ORIGINAL CONTRIBUTION

Minimal Open Hemorrhoidectomy Versus Transanal Hemorrhoidal Dearterialization: The Effect on Symptoms: An Open-Label Randomized Controlled Trial

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BACKGROUND: There is limited evidence on the long-term efficacy of transanal hemorrhoidal dearterialization compared with hemorrhoidectomy. Most studies investigated short-term effects with postoperative pain as the primary outcome. Being a benign disease, the long-term goal of treatment for hemorrhoids is the resolution of symptoms and improvement of quality of life.

OBJECTIVE: The purpose of this study was to compare the effect of minimal open hemorrhoidectomy versus transanal hemorrhoidal dearterialization on patient-reported symptoms.

DESIGN: This was an open-label randomized controlled trial.

SETTINGS: This was a single-center study.

PATIENTS: Patients with symptomatic hemorrhoids grade II to IV (Goligher's classification) were included.

INTERVENTIONS: Patients were randomly allocated to minimal open hemorrhoidectomy or transanal hemorrhoidal dearterialization.

MAIN OUTCOME MEASURES: The primary outcome was symptoms assessed by the Hemorrhoidal Disease Symptom Score 1 year postoperatively. Secondary outcomes included health-related quality of life, patient satisfaction, postoperative pain and recovery, adverse events, recurrence, and hospital costs.

RESULTS: Forty-eight patients received minimal open hemorrhoidectomy, and 50 patients received transanal hemorrhoidal dearterialization. No difference in symptom score at 1-year follow-up was found. Median (range) symptom score was 3 (0–17) after minimal open hemorrhoidectomy and 5 (0–17) after transanal hemorrhoidal dearterialization (median difference = –1.0 (95% CI, –3.0 to 0.0); $p = 0.15$). Residual hemorrhoidal prolapse was reported more frequently ($p = 0.008$), and more patients had treatment for recurrence after transanal hemorrhoidal dearterialization (7 vs 0 patients; $p = 0.013$). Patient satisfaction was higher after minimal open hemorrhoidectomy ($p = 0.049$). No differences were found in the impact on health-related quality of life, average and peak postoperative pain, recovery, or adverse events ($p >$

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Poster presentation at the European Society of Coloproctology's 13th Scientific and Annual Meeting, Nice, France, September 26 to 28, 2018, and presented at the meeting of the Danish Society of Surgery, Copenhagen, Denmark, November 7 to 9, 2018.

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0.05). Transanal hemorrhoidal dearterialization was more expensive (median difference = €555 (95% CI, €472–€693); $p < 0.001$).

LIMITATIONS: No blinding was included in this study.

CONCLUSION: No difference was found in symptom score 1 year postoperatively. Minimal open hemorrhoidectomy had a better effect on the hemorrhoidal prolapse and higher patient satisfaction. More patients needed treatment for recurrence after transanal hemorrhoidal dearterialization. Minimal open hemorrhoidectomy has an immediate postoperative course similar to transanal hemorrhoidal dearterialization. See **Video Abstract** at http://links.lww.com/DCR/B152.

CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT02061176.

HEMORROIDECTOMÍA MÍNIMA ABIERTA VERSUS DESARTERIALIZACIÓN HEMORROIDAL TRANSANAL: EL EFECTO SOBRE LOS SÍNTOMAS: UN ESTUDIO ABIERTO CONTROLADO Y ALEATORIZADO

ANTECEDENTES: Hay evidencia limitada sobre la eficacia a largo plazo de la desarterialización hemorroidal transanal en comparación con la hemorroidectomía. La mayoría de los estudios han investigado los efectos a corto plazo con el dolor postoperatorio como el resultado primario. Al ser una enfermedad benigna, el objetivo a largo plazo del tratamiento de la enfermedad hemorroidal es la resolución de los síntomas y la mejora en la calidad de vida.

OBJETIVO: Comparar el efecto de la hemorroidectomía abierta mínima versus la desarterialización hemorroidal transanal en los síntomas reportados por el paciente.

DISEÑO: Ensayo controlado aleatorizado abierto.

ESCENARIO: Estudio en sede única.

PACIENTES: Pacientes con enfermedad hemorroidal sintomática de grado II-IV (clasificación de Goligher).

INTERVENCIONES: Los pacientes fueron asignados aleatoriamente a hemorroidectomía mínima abierta o desarterialización hemorroidal transanal.

PRINCIPALES MEDIDAS DE RESULTADO: El resultado primario fueron los síntomas evaluados por el Score de Síntomas de Enfermedad Hemorroidal un año después de la operación. Los resultados secundarios incluyeron calidad de vida relacionada con la salud, satisfacción del paciente, dolor y recuperación postoperatorios, eventos adversos, recurrencia y costos hospitalarios.

RESULTADOS: Cuarenta y ocho pacientes recibieron hemorroidectomía abierta mínima y cincuenta pacientes recibieron desarterialización hemorroidal transanal. No se encontraron diferencias en la puntuación de los síntomas al año de seguimiento. La puntuación mediana (rango) de síntomas fue 3 (0-17) después de una hemorroidectomía mínima abierta y 5 (0-17) después de la desarterialización hemorroidal transanal (diferencia mediana [IC95%]: -1.0 [-3.0-0.0], p = 0.15). El prolapso hemorroidal residual se informó con mayor frecuencia (p = 0.008) y más pacientes recibieron tratamiento por recurrencia después de la desarterialización hemorroidal transanal (7 frente a 0 pacientes, p = 0.013). La satisfacción del paciente fue mayor después de una hemorroidectomía abierta mínima (p = 0.049). No se encontraron diferencias en el impacto sobre la calidad de vida relacionada con la salud, el dolor postoperatorio promedio y máximo, la recuperación o los eventos adversos (p> 0.05). La desarterialización hemorroidal transanal fue más costosa (diferencia mediana [IC95%]: € 555 [472-693], p <0.001).

LIMITACIONES: Estudio sin cegamiento.

CONCLUSIÓN: No se encontraron diferencias en la puntuación de los síntomas a un año después de la operación. La hemorroidectomía mínima abierta tuvo un mejor efecto sobre el prolapso hemorroidal y una mayor satisfacción del paciente. Más pacientes necesitaron tratamiento para la recurrencia después de la desarterialización hemorroidal transanal. La hemorroidectomía abierta mínima tiene un curso postoperatorio inmediato similar a la desarterialización hemorroidal transanal. Consulte **Video Resumen** en http://links.lww.com/DCR/B152. *(Traducción—Dr. Jorge Silva Velazco).*

REGISTRO DE ENSAYOS: ClinicalTrials.gov Identifier: NCT02061176.

