A Systematic Review on the Effectiveness of Hemorrhoidal Artery Ligation (Transanal Hemorrhoidal Dearterialization) vs the conventional hemorrhoidectomy for Adult Patients with Grades II and III Internal Hemorrhoids

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A systematic review was by Giordano et al in 2009 showed that transanal hemorrhoidal dearterialization (THD) would appear to be a potential non-excisional technique for the treatment of second-degree and third-degree haemorrhage, the main advantages being minimal postoperative pain and quick recovery. However, it included mostly poor quality studies available at that time, so that the conclusion may be an overestimate of the effectiveness of the technique and did not include trials that have completed and reported after 2009. The aim of this systematic review is to synthesize the best current evidence on the effectiveness of transanal hemorrhoidal dearterialization as compared to the conventional hemorrhoidectomy with post-operative pain, post-operative bleeding and recurrence rate as primary outcomes, and operative time and urinary retention as secondary outcomes, among adult patients with Grades II and III internal hemorrhoids. PubMed was searched for randomized controlled trials done from 1995 up to 2014. Four out of 221 trials met the criteria for inclusion. There was no evidence of any difference between conventional open hemorrhoidectomy and transanal hemorrhoidal dearterialization in terms of post-operative pain, post-operative bleeding (P=0.76), operative time, urinary retention (P = 0.57), post-operative prolapse/recurrence (P=0.38) in adult patients with grades II and III internal hemorrhoids. Because the confidence interval of the summary statistics (Risk Ratio) are very wide, it just shows that not enough data is available to show a precise result. Thus, one cannot conclude whether one technique is better than the other or if they are truly the same.

KEYWORDS: *Hemorrhoidal artery ligation, Transanal hemorrhoidal dearterialization, internal haemorrhoids, hemorrhoidectomy, postoperative complications*

INTRODUCTION

Hemorrhoidal disease is a common form among anal disorders. It is caused by anal cushion descent or abnormal congestion of the internal hemorrhoidal venous plexus.[1] There are different approaches in treating hemorrhoidal disease, including pharmaceutical, instrumental and surgical methods in various therapeutic schemes. The gold standard in treating hemorrhoidal disease is hemorrhoidectomy which includes well-established procedures such as Milligan-Morgan, Parks, and Ferguson. Hemorrhoidectomy is the most effective treatment for hemorrhoids with the lowest rate of recurrence compared to other modalities. It can be performed using scissors, diathermy, or vascular-sealing device such as Ligasure and Harmonic scalpel. Indications for hemorrhoidectomy include failure of non-operative management, acute complicated hemorrhoids such as strangulation or thrombosis, patient preference, and concomitant anorectal conditions such as anal fissure or fistula-in-ano which require surgery. [3] It is a good method to eliminate the pathophysiological factors which causes hemorrhoids, but has disadvantages of having an approximately 10% postoperative complication rate, requiring time for treatment, and requiring significant time to return to daily living.[1]

The arterial blood supply of the internal hemorrhoidal plexus is commonly believed to be associated with the pathogenesis of hemorrhoids. Ultrasound-supported proctoscopic techniques with Doppler-guided ligature of submucosal rectal arteries have been introduced for the therapy of hemorrhoids. The present investigation focuses on caliber and flow changes of the terminal branches of the superior rectal artery supplying the corpus cavernosum recti in patients with hemorrhoids.[4] Transanal hemorrhoidal dearterialization (THD) is an effective treatment for hemorrhoidal disease. It is based on two technical steps: the targeted ligation of hemorrhoidal arteries (called ''dearterialization''), using a very sensitive continuous Doppler probe able to identify the maximal flow; and the plication and lifting of redundant and prolapsing rectal mucosa/submucosa (called ''mucopexy''). Transanal hemorrhoidal dearterialization is a valid therapeutic option in patients with hemorrhoidal disease. The limited number and severity of complications makes THD very safe.[5]

The researchers are in a constant search of new methods of treating hemorrhoidal disease that would offer not only high effectiveness and low morbidity, but also short recovery and good postoperative comfort. It has long been a challenge to surgeons to meet the patient's expectations of resolution of preoperative symptoms such as pain, bleeding and prolapse and also of minimal postoperative pain and bleeding. During the last two decades, nonexcisional surgical approaches to hemorrhoidal disease have shown a high potential for cure with a theoretically reduced morbidity. In 1995, Morinaga, a Japanese surgeon, developed a technique based on Doppler-guided selective ligation of the main hemorrhoidal arteries, branches of the inferior rectal arteries. This technique allows for restoration of normal anatomy using minimally invasive surgery with substantially reduced pain and discomfort. [2] This procedure has grown in popularity because it is easy to perform, has a short learning curve, is minimally invasive, and is associated with positive outcomes, low levels of pain and a low risk of fecal incontinence.

A systematic review was done in 2009 by Giordano, et al which included 17 articles including a total of 1996 patients analyzed. This showed that THD would appear to be a potential non-excisional technique for the treatment of second-degree and third-degree haemorrhage, the main advantages being minimal postoperative pain and quick recovery.[6] However, the limitation of this review is that it included mostly poor quality studies available at that time, so that the conclusion may be an overestimate of the effectiveness of the technique. Also, it does not include trials that have completed and reported after 2009. In the light of the above, the need to do a systematic review that includes new studies, but is limited to randomized controlled trials (which are the best evidence of treatment efficacy / effectiveness) may establish the true effectiveness of the procedure compared with other interventions available for the treatment of haemorrhoids.

The aim of this systematic review is to synthesize the best current evidence on the effectiveness

of transanal dearterialization/hemorrhoidal artery ligation as compared to the conventional hemorrhoidectomy in terms of post-operative pain, post-operative bleeding, length of hospital stay and recurrence rate among adult patients with Grades II and III internal hemorrhoids.

