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REVIEW

A systematic review comparing transanal haemorrhoidal de-arterialisation to stapled haemorrhoidopexy in the management of haemorrhoidal disease

M. S. Sajid · U. Parampalli · P. Whitehouse · P. Sains · M. R. McFall · M. K. Baig

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Abstract
Background The aim of this study was to systematically analyse the clinical trials on the effectiveness of transanal haemorrhoidal de-arterialisation (THD) and stapled haemorrhoidopexy (SH) in the management of haemorrhoidal disease (HD).
Methods Clinical trials on the effectiveness of THD and SH in the management of HD were analysed systematically using RevMan®, and combined outcomes were expressed as risk ratio (RR) and mean difference (MD).
Results Three randomised, controlled trials encompassing 150 patients were analysed systematically. There were 80 THD patients and 70 SH patients. There was no significant heterogeneity ($P = 0.40$) among included trials. Therefore, in the fixed effects model, THD and SH were statistically equivalent in terms of treatment success rate ($P = 0.19$), operation time ($P = 0.55$), postoperative complications ($P = 0.11$) and recurrence ($P = 0.46$) of HD. THD was associated with significantly less postoperative pain (MD, −2.00; 95% CI, −2.06, −1.94; $z = 63.59$; $P < 0.00001$) compared to SH.
Conclusions Both THD and SH are equally effective and can be attempted for the management of HD. However, THD is associated with significantly lesser postoperative pain and therefore may be considered a preferred procedure. This conclusion is based only on treating 150 patients by THD or SH in three moderate-quality randomised trials. A major, multicenter, randomised trial is required to validate this conclusion and investigate other variables like hospital stay, cost-effectiveness and health-related quality of life measurement.

Keywords Stapled haemorrhoidopexy · Bleeding per rectum · Haemorrhoidectomy · Transanal haemorrhoidal de-arterialisation · Procedure for prolapse and haemorrhoids

M. S. Sajid (✉) · U. Parampalli · P. Whitehouse · P. Sains · M. R. McFall · M. K. Baig
Department of Laparoscopic Colorectal Surgery, Worthing Hospital, Worthing, West Sussex BN11 2DH, UK
e-mail: surgeon1wrh@hotmail.com

Introduction

Haemorrhoidal disease (HD) is the most common type of anorectal disorder seen in the proctology clinic [1]. The incidence of rectal bleeding as a consequence of colorectal pathologies is about 20% per year in Western nations and is mostly due to the HD. The prevalence of HD ranges from 4.4 to 86% [1–4]. Multicenter, randomised, clinical trials have demonstrated that conventional haemorrhoidectomy including the Milligan–Morgan and Ferguson methods and their modifications are associated with numerous complications. The major complications include sphincter dysfunction in up to 25% of patients, pain severe enough to prevent patients from working for up to 3 weeks in 75%, bleeding in 5–15% and up to 30% risk of recurrent disease [4]. Rubber band ligation [5] has been proven to be effective in the treatment for internal haemorrhoids but virtually ineffective for treating fourth-degree HD. The suture technique revived by Farag [6] and its modifications [7, 8] have failed to gain widespread acceptance because they are directed mainly at reduction in blood flow to haemorrhoidal cushions, which is associated with initial painful congestion followed by gradual shrinkage of prolapsed haemorrhoids. Similarly, injection sclerotherapy, photocoagulation and cryosurgery have been found to be effective but with low success rates and high recurrence

rates [9–13]. Stapled haemorrhoidopexy (SH) has been reported to be a viable and highly effective alternative compared to other invasive approaches for the management of HD [14–17]. However, a recently published Cochrane Review of 23 randomised controlled trials [18] concluded that SH was not superior to conventional haemorrhoidectomy and its modifications. SH has also been reported to be an expensive procedure, and it is associated with a higher incidence of severe postoperative pain and anal stricture formation than other invasive techniques [19]. Because of a variable success rate, significant postoperative complications and a higher incidence of long-term recurrence following the use of these modalities for the management of HD, efforts are constantly being made to develop an effective and minimally invasive technique to treat haemorrhoids. In 1995, a new technique for the surgical treatment [20, 21] of haemorrhoids called haemorrhoidal artery ligation or transanal haemorrhoidal de-arterialisation (THD) was introduced. This procedure eliminates haemorrhoidal symptoms by ligating the terminal haemorrhoidal branches of the superior haemorrhoidal artery with the help of a specially designed proctoscope (anoscope) coupled with a Doppler probe to aid location of the vessels. Vessel ligation results in the decongestion of haemorrhoidal tissue. This decreased tension allows regeneration of connective tissue within the anal cushions. This in turn facilitates the shrinkage of the piles, reduction in the prolapse and alleviation of symptoms. Since 1995, THD has been evaluated in many case series [1, 4, 22–33] and three randomised controlled trials [34–36]. Currently, both PPH and THD are being investigated quite extensively to evaluate their clinical success to treat HD in terms of postoperative pain, relief of symptoms and recurrence rate. The aim of this review is to systematically analyse the clinical trials on the effectiveness of THD and SH in the management of HD by using the principles of meta-analysis.

