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Transanal hemorrhoidal dearterialization versus stapled hemorrhoidectomy in the treatment of hemorrhoids

A PRISMA-compliant updated meta-analysis of randomized control trials

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Abstract

Background and Objective: The aim of this study was to compare the outcomes of transanal hemorrhoidal dearterialization (THD) and stapled hemorrhoidectomy (SH) in the treatment of hemorrhoids by a meta-analysis.

Methods: Randomized control trials (RCTs) comparing SH with THD were searched for in databases, including MEDLINE, PubMed, Web of science, Embase, and the Cochrane Library database. Data were independently extracted from each study, and a meta-analysis was performed using RevMan5.2 software.

Results: Eight RCTs, including 977 patients, were included in this meta-analysis. No statistically significant differences were noted between THD and SH in terms of total complications (OR, 0.93; 95% CI, 0.69, 1.25), but a significant differences were noted in terms of bleeding (OR, 1.85; 95% CI, 1.10, 3.10). The total recurrence rate was higher in THD than in SH on short-term follow-up; however, the recurrence rate was equal in both the THD and SH groups on long-term follow-up. The present study showed that no significant difference between SH and THD in terms of postoperative pain (OR, 0.43; 95% CI, −0.43, 1.29), operative time (OR, −3.12; 95% CI, −7.01, 0.77), hospital time (OR, −0.00; 95% CI, −0.21, 0.20), time before returning to work (OR,-0.50; 95%CI, −4.42,3.43), and reoperation rate (OR, 1.81; 95% CI, 0.93, 3.54).

Conclusion: Our meta-analysis indicated that THD and SH are equally effective techniques for the treatment of hemorrhoids. However, future studies addressing cost-effectiveness, satisfaction rate, and recurrence rate over a long follow-up period are needed to validate these results.

Abbreviations: CH = conventional hemorrhoidectomy, CI = confidence interval, OR = odds ratio, PPH = prolapse and hemorrhoids, RCTs = randomized control trials, SH = stapled hemorrhoidectomy, THD = transanal hemorrhoidal dearterialization, WMD = weighted mean difference.

Keywords: hemorrhoids, meta-analysis, stapled hemorrhoidectomy, transanal hemorrhoidal dearterialization

1. Introduction

Hemorrhoids are a common benign anorectal disease usually diagnosed at proctology clinics.[1] Conventional hemorrhoidectomy (CH) is the main surgical treatment for hemorrhoids.[2] However, CH is associated with several complications, such as bleeding, pain, residual prolapse, urinary retention anal stenosis, and anal incontinence. Therefore, a more effective method is needed for the treatment of hemorrhoidal diseases.[3]

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Morinaga et al[4] in 1995 first introduced a new technique, namely, transanal hemorrhoidal dearterialization (THD) or hemorrhoidal artery ligation (HAL). Compared with CH, THD conferred advantages, such as limited postoperative pain, shorter operative time, and quicker return to work, which were confirmed through several trials.[5] Longo[6] in 1998 introduced another new technique, namely, stapler hemorrhoidectomy (SH) or procedure for prolapse and hemorrhoids (PPH). Although some postoperative complications have been reported, SH is a fast procedure characterized by less postoperative pain, shorter hospital stay, and quicker return to work.[7,8]

Several randomized control trials (RCTs) comparing SH with THD have been published. A meta-analysis comparing THD with SH was published in 2012.[9] However, only 3 RCTs, encompassing 150 patients, were included, and one of the trials was published as an abstract. In 2015, a network meta-analysis indicated that THD and SH were associated with lesser postoperative pain and quicker return to work, but a higher recurrence rates.[10] However, the superiority of either technique is still under debate.

Since 2015, 3 more RCTs with large numbers of patients have been conducted but they reported inconsistent results. To provide the latest and more certain evidence, and to minimize potential bias caused by limited publications, we performed an updated meta-analysis to further consolidate the effect of THD and SH in the treatment of hemorrhoids.

2. Materials and methods

2.1. Data sources

Relevant prospective RCTs that compared SH with THD were included in this meta-analysis after searching databases including MEDLINE, PubMed, Web of science, Embase, and the Cochrane Library database for publications between January 1, 1996 and June 1, 2018. The search terms included "hemorrhoids," "hemorrhoidal disease," and "prolapsing hemorrhoids" combined with "procedure for residual prolapse and hemorrhoids," "stapled hemorrhoidopexy," "hemorrhoidal artery ligation," "transanal hemorrhoidal de-arterialisation," and "surgical treatment" combined with "randomized trials." Additional publications were searched for in the references list of the included trials. All analyses were based on previously published studies; thus, no patient consent and ethical approval are required.