OBJECTIVES

This review made the comparison of hemorrhoidal artery ligation/transanal hemorrhoidal dearterialiazation versus the conventional hemorrhoidectomy under any kind of anesthesia in terms of post-operative pain, post-operative bleeding, operative time, urinary retention, post operative prolapse/ recurrence in adult patients with grades II and III internal haemorrhoids.

METHODOLOGY

The review utilized an electronic search of literature to identify randomized control trials comparing hemorrhoidal artery ligation/transanal hemorrhoidal dearterialiazation versus conventional hemorrhoidectomy under any kind of anesthesia in adult patients with grades II and III internal haemorrhoids.

SEARCH FOR IDENTIFICATION OF STUDIES

Database searched: PubMed was searched for randomized controlled trials and systematic reviews done from 1995 up to September 2014.

Simple search was done in PubMed limiting the search to include randomized controlled trials and systematic reviews only. The search terms used were "(hemorrhoidal artery ligation) or (transanal hemorrhoidal dearterialization)". The initial search yielded 221 articles. These articles were screened based on the content of their abstracts by two reviewers working independently of each other. Out of 221 articles, 205 were excluded because these were either older than 1995, and/or with interventions and outcomes not relevant in our study. Out of 16 full-text articles (15 randomized controlled trial and 1 systematic review) eligible for study, 12 studies were excluded due to following reasons: 9 studies were not randomized controlled trials, 1 study had study population that did not meet the inclusion criteria (had previous surgery/intervention), 1 study had interventions not relevant to this study, and 1 article was not available for retrieval. From the review of references in the included systematic review, titles were screened. One out of 17 articles is a randomized controlled trial, hence was included in this review. Once deemed eligible, full text was retrieved and information was abstracted as in the other trials picked up by the electronic search. Articles that were excluded included those older than 1995, and those with interventions and outcomes not relevant in our study.

Search Sequence and terms:

1. Hemorrhoidal artery ligation
2. Transanal hemorrhoidal dearterialization
3. Internal haemorrhoids
4. Hemorrhoidectomy
5. Postoperative complications
6. Adults
7. 1 or 2 and 3 or 4 and 5 and 6

CRITERIA FOR SELECTION

The criteria used for the inclusion of studies in this review included :

TYPES OF PARTICIPANTS

Studies included adult patients with grades II and III internal hemorrhoids

TYPES OF INTERVENTION

One arm of the study included patients who underwent hemorrhoidal artery ligation/transanal hemorrhoidal dearterialization which involves selective ligation of the inferior rectal hemorrhoidal arteries with or without the aid of Doppler transducer followed by a mucopexy under any kind of anesthesia while another arm underwent the conventional

hemorrhoidectomy which includes procedures such as Milligan-Morgan, Parks, and Ferguson under any kind of anesthesia.

TYPES OF OUTCOMES

Primary outcomes included incidence of postoperative pain, postoperative bleeding and recurrence rate. Secondary outcomes included operative time and urinary retention.

TYPES OF STUDIES/METHODOLOGIES

Randomized controlled trials and systematic reviews

PROCESS OF SELECTION

Published reports of all potentially eligible studies were evaluated by two reviewers independently, without prior consideration of the results. First screen was done by sorting through the titles and abstracts to know which full text articles to get. Second screen was done by selecting among the full text articles. This only included studies in English language

STUDY APPRAISAL/ASSESSMENT OF THE RISK OF BIAS

The risk of bias in eligible trials was assessed independently by two reviewers using the Cochrane risk of bias tool. Factors that were considered include quality of random allocation and concealment (where appropriate), description of drop-outs and withdrawals and missing data, blinding during intervention and at outcome assessment (where appropriate), description of and protection against possible contamination (where appropriate).

DATA ABSTRACTION

Standardised data extraction forms were used by two reviewers independently and cross-checked. In cases where insufficient data were reported (i.e. standard deviation was not reported) such as in studies done by Elmer et al and De Nardi et al, these authors were contacted through email for further information. However, no response from Elmer noted. De Nardi was able to respond to the correspondence via email wherein she stated that the resident who collected the database of their study is working in another country and not available at the moment.