KEY WORDS: Hemorrhoidal Disease Symptom Score; Hemorrhoidectomy; Hemorrhoids; Minimal open hemorrhoidectomy; Randomized controlled trial; Transanal hemorrhoidal dearterialization.

Hemorrhoidectomy is the operation for hemorrhoidal disease (HD) that has demonstrated the lowest recurrence rates.[1] The operation has, however, been associated with postoperative pain, and some studies point to the risk of impaired anal continence.[2,3] New nonablative methods have been introduced that are aimed at reducing postoperative pain and the risk of complications.[4,5] Transanal hemorrhoidal dearterialization (THD) was described in the mid-1990s.[4] This operation involves no excision: the hemorrhoidal arteries are ligated, and the hemorrhoidal prolapse is treated by a suture mucopexi. THD has gained increased popularity. It is regarded as a safe, efficient, and less painful operation for HD according to initial studies.[6] However, the evidence on long-term efficacy of THD compared with hemorrhoidectomy is limited.[7] Only a few randomized controlled trials (RCTs) have

been published. The majority have been designed to study short-term outcomes, with postoperative pain as the primary outcome.[8–13] Although postoperative pain might influence a patient's preference for a specific operation, the risk of symptom recurrence or complications seems to be of greater importance.[14]

The original operation for open hemorrhoidectomy as described by Milligan and Morgan is no longer used. Several modifications have been proposed to reduce postoperative pain, and the operation is not currently standardized. Some studies have reported reduced postoperative pain when using diathermy for dissection and coagulation of blood vessels instead of ligature and trans-fixation of the hemorrhoid pedicle.[15,16] Other authors have emphasized the importance of dissection in the anatomic plane to reduce the risk of injury to the internal anal sphincter.[17,18] We adapted these principles and additionally minimized the excision to reduce postoperative pain and the risk of influencing anal continence. We called this modification minimal open hemorrhoidectomy (MOH).[19]

The aim of this trial was to compare the long-term effect of MOH versus THD on patient-reported symptoms at 1 and 5 years postoperatively. The results after 1-year follow-up are reported here.

PATIENTS AND METHODS

Study Design and Participants

This study was a single-center, open-labeled, parallel group RCT carried out at the Holbaek Hospital Department of Surgery. The study protocol is available at clinicaltrials.gov (NCT02061176).

Patients referred to the proctologic outpatient clinic for anal symptoms were assessed for eligibility. The attending surgeon identified potential participants and graded hemorrhoids using Goligher's classification.[20,21] Eligible were adult patients (age 18–85 y) with a Hemorrhoidal Disease Symptom Score >4 and grade III to IV hemorrhoids or grade II hemorrhoids if bleeding was present despite previous rubber band ligation or sclerotherapy. All of the patients had an endoscopic examination before inclusion. We excluded patients with acute strangulated hemorrhoids, previous operation for hemorrhoids within 2 years before inclusion, active anal fissure or fistula, anal stenosis, anal incontinence to solid stool, previous operation for anal incontinence, previous pelvic radiation, colorectal malignancy, IBD, cognitive or language inabilities, or ASA score >II. Patients were included after giving oral and written consent. The study was approved by the Regional Committee on Health Research Ethics (SJ-348) and the Danish Data Protection Agency (REG-71-2013).

Randomization and Blinding

Participants were randomly allocated (in a 1:1 ratio) to either MOH or THD. The randomization sequence was computer generated and stratified by sex using blocks of 10. The randomization list was kept in a locker accessible to the study secretary but not to any of the investigators. The allocations were kept in sealed, opaque, consecutively numbered envelopes. The day before the operation, the study secretary opened the envelope and wrote the allocated procedure in the electronic patient record. The study was open labeled without blinding of participants, surgeons, hospital, or research staff.

Operations

Five surgeons (G.O., K.S., H.D.R., G.K.M., and L.I.) examined the patients preoperatively and postoperatively and performed both operations. All of the surgeons had performed at least 10 supervised MOH and THD operations before operating independently. The operations were planned as outpatient surgeries except for patients living alone or who for other reasons could not be discharged without any home surveillance. A preoperative enema was used to evacuate the rectum. No antibiotic prophylaxis was given, and anesthesia was either general or spinal supplemented by a perianal block of 40 mL of ropivacaine 5 mg/mL.[22] The patients were placed in the lithotomy position. MOH was performed without using a retractor.[19] Diathermy was used for both dissection and hemostasis. The external components were grasped by forceps, and the skin was incised midway to one third of the distance from the top of the pedicle, thereby minimizing skin excision. The subdermal fascia, which continues in a membrane covering the internal anal sphincter, was identified. The hemorrhoid was dissected off the internal sphincter in this plane, leaving the internal sphincter unharmed. The anal mucosa was incised at the transition of the hemorrhoid. Only part of the hemorrhoid and overlying mucosa was excised. The hemorrhoid was divided, leaving a residual part intra-anally. Only prolapsing hemorrhoids (grade II–IV) were excised. The THD procedure has been described previously.[8] We used the THD proctoscope (G.F Medical Division, Correggio, Italy) for Doppler-guided localization of the hemorrhoidal arteries at the 1, 3, 5, 7, 9, and 11 o'clock positions (anterior midline representing 12 o'clock). The hemorrhoidal arteries were suture ligated using absorbable suture. The suture was not cut but used to perform a mucopexy reducing prolapsing hemorrhoids. The mucopexy was performed as a running suture ending ≥5 mm above the dentate line. Mucopexy was performed in all of the patients. Median number of mucopexies was 6 (range, 3–8). Additional excision of skin tags was optional in both procedures. The postoperative regimen was equal in the 2 groups. Patients were discharged when pain relief was adequate and they were able to eat, drink, and pass urine. Pain treatment was paracetamol 1 g 4 times daily, ibuprofen 400 mg 3 times daily, and a local anesthetic gel (xylocaine) for the first 7 days, with reduction as needed. Eight tablets of morphine 10 mg or tramadol 50 mg were given to be used if needed. A laxative (magnesium oxide 1 g 2 times daily) was prescribed for the first 7 days. Patients were encouraged to return to work and daily activities as soon as possible.

Procedure

Participants were assessed in the outpatient clinic at inclusion and at planned 3- and 12-month postoperative follow-up. The attending surgeon assessed preoperative and postoperative anal anatomy. Patient questionnaires were distributed on printed paper. In cases of noncompliance, the patient was contacted by telephone and mail first by the study secretary and second by one of the surgeons. If a patient refused to come to the outpatient clinic for follow-up, the patient was asked to complete the questionnaires and mail them to the study secretary.

