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Original Article

Transanal hemorrhoidal dearterialization versus stapled hemorrhoidectomy in the treatment of hemorrhoids: an update meta-analysis of randomized control trials

Qi Yao[1*], Honglei Chen[2*], Xingyang Wan[3], Lanzhen He[3], Yanan Liu[2]

[1]Department of Colonproctology Surgery, Shenzhen People's Hospital, Shenzhen, China; [2]Department of Gastrointestinal Endoscopy, Guangdong Provincial Key Laboratory of Colorectal and Pelvic Floor Diseases, The Sixth Affiliated Hospital of Sun Yat-sen University, Guangdong, China; [3]Department of Colonproctology Surgery, Guangdong Provincial Key Laboratory of Colorectal and Pelvic Floor Diseases, The Sixth Affiliated Hospital of Sun Yat-Sen University, Guangdong, China. [*]Co-first authors.

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Abstract: This study aims to compare the clinical outcomes of stapled hemorrhoidectomy (SH) and transanal hemorrhoidal dearterialization (THD) for the treatment of hemorrhoids diseases by a meta-analysis. Randomized control trials (RCTs), published between January 1, 1996 and June 31, 2017, comparing SH with THD were searched in databases, including MEDLINE, PubMed, Web of science, EMbase and the Cochrane Library database were. Seven RCTs, including 877 patients, were included in this meta-analysis. No statistically significant differences were noted between SH and THD in terms of complications (OR, 1.02; 95% CI, 0.75, 1.38), residual prolapse (OR, 0.61; 95% CI, 0.28, 1.35), urinary retention rate (OR, 1.25; 95% CI, 0.66, 2.34), and satisfaction rate (OR, 1.08; 95% CI, 0.34, 3.41). The bleeding rate and total recurrence rate was higher in THD than in SH. 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, -2.54; 95% CI, -6.85, 1.76), hospital time (OR, -0.00; 95% CI, -0.21, 0.20), time before returning to work (OR, 1.21; 95% CI, -1.35, 3.77), and reoperation rate (OR, 1.81; 95% CI, 0.93, 3.54). In conclusion, both procedures are simple and easy to perform for the treatment of hemorrhoids. However, THD leading to a higher rate of bleeding and recurrence rate in the treatment of hemorrhoids. Future studies addressing with a long follow-up period are needed to validate these results.

Keywords: Meta analysis, hemorrhoids, stapled hemorrhoidectomy, transanal hemorrhoidal dearterialization

Introduction

Hemorrhoids is a common benign anorectal disease diagnosed at the proctology clinic [1]. Conventional hemorrhoidectomy (CH) is the main surgical treatment for hemorrhoids [2]. However, CH is associated with a number of 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].

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

Several randomized controlled trials compared SH with THD have been published. A meta-analysis compared THD with SH was published in 2012. Only three randomized controlled trials encompassing 150 patients were included, and one of the trials was published as abstract. In 2015, a network meta-analysis indicated that

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 (month)	QS
Festen et al. [10]	2009	Netherlands	SH	18 (13/5)	35	2 and 3	26 (20-30)	2
			TDH	23 (16/7)	39			
Khafagy et al. [11]	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. [12]	2011	UK	SH	24 (16/8)	48 (35-78)	2 and 3	36	2
			TDH	28 (20/8)	54 (23-73)			
Infantino et al. [13]	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. [14]	2013	Italy	SH	63 (24/39)	47.8	3 and 4	24	2
			TDH	59 (22/37)	48.9			
Paul et al. [15]	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. [16]	2016	Italy	SH	35 (17/18)	50.2±4.4	3 and 4	36	3
			TDH	35 (18/17)	49.5±5.3			

QS: quality scores.

THD and SH were associated with less postoperative pain and earlier return to work, but a higher recurrence rates. However, which kind of technique is better is still in controversy. Since then, two further RCTs with a large number of patients have reported inconsistent results. In order to provide the latest and more solid evidence and 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.