2.2. Inclusion and exclusion criteria

RCTs comparing THD with SH, published as a full article in English were included. Trials without data for retrieval, abstracts, retrospective trials, duplicate publications, and unpublished trials were excluded.

2.3. Data extraction and outcomes

Two authors (HC and FY) identified and extracted the date from each study independently and blindly and disagreements were resolved through discussion. The following outcomes were used to compare THD with SH:

1. Overall postoperative complications assessed up to 6 months, including bleeding, residual prolapse, and urinary retention.
2. Clinical outcomes including recurrence rate and satisfaction rate.
3. Surgical parameters including early postoperative pain, operative time, length of postoperative hospital stay, and return to normal activity.

2.4. Statistical analysis

The RevMan5.3 software (The Cochrane Collaboration, Oxford, UK) was used for the meta-analysis. For all dichotomous variables, the odds ratio (OR) with 95% confidence interval (CI) was calculated. For continuous variables, the weighted mean difference (WMD) was calculated with 95% CI. Standard deviation was calculated following the guidelines of the Handbook of Cochrane Collaboration. If the mean values were not available for continuous outcomes, the median values were used according to the guidelines of the Cochrane Collaboration. The fixed effects model and the random effects model were used to analyze the overall effect of the combined outcomes. Chi-square statistic, with significance set at $P < .05$, was used to analyze the heterogeneity among the trials. Only the results of the random effects model were reported in case of heterogeneity. We used the forest plot to show the results of the meta-analysis.

2.5. Methodological quality assessment

The modified Jadad scale was used to assess the quality of the included RCTs.[11] Publication bias was evaluated using funnel plots.

3. Results

3.1. Search results

Overall, 21 articles were eligibility for our analysis. After reading the abstracts and full-texts, we excluded 13 of these articles because they were not RCTs or reviews or case reports. Finally, 8 studies met the criteria for inclusion in the meta-analysis.[12–19]Figure 1 presents the search strategy used in this study.

3.2. Trial characteristics

Eight RCTs, including 977 patients, were included in the meta-analysis, and 59.67% (n = 583) patients were men. The 8 studies were published between 2009 and 2018. Four studies evaluated patients from Italy, one evaluated patients from Netherlands, one evaluated patients from the Egypt, one evaluated patients from United Kingdom, and one evaluated patients from France. The sample size was from 30 to 397 patients, and the follow-up period ranged from 3 months to 43 months. The majority of the trials included patients with grade III and IV hemorrhoids.[12,13,15,16,18,19] One trials described patients with grade II and III hemorrhoids.[14] One trial included patients with grade II, III, and IV hemorrhoids.[17] Further selection criteria as well the THD and SH were defined well in all trials. The modified Jadad scores of the 8 included studies were ranged from 2 scores to 3 scores, these results indicated that the included RCTs were middle or low quality. Patients' information extracted from the trials and the methodological quality are showed in Table 1.

Only 2 trials described the symptoms of bleeding. Festen et al[12] reported that patients with postoperative bleeding were admitted to the hospital and received a intra-anal treatment. Lehur et al[17] demonstrated that bleeding included either exteriorized or retroperitoneal. No trials reported the definition of the residual prolapse and urinary retention.

Two trials mentioned the definition of recurrence. Festen et al[12] defined the recurrence resolved preoperative symptoms with no need for further treatment. In the trial from Infantino et al,[15] the PATE 2000 scores was used to evaluate the symptoms of recurrence, including prolapse, and the persistence

