

Subject: Doppler-Guided Transanal Hemorrhoidal Dearterialization**Document #:** SURG.00141**Status:** Reviewed**Publish Date:** 06/28/2023**Last Review Date:** 05/11/2023

Description/Scope

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

Position Statement

Investigational and Not Medically Necessary:

Doppler-guided transanal hemorrhoidal dearterialization is considered **investigational and not medically necessary**.

Rationale

THD interrupts blood circulation by ligating the hemorrhoidal artery in the lower rectum. The artery is located using Doppler equipment. Interrupting blood circulation to the hemorrhoidal artery contributes to shrinkage of the hemorrhoidal cushion and subsequently improves symptoms. Because the ligation is conducted above the dentate line, the pain-sensitive anoderm is preserved.

Giordano and colleagues (2009) conducted a systematic review to assess the current evidence on dearterialization, ascertain the safety and efficacy of the technique, define its indications, and pinpoint its possible advantages and limitations. The primary outcome measures were hemorrhoidal recurrences and postoperative pain. A total of 17 articles (involving 1996 individuals) were analyzed. Overall, the quality of the studies was low. Most of the subjects experienced a 1-day hospital stay and returned to normal activities within a range of 2-3 days. Approximately 18.5% of the subjects experienced postoperative pain. A total of 3 participants experienced significant postoperative hemorrhages. No other major complications were reported. The overall recurrence rate was 9.0% for prolapse, 4.7% for pain at defecation, and 7.8% for bleeding. At 1 year or more follow-up, the recurrence rate was 10.8% for prolapse, 9.7% for bleeding, and 8.7% for pain at defecation. When the results were examined based on hemorrhoidal grade, the recurrence rate was higher for grade IV hemorrhoids (range, 11.1-59.3%). The authors concluded that THD appears to be a potential treatment option for grade II and III hemorrhoids. However, the authors also noted clinical trials with longer follow-up comparing THD to other established procedures used to treat hemorrhoids are needed to determine the possible role of the procedure.

Festen and colleagues (2010) reported results from a randomized trial comparing the procedure for prolapse and hemorrhoids (PPH) and THD in the treatment of grade III and IV hemorrhoids. Subjects with grade III or IV hemorrhoids were randomly assigned to undergo PPH (n=18 individuals) or THD (n=23 individuals). The participants were evaluated postoperatively after 1 week, 3 weeks, and 6 weeks. Resolved symptoms postoperatively at 6 weeks was the primary endpoint. Pain (measured by a visual analogue scale [VAS] after 1 day, 1 week, and 3 weeks), and complications were the secondary endpoints. At 6 weeks postoperatively, the success rates were 83% in the PPH group versus 78% in the THD group. The VAS scores were significantly lower after 1 day and 1 week in the THD group, but were similar after 3 weeks. A total of 12% of the participants after PPH and 4% after THD required an urgent readmission to treat an acute bleeding. Overall, the rate of complications did not differ significantly between the two groups. The authors concluded for grade III and IV hemorrhoids, both PPH and THD are safe interventions with good short-term results and acceptable complication rates. Because the complication rates and short-term results were similar, but less postoperative pain when compared to PPH, THD might be preferred by some. However, the authors noted these preliminary outcomes needed to be validated in larger randomized studies with longer follow-up in order to identify selection criteria.

Ratto and colleagues (2010) performed a retrospective analysis of 170 individuals treated at a single institution with THD from July 2005 through October 2008. Individuals with grade I hemorrhoids were excluded. For individuals with grade II hemorrhoids, enrollment criteria included presentation with significant bleeding and/or prolapse and failure of medical therapy. The procedure involved dearterialization of six arteries in all of the participants, with major mucopexy in 56 subjects (32.9%). General/spinal anesthesia was utilized to treat the first consecutive 11 subjects (6.4%) while sedation with propofol with remifentanyl analgesia support was used for the remaining 159 (93.6%) subjects. Participants were evaluated at 2 weeks, 1 and 3 months, and once a year after THD. The mean follow-up period was 11.5 ± 12 (range, 1-41) months. A total of 13 (7.6%) of the participants had grade II hemorrhoidal disease, 141 (82.7%) had grade III disease and 16 (9.6%) had grade IV disease. Surgical intervention for postoperative bleeding was required for 2 cases (1.2%) and hemorrhoidal thrombosis occurred in 4 of the cases (2.3%). There were no cases of chronic pain or fecal incontinence reported. Continued constipation was reported in 49 (28.8%) participants. A total of 50 participants (29.5%) reported hemorrhoidal prolapse at follow-up, but prolapse was confirmed in only 18 (10.5%) and the prolapse was mild. During the follow-up period, 7 subjects (4.1%) required surgery for recurrence of hemorrhoidal disease. The authors concluded that THD appears to be an effective minimally invasive option to treat hemorrhoids and can be carried out in a day-surgery setting. The authors also noted additional controlled trials comparing THD with other procedures are needed to demonstrate the efficacy of the procedure and to define appropriate selection criteria.