Material and methods

Data sources

Relevant prospective RCTs that compared SH with THD were included in this meta-analysis. Randomizes control trials (RCTs) compared SH with THD were searched from the databases including MEDLINE, PubMed, Web of science, Embase and Cochrane Library database from 1996 to June 31, 2017, using the following search terms: “hemorrhoids”, “hemorrhoidal disease” and “prolapsing hemorrhoids” in combination with “procedure for residual prolapse and hemorrhoids”, “stapled hemorrhoidopexy”, “hemorrhoidal artery ligation”, “transanal hemorrhoidal de-arterialisation”, and “surgical treatment” combinded with “randomized trials”. Additional publications were searched in the references list of the included trials. Two observers identified and extracted the date from each study independently and blindly.

Inclusion and exclusion criteria

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

Statistical analysis

The RevMan5.2 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, weighted mean difference (WMD) was calculated with 95% confidence interval. The standard deviation was calculated following to the guidelines of the handbook Cochrane Collaboration. If mean values were not available for continuous outcomes, median values were used according to the guidelines of the Cochrane Collaboration. The fixed effects model and the random effects model were calculated to analyze the overall effect of the combined outcomes. Chi-Square statistic, with significance set at $P<0.05$, was used to explore the heterogeneity among the trials. Only the results of random effects model were reported in case of heterogeneity. We use the forest plot to show the results of the meta-analysis.

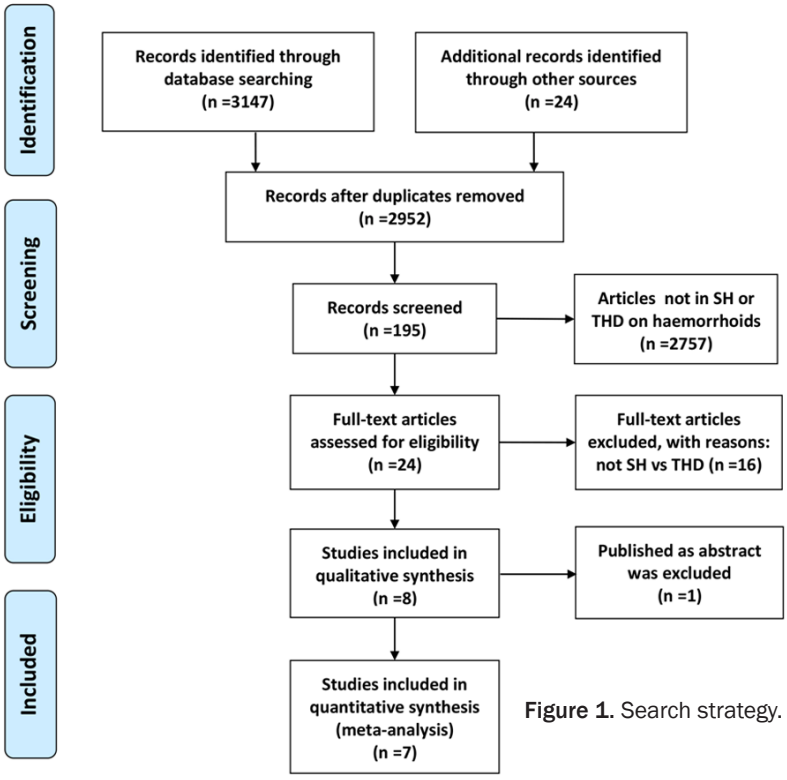


Figure 1. Search strategy.

Methodological quality assessment

Modified Jadad scale was used to assess the quality of included RCTs [9]. Publication bias was evaluated using funnel plots.

Results

Seven RCTs on 877 patients were included for the meta-analysis [10-16]. Patients' information extracted from including trials and methodological quality are showed in **Table 1**. **Figure 1** presents the search strategy of this study. Funnel plots showed no publication bias was exist in this meta-analysis.