Materials and methods

Relevant prospective randomised, controlled trials (irrespective of type, language, blinding, sample size or publication status) on the use of THD versus SH for the management of HD of any grade published before May 2011 were included in this review. The Cochrane Colorectal Cancer Group (CCCG) Controlled Trial Register, the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library, Medline, EMBASE and Science Citation Index Expanded were searched until May 2011 using the medical subject headings (MeSH) "haemorrhoids", "prolapsing haemorrhoids", and "haemorrhoidal disease" in combination with "surgical treatment", "stapled haemorrhoidopexy", "procedure for prolapse and haemorrhoids", "transanal haemorrhoidal de-arterialisation", "haemorrhoidal artery ligation" and "anopexy coupled with Doppler probe". The "related article" function was used to widen the search criteria. All abstracts, comparative studies, non-randomised trials and citations scanned were reviewed in order to get the maximum results from a comprehensive literature search. A filter for identifying relevant studies recommended by the Cochrane Collaboration [37] was used to filter out irrelevant studies in Medline and Embase. The references from the included studies were searched to identify additional trials. Two authors independently identified the relevant studies for inclusion, extracted the data related to the outcomes and secured data on the Microsoft Excel spread sheet. Any conflict about data was resolved by mutual agreement among the authors. The software package RevMan 5.0.1 [38] provided by the Cochrane Collaboration was used for the statistical analysis. The risk ratio (RR) with a 95% confidence interval (CI) was calculated for binary data variables. Summated outcome of the continuous variables was expressed as mean difference (MD). If the standard deviation was not available, then it was calculated according to the guidelines of the Cochrane Collaboration [37]. This process involved the assumptions that both groups had the same variance, which may not have been true, and variance was estimated either from the range or from the *P*-value. The estimate of the difference between both techniques was pooled, depending upon the effect weights in results determined by each trial estimate variance. The random effects model [39] and the fixed effect model [40] were used to calculate the combined outcome in case of both binary and continuous variables. In case of heterogeneity, only the results of the random effects model were reported. Heterogeneity was explored using the χ^2 test, with significance set at $P < 0.05$, and was quantified [41] using I^2, with a maximum value of 30 per cent identifying low heterogeneity [37]. The Mantel–Haenszel method was used for the calculation of RR under the fixed effect model, and the DerSimonian/Laired method was used for the calculation of RR under the random effect model [42]. In a sensitivity analysis, 0.5 was added to each cell frequency for trials in which no event occurred in either the treatment or control group, according to the method recommended by Deeks et al. [43]. The estimate of the difference between both techniques was pooled depending upon the effect weights in results determined by each trial estimate variance. The forest plot was used for the graphical display of the results from the meta-analysis. The square around the estimate stood for the accuracy of the estimation (sample size), and the horizontal line represented the 95% CI.

Results

The PRISMA flow chart to explain the study methodology, literature search and trial selection is given in Fig. 1. Three randomised, controlled trials [34–36], encompassing 150 patients, who underwent THD or SH for HD of any degree were retrieved from the electronic databases. Eighty patients underwent THD and 70 patients underwent SH. Variables used to achieve a combined outcome are given in Table 1.