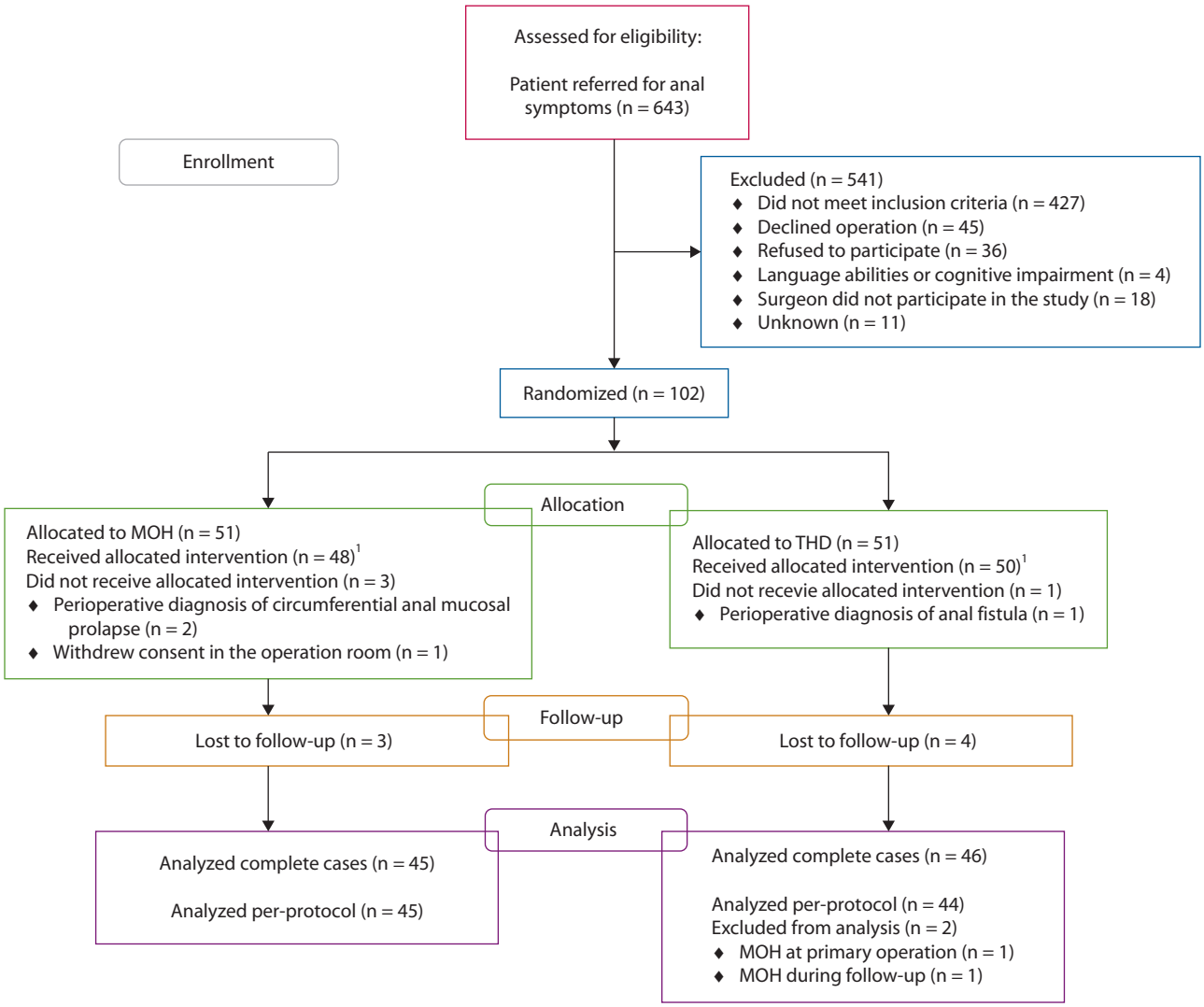
Primary Outcome

The primary outcome was symptoms 1 year after surgery assessed by the Hemorrhoidal Disease Symptom Score (HDSS; Appendix S1, Supplemental Digital Content, http://links.lww.com/DCR/B153).[23] The HDSS consists of 5 items measuring patient-reported frequency of pain, itching, bleeding, soiling, and prolapse. Results from a recent study suggest that HDSS is a valid, reliable, and responsive measure of symptoms in patients with HD.[23]

Secondary Outcomes

Secondary outcomes were health-related quality of life (HRQoL), patient satisfaction with the operation, perioperative blood loss, operative time, time spent in the operating room, length of hospital stay, postoperative pain and recovery, postoperative anatomic assessment, anal continence, adverse events, reinterventions for recurrence, and health costs.

The surgeon and the hospital staff recorded perioperative data. The patients registered in a diary information on average pain, peak pain, pain when passing stool, use of



[1]Patients analyzed in modified intention-to-treat analyses (mITT).

FIGURE 1. CONSORT flow diagram for inclusion of patients. Patients randomly allocated to minimal open hemorrhoidectomy (MOH) or transanal hemorrhoidal dearterialization (THD).

analgesics, and recovery the first 14 days postoperatively. Pain was scored using a numeric rating scale (0= "no pain" to 10= "worst pain imaginable"). Pain scores were summarized to assess the overall experience of pain. Recovery was assessed with a single question, whether well-being was normal, slightly decreased, or decreased (feeling ill).

Recurrent hemorrhoids were graded using Goligher's classification. Grade I hemorrhoids was considered a normal finding. The surgeon also reported his/her global assessment of pathology (1= "no pathology" to 7= "severe pathology"). Anal continence was assessed by the Wexner fecal incontinence score (Wexner score) and the Revised Fecal Incontinence Scale.[24,25]

All adverse events and reoperations were registered. In addition, the hospital patient records were screened 12 months postoperatively to identify missing data. Adverse events were graded using the Clavien–Dindo classification.[26] At follow-up, patients graded their satisfaction with the operation (1= "very unsatisfied" to 7= "very satisfied"), and HRQoL was assessed by the Short Health Scale adapted to HD (SHS_{HD}; Appendix S1),[23] EuroQoL 5-dimensions 5-levels (EQ-5D-5L),[27] and Short-Form 36 version 2 (SF36v2).[28] Quality-adjusted life-years (QALYs) was calculated from EQ-5D-5L scores, using the Danish Time Trade-Off value set.[29] Cost-utility analysis was planned from the healthcare giver perspective (ie, hospital costs per QALY gained). Procedural costs were calculated based on the costs of equipment (cost per unit) and staff (average costs per time unit). Costs of adverse events and reinterventions were estimated based on the Danish disease-related group rates obtained from the Danish National Patient Registry.[30]

Statistical Analyses

We calculated that a sample of 80 patients, 40 in each group, was needed to detect a difference of 1.5 points on the HDSS score with a 0.05 significance level and power of 0.80. Based on this, we initially planned to include 90 patients, but the number of patients lost to follow-up was higher than expected. We therefore increased the sample size to 102 patients.