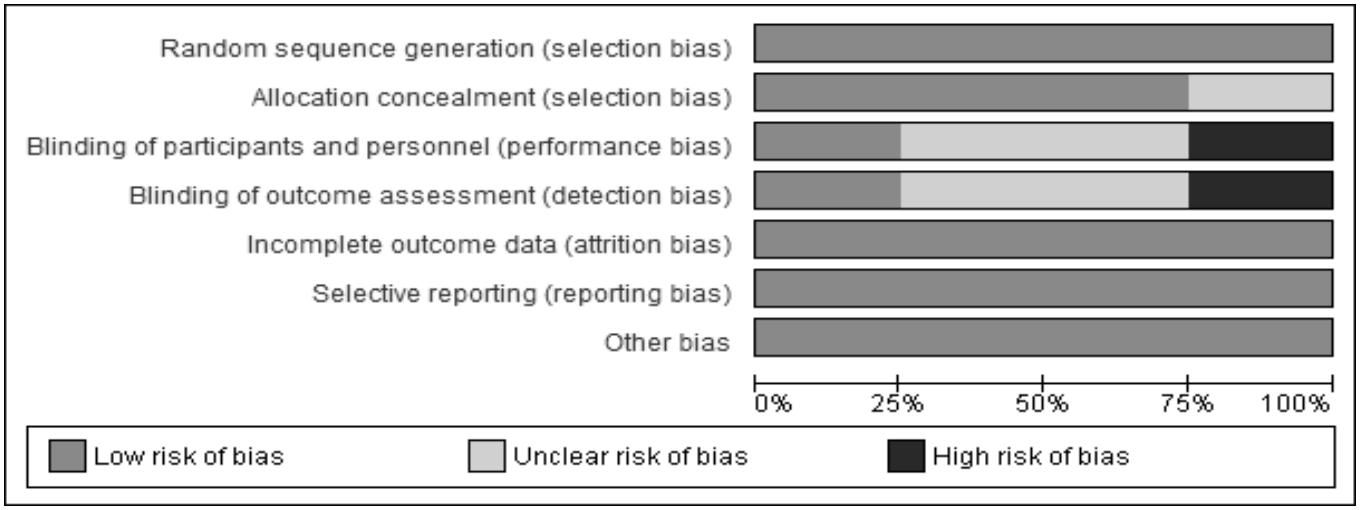
RESULTS

Two hundred twenty-one studies were identified through database search using PubMed. Out of 221 studies, 205 were excluded because these were either older than 1995, and/or with interventions and outcomes not relevant in our study. Out of 16 full-text articles eligible for study, 12 studies were excluded due to following reasons: 9 studies were not randomized controlled trials, 1 study had study population that did not meet the inclusion criteria (had previous surgery/intervention), 1 study had interventions not relevant to this study, and 1 article was not available for retrieval. Four trials met the criteria for inclusion. A total of 198 patients were enrolled from the four trials, from which 190 patients were included in the results. The reasons for withdrawal will be discussed in the summary of quality assessment of the studies included (Table 1.1). Ninety-six patients underwent Hemorrhoidal Arterial Ligation/Transanal hemorrhoidal dearterialization while Ninety-four patients underwent conventional hemorrhoidectomy.

Table 1.1 Summary of Quality Assessment of Included Studies

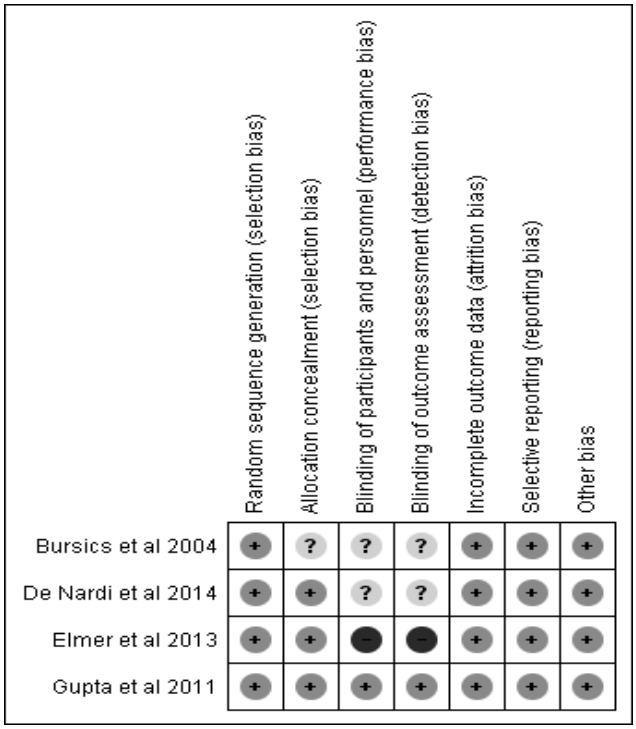
STUDY	RANDOMIZATION	ALLOCATION CONCEALMENT	BLINDING	WITHDRAWALS	ALL OUTCOMES REPORTED	REMARKS
De Nardi et al 2014	An allocation list, which was based on the block random assignment of 5 patients, was used.	For every consecutively enrolled patient, a sealed envelope, with the randomization arm written on a paper that was folded twice, was prepared by a physician who was not involved in the study. The envelope was assigned after the patient provided this consent, and it was opened before the surgical procedure began.	Not mentioned	3 Reasons: 1 patient from the EOH group and 1 from the DM group were lost to follow up. 1 patient from EOH group excluded from analysis (patient because of a stroke that had occured 6 months before)	Yes	The principal weaknesses of the study are that the follow-up, although longer than the majority of the available studies, was not very long; a cost analysis was not performed; and the questionnaires used in the follow-up were not validated
Elmer et al 2013	Randomization between THD and OH was done by a research nurse.	Sealed envelopes were used and opened in the operating room.	None	2 Reasons: 2 patients in open hemorrhoidectomy arm. One did not receive allocated intervention (1 patient did not want to undergo surgery). One patient did not wish to take part in follow-up	Yes	No blinding was possible because it is a surgical intervention. Since there was no blinding in the study, there might be a possible bias in reporting of outcomes
Gupta et al 2011	A single person performed all randomizations, which were done in blocks so that the number of patients in the two groups was balanced over the course of the trial	Recruited patients were randomly allocated, by means of sealed envelopes, to one of the two study arms: (1) ligation and mucopexy [SL group] or (2) DGHAL plus ligation and mucopexy [DSL group]	Yes	2 in DSL group and 1 in SL group Reason: After 1 year, 2 patients from the DSL group and one patient from the SL group were lost to follow up.	Yes	This is a double-blinded randomized control study. There was no reporting bias. No other sources of bias in the study
Bursics et al 2004	Patients were randomized based on the date of the first visit to outpatient department	Not mentioned	Not mentioned	No	Yes	Potential sources of bias would be the allocation concealment and were not mentioned

Figure 1.1 Risk of bias graph



Based on the graph shown above (Figure 1.1), generally, there was a low risk of bias in all the criterias except for blinding of participants and personnel and also the blinding of outcome assessment which is either not mentioned or is not possible since the intervention on both arms are surgical. There is one study (Bursics et al 2004) wherein allocation concealment was not mentioned in the study, hence can be a potential source of bias