Methodological quality of included studies

The methodological quality of the included trials was initially assessed by the published guideline of Jadad et al. and Chalmers et al. [44, 45]. All trials were of moderate strength according to these criteria. Based on the quality of included randomised controlled trials, the strength and summary of evidence was further evaluated by GradePro® [46], a statistical tool provided by the Cochrane Collaboration (Fig. 2). The Mantel–Haenszel fixed effect model was used to compute robustness and susceptibility to any outlier among these trials. The allocation concealment and blinding of investigator or assessor were not clearly reported in most of the trials evaluating surgical procedures. Therefore, qualitatively, the results of this review may be considered relatively weak, but realistically, they may be considered moderate-quality evidence. There was no statistically significant heterogeneity (clinical and methodological diversity) among trials.

Treatment success rate

There was no heterogeneity [$\chi^2 = 0.90$, $df = 2$, ($P = 0.64$); $I^2 = 0\%$] among trials. Therefore, in the fixed effects model, treatment success rate following THD was higher compared to SH but statistically (RR, 0.92; 95% CI, 0.81, 1.04; $z = 1.31$; $P = 0.19$; Fig. 3), it was not

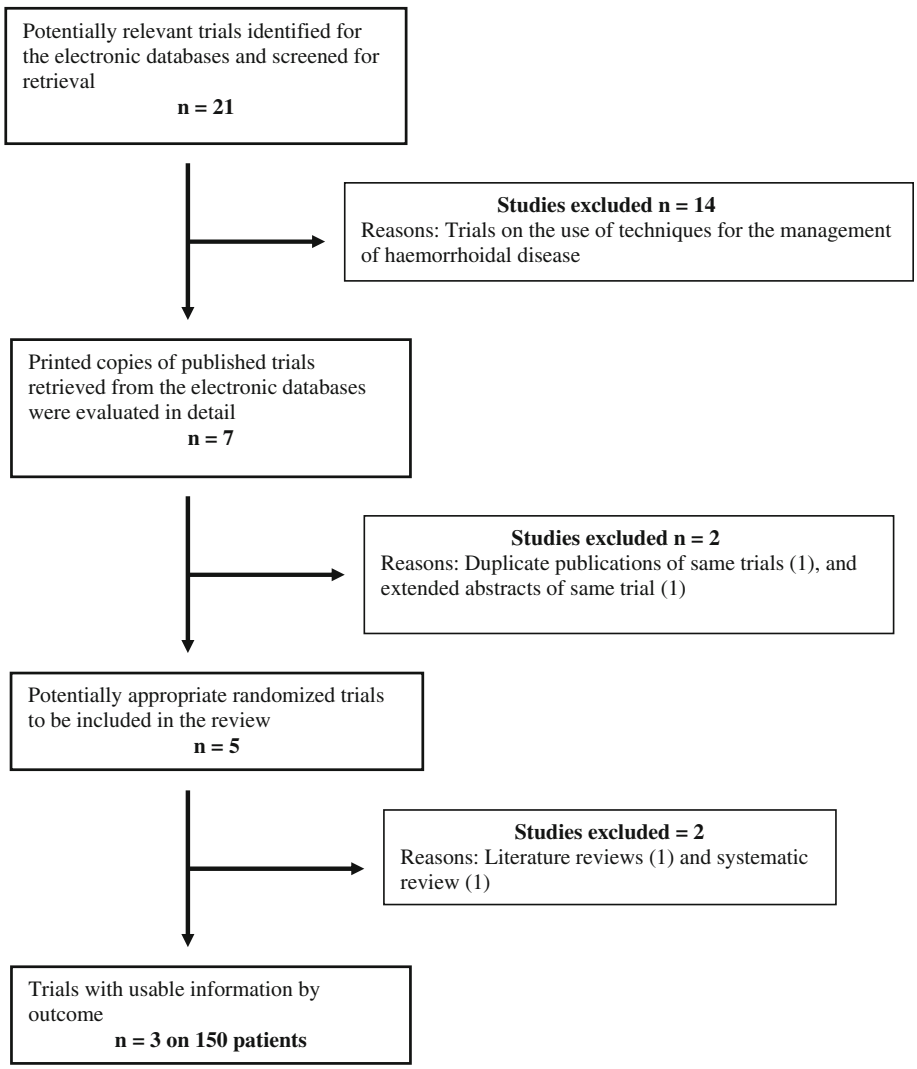

Fig. 1 PRISMA flow chart trial selection methodology

Table 1 Data of outcome variables extracted from included randomised trials

Trial	Patients	Treatment success	Operative time (min)	Complications	Pain VAS score	Recurrence
Festen et al. [34]						
THD	23	18/23	Not reported	2/23	3.1 ± 0.1**	5/23
PPH	18	15/18		3/18	5.1 ± 0.1**	5/18
Giordano et al. [35]						
THD	28	25/28	30 ± 4.5*	4/28	2 ± 2.5*	3/28
PPH	24	22/24	33 ± 20.5*	6/24	3.5 ± 2.5*	2/24
Ramirez et al. [36]						
THD	29	23/29	20 ± 26.7**	0/29	1 ± 4.1**	6/29
PPH	28	26/28	20 ± 26.7**	2/28	3 ± 4.1**	2/28