TABLE 1. Baseline characteristics

Variable	*MOH N = 48*	*THD N = 50*
Women, n (%)	27 (56)	30 (60)
Age, mean (SD), y	53.5 (15.1)	54.0 (14.1)
ASA I/ASA II score, n (%)	25 (52)/23 (48)	22 (44)/28 (56)
BMI, mean (SD), kg/m^2	26.8 (4.3)	27.1 (4.7)
Goligher's classification, n (%)		
Grade II	2 (4)	1 (2)
Grade III	23 (48)	18 (36)
Grade IV	23 (48)	31 (62)
Surgeon's global assessment of pathology (1–7), median (range)	4.0 (2–7)	5.0 (3–6)
Missing, n (%)	1 (2)	2 (4)
Hemorrhoidal Disease Symptom Score (0–20) Median (range) (IQR)	13.0 (3–18) (4.0)	12.0 (3–19) (6.0)
Wexner Fecal Incontinence Score (0–20), median (range) (IQR)	4.0 (0–15) (5.3)	4.0 (0–14) (5.0)
Missing, n (%)	2 (4)	4 (8)
Revised Fecal Incontinence Score (0–20), median (range) (IQR)	1.0 (0–13) (4.0)	1.0 (0–18) (3.0)
Missing, n (%)	2 (4)	5 (10)
Short Health $Scale_{HD}$ (4–28), median (range) (IQR)	14.0 (6–24) (6.0)	17.0 (6–23) (7.0)
Missing, n (%)	3 (6)	3 (6)
SF36v2, median (range) (IQR)		
MCS	54.3 (22.0–63.4) (11.7)	56.3 (14.6–66.1) (12.7)
Missing, n (%)	0 (0)	4 (8)
PCS	53.3 (28.2–66.5) (10.9)	51.1 (28.3–60.5) (10.9)
Missing, n (%)	0 (0)	4 (8)
Previous RBL or sclerotherapy, n (%)		
Yes	15 (31)	13 (26)
No	29 (60)	31 (62)
Unknown	4 (8)	6 (12)
Previous operation for hemorrhoids, n (%)		
Yes	4 (8)	12 (24)
No	40 (83)	35 (70)
Unknown	4 (8)	3 (6)

SF36v2 scores are standardized based on the US general population norm (a score of 50 represents the US 2009 population mean). Higher scores indicate better quality of life.

MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; IQR = interquartile range; RBL = rubber band ligation; SF36v2 = Short Form 36 version 2; MCS = mental component summary; PCS = physical component summary.

Descriptive statistics described demographic data. Data were assessed for normality and, if present, the χ^2 test analyzed frequencies and *t* test continuous data. In cases of nonnormality, the Fisher exact test analyzed frequencies and the Mann–Whitney U test continuous data. Ordinal data were analyzed using Goodman and Kruskal's gamma. Significance level was 0.05 (2-sided). Median differences and CIs for nonparametric analyses were reported using the Hodges–Lehmann estimate (Mdiff). The primary outcome, adverse events, and health-cost analysis were analyzed according to a *modified* intention to treat (*m*ITT) principle: patients who underwent surgery for hemorrhoids were analyzed. Missing HDSS values from patients lost to follow-up were replaced by the group's median, and sensitivity analysis was performed with best and worst outcomes for both groups. Other outcomes were analyzed per protocol, excluding missing data.

IBM SPSS 24 (IBM Corp, Armonk, NY) was used for statistical analyses. SF36v2 scores were obtained using the QualityMetric scoring software (5.1).

RESULTS

Participants

Between November 24, 2013, and October 3, 2016, 102 patients were randomly assigned to receive MOH or THD (51 vs 51; Fig. 1). Follow-up was completed on Novem-

TABLE 2. Per-protocol analysis of outcomes at 1-year follow-up

Outcome	*MOH (N = 45)*	*THD (N = 44)*	*Effect size*	*p*
Symptoms				
Hemorrhoidal Disease Symptom Score, median (range) (IQR)	3.0 (0–17) (5.0)	5.0 (0–17) (9.0)	Mdiff (95% CI) −1.0 (−3.0 to 0.0)	0.18
Improvement in Hemorrhoidal Disease Symptom Score, mean (SD)	8.40 (4.65)	6.36 (5.34)	$\bar{x}$ diff (95% CI) 2.04 (−0.07 to 4.14)	0.058
Patients reporting symptoms of				
Pain, n (%)	15 (33)	20 (45)	OR (95% CI) 0.73 (0.43 to 1.24)	0.24
Itching, n (%)	28 (62)	26 (59)	OR (95% CI) 1.14 (0.49 to 2.67)	0.76
Bleeding, n (%)	16 (36)	15 (34)	OR (95% CI) 1.07 (0.45 to 2.55)	0.89
Soiling, n (%)	22 (49)	20 (45)	OR (95% CI) 1.15 (0.50 to 2.64)	0.75
Prolapse, n (%)	14 (31)	26 (59)	OR (95% CI) 0.31 (0.13 to 0.75)	0.008
Anal continence				
Wexner score, median (range) (IQR)	2.0 (0–12) (4.8)	3.0 (0–13) (4.0)	Mdiff (95% CI) −1.0 (−2.0 to 0.0)	0.11
Missing, n (%)	1 (2)	1 (2)		
Revised Fecal Incontinence Score, median (range) (IQR)	0.0 (0–7) (2.5)	0.0 (0–11) (2.0)	Mdiff (95% CI) 0.0 (0.0 to 0.0)	0.43
Missing, n (%)	0 (0)	3 (7)		
Patient satisfaction and quality of life				
Patient satisfaction (1 = very dissatisfied to 7 = very satisfied), n (%)			γ = −0.32	0.049
1	1 (2)	2 (4)		
2	1 (2)	6 (14)		
3	2 (4)	3 (7)		
4	3 (7)	2 (4)		
5	1 (2)	4 (9)		
6	13 (29)	10 (23)		
7	24 (53)	17 (39)		
Short Health Scale$_{HD}$, median (range) (IQR)	6.0 (4–19) (5.0)	7.0 (4–19) (6.0)	Mdiff (95% CI) −1.0 (−2.0 to 0.0)	0.08
Missing, n (%)	1 (2)	0 (0)		
Postoperative anatomic assessment				
Goligher's classification, n (%)				
Grade I/normal	38 (84)	20 (46)	γ = 0.79	<0.001
Grade II	3 (7)	8 (18)		
Grade III	1 (2)	2 (5)		
Grade IV	0 (0)	9 (21)		
Missing	3 (7)	5 (11)		
Surgeon's overall assessment of pathology (1–7), median (range) (IQR)	2.0 (1–6) (1.0)	2.0 (1–5) (2.0)	γ = 0.62	<0.001
Missing	3 (7)	6 (14)		

