

# Systematic Review & Meta-Analysis of Randomized Control Trials Comparing Stapled Hemorrhoidectomy versus Trans Anal Hemorrhoidal Dearterialization for Treatment of Hemorrhoidal Disease

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## Abbreviations:

SH: stapled haemorrhoidectomy;  
THD: transanal haemorrhoidal  
dearterialization;  
RCTs: randomised control trials;  
RR: risk ratio.

## ABSTRACT

**Background & Aims:** Haemorrhoidal disease is the most common anorectal pathology affecting 50% Irish and 36.4% UK population at some stage in their life. After conservative management with dietary modification and office procedures like rubber band ligation has failed formal haemorrhoidectomy needs to be done. Conventional haemorrhoidectomy has been replaced by new techniques like stapled haemorrhoidectomy (SH) and transanal haemorrhoidal dearterialization (THD) due to its serious complications. We performed this systematic review and meta-analysis of randomised control trials (RCTs) comparing these two modalities.

**Methods:** The search strategy was designed with help of an experienced librarian for Ovid Medline, EMBASE, Cochrane Library and PubMed until 30<sup>th</sup> August 2021. The primary outcome of interest was recurrence and secondary outcomes were operative time, pain score and complications.

**Results:** 10 RCTs pooled a total of 1116 patients with 562 in THD group and 554 in SH group. Based on fixed-effect model the risk ratio (RR) of recurrence among the two groups was 2.44(95% CI 1.70 – 3.51). So, there was a statistical difference among the THD and SH groups in terms of recurrence with more in the THD group, while statistically significant fewer complications 0.57(95% CI 0.39 - 0.84) and reduction in pain scores -0.99(95% CI -1.51 to -0.48) in THD group as compared to SH group was found. Operative times for both groups were similar 4.53(95% CI -0.04 – 9.09) so not statistically significant.

**Conclusions:** Based on a meta-analysis of 10 RCTs it is found that THD has more recurrence than SH with a better safety profile as reduced complications and pain scores were seen.

**Key words:** haemorrhoidal disease, meta-analysis, stapled Haemorrhoidectomy, systematic review

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## INTRODUCTION

Hemorrhoidal Disease HD is one of the most common problems of the anorectal region resulting in a huge number of appointments in general surgery clinics. HD is classified into grade 1 to 4 by Goliger. Traditionally grades 1 and 2 were treated using office procedures after conservative management has failed. But for 3<sup>rd</sup> and 4<sup>th</sup> degree haemorrhoids, surgical procedures were used. With the invention of new procedures and advancement traditional Milligan Morgan technique has been replaced by stapled haemorrhoidectomy SH and THD due to serious complications reported after the former procedure. Sphincter damage leads to incontinence which could be severely debilitating especially in younger patients. Recent network meta-analysis also showed that open procedure resulted in significantly more complications as compared to stapled haemorrhoidectomy and THD. A comparison of these two new techniques was done by Sajid et al (1) in 2012 which compared three RCTs that showed equivocal results after comparison of the two modalities. We felt there is a need to do a systematic review and meta-analysis to find out the superior technique for the treatment of this highly prevalent disease.

### *Protocol and registration*

The preferred reporting items for systematic reviews and meta-analysis PRISMA (2) was used for reporting of the review. The study was registered with the international prospective registry for systematic reviews PROSPERO (3,4) with registration number CRD42017080268 and is online since 21/11/2017 on the registry.

### *Eligibility criteria*

PICOS model was used for devising the search

strategy for the meta-analysis it is explained in detail in *table 1*. We included the randomized control trials that compared THD and stapled haemorrhoidectomy for the treatment of haemorrhoids. The primary outcome of interest was the recurrence of haemorrhoids while secondary outcomes of interest were the number of complications, pain score and operative time. The study designs which were included in the meta-analysis were randomized control trials no other study type was included.