* Standard deviation estimated from range

** Standard deviation estimated from *P*-value

THD compared to PPH for the management of haemorrhoidal disease

Patient or population: patients with haemorrhoidal disease
Settings:
Intervention: THD
Comparison: PPH

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk PPH	Corresponding risk THD	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Treatment success Risk ratio Follow-up: mean 2 years	**Study population**		**RR 0.92** (0.81 to 1.04)	150 (3 studies)	⊕⊕⊕⊟ **moderate**[1]	
	900 per 1000	**828 per 1000** (729 to 936)				
	Medium risk population					
	917 per 1000	**844 per 1000** (743 to 954)				
Operation time Mean difference Follow-up: mean 2 years		The mean Operation time in the intervention groups was **2.2 lower** (9.36 lower to 4.97 higher)		109 (2 studies)	⊕⊕⊕⊟ **moderate**	
Complications Risk ratio Follow-up: mean 2 years	**Study population**		**RR 0.48** (0.20 to 1.18)	150 (3 studies)	⊕⊕⊕⊟ **moderate**	
	157 per 1000	**75 per 1000** (31 to 185)				
	Medium risk population					
	167 per 1000	**80 per 1000** (33 to 197)				
Postoperaitve pain Mean difference Follow-up: mean 2 years		The mean Postoperaitve pain in the intervention groups was **2 lower** (2.06 to 1.94 lower)		150 (3 studies)	⊕⊕⊕⊟ **moderate**	
Recurrence Risk ratio Follow-up: mean 2 years	**Study population**		**RR 1.33** (0.62 to 2.84)	150 (3 studies)	⊕⊕⊕⊟ **moderate**	
	129 per 1000	**172 per 1000** (80 to 366)				
	Medium risk population					
	83 per 1000	**110 per 1000** (51 to 236)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Lack of adequate randomisation technique, study power calculations, blinding, and intention to treat analysis

Fig. 2 Summary and strength of the evidence from trials analysed on GradePro®

significant. Therefore, both techniques may be considered equally effective in the management of HD.

Operative time

Two trials [35, 36] contributed to the combined calculation of this outcome. There was no heterogeneity [$\chi^2 = 0.13$, $df = 1$, ($P = 0.72$); $I^2 = 0\%$] among trials. Therefore, in the fixed effects model, the operation time for THD was shorter compared to SH, but statistically (MD, −2.20; 95% CI, −9.36, 4.97; $z = 0.60$; $P = 0.55$; Fig. 4), it was not significant.

Postoperative complications

There was no heterogeneity [$\chi^2 = 0.45$, $df = 2$, ($P = 0.80$); $I^2 = 0\%$] among trials. By using the fixed effects model, THD was associated with fewer postoperative complications compared to the SH, but statistically (RR, 0.48; 95% CI, 0.20, 1.18; $z = 1.80$; $P = 0.11$; Fig. 5), this was not significant. Therefore, both techniques may be considered equally effective in the management of HD.

Postoperative pain

There was no heterogeneity [$\chi^2 = 0.52$, $df = 2$, ($P = 0.77$); $I^2 = 0\%$] among trials. Postoperative pain following THD was significantly lower compared to SH (MD, −2.00; 95% CI, −2.06, −1.94; $z = 63.61$; $P < 0.00001$; Fig. 6) using the fixed effects model.