In 2011, Gupta reported data from a double-blind, randomized controlled trial involving 48 consecutive individuals requiring surgery for grade III hemorrhoids. The study endpoints were to determine if Doppler-assisted ligation of the hemorrhoid artery prior to mucopexy (DSL) was more advantageous to mucopexy alone (SL). Outcomes were measured by duration of the operation, postoperative morbidity, resolution of hemorrhoidal symptoms, and medium-term recurrence rates. Surgery duration was significantly longer with DSL compared to SL (31 minutes [min] vs. 9 min.; $p < 0.003$). The postoperative pain score was significantly higher for the DSL cohort compared to the SL group (4.4 vs. 2.2; $p < 0.002$) on the visual analogue scale, and the DSL group used higher doses of analgesics for longer periods of time ($p < 0.01$). Between the cohorts, there was no difference in the complication rate. At 1-year follow-up, there was no statistically significant difference in the rate of recurrence in either group. The authors concluded that Doppler-assisted ligation of the hemorrhoid artery did not add extra benefit compared to SL. Limitations of the study included single-center location and medium duration of follow-up. Additional randomized controlled studies in multiple centers with long-term follow-up were recommended.

Elmer and colleagues (2013) compared the early and midterm results of THD with anopexy to open hemorrhoidectomy. A total of 40 participants with grade II to grade III hemorrhoids were randomized to THD with anopexy (group A, n=20) or open hemorrhoidectomy

(group B, n=20). Participants kept a diary during the first 2 postoperative weeks to record pain scores. A self-reported symptom questionnaire was completed, and a clinical examination was performed preoperatively, after 2 to 4 months, and after 1 year. Postoperative pain was the primary outcome measure. During the first week, group A had less postoperative peak pain compared to group B ($p<0.05$); however, there was no difference between the groups for overall pain ($p=0.010$). Analgesic use was not significantly different between the groups. After 1 year, there were significant improvements ($p<0.05$) in pain, bleeding, and the need for manual reduction of the hemorrhoids in both groups. The authors acknowledged that limitations of the study included the small sample size, short follow-up period, the absence of blinding, and use of an unvalidated but frequently utilized questionnaire.

In 2015, Ratto and colleagues described an observational Italian multicenter study consisting of 803 subjects with Grade II ($n=137$), III ($n=548$), and IV ($n=118$) symptomatic hemorrhoids treated using THD. Those with prolapse also underwent rectal mucopexy. Disease was assessed by a specifically designed symptom questionnaire and scoring system. Treatment failure was defined as the presence of recurrent bleeding or recurrent hemorrhoidal prolapse needing medical or surgical therapy. The overall success rate after a follow-up of less than 12 months was 90.7%. Analysis of subjects with a follow-up of 12 months or greater demonstrated a lower success rate of 86.9%. The authors reported that it is necessary to be very careful to avoid complications as this could affect the long-term outcome. Limitations included the observational nature of the study.

A large systemic review and meta-analysis performed by Simillis and colleagues (2015) compared 98 trials consisting of 7827 subjects and 11 surgical treatments for grade III and IV hemorrhoids. Treatments included open, closed, and radiofrequency hemorrhoidectomies, sub-mucosal hemorrhoidectomy, stapled hemorrhoidectomy, 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, and "importantly, the highest probability of being the worst treatment for recurrence of hemorrhoids ($P=0.785$).\" The authors concluded that further higher quality randomized controlled trials are needed to compare surgical treatment for hemorrhoids.