### *Information sources*

Researcher YB designed a search strategy with the librarian DM. official search was undertaken at the end of August 2021 on bibliography databases Ovid Medline, EMBASE, Cochrane Library and PubMed. All the randomized control trials on comparison of THD with stapled haemorrhoidectomy were included. The primary outcome was the recurrence of haemorrhoids while secondary outcomes were complications, pain score and operative time.

### *Search strategies*

Search strategies were designed for Ovid Medline, Cochrane Library, EMBASE and PubMed. MeSH terms and Emtree terms were used as appropriate while using the PICOS model for the structuring of the search strategies. Combination of keywords to identify published studies comparing THD and stapled haemorrhoidectomy for the treatment of haemorrhoids were used. Subject headings and keywords relating to haemorrhoids, procedure for prolapsed haemorrhoids, stapled haemorrhoidectomy and trans anal rectal dearterialization or trans anal hemorrhoidal dearterialization were used. Language, geographical and date restrictions were not applied, additional studies were identified by reference searching.

**Table 1 - PICOS model used for the systematic review as per PRISMA protocol and its explanation**

| PICOS        | Inclusion and Exclusion criteria                                                                             |
|--------------|--------------------------------------------------------------------------------------------------------------|
| Patient      | Inclusion: Patients suffering from haemorrhoids<br>Exclusion: Patients under the age of 18.                  |
| Intervention | Patients treated with Transanal Haemorrhoidal Dematerialisation (THD)                                        |
| Comparison   | Patients treated with Stapled Haemorrhoidectomy (SH)                                                         |
| Outcome      | Primary outcome: Recurrence<br>Secondary outcome: Complications, Pain score, Operative time.                 |
| Study Design | Inclusion: Randomized controlled trials.<br>Exclusion: All other study designs, Animal studies were excluded |

### *Study selection*

After duplicates were removed, all the studies identified in the search were screened independently by two reviewers by YB & QU. Using article title and abstract against predefined inclusion and exclusion criteria. If there was any conflict about a study, it was resolved with consensus. Conference proceedings were also included if they met the inclusion criteria and had the required information, at least primary outcome should be available in order to include the study into meta-analysis. The reviewers were not blinded regarding the authors and the institutes of the studies. If some data were not available, the authors of the study were contacted by email.

### *Data collection process*

Data were extracted by two independent researchers YB and QU using predetermined data extraction forms independently and matched. There were two parts of the form, first gathered general information regarding the article while the second was focused on primary and secondary outcomes.

### *Data items*

Data on primary outcome “recurrence was recorded as a number of patients having recurrence” of haemorrhoids. Secondary outcomes including “complications as number of complications, pain scores mean pain score and operative time as minutes” was recorded using the second part of pre-formed data collection form.

### *Risk of bias in individual studies*

Individual studies were assessed using JADAD scoring also known as the Oxford quality scoring system for randomised control trials. JADAD scoring system independently assess the methodological quality of a clinical trial. It allocates trials scores between zero (very poor) to five (very rigorous).

### *Summary measures & Synthesis of results*

For the primary outcome, risk ratio along with 95% confidence interval was calculated using meta-analysis software Review Manager Copenhagen: The Nordic COCHRANE Collaboration, 2014)(5). For secondary outcomes complications, odds ratio with 95% confidence interval was calculated, while mean difference

with 95% confidence interval for operative time and pain score was calculated.

Using the above-mentioned software, pool estimates of recurrence, pain score, complications and operative time were calculated. I<sup>2</sup> was used as a measure of heterogeneity among the studies while p-value less than 0.05 was considered significant where appropriate.