Postoperative complications and clinical outcomes

Total complications: No heterogeneity was noted among trials in terms of total complications (χ^2=3.24, df=6, *P*=0.78; I^2=0%). In the fixed models, no significant difference was noted in the total complications rate between SH and THD (OR, 1.02; 95% CI, 0.75, 1.38; Z=0.11; P=0.91; **Figure 2A**).

Bleeding: Concerning the major bleeding after operation, no heterogeneity was noted among trials (χ^2=4.76, df=6, *P*=0.58; I^2=0%). In the fixed models, no significant difference was noted in the bleeding rate compared THD with SH (OR, 1.67; 95% CI, 0.96, 2.89; Z=1.83; P=0.07; **Figure 2B**).

Residual prolapse: Data from four trials suggested that no heterogeneity was noted among trials in terms of residual prolapse (χ^2=1.41, df=3, P=0.70; I^2=0%). In the fixed models, no significant difference was noted in the residual prolapse compared THD with SH (OR, 0.61; 95% CI, 0.28, 1.35; Z=1.22; P=0.22; **Figure 2C**).

Urinary retention: Regarding urinary retention, no heterogeneity was observed among trials (χ^2=5.37, df=5, *P*=0.37; I^2=7%). In the fixed models, no statistically significant difference was noted in terms of urinary retention rate compared THD with SH (OR, 1.25; 95% CI, 0.66, 2.34; Z=0.68; P=0.50; **Figure 2D**).

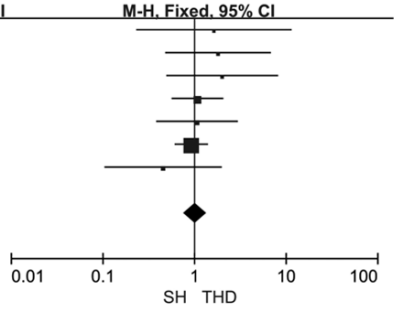
Recurrence: Concerning recurrence after hemorrhoidectomy, no statistically significant heterogeneity among trials (χ^2=3.63, df=4, P=0.46, I^2=0%). In the fixed models, a statistically significant difference was noted in terms of recurrence rate compared THD with SH (OR, 0.51; 95% CI, 0.29, 0.92; Z=2.25; P=0.0.02; **Figure 2E**). The total recurrence rate was higher in THD group than in SH group. For subgroup analysis, we including the trial with a follow up time less three years but more than one, a significant difference was observed in terms of recurrence rate [10]. However, when we only including the two trials with 3 years follow up, no significant difference was observed compared THD with SH [12, 16].

Satisfaction rate: Only two trials reported the information about the satisfaction rate compared THD with SH. No statistically significant heterogeneity was noted among trials (χ^2=1.08, df=1, P=0.30, I^2=7%), therefore, we used the fixed models. No statistically significant differ-

A Total complications

Study or Subgroup	SH Events	SH Total	THD Events	THD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2009 Khafagy	3	15	2	15	1.9%	1.63 [0.23, 11.46]
2009 Festen	7	18	6	23	3.9%	1.80 [0.48, 6.81]
2011 Giordano	6	24	4	28	3.3%	2.00 [0.49, 8.15]
2012 Infantino	27	84	26	85	21.0%	1.07 [0.56, 2.06]
2013 Verre	9	63	8	59	8.5%	1.06 [0.38, 2.97]
2016 Paul	64	196	68	197	54.8%	0.92 [0.61, 1.40]
2016 Venturi	3	35	6	35	6.6%	0.45 [0.10, 1.98]
Total (95% CI)		**435**		**442**	**100.0%**	**1.02 [0.75, 1.38]**
Total events	119		120			

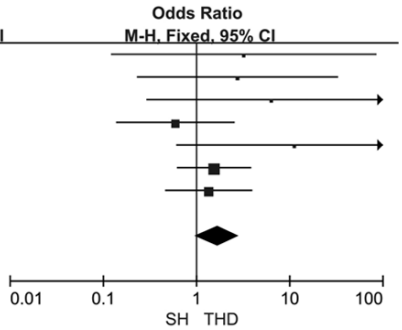
Heterogeneity: Chi² = 3.24, df = 6 (P = 0.78); I² = 0%
Test for overall effect: Z = 0.11 (P = 0.91)



