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Haemorrhoidal artery ligation compared to alternative surgical techniques for the treatment of grade II-IV haemorrhoids: A systematic review

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ABSTRACT

Background. Haemorrhoidal disease is a common disorder in the Western World that commonly requires surgical treatment, but original open techniques were associated with significant complications and pain. Haemorrhoidal Arterial Ligation (HAL) has gained popularity for relatively low complication and postoperative pain rates. This review assesses clinical outcomes of this technique in comparison to alternative modern techniques. *Methods*. The literature was searched on MEDLINE, EMBASE, Google Scholar, and Cochrane Library databases. Search terms: dearterialization, artery ligation, mucopexy, recto-anal repair. Inclusion criteria: RCTs, original publications, grade II, III and/or grade IV haemorrhoids, elective procedures. Exclusion criteria: non-English, non-adults, published pre-2016. *Results*. 14 RCTs were included in the systematic review. HAL performed poorly in terms of recurrence, with a pooled recurrence rate of 10.34% for grade III haemorrhoids. HAL had a similar recurrence rate to Procedure for Prolapse and Haemorrhoids. Pain was comparable between groups. *Conclusion*. HAL is a safe surgical technique for the treatment of grade II to grade IV haemorrhoids. It still has a relatively low complication rate, and pain scores are comparable to other non-invasive techniques, and superior to open techniques. HAL still performs poorly in terms of recurrence rates. New modified procedures including suture-mucopexy only and tissue-selecting techniques appear to have better therapeutic potential.

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Introduction

Haemorrhoidal disease is a common proctological disorder which occurs commonly in the Western World. Haemorrhoids are vascular cushions in the anal canal, and contribute to normal anal anatomy. They are classified as internal or external, separated by the dentate line and are considered a disease entity once they become symptomatic [1,2]. Internal haemorrhoids are those that arise from the internal haemorrhoidal plexus, and give rise to the 3 soft engorgements seen in the lumen of the anal canal above the dentate line [2]. Less commonly, External Haemorrhoidal Disease commonly presents in a patient in exquisite pain with a swollen, hard lump on external inspection of the anus, and are of separate vascular aetiology. These will not be discussed in this paper. Symptomatic haemorrhoidal disease occurs when the internal vascular tissue prolapses and abnormally dilates, causing the classical symptoms one would associate with haemorrhoidal disease (i.e., bleeding, pruritis, and/or prolapse).

Internal haemorrhoidal disease is most commonly classified by the Goligher classification system, first described in 1975 [3]:

Grade I – protrude into anal canal without prolapse

Grade II – prolapsing beyond the anal canal but reduce spontaneously

Grade III – prolapsing outside the anal canal on straining, requiring manual reduction

Grade IV – prolapsed constantly, irreducible.

Management of haemorrhoidal disease is dependent on the Goligher grade of disease and the individual patient. Low grade haemorrhoidal disease (Grades I-II) is often treated first line with conservative measures, including dietary and lifestyle modification, and topical agents (e.g., topical steroid agents). After a trial of the above fails, the next step is commonly Rubber Band Ligation (RBL) which

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can be performed in an outpatient setting, which strangulates and causes the haemorrhoidal tissue to eventually slough off within a few days. RBL is said to only be effective in grades I, II and select grade III haemorrhoids [4].

Surgical treatment is then considered for higher grade haemorrhoids (grades III, IV and select grade II). Traditionally, this has been in the form of an excisional haemorrhoidectomy, first described by Drs Milligan and Morgan in 1937 [5]. Their Open Haemorrhoidectomy (OH) technique, and the various modified excisional techniques, such as the Closed Haemorrhoidectomy (CH) by Ferguson et al, have been very successful in past as a definitive form of treatment [6]. Despite success in low recurrence rates, there were relatively high rates of postoperative pain and incontinence; risks which many modern colorectal surgeons would deem as unacceptable [7].