Figure 1.2 Risk of bias summary

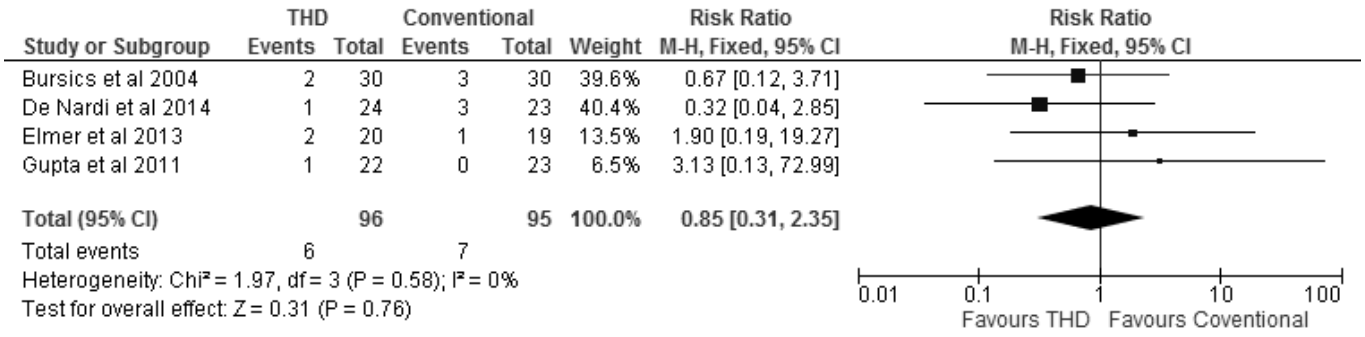


As seen in Figure 1.2, there was generally a low risk of bias in all 3 studies. In the study done by De Nardi et al (2014), blinding was not mentioned which gave the study a Unclear Risk for blinding. In contrary, blinding was not done in the study of Elmer et al (2013), therefore there is a high risk of bias in the study done. In the study done by Bursics et al (2004), allocation concealment was not mentioned.

All the three studies reported on the comparison of postoperative pain between the two interventions. However, a metaanalysis could not be done since standard deviation was not reported in these studies. Gupta et al reported that the postoperative pain score was significantly higher in the Doppler group (VAS of 4.4) than in control (VAS of 2.2) with P value less than 0.002. The mean total analgesic dose and duration of pain control using analgesics were greater and longer for the Doppler group (17 vs 11 tablets, and 13 day vs 9 days), respectively. In the study done by De Nardi et al (2014), one gram of paracetamol was administered every 8 hours, and the patients were discharged with 10 mg ketoprofen or 50mg tramadol, as needed. The following mean postoperative VAS pain scores were recorded in the open hemorrhoidectomy and dearterialization groups: 7 vs 5.5 (p=0.67) on first postoperative day, 3 vs 2.5 (p = 0.71) on 7^{th} postoperative day, 1 vs 0 (p = 0.71) on 14^{th} postoperative day and 0 vs 0 (p = 0.98) on the 30^{th} postoperative day. The mean VAS pain score during defecation was 5 vs 3 (p=0.07) on 7^{th} postoperative day and 2 vs 1 (p = 0.51) on the 14^{th} postoperative day.

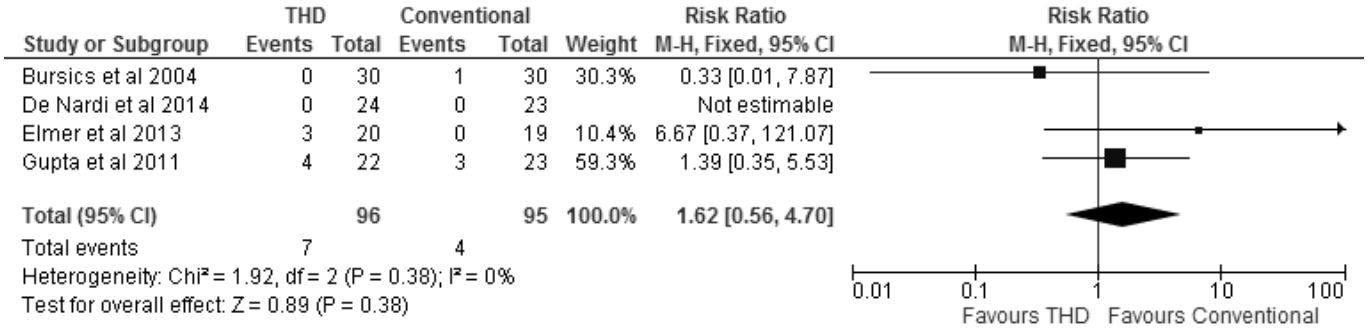
In the study done by Elmer et al (2013), The peak pain scores were significantly lower in the THD group for 5 days during the first week ($p < 0.05$). A peak pain score of more than 3 was reported for a median of 7 days (range of 0 to 13 days) in the THD group in comparison with 12 days (range of 5 to 14 days) in the open hemorrhoidectomy group. The overall pain did not differ between the two groups. The use of analgesics was similar among the groups.

Figure 1.3 Postoperative Bleeding



There was no significant difference (P = 0.76) in the risk of postoperative bleeding between conventional hemorrhoidectomy and transanal dearterialization. Risk ratio was 0.85 (95% CI 0.31, 2.35).

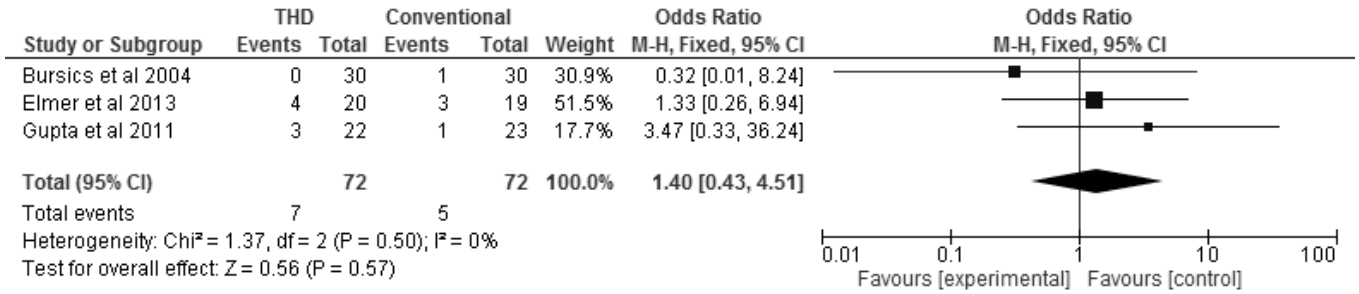
Figure 1.4 Prolapse/Recurrence



There was no significant difference (RR = 1.62, 95%CI 0.56, 4.70) in prolapse/recurrence between the conventional hemorrhoidectomy and THD.