B Bleeding

Study or Subgroup	SH Events	SH Total	THD Events	THD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2009 Khafagy	1	15	0	15	2.3%	3.21 [0.12, 85.20]
2009 Festen	2	18	1	23	3.9%	2.75 [0.23, 33.01]
2011 Giordano	2	24	0	28	2.1%	6.33 [0.29, 138.67]
2012 Infantino	3	84	5	85	23.8%	0.59 [0.14, 2.56]
2013 Verre	5	63	0	59	2.3%	11.19 [0.60, 206.92]
2016 Paul	12	196	8	197	37.2%	1.54 [0.62, 3.86]
2016 Venturi	27	35	25	35	28.4%	1.35 [0.46, 3.96]
Total (95% CI)		**435**		**442**	**100.0%**	**1.67 [0.96, 2.89]**
Total events	52		39			

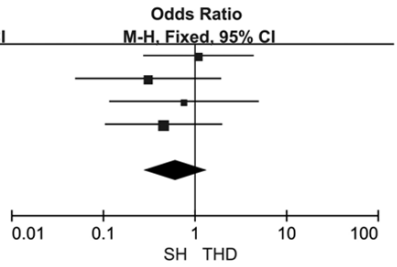
Heterogeneity: Chi² = 4.76, df = 6 (P = 0.58); I² = 0%
Test for overall effect: Z = 1.83 (P = 0.07)



C Residual prolapse

Study or Subgroup	SH Events	SH Total	THD Events	THD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2009 Khafagy	5	18	6	23	23.5%	1.09 [0.27, 4.37]
2009 Festen	2	15	5	15	26.8%	0.31 [0.05, 1.93]
2011 Giordano	2	24	3	28	15.7%	0.76 [0.12, 4.96]
2016 Venturi	3	35	6	35	33.9%	0.45 [0.10, 1.98]
Total (95% CI)		**92**		**101**	**100.0%**	**0.61 [0.28, 1.35]**
Total events	12		20			

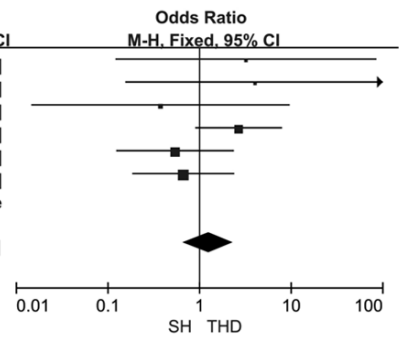
Heterogeneity: Chi² = 1.41, df = 3 (P = 0.70); I² = 0%
Test for overall effect: Z = 1.22 (P = 0.22)



D Urinary retention

Study or Subgroup	SH Events	SH Total	THD Events	THD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2009 Khafagy	1	15	0	15	2.6%	3.21 [0.12, 85.20]
2009 Festen	1	18	0	23	2.4%	4.03 [0.15, 104.93]
2011 Giordano	0	24	1	28	7.9%	0.37 [0.01, 9.62]
2012 Infantino	12	84	5	85	24.7%	2.67 [0.90, 7.94]
2013 Verre	3	63	5	59	28.5%	0.54 [0.12, 2.37]
2016 Paul	4	196	6	197	34.0%	0.66 [0.18, 2.39]
2016 Venturi	0	35	0	35		Not estimable
Total (95% CI)		**435**		**442**	**100.0%**	**1.25 [0.66, 2.34]**
Total events	21		17			

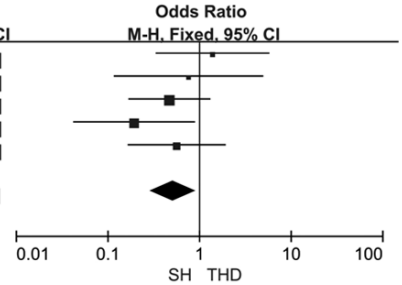
Heterogeneity: Chi² = 5.37, df = 5 (P = 0.37); I² = 7%
Test for overall effect: Z = 0.68 (P = 0.50)