Ratto and colleagues (2017) conducted a single-center, retrospective study to evaluate the long-term outcomes of THD. A total of 1000 subjects were given a clinical evaluation and symptoms-based questionnaire before and after the THD procedure. Hemorrhoidal dearterialization and mucopexy were done in 931 subjects, and only dearterialization was done in 69 subjects. Concomitant procedures were done for 243 subjects including: skin tag removal (145), internal lateral sphincterotomy (103), and fistulotomy (10). After THD, 31 subjects (3.1%) required pain medication for more than 5 days, 23 subjects (2.3%) had urinary retention treated with catheterization, 8 subjects (0.8%) had thrombosed external hemorrhoids, and 14 subjects (1.4%) had acute bleeding that required surgical or endoscopic hemostasis. Long-term follow-up ranged from 6-124 months (mean 44 ± 29 ; median 36). The subjects reported a significant mean reduction on the symptom-based questionnaire (baseline 13.8 ± 2.3 versus last follow-up 1.1 ± 0.8 ; $p<0.0001$). A total of 95 subjects (9.5%) had recurrence: bleeding (12; 1.2%), prolapse (46; 4.6%), and bleeding and prolapse (37; 3.7%). A total of 26 subjects (2.6%) needed to reduce prolapsing piles every day, 14 (1.4%) had daily pain, and 12 (1.2%) had a decrease in quality of life. A total of 70 subjects had a redo or second surgery (32 THD, 23 Milligan-Morgan hemorrhoidectomy, 11 Ferguson hemorrhoidectomy, 2 stapled hemorrhoidectomy, and 2 stapled transanal rectal resection). Including the second/redo surgeries, 95.7% of subjects were free of hemorrhoids at final follow-up. There were no reports of defecatory urgency, fecal incontinence, or chronic pain. Limitations of the study included the retrospective design, single-center location, and variable techniques and equipment. The authors concluded that THD "seems a valid therapeutic option for primary hemorrhoidal disease and selected recurrences."

In a single-center, longitudinal, comparative study, Trenti and colleagues (2017) compared THD to conventional hemorrhoidectomy for long-term postoperative morbidity and recurrence. A total of 83 individuals underwent either distal Doppler-guided THD with low ligation of the hemorrhoidal artery and mucopexy ($n=49$) or conventional hemorrhoidectomy ($n=34$; Milligan and Morgan [$n=13$] or Ferguson technique [$n=21$]) for grade III and IV hemorrhoids. Postoperative morbidity was reviewed using medical reports and the prospective database of the colorectal unit. Baseline and recurrent hemorrhoid symptoms were evaluated before surgery and at 1 year postsurgery using a 5-parameter questionnaire (bleeding, prolapse, manual reduction, discomfort or pain, and impact on quality of life). Fecal incontinence was measured preoperatively and at a minimum of 1 year postoperatively using the Vaizey score. A total of 5 individuals were lost to follow-up, 4 in the THD group and 1 in the conventional group. Mean follow-up was 1.9 years for the THD group and 2.89 years for the conventional group. The 30-day postoperative surgical morbidity was 26.5% in the THD group and 8.82% in the conventional group ($p=0.085$). There were no significant differences between the groups for bleeding, prolapse, need for manual reduction in prolapse, pain, and quality of life. Further surgery was needed for 1 individual in the THD group and 2 individuals in the conventional group. In the THD group, 2 individuals reported persistent postsurgical urgency of defecation at the last follow-up. In the conventional group, 2 individuals reported fecal incontinence. The researchers found that the THD procedure was not inferior to conventional surgery for postoperative complications and long-term symptom relief. The study was limited by a small sample at a single-center, and the researchers noted the need to validate the findings in large, multicenter randomized trials.

Du and colleagues (2019) published a network meta-analysis that compared surgical procedures for individuals with grade III and IV hemorrhoids. They included 21 studies ($n=2799$) that involved 9 surgical procedures: THD, stapled hemorrhoidectomy, 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 stapled hemorrhoidectomy were found to be associated with more complications and higher recurrence rates. They noted that further high-quality studies with larger sample sizes and longer follow-up periods are needed.