Three out of four included studies had data on duration of surgery. However, metaanalysis was not possible because standard deviation was not reported. All studies reported longer operative time with THD. Gupta et al (2011) reported that the duration of surgery was significantly higher in the Doppler group (31 minutes vs 9 minutes with P value of less than 0.003. In the study done by De Nardi et al (2014), mean operative time was 25 ± 10 minutes in the open hemorrhoidectomy and 35 ± 20 minutes in dearterialization and mucopexy group with P value less than 0.001. In the study done by Elmer et al (2013) operative time was longer for THD (36 minutes) as compared to Open hemorrhoidectomy (20minutes) with p value < 0.001.

Figure 1.5 Urinary Retention



Only three out of the four studies had data regarding urinary retention (Elmer et al and Gupta et al). There was no significant difference (RR= 1.40, 95%CI 0.43, 4.51) in urinary retention between THD and conventional hemorrhoidectomy.

DISCUSSION

Summary of main results

The overall postoperative pain did not differ between the hemorrhoidal artery ligation and the conventional hemorrhoidectomy. There was no significant difference in postoperative bleeding between the 2 interventions.

There was no significant difference in urinary retention, prolapse/recurrence between the conventional hemorrhoidectomy and THD. There was generally a longer duration of surgery in THD as compared to the conventional method.

Limitations of the study

Our study was limited since there were only few randomized controlled studies comparing the two interventions. Majority of the available studies were either prospective or retrospective cohorts, or observational studies consisting of case series of surgeons pioneering the technique, which were excluded in this study. The size of population analyzed in this study is small, therefore, randomized controlled trials with larger population are recommended to come up with better results. Authors of these trials should be encouraged to report mean and standard deviation data (or make them available on request) to allow accurate representation of summary data within a meta-analysis or systematic review when required. Well-designed methodology of randomized controlled trials is recommended which includes the population excluded in these trials .

Potential biases in the review process

The potential sources of bias in the review process would include the limitation of the selection of studies to English language papers only, the failure to get the necessary missing information from the authors which included important elements in the raw data of their studies which are essential in the metaanalysis.

Agreements and disagreements with other studies or reviews

A systematic review on transanal hemorrhoidal dearterialization was done in 2009 by Giordano et al which included all published studies on dearterialization without language restrictions. Seventeen articles including a total of 1,996 patients were analyzed. In general, the quality of the studies was low. Primary outcome measures were postoperative pain and hemorrhoidal recurrences. In this systematic review, transanal hemorrhoidal dearterialization appeared to be a potential treatment option for second-degree and third-degree hemorrhoids.

The present systematic review included only randomized controlled trials in English language wherein there was no significant difference was noted between the two interventions. However, more randomized trials with larger population is needed to establish a possible role and to further evaluate the advantages and disadvantages of this technique.

Implications to Practice

Since there was no significant difference noted between conventional hemorrhoidectomy and hemorhoidal artery ligation/transanal hemorrhoidal dearterialization, it is still recommended not to change the conventional method of performing hemorrhoidectomy.

Implications to Research

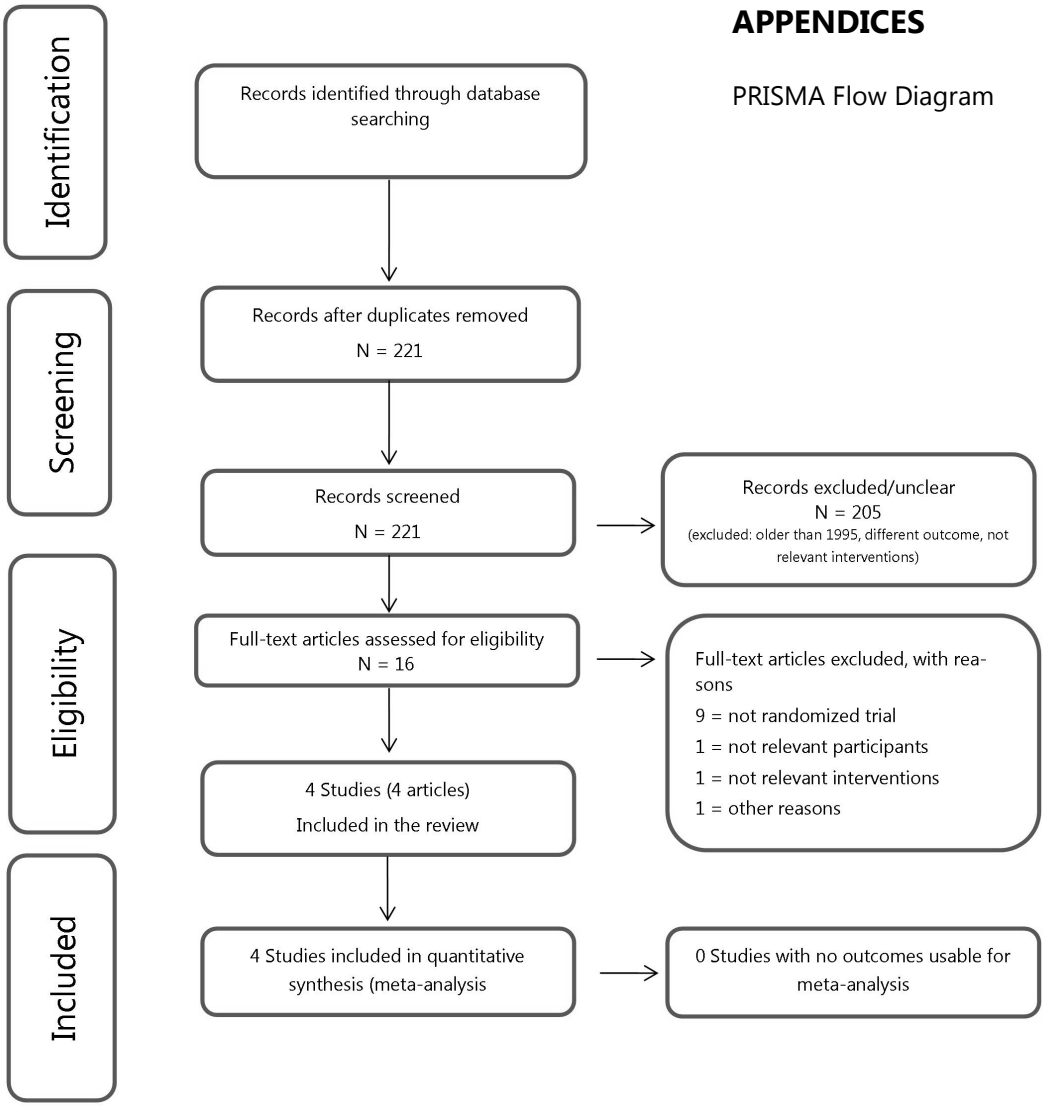
More randomized controlled trials regarding transanal hemorrhoidal dearterialization/hemorrhoidal artery ligation are needed with larger population in each study to yield better results.