E Recurrence

Study or Subgroup	SH Events	SH Total	THD Events	THD Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2009 Festen	5	18	5	23	9.5%	1.38 [0.33, 5.79]
2011 Giordano	2	24	3	28	7.6%	0.76 [0.12, 4.96]
2012 Infantino	6	84	12	85	33.0%	0.47 [0.17, 1.31]
2016 Paul	2	196	10	197	29.5%	0.19 [0.04, 0.89]
2016 Venturi	5	35	8	35	20.5%	0.56 [0.16, 1.93]
Total (95% CI)		**357**		**368**	**100.0%**	**0.51 [0.29, 0.92]**
Total events	20		38			

Heterogeneity: Chi² = 3.63, df = 4 (P = 0.46); I² = 0%
Test for overall effect: Z = 2.25 (P = 0.02)



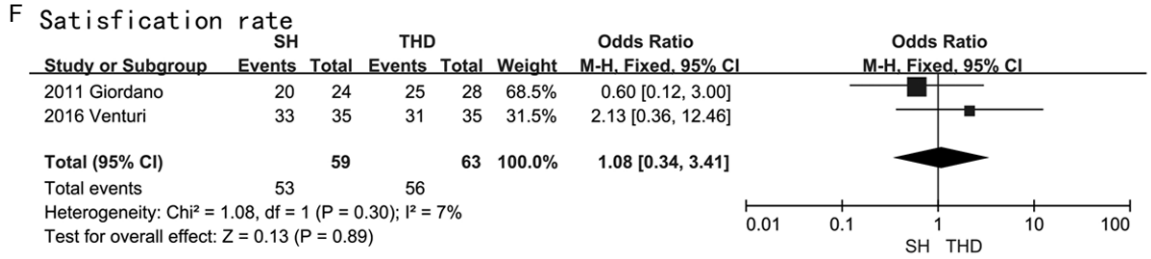


Figure 2. Postoperative complications and Clinical outcomes: (A) Total complications (B) Bleeding; (C) Residual prolapse; (D) Urinary retention. (E) Recurrence; (F) Satisfaction rate.

ence was observed regarding the satisfaction rate (OR, 1.08; 95% CI, 0.34, 3.41; Z=0.13; P =0.89; **Figure 2F**).

Surgical parameters

Postoperative pain scores: Data from five trials suggested that there was a significant heterogeneity among trials regarding postoperative pain (Tau^2=0.68, χ^2=34.99, ,0001, 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*=0.33; **Figure 3A**).

Operative time: Data from six trials suggested that a statistically significant heterogeneity was noted among trials regarding operative time (Tau^2=27.05, χ^2=93.07, df=5, *P*<0.00001, I^2= 95%). In the random-effects model, there was no statistically significant difference regarding operative time compared THD with SH (OR, -2.54; 95% CI, -6.85, 1.76; Z=1.16; *P*=0.25; **Figure 3B**).

Return to work time: Four trials provided the information about the average hospital stay after hemorrhoidectomy, there was a significant heterogeneity among trials (Tau^2=0.03, χ^2=11.40, df=3, *P*=0.01, I^2=74%). No statistically significant difference was noted in terms of hospital stay compared THD with SH in the random-effects model (OR, -0.00; 95% CI, -0.21, 0.20; Z=0.04; *P*=0.96, **Figure 3C**).

Hospital stay: Three trials provided the information about the average time of return to work after hemorrhoidectomy, a statistically significant heterogeneity was observed among trials (Tau^2=3.79, χ^2=7.87, df=3, P=0.02, I^2=75%), 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, 1.21; 95% CI, -1.35, 3.77; Z=0.92; *P*=0.36; **Figure 3D**).