In 2019, Popov and colleagues reported the results of a prospective study that compared Doppler-guided THD and conventional hemorrhoidectomy for early and long-term postoperative results. The study included a total of 287 subjects who underwent conventional hemorrhoidectomy (167 cases) or Doppler-guided THD with mucopexy (120 cases) between November 2010 and December 2015. The researchers obtained information on hemorrhoidal stage, demographic data, presenting symptoms, complications, duration of hospital stay, postoperative pain, participants' satisfaction and follow-up. No significant difference was observed between the studied groups based on gender, mean age, preoperative prolapse, pain and pruritus, hemorrhoidal stage and postoperative complications. Preoperative bleeding occurred more frequently in the THD group ($p=0.002$). The results of the mean visual analog scale (VAS) pain scores in conventional hemorrhoidectomy and THD groups on days 1, 2 and 7 were 7.01 vs 5.03 , 5.07 vs 2.98 , 2.39 vs 0.57 ($p=0.000$). There was no significant difference in VAS on day 30 and participants' satisfaction at the 18th month. The mean postoperative follow-up period was 46 ± 16 months (median 45 months, range 18–78 months). During this period, 5 participants (2.99%) in the conventional hemorrhoidectomy group needed surgery for recurrence. In the THD cohort, 3 subjects (2.5%), all with 4th-degree hemorrhoids, underwent additional procedures ($p=0.802$). The most frequent reasons for re-operation were recurrent bleeding in the conventional hemorrhoidectomy cohort (3 of 5 individuals), and prolapse in the THD group (2 of 3 individuals). The authors concluded that Doppler-guided THD appeared to be a safe and efficient option for treatment of hemorrhoids, and resulted in lower postoperative pain and similar long-term outcomes compared to conventional hemorrhoidectomy. For advanced grades of hemorrhoids, Doppler-guided THD could be a valuable alternative, but there is a need for patient selection. The authors acknowledged that limitations of the study include a limited number of participants, the lack of randomization, variation in the grade of hemorrhoids included and validated questionnaires were not used.

Rorvik and colleagues (2020) conducted an open-label randomized controlled trial that compared the patient-reported symptoms following minimal open hemorrhoidectomy versus THD. The study included a total of 102 participants with grade II to IV symptomatic hemorrhoids (Goligher's classification) who were randomly allocated (in a 1:1 ratio) to either the open (n=48) or TRD (n=50) group. Study participants were assessed in the outpatient clinic at inclusion and at planned 3- and 12-month postoperative follow-up. Secondary outcome measures included health-related quality of life, postoperative pain, patient satisfaction, recovery, recurrence, adverse events and hospital costs. With regards to the primary outcome, the authors reported no difference in symptom score 1 year postoperatively. In completed cases, the HDSS (median [range]) post MOH was 3 (0–17) and following THD 5 (0–17; Mdiff = -1.0 (95% confidence interval [CI], -3.0 to 0.0; p=0.15). The authors reported residual hemorrhoidal prolapse (p=0.008) and treatment for recurrence (p=0.013) was more frequently reported following TED compared to open hemorrhoidectomy. Patient satisfaction was greater following minimal open hemorrhoidectomy (p=0.049). No group-wise differences were identified in the impact on average or peak postoperative pain, recovery, health-related quality of life, or adverse events. Limitations of the study include, but are not limited to its small sample size, the single institution setting, the absence of blinding and the short follow-up period of 12 months.

Giordano and colleagues (2021) reported the results of a prospective study that assessed the safety and efficacy of adjunct mucopexy to conventional dearterialization. The procedure, which has been referred to as the THD Anolift, consisted of two parts: one focused on the dearterialization and the other aimed at the management of the prolapsing component. After the identification and transfixation of the arteries was completed, an Anolift targeted mucopexy was performed using a continuous barbed suture with a synthetic absorbable monofilament (Polydioxanone) 2/0 Filbloc (Assut Europe) stitch mounted on a 4/8 30 mm needle. All of the Anolift procedures in this study were performed by a single surgeon. Researchers utilized the Hemorrhoidal Assessment Severity Score (HASS) to quantify the severity of hemorrhoidal symptoms. From May 2018 to November 2020, a total of 60 individuals with hemorrhoidal disease (HD) underwent a THD Anolift procedure. Concomitant procedures were carried out in 5 cases (2 botox injections, 2 skin tag removals, 1 open lay submucosal fistula, and 1 single nodule hemorrhoidectomy). Post-operatively, 3 subjects (5%) complained of severe post-operative pain which settled within 7 days in all cases. Four individuals experienced fecal impaction (6%), and 10 (16%) reported some difficulty in evacuation which all resolved within 5 days. The median follow-up period was 15.5 months (range 2–32 months). The mean HASS improved from 16.43 pre-operatively to 1.95 post-operatively (p<0.0001). Pre-operative HASS was strongly correlated with the degree of hemorrhoids (p<0.001), while there was no correlation between the pre-operative HASS or the degree of hemorrhoids and the post-operative HASS (p=0.163). Researchers did not identify any significant difference in predicted post-operative HASS according to the pre-operative HD stage. One subject (1.6%) with circumferential IV hemorrhoids had a recurrence and required an additional THD procedure. Two participants underwent skin tag excision (3%). While the authors concluded that the Anolift technique is safe and effective for the management of HD even in individuals with advanced stages, they also acknowledged limitations of the study included its single center design, lack of a control group and the surgical procedure being performed by a single surgeon. The authors also acknowledged that a larger multicenter study, with a control group, could further assess the role of the THD Anolift in the management of symptomatic hemorrhoids.