CONCLUSION

In conclusion, there was no evidence of any difference between conventional open hemorrhoidectomy and transanal hemorrhoidal dearterialization in terms of post-operative pain, post-operative bleeding, operative time, urinary retention, post-operative prolapse/recurrence in adult patients with grades II and III internal hemorrhoids. Because the confidence interval of the summary statistics (RR) are very wide, it just shows that not enough data is available to show a precise result. Thus, one cannot conclude whether one technique is better than the other or if they are truly the same.

APPENDICES

PRISMA Flow Diagram



DATA ABSTRACTION

1. De Nardi et al 2014

STUDY IDENTIFIER	De Nardi et al 2014
STUDY TITLE	A Prospective, Randomized Trial Comparing the Short- and Long-term Results of Doppler-Guided Transanal Hemorrhoid Dearterialization With Mucopexy Versus Excision Hemorrhoidectomy for Grade III Hemorrhoids
AUTHORS	Paola De Nardi, M.D., Giovanni Capretti, M.D., Antonino Corsaro, M.D., Carlo Staudacher, M.D.
CITATION	Dis Colon Rectum. 2014 Mar;57(3):348-53. doi: 10.1097/DCR.0000000000000085.
PARTICIPANTS	
Description	From July to November 2010, 50 consecutive patients, with Goligher grade III hemorrhoids and prolapse, occurring in at least 80% of their bowel movements, were randomly assigned to undergo excisional hemorrhoidectomy (EOH) or Doppler-guided dearterialization and mucopexy (DM)
Total Number enrolled (exp/ctrl)	25/25
INTERVENTION	
Experimental	
Description	In the DM group, the arterial ligation of the terminal branches of the superior rectal artery was performed with 2-0 absorbable polyglycolic acid suture and a 5/8 curved needle after identifying the blood flow approximately 3 cm above the dentate line by using Doppler guidance. Subsequently, a running suture was added from the suture point to 1 cm above the dentate line to lift the prolapsing tissue. A transanal hemorrhoidal dearterialization instrument (THD S.p.a., Medical Division, Correggio, Reggio Emilia, Italy) was used.
Number (enrolled/analyzed)	25/24
Control	
Description	The EOH patients underwent a conventional, 3-quadrant open, diathermy hemorrhoidectomy.
Number (enrolled/analyzed)	25/23
OUTCOMES	The primary end point was postoperative pain on the first postoperative day. The secondary outcome measures were postoperative morbidity, resumption of social and working activity, patient satisfaction, and relapse of symptoms at 1 and 24 postoperative months..
METHODOLOGY/DESIGN	Prospective Randomized Trial
REMARKS	

STUDY IDENTIFIER	De Nardi et al 2014
RANDOMIZATION (Description)	An allocation list, which was based on the block random assignment of 5 patients, was used.
ALLOCATION CONCEALMENT (Description)	For every consecutively enrolled patient, a sealed envelope, with the randomization arm written on a paper that was folded twice, was prepared by a physician who was not involved in the study. The envelope was assigned after the patient provided this consent, and it was opened before the surgical procedure began.
BLINDING (yes/No)	Not mentioned
WITHDRAWALS	
Yes/No	Yes
How many?	3
Reasons for withdrawal	1 patient from the EOH group and 1 from the DM group were lost to follow up. 1 patient from EOH group excluded from analysis (patient because of a stroke that had occured 6 months before)
ALL OUTCOMES REPORTED?	Yes
Remarks	The principal weaknesses of the study are that the follow-up, although longer than the majority of the available studies, was not very long; a cost analysis was not performed; and the questionnaires used in the follow-up were not validated.

