increasing dietary fiber, avoiding straining with defecation, rectal suppositories, and Sitz baths. Other conservative interventions such as infrared photocoagulation, injection sclerotherapy, and rubber band ligation have been used to fixate the hemorrhoid's cushion. If conservative interventions are ineffective, surgical treatments may be used.

The conventional hemorrhoidectomy is accepted by most surgeons as the gold standard for the treatment of hemorrhoids that have not responded to conservative management. Milligan-Morgan's and Ferguson's procedures are the most commonly used surgical techniques. Although these techniques tend to yield excellent results and have low complication rates, they are usually associated with significant postoperative pain. In order to reduce pain, alternative procedures, including but not limited to transanal hemorrhoidal dearterialization, are being explored. Transanal hemorrhoidal dearterialization is a minimally invasive procedure utilizing Doppler guidance to interrupt the blood supply by ligation of the hemorrhoidal arteries in the lower rectum.

EVIDENCE SUMMARY

Systematic Reviews

Aibuedefe (2021) published the results of a systematic review (SR) with meta-analysis of data from randomized controlled trials (RCTs) of surgical treatment of hemorrhoidal disease.^[1] A total of 26 studies (N=3137) of 14 surgical treatments including open hemorrhoidectomy, closed hemorrhoidectomy, transanal hemorrhoidal dearterialization (THD), harmonic scalpel, LigaSure, Starion, suture ligation, semi-closed, bipolar diathermy, partial stapled, stapled, Doppler-guided hemorrhoidal artery ligation, infrared photocoagulation, and laser, for grade 3 or grade 4 hemorrhoids were included. Random effects modeling found conventional hemorrhoidectomies (closed and open) were associated with the worst postoperative pain outcomes; more patients experienced mild, moderate, and severe pain with these approaches compared to laser (odds ratio [OR] 0.34, confidence interval [CI] 0.01-6.51), infrared photocoagulation (OR 0.38, CI 0.02-5.61), and stapling (OR 0.48, CI 0.19-1.25). Cumulative ranking of postoperative pain outcomes found THD to be among the lowest ranked treatment, only ranking higher than open and closed hemorrhoidectomy. Recurrence was lower in patients treated with Starion (OR 0.01, CI 0.00-0.46), harmonic scalpel (OR 0.00, CI 0.00-0.49), and suture ligation (OR 0.01, CI 0.00-0.36) compared to infrared photocoagulation and THD.

A SR published by Xu compared clinical outcomes of stapled hemorrhoidectomy (SH) and THD across nine RCTs (1077 patients, 535 SH and 542 THD).^[2] The included studies were of moderate quality with minimal publication bias noted. When reported, the follow-up time of the studies ranged from 3 to 60 months. Meta-analysis found the bleeding rate (major bleeding incidence) to be higher in the SH patient group than in the THD group (OR 1.79, 95% CI 1.10-2.93, Z=2.33, p=0.02). No significant difference residual prolapse or urinary retention was found between groups. Significant heterogeneity among trials required the use of random-effects models for operative time, post-operative pain, hospital time, and return-to-work time. No significant difference between groups was found in these outcomes. Fixed effects models of recurrence rate revealed a significantly lower rate in the SH group than in the THD group (OR 0.55, 95% CI 0.34-0.90, Z=2.38, p=0.02), while no difference in satisfaction rate or reoperation rate between groups was found. Noted limitations of the studies include

heterogeneity in patient population, perioperative protocols, and follow-up times. Larger RCTs are needed to overcome these limitations. Emile published a meta-analysis that compared THD to stapled hemorrhoidopexy in 554 patients for the treatment of internal hemorrhoids.^[3] The primary outcomes the authors evaluated were postoperative pain, persistence or reoccurrence of hemorrhoids, complications, and duration to return to work. THD showed higher rates of persistence or reoccurrence of hemorrhoids compared to the patients who were treated with stapled hemorrhoidopexy. There were no significant differences between groups on the other outcomes of interest.

Du (2019) published a network meta-analysis that compared surgical procedures for individuals with grade III and IV hemorrhoids.^[4] There were 21 studies included involving nine surgical procedures: THD, SH, Starion hemorrhoidectomy, harmonic or ultrasonic scalpel hemorrhoidectomy, Ligasure device hemorrhoidectomy, mucopexy, closed or Ferguson hemorrhoidectomy, open or Milligan-Morgan hemorrhoidectomy, and semi-closed or Park's hemorrhoidectomy. The overall quality of the studies was determined to be moderate. THD and SH were found to be associated with more complications and higher recurrence rates than other procedure types. The authors concluded that further high-quality studies with larger sample sizes and longer follow-up periods are needed.

Song (2018) published a SR consisting of eight RCTs with 977 patients comparing THD to SH.^[5] The primary outcomes were total complications and recurrence and there were no significant differences between groups in these outcomes. The THD group had significantly higher bleeding complications compared to the staple hemorrhoidectomy group and the total short-term recurrence rates were higher in the THD group. The authors also noted that postoperative pain, operative time, hospital time, time to return to work, and reoperation rates were similar between groups. Additional high-quality evidence addressing cost-effectiveness, satisfaction rate, and recurrence rate over long-term follow up are needed.

Simillis (2015) published a systemic review comparing 98 trials consisting of 7827 subjects and 11 surgical treatments for grade III and IV hemorrhoids.^[6] Treatments included open, closed, and radiofrequency hemorrhoidectomies, sub-mucosal hemorrhoidectomy, SH, THD, Ligasure and Harmonic procedures, laser hemorrhoidectomy, Starion hemorrhoidectomy, and bipolar scissors hemorrhoidectomy. Although some benefits were noted as a result of THD, it also had a higher recurrence rate than open, closed, Ligasure, laser, and radiofrequency hemorrhoidectomies. The authors concluded that further higher quality RCTs are needed to compare surgical treatment for hemorrhoids.