Mdiff = Hodges-Lehmann estimate of median difference; $\bar{x}$ diff = mean difference; γ = Goodman and Kruskal's gamma; IQR = interquartile range; MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization.

ber 22, 2017. Of 48 (MOH) and 50 (THD) patients who received the allocated treatment, primary outcome data were obtained in 45 (MOH) and 46 (THD) patients at 1-year follow-up (complete cases). In 1 patient operated with THD, the surgeon could not reduce the hemorrhoidal prolapse with mucopexies and added hemorrhoidal excision. Another patient in the THD group received hemorrhoidectomy for recurrence during the follow-up period. These patients were included in the *m*ITT analyses, but the first patient was excluded in the analysis of postoperative pain and recovery, and both patients were excluded in the per-protocol analysis of patient-reported outcomes and anatomic assessment at 12-month follow-up. One patient in the THD group had a missing item (itching) in the baseline HDSS, which was replaced by zero. Baseline data were similar in the 2 groups (Table 1).

Primary Outcome

We found no difference in symptom score 1 year postoperatively. In complete cases, HDSS (median (range)) after MOH was 3 (0–17) and after THD 5 (0–17; Mdiff = –1.0 (95% CI, –3.0 to 0.0); $p = 0.15$). The *m*ITT and sensitivity analyses showed a significant difference in HDSS only in case of the worst outcomes of THD versus the best and median outcomes of MOH (Appendix S2, Supplemental Digital Content, http://links.lww.com/DCR/B154).

Per-Protocol Analyses: Patient-Reported Outcomes and Anatomic Assessment

Table 2 presents the results of the per-protocol analyses. Higher patient satisfaction and a nonsignificant trend toward greater improvement of symptoms after MOH were seen. More patients reported symptoms of prolapse after THD, whereas no difference was found for pain, bleeding, itching, or soiling. Postoperative anatomic assessment by the surgeon showed that more patients in the THD group had residual hemorrhoidal prolapse at 1-year follow-up. Postoperative incontinence scores were without differences between the 2 groups.

We found no difference in the impact on HRQoL. The SHS_{HD} had improved after both operations but without any difference in improvement between the groups. Similarly, no differences in the improvement of SF36v2 scores were seen (Fig. 2).

Postoperative Pain and Recovery

Figure 3 presents the postoperative pain scores. Summed average and peak pain scores for postoperative days 1 to 14 were similar after MOH and THD. The MOH group reported pain a few days longer than the THD group. Summed scores for pain when passing stool were higher in the MOH group. Use of analgesics and recovery were similar in the 2 groups (Table 3). When we excluded patients in

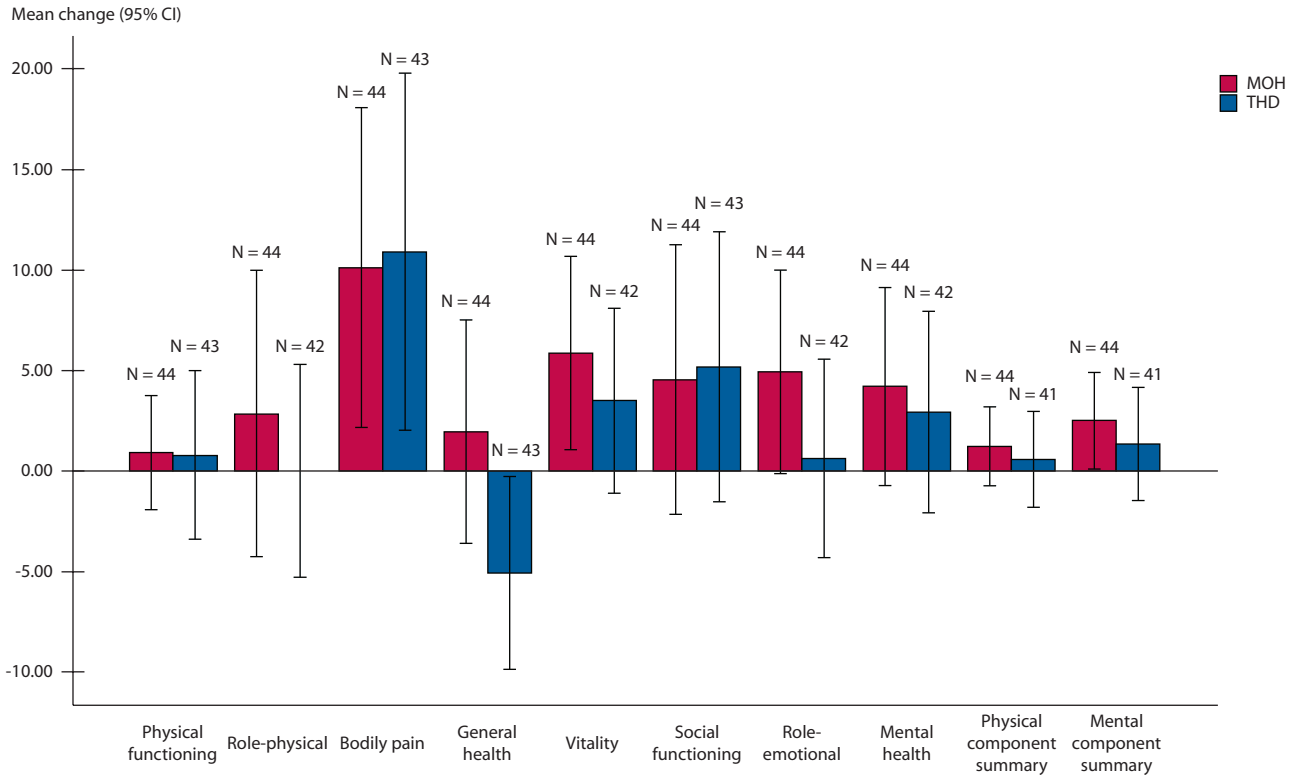


FIGURE 2. Health-related quality of life. Changes in Short Form 36 version 2 scores from baseline to 1-year follow-up. A positive change indicates improvement. No differences were found between the groups. MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization.