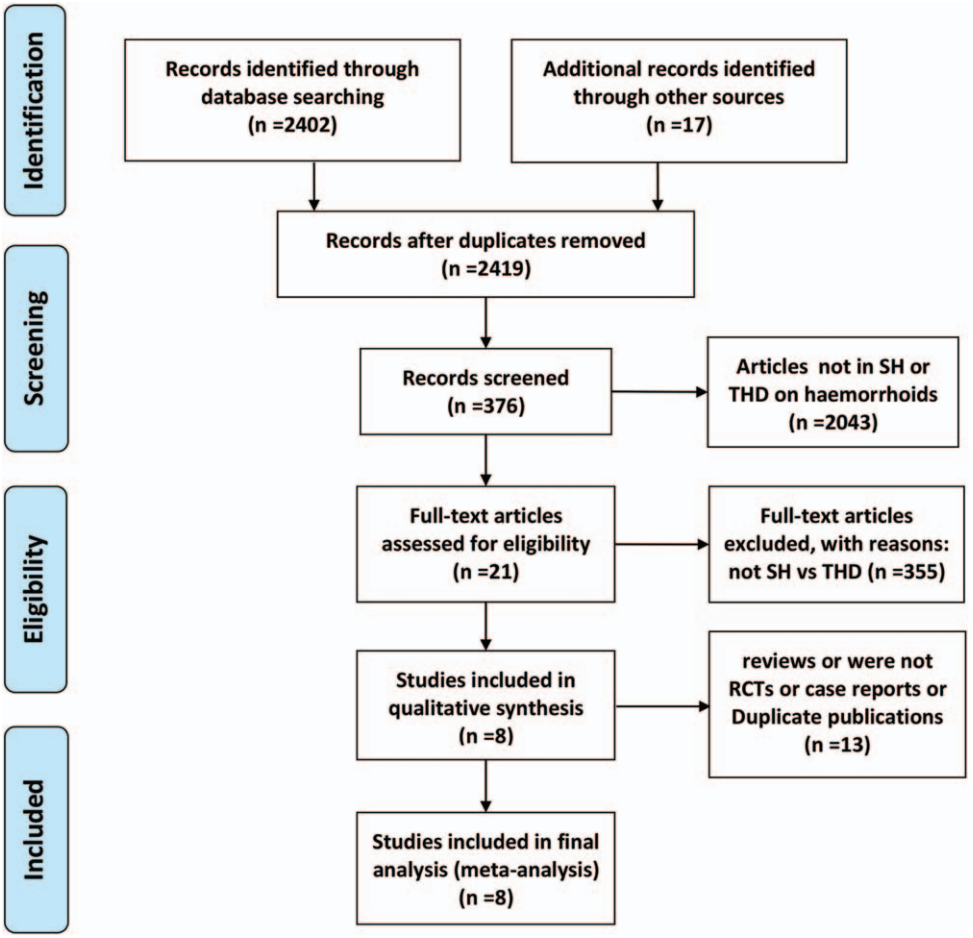

Figure 1. Search strategy.

of other anal symptoms at the end of the follow-up time. Two trials reported the definitions of satisfaction rate. Giordano et al classified the satisfaction as 4 categories: excellent, good, fair and poor[18] and Giarratano et al[19] classified as 3 categories: excellent, good and poor.

In the 8 included trials, visual analog scale (VAS) score was used to evaluate the postoperative pain and early postoperative pain was defined as 24 hours after operation.[19] Verre et al[16] defined the operative time as the duration from the first introduction of operation until dressing, not included the waiting

Table 1

Patients characteristics and methodological quality scores.

Trial	Year	Country	Type	Patients, n (M / F)	Mean age, years	Grade of hemorrhoids	Follow-up time, months	QS
Festen et al[12]	2009	Netherlands	SH	18 (13/5)	35	3 and 4	26 (20–30)	2
			TDH	23 (16/7)	39			
Khafagy et al[13]	2009	Egypt	SH	15 (9/6)	40.1 ± 11.2	3 and 4	3	2
			TDH	15 (13/20)	40.1 ± 9.8			
Giordano et al[14]	2011	UK	SH	24 (16/8)	48 (35–78)	2 and 3	36	2
			TDH	28 (20/8)	54 (23–73)			
Infantino et al[15]	2012	Italy	SH	84 (58/26)	47.6 ± 11.9	3 and 4	35 (27–43)	3
			TDH	85 (58/27)	46.2 ± 11.5			
Verre et al[16]	2013	Italy	SH	63 (24/39)	47.8	3 and 4	24	2
			TDH	59 (22/37)	48.9			
Lehur et al[17]	2016	France	SH	196 (126/70)	50 ± 11.7	2, 3 and 4	12	3
			TDH	197 (121/76)	50.5 ± 12.6			
Venturi et al[18]	2016	Italy	SH	35 (17/18)	50.2 ± 4.4	3 and 4	36	3
			TDH	35 (18/17)	49.5 ± 5.3			
Giarratano et al[19]	2018	Italy	SH	50 (25/25)	56 ± 10.5	3 and 4	24	3
			TDH	50 (27/23)	56 ± 9.9			

SH = stapled hemorrhoidectomy, THD = transanal hemorrhoidal dearterialization, QS = quality scores.