There are over 14 different types of surgical techniques for haemorrhoidal disease described since the movement for a more pain-free technique began. One of these techniques that became widely accepted early on was the Procedure for Prolapse and Haemorrhoids (PPH) otherwise referred to as the Circular Stapled Haemorrhoidopexy (SH). PPH was first described by an Italian surgeon, Dr. Longo, in 1998 [8]. This approach uses a circular stapling device to create a mucosal anastomosis in the treatment of haemorrhoids. Initially this gained popularity due to low postoperative pain and early return to work [9,10]. However, this method quickly fell from practice following the publication of rare but potentially devastating side effects associated (e.g., rectovaginal fistulas, rectal perforation or obliteration), relatively high reintervention rate, a postoperative complication rate of up to 20.2%, and adverse events in over one-third of patients [11-14].

Another method that became widely accepted is Haemorrhoidal Artery Ligation (A.M.I, Austria) or Transanal Haemorrhoidal Dearterialization (Correggio, Italy) (depending on the device used, technique remaining essentially the same). This non-excisional procedure consists of ligating the feeding haemorrhoidal artery, which may be aided by the use of ultrasonic doppler (Doppler-Guided Haemorrhoidal Arterial Ligation/ DGHAL), however this has been suggested to lengthen operation time with questionable additional benefit towards patient outcomes [15,16]. As an important endpoint of procedure-related outcomes, recurrence of disease is thought to be related to the mucosal prolapse. Thus, 'mucopexy', or termed by A.M.I. through their own technique, "Recto-Anal Repair/RAR", was an additional procedural adjunct that has become standard practice [17]. It acts to correct the prolapse by means of tacking the redundant tissue more proximally, whilst avoiding anal stenosis [18,19]. HAL with mucopexy (HALm) has been shown in a recent meta-analysis to require less post-procedure time to return to work, but no significant recurrence in comparison to OH, a lower overall complication rate and less post-procedural pain when compared to other surgical techniques [20,21]. It may also be used safely in patients who are anticoagulated [22]. However, despite the initial excellence this procedure had promised, more recent literature has shown that HAL may indeed have one of the highest recurrence rates [20,23]. For the purposes of this paper, "HAL" refers to all techniques under haemorrhoidal artery ligation techniques including DGHAL (unless otherwise specified), THD, and DGHAL-mucopexy.

One of the first systematic reviews performed on HAL was by Giordano et al, published in 2009 [24]. At the time of the study, there was only one trial published in full. The remainder were mostly observational studies. They suggested HAL performed well in terms of postoperative pain, had a relatively low complication rate and a quick recovery in grade II-III haemorrhoids. Grade IV haemorrhoids were seen to have a recurrence rate of up to 60%. A systematic review performed in 2013 by Pucher et al. on HAL also suggested the procedure as safe and effective, particularly for grade II and III haemorrhoids and recommended HAL as first line [25]. They also found a recurrence rate as high as 60% in grade IV haemorrhoidal disease. This study was limited to only five RCTs and two comparative cohort studies with the remainder mostly observational studies.

Since the review by Pucher et al, there were many RCTs assessing HAL as a primary procedure [25-30]. Thus, a new systematic review is required to be performed to establish the safety and efficacy of HAL in our practice today. Additionally, given there are now more than 14 different surgical procedures for the treatment of grade II-IV haemorrhoids. Many previous systematic reviews had discussed the use of these procedures for treatment of grade III-IV haemorrhoids exclusively, whereas HAL may actually have a niche setting as an option for grade II haemorrhoids which warrants discussion. The aim of this study is to perform a systematic review of the literature from 2015 to 2021 to compare HAL with other surgical procedures used in the treatment of grade II to IV haemorrhoids in recent literature, to have a thorough understanding of the procedure that has gained great popularity in recent years. Patient and procedural outcomes will be assessed when reported including recurrence rates, postoperative complications, postoperative pain, and cost if provided.