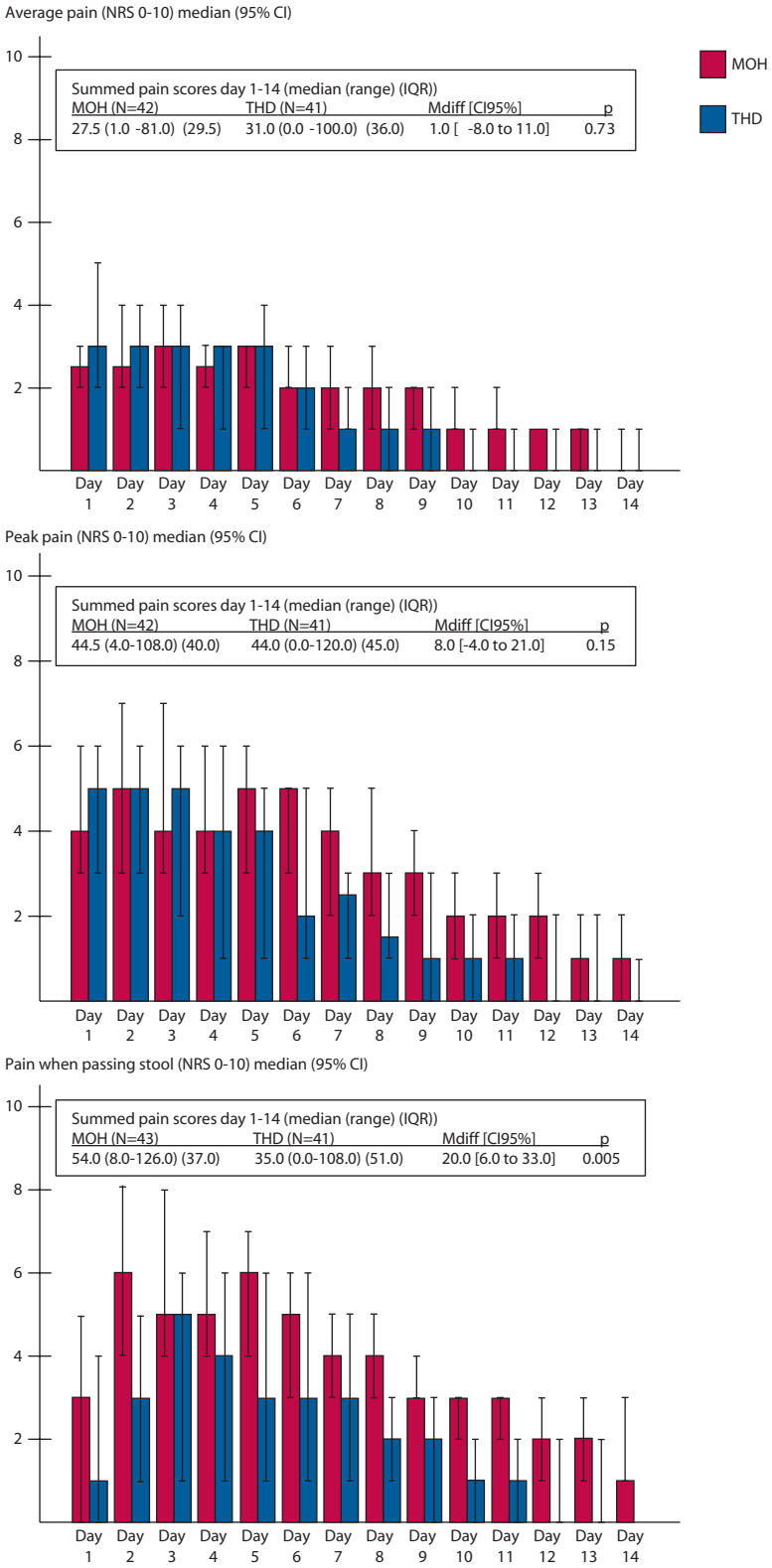


FIGURE 3. Postoperative pain the first 14 days. The patients reported pain on a numeric rating scale (NRS 0-10). MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; Mdiff = Hodges-Lehmann estimate of median difference; IQR = interquartile range.

TABLE 3. Perioperative data and recovery

Variable	MOH (N = 48)	THD (N = 50)	Mean diff (95% CI)	OR (95% CI)	p
Anesthesia, general/spinal, n (%)	45 (94)/3 (6)	45 (90)/5 (10)			NT
Local anesthesia, n (%)	48 (100)	49 (98)			NT
Hemorrhoids excised, n (%)					
0	0 (0)	49 (98.0)			NT
1	4 (8)	0 (0)			
2	9 (19)	1 (2)			
3	35 (73)	0 (0)			
Mucopexies, median (range) (IQR)	–	6.0 (3–8) (0.0)			NT
Excision of skin tags, n (%)	18 (37)	7 (14)			NT
Estimated blood loss, n (%)					
<50/50–100 mL	43 (90)/3 (6)	46 (92)/2 (4)		0.62 (0.10 to 3.91)	0.67
Missing	2 (4)	2 (4)			
Operative time, mean (SD), min	29.0 (14.2)	57.6 (13.2)	−28.6 (−34.1 to −23.1)		<0.001
Missing, N(%)	1 (2)	0 (0)			
Time in operating room, mean (SD), min	75.0 (19.6)	106.6 (18.6)	−31.6 (−39.3 to −23.9)		<0.001
Missing, n (%)	1 (2)	0 (0)			
Hospital stay, mean (SD), d	0.40 (0.24)	0.56 (0.36)	−0.15 (−0.28 to −0.03)		0.015
Discharged the same day, n (%)[a]	45 (96)	41 (87)		0.30 (0.06 to 1.59)	0.27
Analgesic consumption[b]	N = 43	N = 41			
Paracetamol day 1–14 (tablets à 500 mg), mean (SD)	54.0 (27.0)	54.6 (29.0)	−0.6 (−12.7 to 11.5)		0.92
Ibuprofen day 1–14 (tablet à 400 mg), mean (SD)	17.6 (9.2)	18.8 (11.9)	−1.3 (−5.9 to 3.4)		0.60
Opioids day 1–14 (tablets à 10 mg), median (range) (IQR)	1.0 (0–52) (3.5)	1.0 (0–64) (4.8)	0.0 (−0.5 to 0.0)[c]		0.84
Recovery	N = 43	N = 41			
Well-being day 7, n (%)					
Normal/slightly decreased	35 (81)	27 (66)		2.41 (0.85 to 6.86)	0.10
Feeling ill	7 (16)	13 (32)			
Missing	1 (2)	1 (2)			
Well-being day 14, N (%)					
Normal/slightly decreased	37 (86)	36 (88)		0.26 (0.03 to 2.41)	0.36
Feeling ill	4 (9)	1 (2)			
Missing	2 (5)	4 (10)			

MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; Mean diff = mean difference; IQR = interquartile range; NT = not tested.
[a]Data are of patients scheduled for day surgery.
[b]Data include summed analgesic consumption day 1–14.
[c]Data show the Hodges–Lehmann estimate of median difference (95% CI).

the THD group who had concomitant skin excision from the analysis, results remained the same.