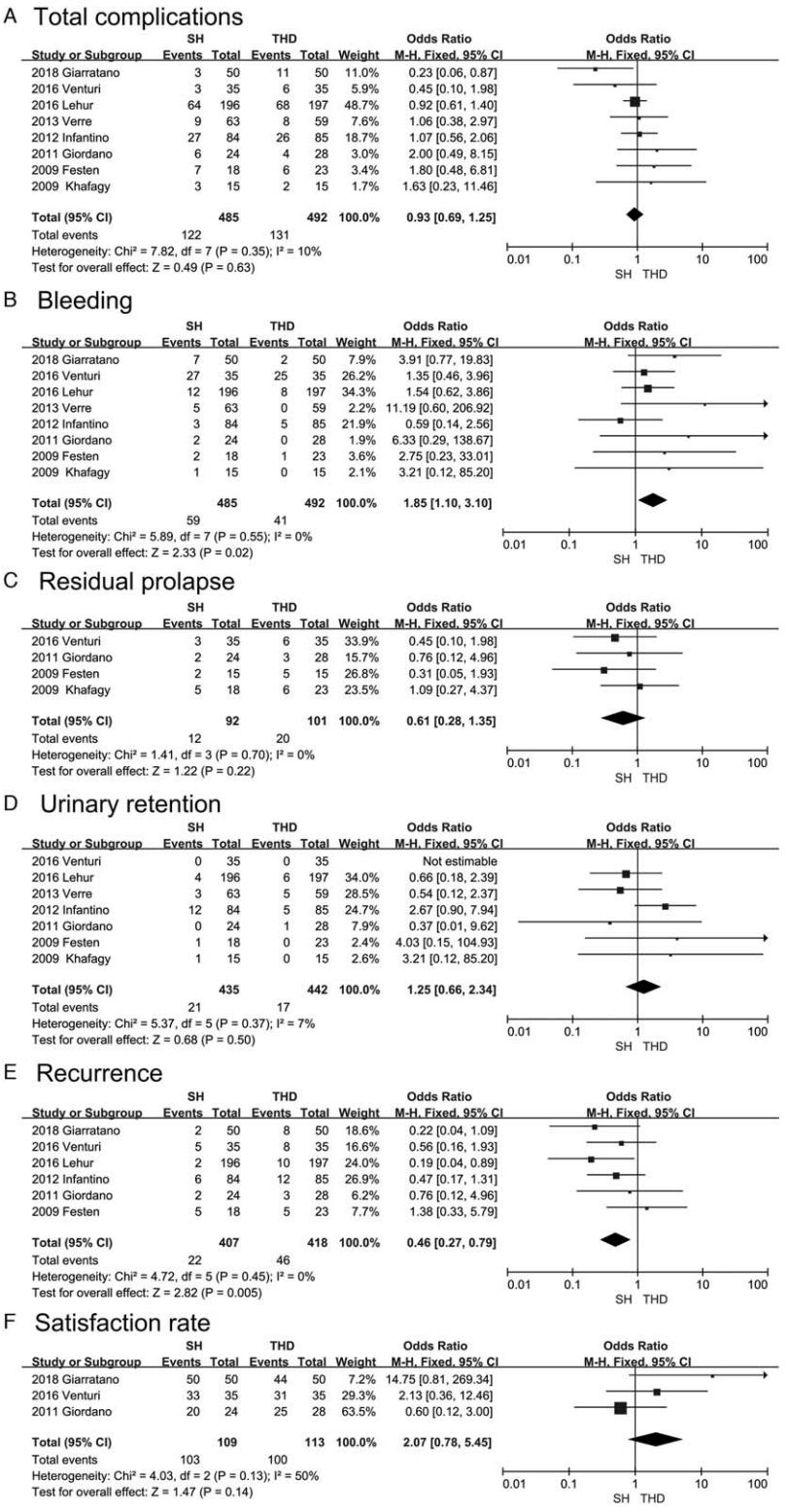

Figure 2. Postoperative complications and clinical outcomes: (A) total complications (B) bleeding; (C) residual prolapse; (D) urinary retention. (E) recurrence; (F) satisfaction rate.

time in the operation room. No trials reported the definitions of length of postoperative hospital stay and return to normal activity. The above findings indicated that the definitions of the outcomes were inconsistent and a methodological bias might exist.

3.3. Postoperative complications and clinical outcomes

3.3.1. Total complications. Eight RCTs included 977 patients reported the total complications. No heterogeneity was noted among the trials in terms of total number of complications ($\chi^2 = 7.82$, df = 7, $P = .35$; $I^2 = 10\%$). In the fixed models, no significant

difference was noted in the total complication rate between SH and THD (OR, 0.93; 95% CI, 0.69, 1.25; $Z=0.49$; $P=.63$; Fig. 2A).