Materials and Methods

Search Strategy

The review was conducted in keeping with PRISMA guidelines when possible [31]. MEDLINE, EMBASE, Google Scholar, and Cochrane Library databases (from 2011 to Aug 2021) were searched using MeSH headings and the following search terms: dearterialization, artery

ligation, mucopexy, recto-anal repair, combined with Boolean search term 'haemorrhoid'. The searches were limited to Randomized Controlled Trials. The last search was performed August 17, 2021. The references of identified trials were searched to identify additional trials for inclusion. All searches were exported into EndNote X9. Duplicates were removed automatically and manually by 1 reviewer.

Title and abstract screening were performed to identify irrelevant studies and exclude them from the screening group. Studies that were not published, or conference abstracts without full texts, were excluded. Duplicates were excluded with the most recently published version used. See the inclusion and exclusion criteria presented below.

Inclusion Criteria

- Papers that reported randomized controlled trials (RCTs)
- Original publication (reviews, opinions, letters, protocols and conference proceedings excluded)
- Papers where Haemorrhoidal Artery Ligation (or Transanal Haemorrhoidal Dearterialilzation) were compared with other surgical treatments
- Papers that included the treatment of grade II, III, and/or IV Goligher grade of haemorrhoids
- Only papers including elective surgical procedures (studies reporting emergency treatment excluded)

Exclusion criteria

- Papers in languages other than English
- Papers published prior to 2016
- Papers where data was unavailable, unpublished or uninterpretable and authors uncontactable
- Studies in children

Articles were screened by one independent reviewer. The same reviewer worked independently to conduct data extraction from the selected studies. Only data that was necessary for the purpose of this review was extracted, including primary and secondary end-points. Primary outcome measures of our review included haemorrhoidal recurrence and post-operative pain. Secondary end-points included operation time, postoperative complications (bleeding, anal stenosis, faecal incontinence), symptom recurrence, reoperation rate, and cost if studied. Jadad scores were applied to all selected RCTs to assess overall quality.

Pain outcomes would be extracted in the form of a 11-point numerical score of 0-10 immediately postoperatively and within the first week postoperatively. Recurrence rates were sought in the form of percentages, and were stratified by grade of haemorrhoid. Number of patients that reached analysis plus their anaesthetic route, operation time (in minutes), the length of hospitalization (days) and return to work (days) were recorded. Total follow-up time (months) were recorded with total complication rate, plus those which were deemed to be the most important for the study were recorded, including: Incontinence, Retention, Thrombosis, Anal stenosis. Symptoms at follow up (and follow-up interval) and reoperation rate were recorded when possible. When outcome results were not clear these were not recorded.

In data extraction, when an average was only reported as a median, the Hozo method was performed to estimate the mean and variance [32]. When values were reported graphically, numerical values were estimated [32]. THD and A.M.I. arms were combined for cumulative symptoms and complication rates in the Venara study [33]. When symptoms were not reported in proportions, these were excluded from the synthesis [34]. In study by Titov et al, complications that occurred were not stratified by group and thus were excluded from synthesis [35]. Persistent symptoms were not stratified into groups in the Brown report therefore were excluded [36]. In the study by Aigner et al. their definition of incontinence was unclear thus data could not be extrapolated [37]. We defined recurrent haemorrhoids grade II or above, but there was no uniform recurrence definition between studies [38]. For the purposes of data synthesis, when reported as THD, this and HAL procedures were assumed to be the same.

Follow-up interval standard was set at 12 months, and was highlighted when recoded alternatively. Due to the lack of standardization between studies, outcomes including incontinence, quality of life and patient satisfaction were excluded. Reporting bias thus exists within significant areas of the review due to the lack of standardized reporting of outcomes between the studies included.

Results

Study Selection & Quality Assessment

The selection process for the included studies is summarized in Figure 1.