### *Study selection*

A total of 263 articles were identified using electronic databases including Ovid MEDLINE, PubMed, Cochrane Library and EMBASE. One more article was found using a hand search of the bibliographies of the relevant papers. 206 articles were left once duplicates were removed. The screening was done using titles and abstracts against a pre-determined criterion using PICOS model which is explained in detail in *table 1*. 14 articles were selected for full text, which were studied in detail and out of them 10 (6-15) met all the criteria and were included in systematic review and meta-analysis. PRISMA flowchart in *fig. 1* can be seen for a full explanation of each step. Out of 4 which were excluded at full-text level, two were presentations which later became full articles and are included in the meta-analysis, the primary outcome of interest was not declared in one study (16) and one article was found to have unreliable data and was retracted by the journal (17).

### *Risk of Bias within studies*

All these studies were independently assessed by two reviewers YB and QU for quality and assessment with a JADAD score (18) also known as the Oxford quality scoring system. JADAD scoring system is for assessment of RCT's for bias scores ranging between 0 being very poor and five being very rigorous randomized control trial score for the studies range between 1 and 3. So the studies were low to moderate quality

### *Synthesis of results*

There was a total of 1116 patients pooled from 10 RCTs included in the meta-analysis. Roughly similar numbers i-e 562 and 554 patients were present in THD and stapled haemorrhoidectomy (SH) groups respectively. Based on fixed-effect model risk ratio of recurrence was found to be 2.44 (95% CI 1.70 – 3.51), showing increased recurrence with THD as compared to