3.3.2. Bleeding. Eight RCTs included 977 patients reported the complication of bleeding. Regarding major bleeding incidences after operation, no heterogeneity was noted among trials ($\chi^2=5.89$, df=7, $P=.55$; $I^2=0\%$). In the fixed model, no significant difference was noted in the bleeding rate between THD and SH (OR, 1.85; 95% CI, 1.10, 3.10; $Z=2.23$; $P=.02$; Fig. 2B).

3.3.3. Residual prolapse. Data from 4 trials included 193 patients suggested that no heterogeneity was present among the trials in terms of residual prolapse ($\chi^2=1.41$, df=3, $P=.70$; $I^2=0\%$). In the fixed model, no significant difference was noted in the residual prolapse between THD and SH (OR, 0.61; 95% CI, 0.28, 1.35; $Z=1.22$; $P=.22$; Fig. 2C).

3.3.4. Urinary retention. Seven RCTs included 877 patients reported the complication of urinary retention, and no heterogeneity was observed among the trials ($\chi^2=5.37$, df=5, $P=.37$; $I^2=7\%$). In the fixed model, no significant difference was noted in terms of urinary retention rate between THD and SH (OR, 1.25; 95% CI, 0.66, 2.34; $Z=0.68$; $P=.50$; Fig. 2D).

3.3.5. Recurrence. Five RCTs included 725 patients reported the recurrence rate,and no statistically significant heterogeneity was noted among the trials ($\chi^2=4.72$, df=5, $P=.45$, $I^2=0\%$). In the fixed models, a statistically significant difference in recurrence rate was noted between THD and SH (OR, 0.46; 95% CI, 0.27, 0.79; $Z=2.82$; $P=.005$; Fig. 2E). The total recurrence rate was higher in the THD group than in the SH group. For subgroup analysis, when we included the trials with a follow-up time of <3 years but more than 1 year and a significant difference was observed in recurrence rate.[12] However, when we only included the 2 trials with 3 years of follow-up, no significant difference was observed between THD and SH.[14,18]

3.3.6. Satisfaction rate. Only 3 trials include 222 patients reported information on the satisfaction rate. No statistically significant heterogeneity was noted among the trials ($\chi^2=4.03$, df=2, $P=.13$, $I^2=50\%$), therefore, we used the fixed model. No statistically significant difference was observed in the satisfaction rate between THD and SH (OR, 2.07; 95% CI, 0.78, 5.45; $Z=0.147$; $P=.14$; Fig. 2F).

3.4. Surgical parameters

3.4.1. Postoperative pain scores. Data from 5 trials included 586 patients suggested that there was a significant heterogeneity among trials regarding postoperative pain ($Tau^2=0.68$, $\chi^2=34.99$, df=4, $P<.00001$, $I^2=89\%$). In the random-effects model, no statistically significant difference was noted in the postoperative pain compared THD with SH (OR, 0.43; 95%CI, −0.43, 1.29; $Z=0.97$; $P=.33$; Fig. 3A).

3.4.2. Operative time. Data from 7 trials included 936 patients suggested that statistically significant heterogeneity was present among the trials in terms of operative time ($\tau^2=25.77$, $\chi^2=114.01$, df=6, $P<.00001$). In the random-effects model, there was no statistically significant difference in operative time between THD and SH (OR, −3.12; 95% CI, −7.01, 0.77; $Z=1.57$; $P=.12$; Fig. 3B).

3.4.3. Return to work time. Four trials included 344 patients provided the information on the average time to return to work after hemorrhoidectomy; statistically significant heterogeneity was observed among the trials ($\tau^2=14.84$, $\chi^2=43.76$, df=3, $P<.00001$, $I^2=93\%$); therefore, we used the random-effects model for analysis. There was no statistically significant difference in the return to work time compared THD with SH (OR, −0.50; 95%CI, −4.42,3.43; $Z=0.25$; $P=.80$; Fig. 3C).

3.4.4. Hospital stay. Four trials included 662 patients provided information about the average hospital stay after hemorrhoidectomy. There was significant heterogeneity among the trials in hospital stay ($\tau^2=0.03$, $\chi^2=11.40$, df=3, $P=.01$, $I^2=74\%$). No statistically significant difference in hospital stay was noted between THD and SH in the random-effects model (OR, −0.00; 95% CI, −0.21, 0.20; $Z=0.04$; $P=.96$ Fig. 3D).