STUDY IDENTIFIER	De Nardi et al 2014	
OUTCOME	Excisional hemorrhoidectomy	Transanal Hemorrhoidal Dearterialization
Mean Operative time	25 ± 10 minutes	35 ± 20 minutes
Mean Postoperative VAS pain scores (First postop day)	7	5.5
Mean Postoperative VAS pain scores (7th postop day)	3	2.5
Postoperative compications	0/23	0/24
Pain on 24th month	1/23	4/24
Bleeding on 24th month	3/23	1/24
Work or normal activity resumed	22 ± 21 days	10 ± 11 days
Prolapse/Recurrence	0/23	0/24

2. De Nardi et al 2013

STUDY IDENTIFIER	Elmer et al 2013
STUDY TITLE	A Randomized Trial of Transanal Hemorrhoidal Dearterialization With Anopexy Compared With Open Hemorrhoidectomy in the Treatment of Hemorrhoids
AUTHORS	Solveig E. Elmér, M.D. • Jonas O. Nygren, M.D., Ph.D. • Claes E. Lenander, M.D., Ph.D
CITATION	Dis Colon Rectum. 2013 Apr;56(4):484-90. doi: 10.1097/DCR.0b013e31827a8567.
PARTICIPANTS	
Description	All eligible patients with symptomatic second- to third-degree hemorrhoids were considered for a randomized study comparing THD/A with OH. Inclusion criteria were symptomatic (bleeding, pain, pruritus, soiling, and prolapse) hemorrhoids grades 2 to 3 requiring surgical treatment. Exclusion criteria were acutely thrombosed hemorrhoids, anal fissure, anal abscesses, anal fistulas, inability to understand the study instructions, age more than 80 years, continuous consumption of analgesics, IBD, fecal incontinence, anal stenosis, bleeding disorder, and rectal prolapse. Patients who had undergone rubber band ligation or sclerotherapy in the past 3 months, OH within 3 years, or any previous operation with HAL, THD, or stapled anopexy were excluded.
Total Number enrolled (exp/ctrl)	20/20
INTERVENTION	
Experimental	Transanal hemorrhoidal dearterialization (THD)
Description	For arterial ligation and anopexy, the THD instrument was introduced to reduce the anal prolapse and to locate the arteries by using the incorporated Doppler probe. Six terminal branches of the superior rectal artery (located at 1, 3, 5, 7, 9, and 11 o'clock (anterior midline representing 12 o´clock)) were identified and ligated with a figure-8 stitch in all cases except 1 (8 ligations). With the same suture, an anopexy was performed by a continuous running suture making 2 to 4 mucosal stitches ending at least 5 mm above the dentate line.
Number (enrolled/analyzed)	20/20
Control	Open hemorrhoidectomy (OH)
Description	Open hemorrhoidectomy was performed without a retractor. The external component was grasped by a forceps, and the hemorrhoids were excised up to the anorectal ring by the use of diathermy for dissection and hemostasis. No ligations were performed, and the wounds were left open. The number of excisions was individualized (2 large excisions in 9 patients and 3 excisions in 10 patients), and adequate mucosal and skin bridges were left between them.
Number (enrolled/analyzed)	20/18
OUTCOMES	Postoperative pain and well-being, complications,
METHODOLOGY/DESIGN	Randomized trial
REMARKS	

STUDY IDENTIFIER	Elmer et al 2013
RANDOMIZATION (Description)	Randomization between THD and OH was done by a research nurse.
ALLOCATION CONCEALMENT (Description)	Sealed envelopes were used and opened in the operating room.
BLINDING (yes/No)	None
WITHDRAWALS	
Yes/No	Yes
How many?	2
Reasons for withdrawal	2 patients in open hemorrhoidectomy arm. One did not receive allocated intervention (1 patient did not want to undergo surgery). One patient did not wish to take part in follow-up
ALL OUTCOMES REPORTED?	Yes
Remarks	

STUDY IDENTIFIER	Elmer et al 2013	
OUTCOME	Transanal hemorrhoidal dearterialization	Open hemorrhoidectomy
Operating time, min, mean (range)	36 (30–45)	20 (10–34)
Secondary hemorrhage	0/20	2/19
Partial reprolapse/Recurrence	3/20	0/19
Reoperation	1/20	0/19
Bleeding after 2 to 4 months	2/20	0/19
Pain after 2 to 4 months	2/20	1/19
Urinary Retention	4/20	3/19

3. De Nardi et al 2011

STUDY IDENTIFIER	Gupta et al 2011
STUDY TITLE	Doppler-guided hemorrhoidal artery ligation does not offer anyvadvantage over suture ligation of grade 3 symptomatichemorrhoids
AUTHORS	P. J. Gupta • S. Kalaskar • S. Taori • P. S. Heda
CITATION	Tech Coloproctol (2011) 15:439–444 DOI 10.1007/s10151-011-0780-7
PARTICIPANTS	
Description	All consecutive patients with symptomatic grade III hemorrhoids, that is, piles that prolapse during defecation but are manually reducible, were enrolled. The following patients were excluded: (1) patients with acute thrombosed hemorrhoids; (2) patients with external hemorrhoids or other concomitant anal diseases (such as fissure, fistula, or abscess); (3) patients with inflammatory bowel disease or hematological disorders; (4)patients on anticoagulants; and (5) patients with a previous history of anorectal surgery, including previous hemorrhoidectomy or fistula surgery.
Total Number enrolled (exp/ctrl)	24/24
INTERVENTION	
Experimental	
Description	Doppler-guided hemorrhoidal artery ligation followed by ligation and mucopexy [DSL]
Number (enrolled/analyzed)	24/22
Control	
Description	ligation and mucopexy [SL]
Number (enrolled/analyzed)	24/23
OUTCOMES	postoperative pain scores, amount of analgesics consumed, and complications encountered. The observer also assessed recurrence of hemorrhoids after 1 year.
METHODOLOGY/DESIGN	double-blind, randomized controlled study
REMARKS	

STUDY IDENTIFIER	Gupta et al 2011
RANDOMIZATION (Description)	A single person performed all randomizations, which were done in blocks so that the number of patients in the two groups was balanced over the course of the trial
ALLOCATION CONCEALMENT (Description)	Recruited patients were randomly allocated, by means of sealed envelopes, to one of the two study arms: (1) ligation and mucopexy [SL group] or (2) DGHAL plus ligation and mucopexy [DSL group]
BLINDING (yes/No)	Yes
WITHDRAWALS	
Yes/No	Yes
How many?	2 in DSL group and 1 in SL group
Reasons for withdrawal	After 1 year, 2 patients from the DSL group and one patient from the SL group were lost to follow up.
ALL OUTCOMES REPORTED?	Yes
Remarks	