Recurrence of haemorrhoids

There was no heterogeneity [$\chi^2 = 1.95$, $df = 2$, ($P = 0.38$); $I^2 = 0\%$] among trials. Therefore, in the fixed

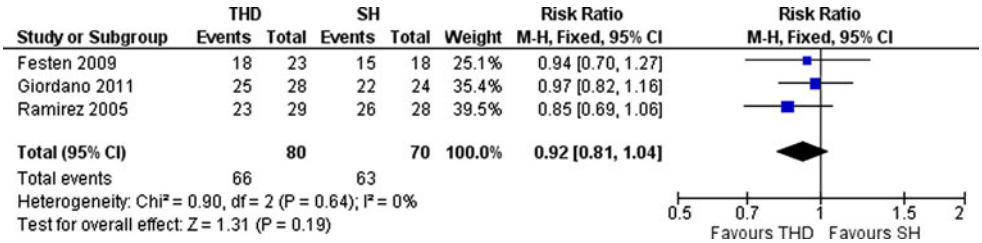

Fig. 3 Treatment success rate

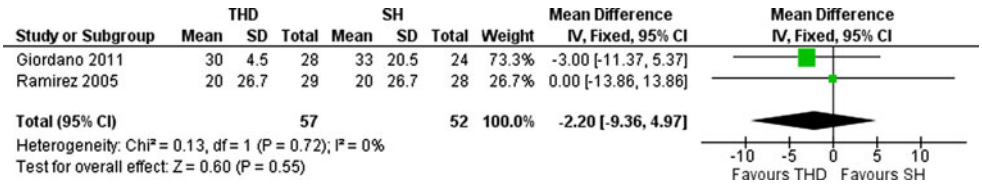

Fig. 4 Operative time

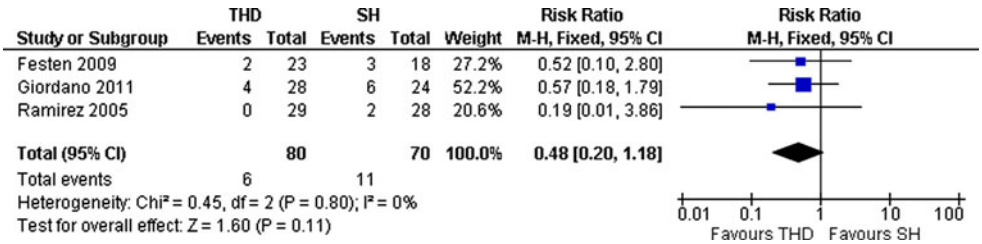

Fig. 5 Postoperative complications

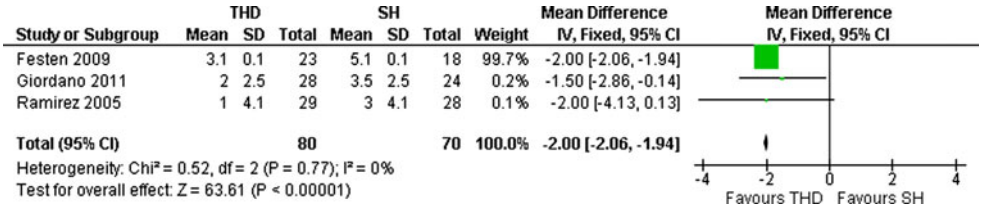

Fig. 6 Postoperative pain

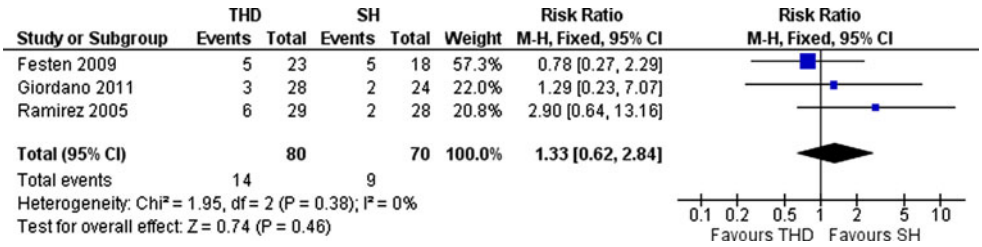

Fig. 7 Recurrence of haemorrhoids

Table 2 Reported articles on THD

Article	Patients *n* =	Type of article	Outcome
Faucheron et al. [22]	100	Case series	88% cure rate
Ratto et al. [23]	170	Case series	93.5% cure rate
Theodoropoulos et al. [24]	147	Case series	96% cure rate
Pol et al. [25]	243	Case series	67% cure rate
Infantino et al. [26]	112	Case series	85.7% cure rate
Wilkerson et al. [27]	113	Case series	77% symptomatic relief
Walega et al. [4]	507	Case series	92.4% symptomatic relief
Dal Monte et al. [1]	330	Case series	92.5% symptomatic relief
Greenberg et al. [28]	100	Case series	94% cure rate
Scheyer et al. [29]	308	Case series	72.5% patient satisfaction rate
Narro [30]	281	Case series	Not available
Lienert et al. [31]	248	Case series	87.7% symptomatic relief
Tagariello et al. [32]	138	Case series	90% cure rate
Arnold et al. [33]	105	Case series	Not available