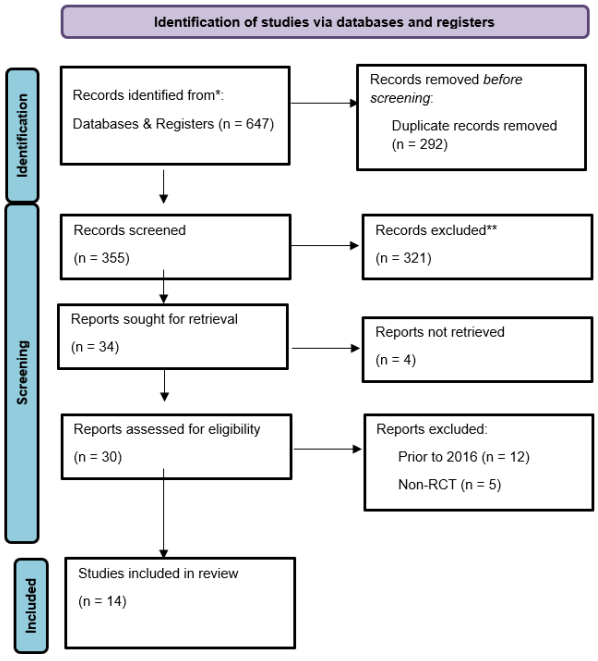

Figure 1. PRISMA 2020 Flow Diagram

Initial searches returned 647 references, and by applying selection criteria through the titles and abstracts, 34 publications were considered for further assessment. Four studies were excluded as retrieval of the reports was unsuccessful [26,38-40]. It was decided upon at that time to exclude studies which were published prior to 2016 to ensure only studies performed in the last five years were included, Table 1 [15,41-51]. Five reports were excluded at this stage not fitting an RCT [52-55]. Four were excluded as they were not relevant to our inclusion criteria [56-59]. This left 14 RCTs (Table 2), including 2039 participants, to be included in the final analysis.

Table 1. Systematic Reviews +/- Meta-analysis studying the Surgical Treatment for Haemorrhoids published in the last 10 years

AUTHOR	YEAR	STUDY TYPE	STUDY OVERVIEW	INCLULDED STUDIES
Pucher et al. [25]	2013	SR	SR to assess safety + efficacy	28 studies of poor overall quality, onlyl 6 RCTs
Cerato et al. [84]	2014	SR	SR – critical appraisal of surgical tx of haemorrhoidal dz	UptoDate, poor quality studies
Liu et al. [85]	2015	MA	DGHAL – clinical outcomes	5 RCTs, small studies (2009-2012)
Simillis et al. [21]	2015	SR + MA	Comparing all surgical treatments for grade III-IV haemorrhoids– outcomes + effectiveness	98 studies, poor overall quality
Vinson-Bonnet et al. [86]	2015	SR	Systematic review of ambulatory haemorrhoidal surgery & reasons for failure	50 studies, poor overall quality
Xu et al. [20]	2016	MA + SR	HALm vs OH	4 RCTs
Emile et al. [72]	2018	MA + SR	HAL vs SH	6 RCTs
Song et al. [71]	2018	MA + SR	HALm vs TSH	8 RCTs
Du et al. [19]	2019	MA + SR	Comparing 9 surgical procedures for grade III-IV haemorrhoids - complications and recurrence rates	21 RCTs (2000-2018)
Aibuedefe et al. [23]	2021	MA + SR	Comparing all surgical management options for grade III-IV	26 studies (2013-2018)