STUDY IDENTIFIER	Gupta et al 2011	
OUTCOME	Doppler-guided hemorrhoidal artery ligation followed by ligation and mucopexy [DSL]	ligation and mucopexy [SL]
Operation time (min) (mean(SD))	31 (5.4)	9 (6.3)
Pain VAS score# (0–10) (median)	4.4 (2.9–6.3)	2.2 (1.7–5.9)
Analgesic tablets (n)	17 (8–18)	11 (4–13)
Days analgesic consumed (n)	13 (9–12)	9 (4–9)
Patients with postoperative complications (n)	4/22	4/23
Patients with recurrence at 12-month follow-up (n)	4/22	3/23
Urinary Retention	3/22	1/23
Postoperative Bleeding	1/22	0/23

4. Bursics et al 2004

STUDY IDENTIFIER	Bursics et al 2004
STUDY TITLE	Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study
AUTHORS	Bursics A, Morvay K, Kupcsulik P, Flautner L.
CITATION	Int J Colorectal Dis 2004;19:176 – 80. DOI 10.1007/s00384-003-0517-9
PARTICIPANTS	
Description	60 consecutive patients (27 men, 33 women; mean age 47.5 ± 3.9 years).
Total Number enrolled (exp/ctrl)	30(18men, 12women)/30 (9 men,21 women)
INTERVENTION	
Experimental	
Description	Doppler-guided-hemorrhoidal artery ligation
Number (enrolled/analyzed)	30/30
Control	
Description	Standardized closed scissors hemorrhoidectomy
Number (enrolled/analyzed)	30/30
OUTCOMES	Length of postoperative inpatient care, negative reactions, complications need for pain killers especially opioids, prolapse, return to normal daily activity, recurrence, late complications (stricture, fistula, impaired defecation, incontinence)
METHODOLOGY/DESIGN	prospective, longitudinal, randomized study
REMARKS	

STUDY IDENTIFIER	Bursics et al 2004
RANDOMIZATION (Description)	Patients were randomized based on the date of the first visit to outpatient department
ALLOCATION CONCEALMENT (Description)	Not mentioned
BLINDING (yes/No)	Not mentioned
WITHDRAWALS	
Yes/No	No
How many?	0
Reasons for withdrawal	none
ALL OUTCOMES REPORTED?	Yes
Remarks	

STUDY IDENTIFIER	Bursics et al 2004	
OUTCOME	Conventional hemorrhoidectomy	Hemorrhoidal Artery Ligation (DG-HAL)
Urinary retention	1/30	0/30
Length of hospital stay (hours)	62.9 ± 29.0	19.8 ± 41.8
Return to normal daily activities (days)	24.9 ± 24.5	3.0 ± 5.5
Needed opioid analgesics	9/30	0/30
Bleeding	3/30	2/30
Pain	4/30	4/30
Prolapse/Recurrence	1/30	0/30

RISK OF BIAS TABLES

Risk of bias table De Nardi et al 2014

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	There was no significant difference of the baseline characteristics among the two groups
Allocation concealment (selection bias)	Low risk	For every consecutively enrolled patient, a sealed envelope, with the randomization arm written on a paper that was folded twice, was prepared by a physician who was not involved in the study. The envelope was assigned after the patient provided this consent, and it was opened before the surgical procedure began
Blinding of participants and personnel (performance bias)	Unclear risk	Blinding was not mentioned but since the two arms are surgical interventions, it would not be possible to blind patients
Blinding of outcome assessment (detection bias)	Unclear risk	Not mentioned
Incomplete outcome data (attrition bias)	Low risk	All outcomes were reported at the end of the study
Selective reporting (reporting bias)	Low risk	There was no bias note on the reporting of outcomes
Other bias	Low risk	No other sources of bias noted

Risk of bias table Elmer et al 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	There was no significant difference among the baseline characteristics of the two groups
Allocation concealment (selection bias)	Low risk	Randomization between THD and OH was done by a research nurse. Sealed envelopes were used and opened in the operating room.
Blinding of participants and personnel (performance bias)	High risk	No blinding was possible because it is a surgical intervention.
Blinding of outcome assessment (detection bias)	High risk	Since there was no blinding in the study, there might be a possible bias in reporting of outcomes
Incomplete outcome data (attrition bias)	Low risk	All outcomes were reported at the end of study
Selective reporting (reporting bias)	Low risk	No bias in the reporting of outcomes in this study
Other bias	Low risk	No other bias noted in the study

Risk of bias table Gupta et al 2011

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A single person performed all randomizations, which were done in blocks so that the number of patients in the two groups was balanced over the course of the trial
Allocation concealment (selection bias)	Low risk	Recruited patients were randomly allocated, by means of sealed envelopes, to one of the two study arms: (1) ligation and mucopexy [SL group] or (2) DGHAL plus ligation and mucopexy [DSL group]
Blinding of participants and personnel (performance bias)	Low risk	This is a double-blinded randomized control study
Blinding of outcome assessment (detection bias)	Low risk	This is a double-blinded randomized control study
Incomplete outcome data (attrition bias)	Low risk	All outcomes were reported at the end of the study
Selective reporting (reporting bias)	Low risk	No reporting bias noted in the study
Other bias	Low risk	No other sources of bias noted in the study

Risk of bias table Burics et al 2004

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomized based on the date of the first visit to outpatient department
Allocation concealment (selection bias)	Unclear risk	Not mentioned
Blinding of participants and personnel (performance bias)	Unclear risk	not mentioned
Blinding of outcome assessment (detection bias)	Unclear risk	Not mentioned
Incomplete outcome data (attrition bias)	Low risk	All outcomes were reported
Selective reporting (reporting bias)	Low risk	No bias noted on reporting of outcomes
Other bias	Low risk	No other sources of bias

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