effects model, THD was associated with a higher incidence of HD recurrence as compared to SH, but statistically (RR, 1.33; 95% CI, 0.62, 2.84; $z = 0.74$; $P = 0.46$; Fig. 7), it was not significant. Both techniques may be considered equally effective in the management of HD.

Discussion

Based on this review of three randomised, controlled trials conducted on 150 patients with symptomatic HD, THD is as effective as SH in terms of treatment success rate, operation time, postoperative complications and incidence of HD recurrence. In addition, THD is also associated with significantly less postoperative pain compared to SH. On the evaluation of published case series each with more than 100 patients undergoing THD, the authors found this outcome was comparable to SH for treatment success rate, relief of symptoms and recurrence. There were 14 reported case series [1, 4, 22–33] on THD (Table 2) encompassing 2,902 patients. The reported relief of symptoms after THD varied from 71 to 96%. The disease cure rate was reported to be between 80 and 96%. The isolated symptom control rate was 70–97.5% for pain, 88–91% for rectal bleeding and 92–94% for prolapse. A recently published systematic review of 17 articles including a total of 1,996 patients reported a wide range of operative times for THD (5–50 min). In the majority of cases, the procedure could be performed as a day-case procedure. The overall recurrence rate was 9.0% for prolapse, 7.8% for bleeding and 4.7% for pain at defecation. The recurrence rate at 1 year or more was 10.8% for prolapse, 9.7% for bleeding and 8.7% for pain at defecation. When reported as a function of the haemorrhoidal grade, the recurrence rate was higher for fourth-degree haemorrhoids (range, 11.1–59.3%) [47]. A randomised trial [48] comparing THD with conventional haemorrhoidectomy concluded that the advantages of THD were the following: day-case procedure, less pain, early return to work and minimally invasive. No comparison of THD with rubber band ligation in the management of HD has been reported. However, one would assume that THD is superior to rubber band ligation because of a lower recurrence rate (approximately 18% vs. 85%) [49], a higher cure rate [49] and less postoperative pain [50].

There are several limitations to this review. First, the study by Ramirez et al. [36] is published as an abstract only. It had substantial influence on the combined risk ratio and effect weight of the meta-analysis (39.5%). Considering it is a relatively low-quality randomised trial investigating THD, SH and CH, it may be considered a potential source of

contamination of the overall outcome. Second, the quality of included trials was not necessarily high due to the lack of adequate randomisation technique, allocation concealment, single or double blinding, intention-to-treat analysis and power of the study calculations, which are potential sources of higher degree of bias. Third, there were significant differences about inclusion (e.g. degree of haemorrhoids, presence of external haemorrhoids and presence of perianal skin tags) and exclusion criteria among included trials. Fourth, varying degrees of differences also exist among included trials concerning the definitions of "treatment success rate", "symptom relief rate" and "measurement scales for postoperative pain". Fifth, studies recruiting a very small number of patients in this review may not have been large enough to make possible the identification of small differences between THD and SH. Lastly, because there was no difference in primary outcomes (treatment success rate, postoperative pain, postoperative complications, operative time and recurrence rate) between the two techniques, type of investigated variable in included trials should have been made after taking into account the importance of other outcomes such as overall mortality, length of hospital stay, measurement of health-related quality of life and cost analysis.

Conclusions

To the best of our knowledge, this is the first meta-analysis exploring the role of THD in the management of HD. Although the conclusion of this review based upon the strength of the evidence may be considered weak, we believe this article will pave the way for further investigation of THD in the form of a major, multicenter, randomised, controlled trial. Meanwhile, this review may provide some evidence to help colorectal surgeons in decision making about the type and technique of surgical intervention for the management of HD.

Conflict of interest None to declare.

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