Table 2. RCTs included, including study characteristics and Jadad score

Author	Year	Country	Intervention	Grade of Hemorrhoids (no. patients)	Participants (n)	Age in years (SD)	Blinding	Jadad Score
Perivoliotis et al.	2021	Greece	Doppler + haemorrhoidopexy under pudendal n bock vs under spinal	</= III	60	52.67 (17.6)	SB	3
Rørvik et al.	2020	Denmark	HALm vs MOH	II - IV	98	54 (14.0)	OL*	3
Trenti et al.	2019	Spain	HALm vs.VSH	III – IV	80	53.8 (11.6)	OL	2
Shehata et al.	2019	India	DGHAL vs RBL	II – III	50	45.4 (14.2)	OL	1
Carvajal López et al.	2019	Spain	HAL-RAR vs EH	III – IV	40	49.85 (10.67)	OL	3
Venara et al.	2018	France	DGHALm vs SH	II – III	377		OL	2
Giarratano et al.	2018	Italy	THDm vs SH	III – IV	100	56 (9.9)	OL	1
Tsunoda et al.	2017	China	THDm vs USH	III	44	54.5 (16.1)	OL	3
Leung et al.	2016	China	THDm vs TST	II-III	80	52 (15.5)	OL	3
Zhai et al	2016	China	THDm vs suture mucopexy	III	100	50.56 (14.44)	DB	4
Titov et al.	2016	Russia	DGHALm vs Harmonic	III – IV	240	44.2 (13.2)	OL	2
Lehur et al.	2016	France	DGHAL vs SH	II – III	393	50.0 (11.7)	OL	2
Brown et al.	2016	UK	HAL vs RBL	II – III	337	48·5 (13·5)	OL	3
Aigner et al.	2016	Germany	DGHALm vs mucopexy-alone	III	40	49.2 (12.6)	SL	2

*OL = Open Labelled, DB= Double-Blinded, SB = Single-Blinded

Study Summary

Summarized results of each study can be found in Table 4. The majority of the included studies were from European centres, except for one Indian study [60], three Chinese studies [34,61,62], one Russian study [62], and one study from the UK [36]. Table 2 summarizes study and patient characteristics. Studies were critically appraised and the Jadad scoring system was applied, seen in Table 3 [63].

11 of the 14 studies performing HAL used Doppler. 12 of the 14 studies used a mucopexy/"haemorrhoidopexy" as part of the control HAL procedure, as a form of recto-anal repair. Three Studies had over 300 participants included in their analysis [36,60,64]. The RCT performed by Zhai and colleagues was the only double-blinded study in this group. Two RCTs were single-blinded [62-66].

Table 3. Jadad Score Calculation [63].

ITEM	SCORE
Was the study described as randomized (this includes words such as randomly, random, and randomization)?	0/1
Was the method used to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, etc)?	0/1
Was the study described as double blind?	0/1
Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc)?	0/1
Was there a description of withdrawals and dropouts?	0/1
Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc).	0/−1
Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy).	0/−1
GUIDELINES FOR ASSESSMENT	
Randomization A method to generate the sequence of randomization will be regarded as appropriate if it allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.	
Double blinding A study must be regarded as double blind if the word "double blind" is used. The method will be regarded as appropriate if it is stated that neither the person doing the assessments nor the study participant could identify the intervention being assessed, or if in the absence of such a statement the use of active placebos, identical placebos, or dummies is mentioned.	
Withdrawals and dropouts Participants who were included in the study but did not complete the observation period or who were not included in the analysis must be described. The number and the reasons for withdrawal in each group must be stated. If there were no withdrawals, it should be stated in the article. If there is no statement on withdrawals, this item must be given no points.	

Follow-up ranged from one month to 33.7 months on average in the included studies (Table 6). Studies by Trenti and Perivoliotis had a follow-up of one month, Titov of 1.5 months, Shehata of six months, and the remainder at least 12 months. Most studies reported patients lost to follow-up [28,65].

The average operative time ranged from 16.7 mins to 57.6 mins (Table 5).

The average length of stay in hospital was reported by 6 studies, and ranged from 0.56 days to 4.6 days (Table 5). This mean stay of 4.6 days was well above the average time one would expect to stay following a HAL [62]. There was no suggestion of Titov et al. why their mean hospital stay appeared at least 2 days longer on average than others. Their disability period was mean 14.4 days, which in comparison to the comparator excisional haemorrhoidectomy group (30.5 days), was significantly reduced.