Adverse Events and Reintervention for Recurrence

Table 4 presents adverse events. No difference in the number of patients with adverse events was seen. Anal stenosis was reported in 3 patients after MOH. In 1 patient the stenosis subsided after dilatation under general anesthesia. In another patient the stenosis subsided after self-dilatations. The third patient was still using self-dilatations at 1-year follow-up. Anal incontinence was reported in 2 patients after MOH. One patient responded to conservative treatment. The second patient had preoperative compromised anal continence and reported deterioration. This patient did not respond satisfactorily to conservative treatment and was referred to a specialist clinic.

Seven patients had a reintervention for recurrence in the THD group (7 vs 0 patients; $p = 0.013$; Table 5). Of the 7 patients with a reintervention for recurrence, 3 patients had preoperative grade III hemorrhoids and 4 patients had preoperative grade IV hemorrhoids.

TABLE 4. Patients with AEs classified according to the Clavien–Dindo grading system during the first year after surgery

AEs	*MOH (N = 48), n (%)*	*THD (N = 50), n (%)*	*OR (95% CI)*	*p*
Grade I				
Reevaluation (outpatient clinic) without intervention (pain, bleeding, or other concerns)	5 (10)	2 (4)		
Local anal complication (fissure, eczema, anal spasm)	6 (12)	3 (6)		
Fever without identification of source	–	1 (2)		
Patients with AEs grade I	11 (23)	6 (12)	0.46 (0.16–1.36)	0.15
Grade II				
Prolonged hospital stay or readmission because of pain, nausea, or bleeding	2 (4)	6 (12)		
Bleeding (readmission and observation)	1 (2)			
Urinary retention	–	3 (6)		
Infection (pneumonia, urinary tract)	–	2 (4)		
Anal incontinence (conservative treatment)[a]	1 (2)	–		
Anal incontinence (referred to specialist center)	1 (2)	–		
Patients with AEs grade II	5 (10)	11 (22)	2.43 (0.77–7.60)	0.12
Grade IIIa				
Stomach ulcer (diagnostic endoscopy)	1 (2)	–		
Anal stenosis (responding to conservative treatment)[b]	2 (4)	–		
Grade IIIb				
Bleeding (reoperation)	1 (2)	1 (2)		
Perianal abscess	–	2 (4)		
Anal stenosis (reoperation)	1 (2)	–		
Patients with AEs grade III	5 (10)	3 (6)	0.45 (0.11–1.90)	0.48

No AEs grade IV (severe organ failure/intensive care required) or V (death) were registered.
MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; AEs = adverse events.
[a]Conservative treatment with fiber supplements and pelvic floor exercises is included.
[b]Conservative treatment with laxatives and self-dilatations is included.

Health-Cost Analysis

Figure 4 presents the health-cost analysis. THD had higher hospital costs than MOH, without a difference in QALYs during the first 12 months postoperatively. The difference in costs was mainly because of the costs of the THD instruments and longer operative time in the THD group. We performed a sensitivity analysis reducing operative time in the THD group to 30 minutes and excluding patients not planned for outpatient surgery. Nevertheless, the difference in hospital costs was significant (Mdiff = € –429 (95% CI, € –525 to –368); $p < 0.001$).

DISCUSSION

This RCT compared the effect of MOH and THD on symptoms in patients with grade II to IV hemorrhoids. We found no difference in symptom score 1 year postoperatively, although higher patient satisfaction and a tendency toward greater improvement of symptoms after MOH were noted. More patients reported symptoms of prolapse and needed a reintervention for recurrence after THD. HRQoL improved postoperatively but without any differences between the 2 operations. THD had higher hospital costs. Postoperative pain pattern and recovery were in the same range for the 2 groups.

To our knowledge this study is the first RCT designed to compare THD with hemorrhoidectomy in terms of effect on symptoms. Comparing our results with those of other studies is challenging, because different outcome measures for symptoms have been used. Most studies have reported equal control of symptoms after hemorrhoidectomy and THD.[9,11,12,31] This study is the first to report a difference in the effect on hemorrhoidal prolapse. A likely explanation is that our study included a relatively high proportion of patients with grade IV hemorrhoids. Only 2 of the previous RCTs included patients with grade

TABLE 5. Patients with reinterventions after the primary operation

RIs	*MOH (N = 48), n (%)*	*THD (N = 50), n (%)*	*OR (95% CI)*	*p*
Excision of skin tags[a]	3 (6)	6 (12)		
Rubber band ligation	–	4 (8)		
Reoperation	–	4 (8)[b]		
Patients with RIs for recurrence[a]	–	7 (14)[c]	Undeterminable	0.013

MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; RI = reintervention.
[a]Excision of skin tags was not considered recurrence.
[b]Data include 1 patient operated during follow-up period and 3 patients scheduled for operation at 1-year postoperative follow-up.
[c]One patient had new recurrence after rubber band ligation and was scheduled for operation.