Reoperation: Three trials reported the date about the reoperation rate after hemorrhoidectomy, a statistically significant heterogeneity was observed among trials (χ^2=5.50, df=4, P=0.24, I^2=27%), therefore we used the fixed-effects model for analysis. No statistically significant difference in the reoperation rate was noted compared THD with SH (OR, 1.81; 95% CI, 0.93, 3.54; Z=1.74; P=0.08; **Figure 3E**).

Publication bias analysis

The summary of risk of bias assessment and funnel plot are presented in **Figures 4**, **5**. Overall, the included studies were of moderate quality with minimal publication bias.

Discussion

To improve clinical outcomes of treatment for hemorrhoids, several less invasive and effective techniques, such as ligasure, harmonic and laser hemorrhoidoplasty procedure, were developed. However, none has proven clearly superior to the others [17-21]. SH and THD were described as more effective and a less painful alternative to CH [22, 23]. A retrospective study indicated that both SH and THD are safe procedures and have similar effectiveness for treating grade III hemorrhoids [24]. However, THD seems less effective for Grade III hemorrhoids in a long term follow up [25]. Meanwhile, SH was considered as a safe and effective procedure with sustained 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 inconsistency.

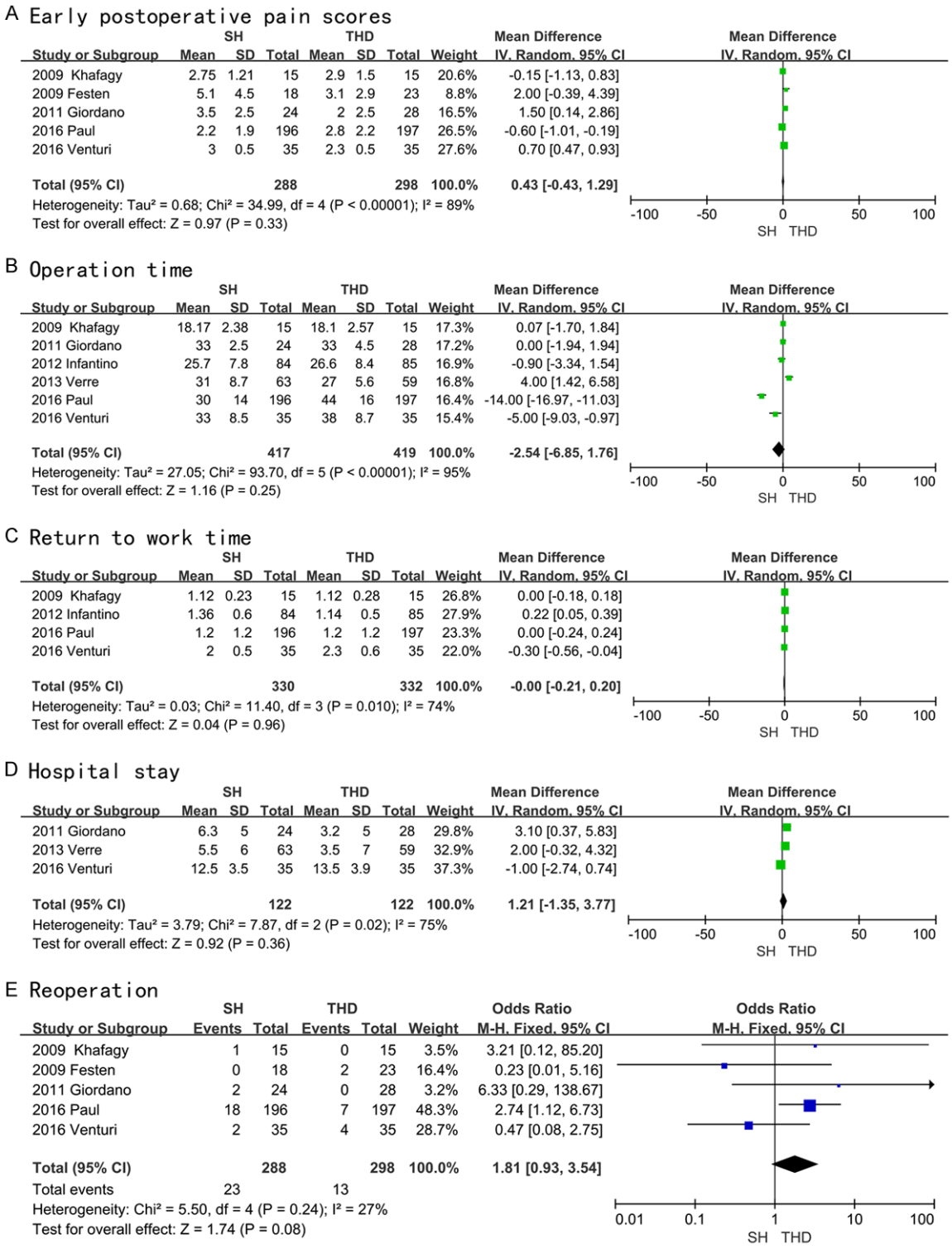


Figure 3. Surgical parameters: (A) Early postoperative pain scores; (B) Operation time; (C) Return to work time; (D) Hospital stay; (E) Reoperation.