Recurrence

Recurrence varied from 0% to 50% at one month to 24 months. Pooled total recurrence rate was 18.97%. Selecting only studies who reported recurrence at 12 months, pooled recurrence rate was 23.65%. Of the four studies that stratified recurrence rates by grade, the pooled recurrence for grade III haemorrhoids was 10.34% [37,60,62,67]. Shehata et al. reported recurrence of 0% in grade II and 10% in grade III disease at 6 months follow-up [60]. They found this to be significantly smaller than that of their comparison RBL group of 9.1% and 14.3% of grade II and III haemorrhoids respectively. Brown et al found the recurrence rate of HAL was significantly lower than that of RBL (single treatment) (30% vs 49%, p=0.001) [36].

Of the highest recurrence rates reported, Leung et al found a recurrence rate of 42.5% of their patients with grade II and III haemorrhoids by 12 months but this was not stratified by grade [34]. Perivoliotis et al had an overall recurrence rate of 33.3% at one month; 50% in those who underwent DGHAL-RAR under spinal anaesthetic, versus 16.7% in those who underwent non-doppler HAL-RAR under pudendal nerve block, but these were not stratified by grade [65]. Carvajal et al experienced no recurrence in their HAL-RAR group after 12 months follow-up, after

starting with 20 grade III-IV haemorrhoids [30]. Titov et al had a relatively low recurrence rate of 1.7% at 1.5 months in grade III and IV haemorrhoids [35]. Roervik et al found-on surgeon's anatomical assessment at 12 months postoperatively, an overall recurrence rate of 34%; 18% grade II, 5% grade III, 21% grade IV [67]. In comparison to the new Tissue Selecting Technique (TST) that acts as a modified, more controlled PPH technique, one-year recurrence was worse in HAL (42.5%) versus TST (10%), p=0.00161.