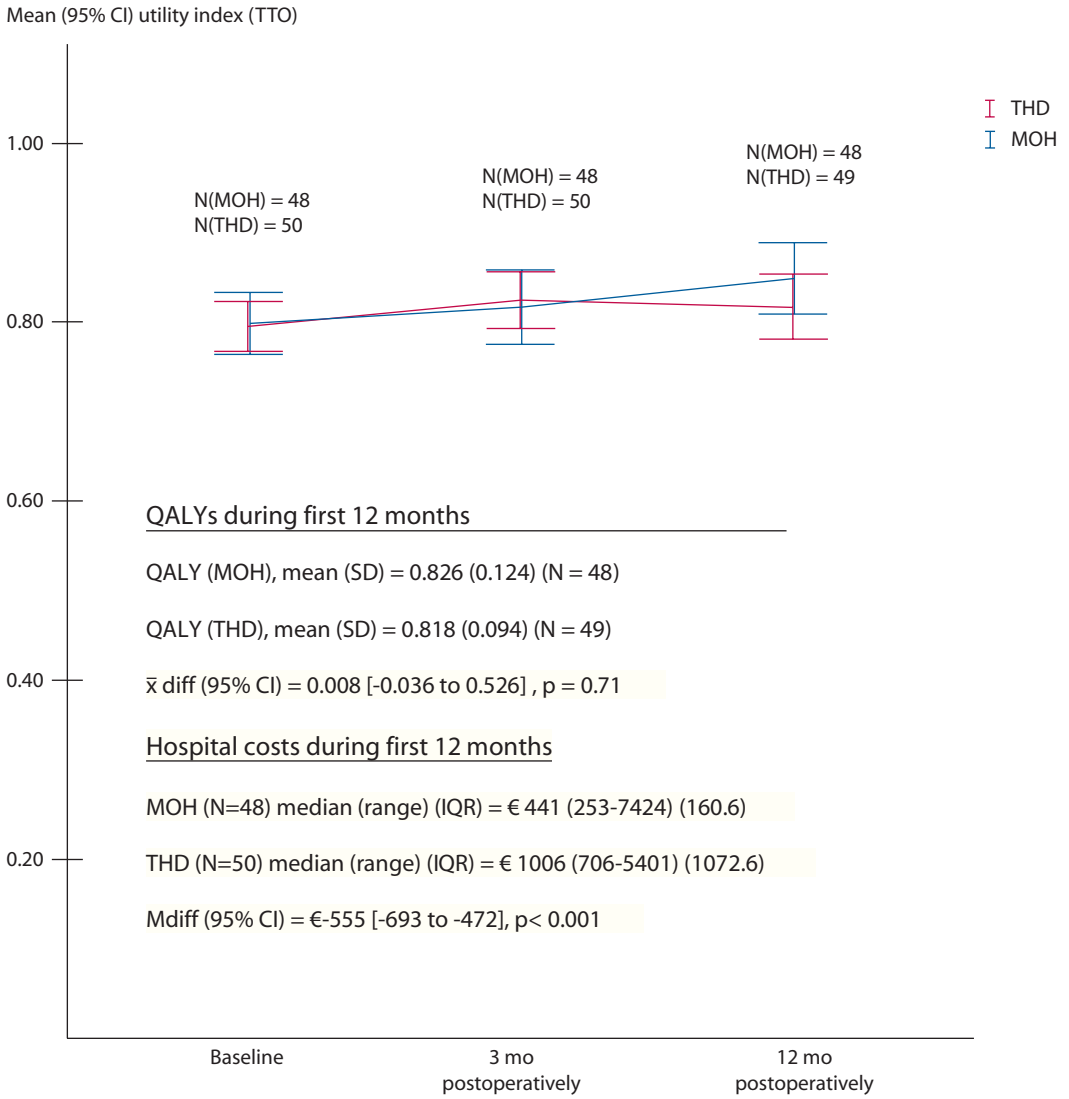


FIGURE 4. Cost-utility analysis. Data include the utility index, quality adjusted life-years (QALYs), and hospital costs during the first year postoperatively. Missing data for utility indices were replaced by linear interpolation. In 1 patient (MOH group), missing data for operative time and time the operative theater were replaced by the group mean. MOH = minimal open hemorrhoidectomy; THD = transanal hemorrhoidal dearterialization; TTO = time trade-off; x diff = mean difference; Mdiff = Hodges–Lehmann estimate of median difference; IQR = interquartile range.

IV hemorrhoids.[10,11] Our results are in line with previous findings that a high grade of prolapse preoperatively will negatively affect outcome and patient satisfaction after THD and that restored anal anatomy postoperatively predicts symptom control.[32–35]

Postoperative pain is reported to be higher after open hemorrhoidectomy compared with THD.[7] Interestingly, we found no difference in average and peak pain during the first 14 days postoperatively. The median pain scores for these variables were low, not exceeding 3 for average pain and 5 for peak pain in both groups. This is in line with our preliminary observations of similar postoperative pain pattern after MOH, THD, and LigaSure Haemorrhoidectomy.[19] Dissection in a defined anatomic plane without harming the internal sphincter and minimized resection of hemorrhoid and skin make open hemorrhoidectomy less painful. The old notion of open hemorrhoidectomy as a very painful operation might need to be revised. Pain at defecation was still higher after MOH. The clinical importance of this difference could be questioned, because no difference in recovery or the use of analgesics was seen.

The optimal operation for hemorrhoids should resolve symptoms with a minimal risk of recurrence and complications. We found that treatment for recurrence was more frequent after THD and that patient satisfaction was higher after hemorrhoidectomy. In MOH we left a part of the hemorrhoid intra-anally. This may increase the risk of recurrence, but this was not seen within a 1-year follow-up. THD is a less invasive procedure, and serious

complications are rare.[1,34] In this study most complications after MOH and THD were mild and transient. However, the impact on anal continence after hemorrhoidectomy may still be a concern. Nonablative techniques could be a better choice for patients with preoperative compromised anal continence.[3]

The present study has strengths and limitations. The strengths are that symptoms were assessed using a validated symptom score and the operations were performed by a small group of trained surgeons who performed both operations. A learning curve for the hemorrhoidal operations has not been determined, but poorer results in initial cases have been reported.[36] Our criteria for surgeon participation were comparable to those of other studies.[9,37] The postoperative treatment was standardized, and the assessment of postoperative pain was thorough. This study is the first trial to compare the costs of THD and hemorrhoidectomy. However, the single-center design reduces generalizability. The cost-utility analysis did not include costs of sick leave or consultations with the general practitioner, but our results did not indicate a difference in postoperative recovery. This study was open labeled. We did not consider blinding of patients or surgeons a realistic option when comparing an ablative with a nonablative method. However, a neutral observer could have limited potential bias in the postoperative assessment of pathology and anatomic recurrence. Goligher's classification was used to grade hemorrhoids. The classification is the most widely used and facilitates comparison with other studies. However, the interrater reliability is unknown, and the risk of misclassifications has been highlighted.[35,38] A follow-up period of 12 months might be too short, and follow-up after 5 years is planned.

CONCLUSION

This RCT compared the effect on symptoms of MOH and THD in patients with grade II through IV hemorrhoids. We found no difference in symptom score 1 year after surgery. MOH had a better effect on the hemorrhoidal prolapse and higher patient satisfaction. More patients needed treatment for recurrence after THD. MOH has an immediate postoperative course similar to that of THD.

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