3.4.5. Reoperation. Three trials included 586 patients reported the date on the reoperation rate after hemorrhoidectomy; a statistically significant heterogeneity was observed among trials ($\chi^2=5.50$, df=4, $P=.24$, $I^2=27\%$); therefore, we used the fixed-effects model for analysis. No statistically significant difference in the reoperation rate was noted between THD and SH (OR, 1.81; 95% CI, 0.93, 3.54; $Z=1.74$; $P=.08$; Fig. 3E).

3.4.6. Publication bias analysis. The summary of risk of bias assessment and funnel plot are presented in Figures 4 and 5. Among 8 RCTs, the methodological quality of the included trials was moderate because some of the trials did not give complete information for a formal assessment of their quality. Seven trials had low risk of bias in random sequence generation, however most trails showed either unclear or high risks of bias in allocation concealment, which suggested that a selection bias may be exist. Only 2 trials reported that blinding was used. The performance bias and detection bias were exist according to the summary, while the attrition bias and reporting bias were in low risk. The funnel plot showed that a minimal bias was exist. Overall, the included studies were of moderate quality with minimal publication bias.

4. Discussion

To improve clinical outcomes of the treatment for hemorrhoids, several less invasive and effective techniques, such as LigaSure and the harmonic and laser hemorrhoidoplasty procedure, were developed. However, none has proven to be clearly superior to the others.[20–24] SH and THD were described as more effective and less painful alternatives to CH.[25,26] A retrospective study indicated that both SH and THD are safe procedures and have similar effectiveness for treating grade III hemorrhoids.[27] However, THD was observed to be less effective for Grade III hemorrhoids in a long term follow-up.[28] Meanwhile, SH was considered a safe and effective procedure with long-lasting favorable results for grades II-IV hemorrhoids.[7] Although previous studies indicated that both THD and SH are safe and effective procedures for hemorrhoids, the outcomes in the mid-term and long-term period still show inconsistency.

In this meta-analysis, we found that both THD and SH are safe and effective procedures for hemorrhoids. No significantly difference was noted in postoperative outcomes, including total complication rate, residual prolapse, urinary retention rate, and satisfaction rate. The postoperative bleeding rate was lower in THD group than SH group, which indicated that THD was a safe procedures in term of bleeding rate compared with SH. The total recurrence rate was higher in the THD group than in the SH group in the short term follow-up;