Table 4. Summary of RCT results

AUTHOR	COMPARISON	OUTCOME
Perivoliotis et al.	DGHAL-RAR vs. HAL-RAR under pudendal bock	DGHAL a/w longer operative time (35.03 vs 16.67, P <0.001). Comparable analgesia requirements between groups. Increased postop A/Es* a/w spinal (control) vs pudendal (53.3 vs, 16.6%, *P* = 0.002), but no sig difference at medium-term (*p* = 0.22). Higher symptom remission rate in HAL + P group (96.7% vs 73.3%, *p* = 0.01).
Rørvik et al.	HALm vs MOH	No significant difference in symptoms of pain, pruritis, bleeding, or incontinence postop. 59% vs 31% HAL pts reporting residual prolapse postop (*p* = 0.008), and more patients having treatment for recurrence after HAL (7 vs 0, *p* = 0.013). No sig difference in recovery or AEs (*p* > 0.05). HAL more expensive (median difference €555 (*p* < 0.001)
Trenti et al.	HALm vs.VSH (Ligasure)	No difference in mean average pain between first and second weeks, but more patients taking analgesia in second postop group in VSH group (87.8% vs 53.8%, *p* = 0.002). Mean operation time higher for HALm vs. Ligasure group (45min vs. 20min, *p* < 0.001). Postop complications rate, satisfaction, Vaizey score, haemorrhoidal symptoms, return to work, and quality of life were comparable at 1 month between groups.
Shehata et al.	DGHAL vs RBL	No difference between grade II or III in terms of postoperative complications or recurrence between RBL or DGHAL.
Carvajal López et al.	HAL-RAR vs EH	HAL-RAR resulted in a day-case 60% vs. 15% (*p* = 0.003). no difference between groups in reoperation. Postop pain was lower in HAL-RAR until the 15th postop day (*p* = 0.05), after d30 difference disappeared. Symptom persistence rate at d15 postop significant higher in the EH group (45% vs. 15%, *p* = 0.03). No significant difference in symptoms at 1 month. No significant difference in persistent bleeding, prolapse, pruritis.
Venara et al.	DGHALm vs SH	No statistical difference seen between arms in terms of grade II-III recurrence or outcome at 12mo postop regardless of device used.
Giarratano et al.	HALm vs SH	Recurrence rate was 4% in SH vs. 16% in THD group (*p* = 0.04). No difference in complication rates. Pain score significantly higher in THD group, with faster improvement in SH group. Mean op time shorter in SH. Patients in THD returned to work significantly later vs SH (11.85 vs 6.12 days, *P* = 0.00).
Tsunoda et al.	HALm vs USH	Postop pain less in HAL vs USH group during week 1 (*p* <0.05), no difference after 2 weeks. More HAL pts returned to work in 3d (*p* < 0.05*).* No differences in QOL
Leung et al.	HALm vs TST	Median symptom scores significantly lower at 1yr for TST (bleeding 1 vs 2, *p* = 0.001; prolapse 1 vs 2, *p* 0.025). Significantly less recurrence requiring reintervention in TST (4/40 vs 17/40, *p* = 0.001). Satisfaction significantly greater for TST. Similar short term outcomes.
Zhai et al.	HALm vs suture mucopexy	No significant difference in short-term recurrence. Comparable postoperative complications. Recurrence of prolapse or bleeding at 12mo had no difference. Recurrence at 2y significantly more common in DGHAL (19% vs 2.3%, *p* = 0.030).
Titov et al.	DGHALm vs Harmonic	Duration of surgery was significantly shorter for DGHAL (17.9 vs 34.5 mins, *p* = <0.01). Postoperative analgesics less in DGHAL group (1.3 vs 6.1xdose, *p* <0.01), post-op hospital stay was lower in DGHAL group (4.6 vs 7.3 days, *p*<0.01), and disability period was shorted in DGHAL (14.4 vs 30.3 days, *p* <0.01). Postoperative complications up to d45 were less in DGHAL (7.5% vs 15.8%, *p* = 0.03). Recurrence was seen in 1.7% but significance was not commented on.
Lehur et al.	DGHAL vs SH	No significant differences seen regarding AEs at D90. DGHAL resulted in longer operating time (44 vs 14 mins, *P* <0.001), less pain (postop and 2wks, VAS, *p* = 0.03 and *p* =0.013 respectively), and shorter sick leave (p = *0.045).* 1yr: DGHAL resulted in higher residual grade III haemorrhoids, and higher reoperation rate. No difference was seen at d90. Cost was higher in DGHAL group.
Brown et al.	HAL vs RBL	At 1yr, RBL had higher recurrence (49% vs 30%, *p* = 0.005). Pain higher in HAL group at d1 and d7 (*p* = 0.002, *p <0.001),* but did not differ at d21 and 6wks. 1% vs. 7% in the HAL group experienced serious AEs requiring hospital readmission, including bleeding, urinary retention, sepsis, pain, vasovagal upset. Cost was significantly more in the HAL group (*p <0.0001)* but no difference in QALs
Aigner et al.	DGHALm vs mucopexy-alone	There were no significant differences seen in terms of bleeding, urgency, discharge or pruritis symptoms at 1-mo, 6-month, 12-months, except for mucopexy alone having more discharge at 1-month postoperatively (4/16 vs. 0/20, *p* = 0.035). Postoperative pain scores were tolerable in each group (NRS <3) after postop week 1. No statistical difference was seen in recurrence of haemorrhoids or symptoms.