Saleem and colleagues (2023) reported the results of an RCT that compared the outcomes of open hemorrhoidectomy versus Doppler-guided THD with recto-anal repair in 3rd and 4th degree hemorrhoids. The study was conducted at a single institution and included 70 participants (49 [70%] males and 21 [30%] females). Participants underwent open hemorrhoidectomy (Group A) or Doppler-guided THD (Group B). Outcomes assessed post-operative pain, bleeding and length of hospital stay. The researchers found that mean post-operative pain on day 7 for participants in Group A was 1.12 ± 0.72 and 1.06 ± 0.52 for Group B. Post-operative bleeding was 1.9 ± 0.30 in Group A and 1.86 ± 0.34 in the Group B. Mean hospital stay for open procedure group was 2 ± 0.45 and 1.20 ± 0.40 for Groups A and B, respectively. Overall, the researchers found there was a significant difference in terms of mean hospital stay between the two groups, but no significant difference in mean postoperative pain on day 7 or in postoperative bleeding.

According to the American Society of Colon and Rectal Surgeons (ASCRS; Davis, 2018):

Surgical excision of hemorrhoids remains a very effective approach for patients who fail or cannot tolerate office-based procedures, those who have grade III or IV hemorrhoids, or patients with substantial concomitant skin tags... In general, prospective studies using HAL have demonstrated favorable short-term results.

In its guidelines on the "Management of Benign Anorectal Disorders", the American College of Gastroenterology indicates that "doppler-guided procedures such as hemorrhoidal artery ligations have similar outcomes to hemorrhoidectomy for symptomatic grade 3 hemorrhoids". However, the authors indicate that this is a conditional recommendation based on very low quality evidence (Wald, 2021).

THD appears to be a promising, less invasive treatment option for symptomatic internal hemorrhoids. There are published reviews, retrospective case series, and several studies of THD and THD in combination with procedures for prolapsed hemorrhoid (PPH). THD has demonstrated encouraging but mixed results in terms of pain, operation time, and complications. Larger, multicenter studies comparing THD with the gold standard procedures used to treat symptomatic hemorrhoids and longer follow-up are needed to establish a possible role for this technique and to identify selection criteria.

Background/Overview

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 mucus. 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 tend to have low complication rates, they are usually associated with significant postoperative pain. In order to reduce pain, alternative procedures, including but not limited to THD, are being explored.

In 2008, the U.S. Food and Drug Administration (FDA) issued a 510K approval for the THD Slide system (S.p.a Medical Division, Correggio, Italy; THD America, Inc., Natick, MA). The approved indication for the THD Slide Doppler-guided proctoscope system was for the surgical treatment of second and third degree hemorrhoids. The approval was based on predicate devices with similar acoustic emissions.

Definitions

Classification of internal hemorrhoids:

- Grade I Prominent hemorrhoidal vessels, no prolapse
- Grade II Prolapse with Valsalva and spontaneous reduction
- Grade III Prolapse with Valsalva requires manual reduction
- Grade IV Chronically prolapsed manual reduction ineffective

Ligation: A procedure where a structure is bound or tied.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

For the following procedure code or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

46948 Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed

ICD-10 Diagnosis

All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

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Transanal hemorrhoidal dearterialization (THD)
Transanal hemorrhoidal artery ligation (HAL)

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Definitions, References, and Websites for Additional Information sections.
Reviewed	05/12/2022	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/14/2020	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; added 46948 replacing 0249T deleted 12/31/2019.
Reviewed	06/06/2019	MPTAC review. Rationale, References, and Websites sections updated.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Rationale, References, and Websites sections updated.
Reviewed	08/03/2017	MPTAC review. Rationale and References sections updated.
Reviewed	08/04/2016	MPTAC review. References updated. Removed ICD-9 codes from Coding section.
New	08/06/2015	MPTAC review. Initial document development.

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