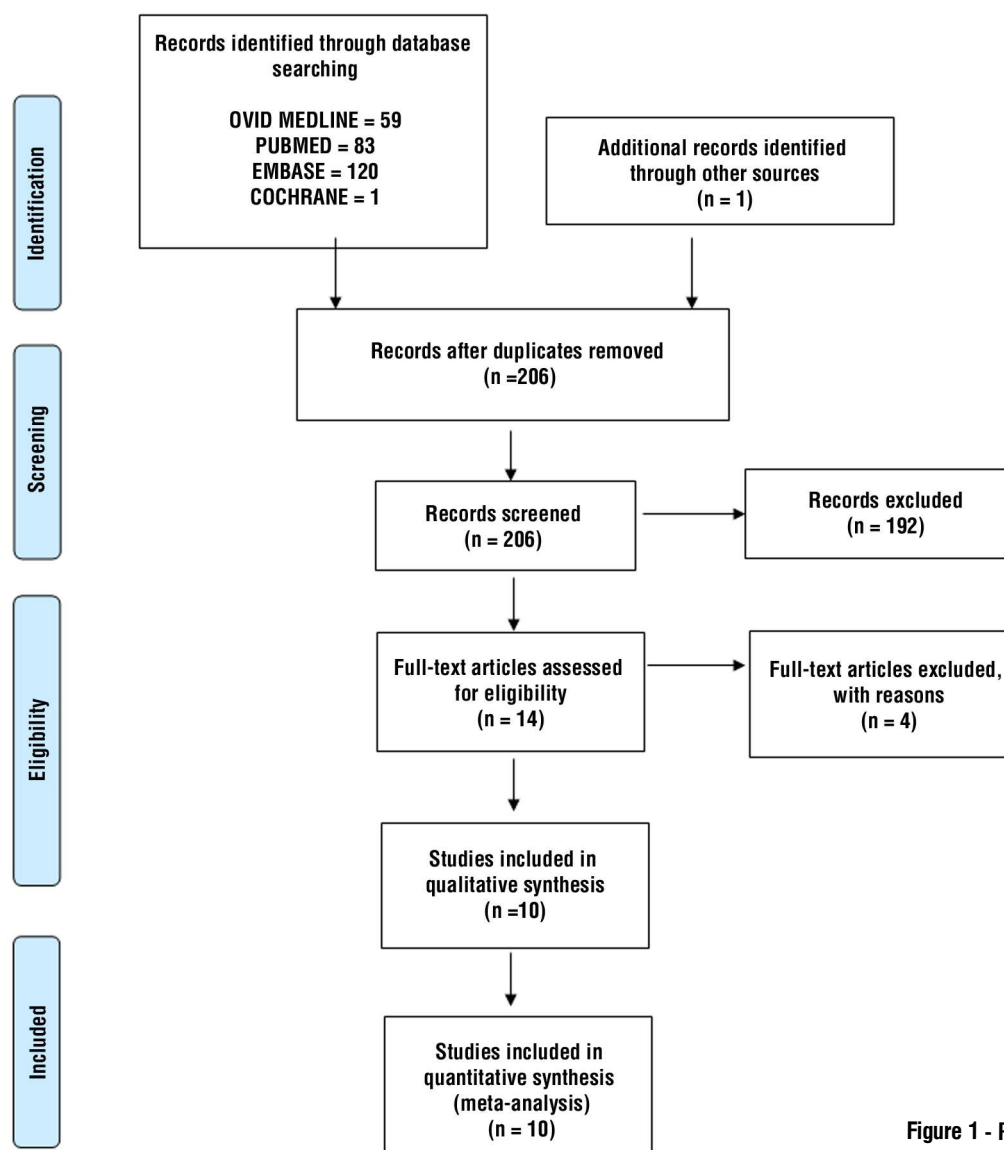


Figure 1 - PRISMA flow sheet of all the processes of the Meta-analysis

SH (*fig. 2*).  $I^2$  which is a measure of heterogeneity was 22% which is low showing significant homogeneity among the studies.

Secondary outcomes of interest were complications, operative time and pain. They were analysed by the data provided by the studies. Using fixed model effect studies showed odds of 0.57(95% CI 0.39 - 0.84) showing a statistically significant reduced chance of having complications with THD as compared to Stapled haemorrhoidectomy, while  $I^2$  was 0% showing homogeneity among the studies (*fig. 3*). Pain scores when compared among the two modalities also showed similar results, using random-effect model mean difference among the two procedures was -0.99(95% CI -1.51 to -0.48) showing statistically reduced pain scores

with THD (19) as compared to stapled group (*fig. 4*). While similar operative times were found between the two procedures, using random-effect model mean difference of 4.53(95% CI -0.04 – 9.09) was found, which is not statistically significant (*fig. 5*).

## DISCUSSION

The haemorrhoidal disease is one of the most prevalent diseases of the anorectal region with 36.4% population of United Kingdom (20) affected by the disease, while 10 million people are affected with haemorrhoidal disease in the USA (21) at some stage in their life. 1<sup>st</sup> and 2<sup>nd</sup> - degree haemorrhoids are treated by office procedures (22) while surgical treatment is

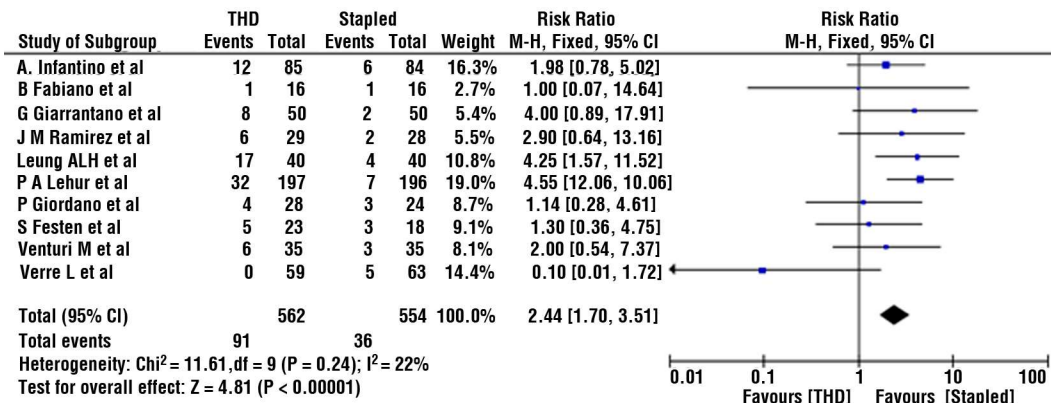


Figure 2 - Forest plot of recurrence of haemorrhoids after THD vs SH showing more recurrence after THD as compared to THD with risk ratio of 2.44 and (95% CI 1.70 – 3.51)