In this meta-analysis, we found that both THD and SH are safe and effective procedures for hemorrhoids. No significantly different was noted in terms of postoperative outcomes including total complications, bleeding, residual prolapse, urinary retention rate and satisfaction rate. The total recurrent rate was higher in THD compared with SH in the short term follow

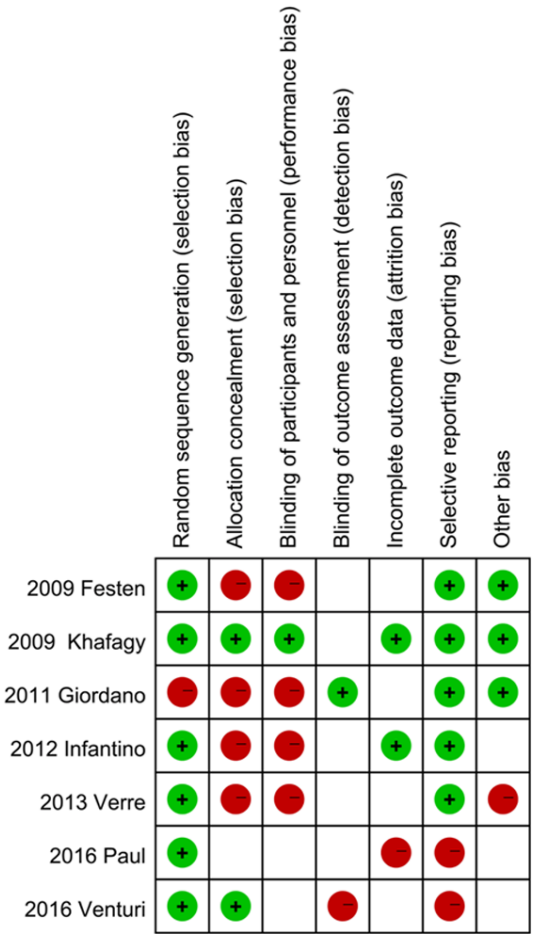


Figure 4. Summary of risk of bias assessment.

up, however, the mid-term outcomes suggested that the recurrent rate was equal in both THD and SH group. These results indicated that the researches focus on the recurrent rate compared SH with THD in a long term follow up are needed in the future.

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

Cost-effectiveness is an important factor for the surgeons and patients when deciding which technique to use [26]. Due to the exchange rate and different health polices, medical fee was non-uniform in different countries, and therefore, we could not include them in this meta-analysis. Lehur et al. indicated that a significant difference was noted compared THD with Doppler guidance with SH as regards the cost [15]. A longer operative time and hospital stay time in the THD group may explain this result [12, 16]. However, Venturi et al. reported that THD without Doppler guidance was associated with less cost than SH. Satisfaction rate is another important factor for decision making [16]. Only two studies reported the satisfaction of the patients and there was no significant difference between THD and SH. Base on the above results, SH and THD are equal techniques in the treatment of the hemorrhoids, thus, the present study calls into question the cost-effectiveness and satisfaction rate of THD versus SH in different countries for the surgeons and patients when deciding which technique to use [27].