Randomized Controlled Trials

An open-label RCT published by Rorvik (2020) compared the patient-reported symptoms following minimal open hemorrhoidectomy versus THD for the treatment of grade II to IV hemorrhoids.^[7] Patients were randomly assigned to either the open (n=48) or TRD (n=50) group and outcomes were assessed at one year post-procedure. Median (range) symptom score was not different between groups (3 [0-17] open hemorrhoidectomy and 5 [0-17] TED, median difference = -1.0 [95% CI, -3.0 to 0.0]; p=0.15). Residual hemorrhoidal prolapse (p=0.008) and treatment for recurrence (p=0.013) was more frequently reported after TED compared to open hemorrhoidectomy. Patient satisfaction was higher after minimal open hemorrhoidectomy (p=0.049). No group-wise differences were found in the impact on health-related quality of life, average or peak postoperative pain, recovery, or adverse events.

Trenti (2019) published a multi-center RCT comparing transanal hemorrhoidal dearterialization (THD) with mucopexy to vessel-sealing device hemorrhoidectomy for grade III or IV hemorrhoids.^[8] A total of 80 patients were randomized into two groups with the primary outcome being mean postoperative number of days in which patients were taking analgesics. Additional outcomes included postoperative pain, 30-day morbidity, patient satisfaction, Vaizey score, hemorrhoid symptoms score, return to work, and quality of life. More patients were taking analgesics in the vessel-sealing device hemorrhoidectomy group compared to the THD group. The mean postoperative pain for groups did not differ significantly and the mean operative time was higher for the THD procedure. The other secondary outcomes including patient satisfaction, complication rate, return to work, and quality of life did not differ between the two groups. Trenti (2022) published a follow-up study to evaluate long-term outcomes from the multi-center RCT.^[9] Two years after treatment no significant differences between the THD group and the group that had vessel-sealing device hemorrhoidectomy were found in symptom recurrence ($p=0.080$), need for additional procedures ($p=0.106$), chronic open wound occurrences ($p=0.116$), fecal incontinence ($p=0.657$), or patient satisfaction ($p=0.483$).

Nonrandomized Studies

Sobrado (2020) published the results of a prospective, single-arm study of 200 patients with symptomatic prolapsed hemorrhoids (Grades II, III and IV) treated with THD.^[10] Mean follow-up of 43 months (range 29 - 57 months). Postoperative complications included transient tenesmus (26.5%), pain (14%) and fecal impaction (2.5%). Recurrence rates were 0, 2.4% and 17.1% for prolapse and 2.9%, 4% and 9.8% for bleeding in grades II, III and IV, respectively. After 12 weeks of follow-up, 85% of patients were either very satisfied or satisfied; 8.5% were dissatisfied. This study is limited by the lack of controlled comparison to standard of care.

A prospective, observational study published by Cuong (2020) evaluated anorectal function outcomes in 40 patients with grade III ($n=32$) or grade IV ($n=8$) hemorrhoids treated with THD.^[11] The mean length of the anal sphincter was unchanged pre-to-post THD (3.64 ± 0.40 cm prior to treatment vs. 3.66 ± 0.48 cm following treatment; $p=0.57$). Significant differences in treatment-related changes were detected for all anorectal manometric measurements other than maximum squeezing pressure ($p<0.05$). No occurrence of anal stenosis or fecal incontinence following THD were reported. This study is limited by its small sample size, lack of a comparison group, lack of long-term outcomes.

Popov (2019) published a prospective study comparing THD to conventional hemorrhoidectomy which included 287 patients.^[12] The primary outcomes reported on were pain scores, patient satisfaction, and duration of hospital stay. Postoperative pain scores were significantly lower in the THD group after one week but there were no differences after one month follow up. There were no significant differences in patient satisfaction after 18 months follow up.

Trenti (2017) published a single-center longitudinal comparative study of patients who underwent THD or conventional hemorrhoidectomy for grade III or IV hemorrhoids.^[13] A total of 83 patients were included in the study and the 30-day postoperative surgical morbidity rates were 26.5% for THD and 8.8% for conventional hemorrhoidectomy. No significant differences were identified between groups for persistence of bleeding, prolapse, or need for annual reduction in prolapse and pain. The results of this study are limited by the nonrandomized design and small sample size.

The American Society of Colon and Rectal Surgeons^[14]

The 2018 American Society of Colon and Rectal Surgeons guidelines for the management of hemorrhoids provide a Class IA recommendation for hemorrhoidectomy for grades III and IV hemorrhoids. The guidelines list transanal hemorrhoidal dearterialization as a potential treatment option but do not support its efficacy with high quality evidence.

American College of Gastroenterology^[15]

The 2021 American College of Gastroenterology clinical guideline for the management of benign anorectal disorders states Doppler-guided procedures such as hemorrhoidal artery ligations have similar outcomes to hemorrhoidectomy for symptomatic grade 3 hemorrhoids (conditional recommendation; quality of evidence: very low).

SUMMARY

There is a lack of long-term, high-quality evidence supporting the efficacy of transanal hemorrhoidal dearterialization compared to standard of care treatments options. More research is needed to show that transanal hemorrhoidal dearterialization is a safe and effective treatment option. Therefore, transanal hemorrhoidal dearterialization is considered investigational for all indications, including but not limited to the treatment of internal hemorrhoids.

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CODES

Codes	Number	Description
CPT	46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed
HCPCS	None	

Date of Origin: December 2018