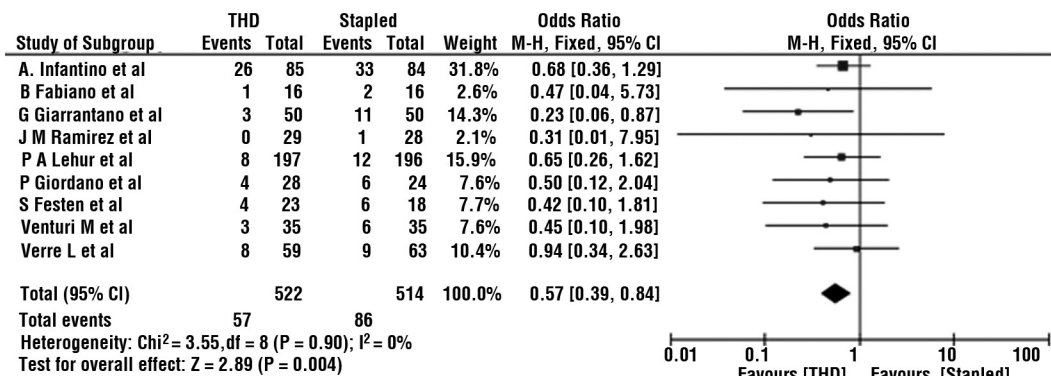


Figure 3 - Forest plot of complications after THD vs SH showing statistically significant more complications after SH as compared to THD with odds ratio of 0.54 and (95% CI 0.39 – 0.84)

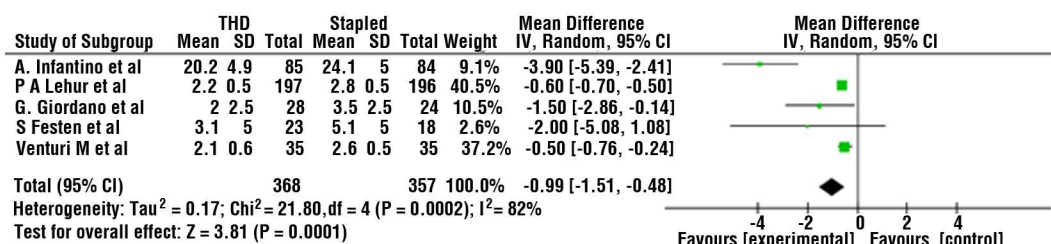


Figure 4 - Forest plot of pain after THD vs SH showing statistically significant more pain after SH as compared to THD with mean score of -0.99 and (95% CI -1.51 – -0.48)

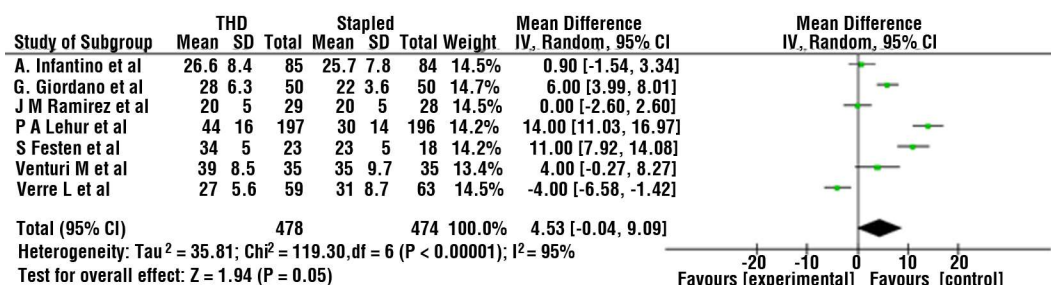


Figure 5 - Forest plot of operative time of THD vs SH showing similar time for SH and THD with mean score of 4.53 and (95% CI -0.04– 9.09)