Our study was in line with previous two studies. A meta-analysis was published in 2012, and only three RCTs encompassing 150 patients were included and one of the trials was published as abstract [28]. THD was associated with significantly less postoperative pain compared to SH. In 2015, a network meta-analysis demonstrated that THD was a safe and quick recover surgical option for the treatment of hemorrhoids with a low complication rate, less postoperative pain and shorter operating time compared with SH [29]. In our study, we reported a latest and more solid evidence results for 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 suggested that both THD and SH are safe treatments for hemorrhoids with acceptable complication rates and good short-term and mid-term outcomes. Never the less, our results also suggested that cost and satisfaction rate may be the initial consideration for surgeon and patients when choosing THD or SH and this result was similar with the previous studies.

There are a number of limitations with the study. First, patients with different grade of hemorrhoids were involved in the including studies which implied that the quantitative

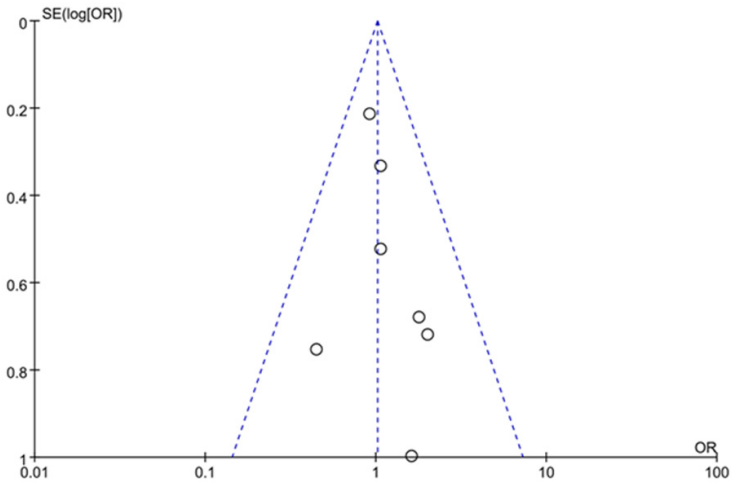


Figure 5. Funnel plot evaluating publication bias. Diagonal lines indicate 95% CI. Trials within these boundaries indicate minimal publication bias.

analysis was not very powerful and patients selection bias may exist. Second, the statistical heterogeneity was high in terms of operative time, hospital stay and return to work time during operation because of the different outcome measures and treatment considered. Surgical protocol, postoperative care regiment and the methods of outcome measures were various in included studies. Third, these trials only reported the short-term and mid-term outcomes of the THD versus SH. Standardized outcome measures, especially for recurrence with a long term follow up are required. Fourth, although our meta-analysis demonstrated that there was no significantly difference between SH and THD in postoperative pain scores 24 hours after operations. The quantity of analgesia used by patients varied which may influence 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 west countries, studies in the other races may need for further research.

In conclusion, THD and SH are safe and effective method for hemorrhoids in the short-term and mid-term period. Large volume multicenter trials are required to elucidate and confirm these results in long term periods.

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Disclosure of conflict of interest

None.

Address correspondence to: Qi Yao, Department of Colonproctology Surgery, Shenzhen People's Hospital, No 1017 Dongmen North Road, Luohu District, Shenzhen 518020, Guangdong, China. Tel: 0086-755-22948470; Fax: 0086-755-2553-3497; E-mail: yaoqi19832002@163.com; Honglei Chen, Department of Gastrointestinal Endoscopy, Guangdong Provincial Key Laboratory of Colorectal and Pelvic Floor Diseases, The Sixth Affiliated Hospital of Sun Yat-sen University, No 26, Yuancun Er Heng Road, Tianhe District, Guangzhou 510655, Guangdong, China. Tel: 0086-20-38254092; Fax: 0086-20-38254116; E-mail: chl_830830@163.com

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