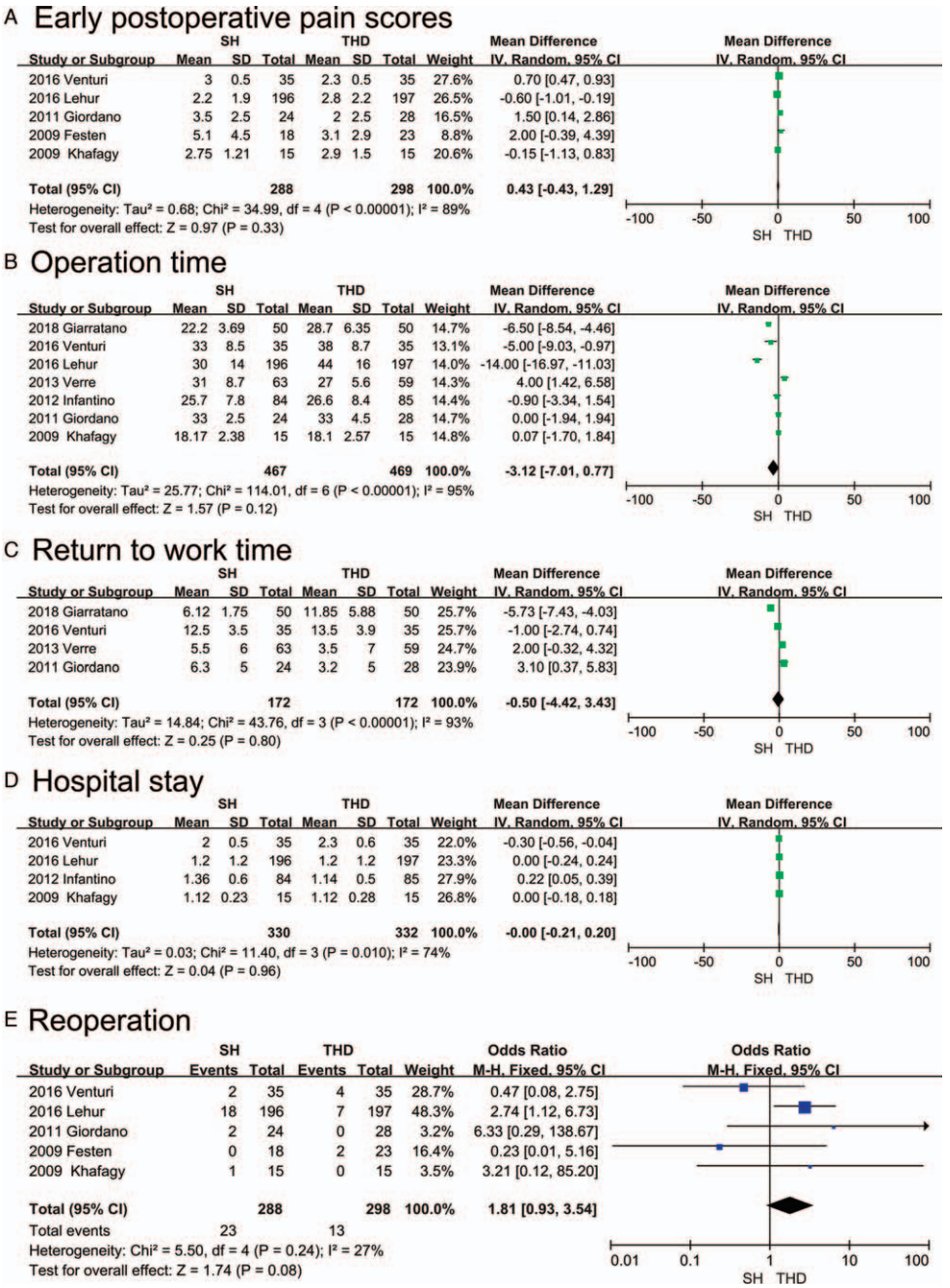

Figure 3. Surgical parameters: (A) early postoperative pain scores; (B) operation time; (C) return to work time; (D) hospital stay; (E) reoperation.

however, the long-term outcomes suggested that the recurrence rate was comparable in both THD and SH group. These results demonstrated that the short-term and long-term recurrence rate are inconsistent and further future studies are need to verify these results.

Postoperative pain is well accepted as a serious problem of patients undergoing hemorrhoidectomy. In this study, we only analyzed the pain scores 24 hours after operations. The present study showed that there was no significant difference in the postoperative pain scores between THD and SH. The 2 techniques were not statistically significantly different in terms of operative time, hospital time, and return to work time, and reoperation rate.

Cost-effectiveness is an important factor for the surgeons and patients when deciding which technique to use.[29] Because of the exchange rate and different health polices, medical fee is nonuniform in different countries. Therefore, we could not include them in this meta-analysis. Lehur et al[17] reported a significant difference in terms of cost of the procedure between THD with Doppler guidance with SH. A longer operative time and hospital stay time in the THD group may explain this result. However, Venturi et al[18] reported that THD without Doppler guidance is associated with less cost compared with SH. Satisfaction rate is another important factor for decision making. Only 3 studies reported information on satisfaction of the patients and there was no significant difference in satisfaction between THD and SH.