reserved for the 3<sup>rd</sup> and 4<sup>th</sup> degree haemorrhoids. In 1990s two new techniques were invented Transanal Haemorrhoidal Dearterialisation (23) and Stapled haemorrhoidectomy (24) and both became quite popular among surgeons. The reasons were simple, serious complications were reported secondary to the Milligan-Morgan procedure (conventional haemorrhoidectomy) along with severe post-op pain (25). Both of these techniques are quite promising with excellent results reported in the literature. There is only one systematic review done on the direct comparison of the two techniques by Sajid et al (1) in 2012 included 3 randomised control trials. We took this opportunity to search the literature and ascertain the randomised control trials done on comparison of the two techniques and analyse the pooled data for both.

Our literature search revealed 14 articles that were analysed for full text and we included 10 RCT's in our systematic review and meta-analysis. Our analysis of the data revealed that our meta-analysis included 562 patients in the THD group vs 554 patients pooled in stapled haemorrhoidectomy group. The primary outcome of interest was recurrence and when we analysed the pooled data it showed that SH. The risk ratio was 2.44 with 95% CI 1.70-3.51 between the two procedures, thus THD has more recurrence than SH. These results are consistent with results by Sajid et al in 2012 (1).

A systematic review by Sajid et al reported a statistically non-significant difference in terms of complications and operative time between the two techniques. But it has been shown by the same review that was statistically significant difference in pain scores between them. We pooled the data for all the above-mentioned variables where available, and analysed and found that there were statistically significant more complications and pain score by stapled haemorrhoidectomy (SH) as compared to THD. While similar operative time was found between the two methods. THD procedure is less invasive as compared to stapled haemorrhoidectomy as earlier does not involve any excision. Consequently, although statistically more complications were reported in the stapled group, the complications reported secondary to stapled haemorrhoidectomy are also more serious including pelvic sepsis, suture dehiscence, anal strictures, anal strictures and incontinence secondary to the stapled haemorrhoidectomy (26,27). Also, network meta-analysis in 2015 comparing all types of treatments for haemorrhoids found significantly lower re-operation rates for THD as compared to any other form of haemorrhoidal surgery.

An RCT published in 2017 by A.L.Leung et al (9) caught our attention as results shown by this RCT were quite different from the other RCTs and available literature. C.Ratto et al (28) mentioned a few weaknesses in the RCT and our surgical group also found serious discrepancies (29) which were mentioned. The objections and responses (30) to the objections can also be viewed by readers. We leave it to our readers to make their own opinion using their clinical experience and judgment. The pooled results after including RCT by Leung et al showed there is statistically significant increased recurrence after THD as compared to stapled haemorrhoidectomy. But we leave it to our readers to make decisions about the outcome.

## CONCLUSIONS

To conclude, more recurrence found in THD group as compared to SH group in the pooled data of 10 RCTs but 9 trials provided data on complications and analysis showed more complications associated with stapled haemorrhoidectomy than THD. Readers should keep this in mind that the complications reported after stapled haemorrhoidectomy can range from very minimal like bleeding to very severe like pelvic sepsis while no serious life-threatening complication has been reported after THD. Some studies have also shown damage to the sphincter resulting in incontinence or soiling after stapled haemorrhoidectomy. While urine retention is the most common complication reported after THD. This result is different from the one shown by Sajid et al which mentioned no statistically significant difference in complications among the two groups.

More pain postoperatively with staple haemorrhoidectomy as compared to THD was found.

Analysis of operative time showed no difference between SH and THD. All studies showed less operative time for SH as compared to THD. Only Verre et al (14) showed longer operative time of SH as compared to THD. This result is consistent with results shown by Sajid et al.

## *Conflict of interest*

The authors declare no conflict of interests.

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## *Ethical approval*

Project ID: 0422 for SJH/TUH Joint Research and Ethics Committee.

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