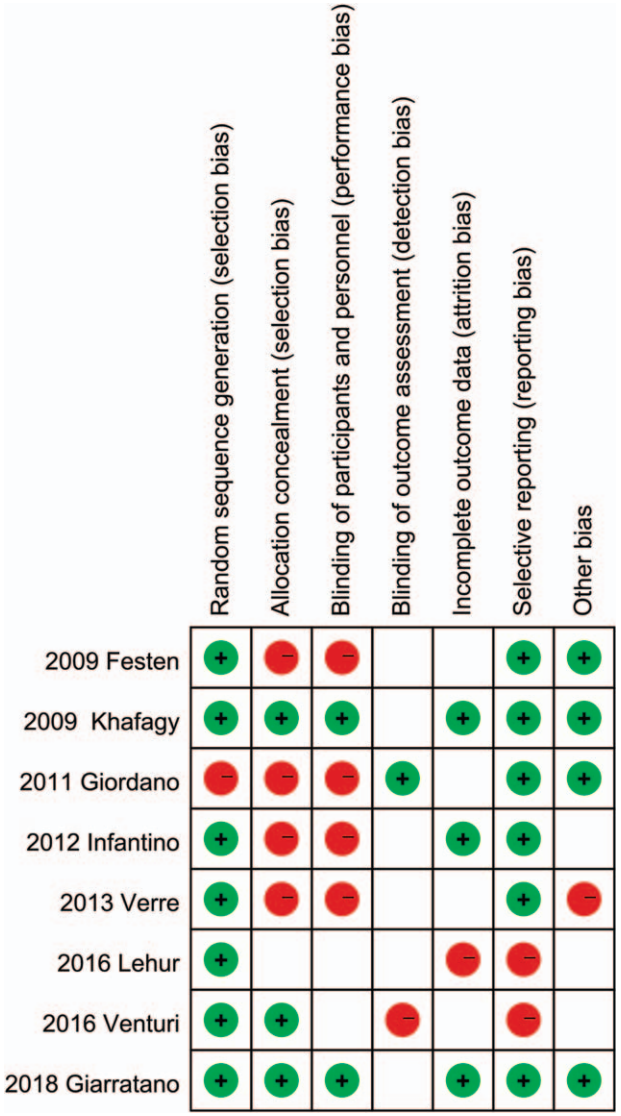

Figure 4. Summary of risk of bias assessment.

Based on the above results, SH and THD are comparable techniques in the treatment of the hemorrhoids. Thus, the present study calls into question the cost-effectiveness and satisfaction rate for the surgeons and patients of THD versus SH in different countries when deciding which technique to use.[30]

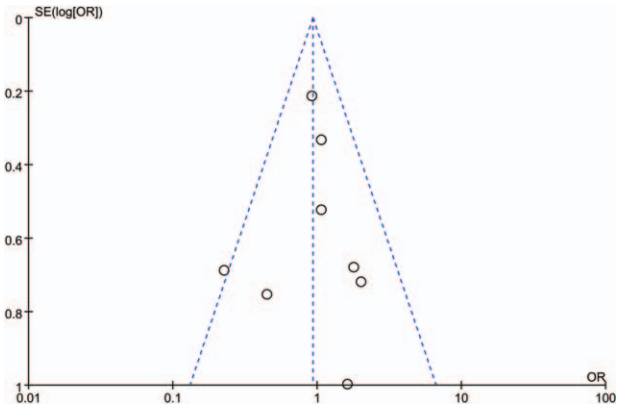

Figure 5. Funnel plot evaluating publication bias. Diagonal lines indicate 95% CI. Trials within these boundaries indicate minimal publication bias.

Our study was in line with 2 previous studies. A meta-analysis was published in 2012, and only 3 RCTs, encompassing 150 patients, were included, and one of the trials was published as an abstract.[9] THD was found to be associated with significantly less postoperative pain compared to SH. In 2015, a network meta-analysis reported that THD was a safe and quick surgical option for the treatment of hemorrhoids with a lower complication rate, lesser postoperative pain, and shorter operating time compared with SH.[10] In our study, we report latest and more certain evidence comparing THD versus SH. Although the recurrence rate of THD was higher in the short term follow-up, the recurrence rate was similar in the mid-term follow-up between THD and SH. These results suggest that both THD and SH are safe treatment options for hemorrhoids with acceptable complication rates and good short-term and mid-term outcomes. Nevertheless, our results also suggest that the cost of the procedure and the satisfaction rate may be the initial consideration for the surgeon and the patient when choosing THD or SH and this result was similar with the previous studies.

There are several limitations of this study. First, patients with different grades of hemorrhoids were included in the RCTs studied, which resulted in the quantitative analysis not being very powerful and the possibility of patient selection bias. Second, the statistical heterogeneity was high in terms of operative time, hospital stay, and return to work time, because the surgical protocol, postoperative care regimen, and the methods of outcome measures varied in the included studies. Third, the follow-up time variously from 3 months to 43 months in the included studies, and the short-term and long-term outcomes of THD and SH were difference. Standardized outcome measures, especially for recurrence, with a long term follow-up are required. Fourth, although our meta-analysis demonstrated that there was no significant difference between SH and THD in postoperative pain scores 24 hours after operation, the quantity of analgesics administered to patients varied, which may have influenced the results of the pain scores. Fifth, they should also investigate whether different surgical approaches should be used for single versus circumferential. Finally, all the published RCTs are from Western countries. Studies on races in other parts of the world may be needed for further research.

In conclusion, THD offers a safe surgery with significantly less postoperative bleeding compared with SH. However, SH had a lower recurrence rate compared with THD. High quality trials with large sample sizes are required to elucidate and confirm these results in long term periods.

Author contributions

Conceptualization: Yan Song, Honglei Chen, Yongheng He.
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Resources: Yan Song, Fang Yang,
Writing – original draft: Yan Song, Honglei Chen.
Writing – review & editing: Huiyong Huang, Yongheng He.

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