*AE's = Adverse Events (Complications)

Table 5. Study Results 1

Study	Patients (n)	Anaesthesia	Doppler (Y/N)	Op time (mins)*	Recurrence of Haemorrhoid Rate (%)	LOS**	Post-op Pain (Score 0-10)		Return to Work/Normal function (days)
							<24h	d1-7d	
Perivoliotis et al.	30	Spinal	Y	35.03	50		6.33 (1.66)	4.53 (2.34)	6.2 (3.89)
	30	Pudendal n. block	N	16.67 (4.59)	16.7		2.5 (2)	1.63 (1.8)	3 (3.7)
Rørvik et al.	44	LA + GA (10% spinal)	N	57.6 (13.2)	Grade II – 18 Grade III – 5 Grade IV - 21	0.56 (0.36)	3	3	19.75 (6.7)
Trenti et al.	39	GA	N		2.56				
Shehata et al.	35	Spinal	Y		0% (grade II), 1 (10% grade III)				
Carvajal López et al.	20	undisclosed	Y	41	0		5.5	4.5	
Venara et al.	193	undisclosed	Y		(12mo) 13.9				
Giarratano et al.	50	GA or Spinal	N	28.7 (6.35)	16	<1			11.85 (5.88)
Tsunoda et al.	22	Spinal	Y	35.9 (32.7 - 39.0)		2.1 (0.21)	2.5	1.3	3.7 (0.605-0.778)
Leung et al.	44	undisclosed	Y	38.9 (14.0)	42.5	1.13 (0.853)		3.72 (5.22-2.28)	1.58 (0.93)
Zhai et al.	50	Spinal or GA	Y		(12mo) 11.1 (24mo) 23.8		3.4 (2.8)		5.3 (1.25)
Titov et al.	120	undisclosed	Y	17.9 (6.1)	1.7	4.6 (1.3)	2.5		
Lehur et al.	197	GA	Y	44 (16)	(12mo) 25.1	1.2 (1.2)		2.2 (1.9)	12.3
Brown et al.	176	undisclosed	Y		(12mo) 30		4.6 (2.8)	3.1 (2.4)	
Aigner et al.	20	GA	Y		(12mo) 15		3		

Op time reported as mean (+/- SD or range when possible)
LOS = Length of stay in hospital.

Symptoms of recurrence were reported in various studies to varying degrees and can be found in Table 6.

After a mean follow-up period of 33.7 months, Giarratano et al found that PPH performed better than HAL in terms of recurrence (4% vs. 16%, p=0.04), but this was a small study of 50 patients in each arm [68]. In the study by Lehur et al, there were no statistical differences between HAL or PPH in terms of recurrence (9% vs 4%, p=0.27) [64]. No statistical difference was seen between DGHAL and PPH groups in the study by Venara et al. [33].

Symptoms of recurrence were reported in varying degrees. Prolapse was reported in 59% at 12mo follow-up in Rørvik et al, but this was not stratified to grade [67]. Venara et al. reported prolapse 13.9% of their patients at 12mo follow-up, but began with grade II-III haemorrhoids [33]. Zhai et al had 8.9% patients reporting prolapse at 12mo, but at longer term follow-up this increased to 19% [62]. Pruritis was reported in 3 studies, including 59% at 12 months in Rørvik et al, 14.2% at 6 months in Carvajal Lopez et al., and 0% at 3 months in Tsunoda et al. [30,61,67].

Pain

Pain scores measured on an 11-point scale of 0-10 (0=minimal, 10=worst pain) were reported in 11 of the 14 studies. In the first day postoperatively, the pain score ranged from 2.5 to 6.33 on average. Pain reduced by roughly 1 point on the scale across the board from the first 24h to when recorded in the first week. In the study by Perivoliotis et al. there was a significantly reduced pain score in those who underwent the procedure via pudendal nerve block (2.5 <24h, 1.63 in first week) versus those who had spinal (6.33 <24h, 4.53 in first week) [65]. This study reported pain measurements significantly higher than the other studies, particularly in their control spinal DGHAL-RAR group. Brown et al reported moderate pain in the first few days after HAL, which subsided in almost all patients by three weeks [36]. However, there were 5 patients (3%) requiring prolonged hospital stay due to pain postoperatively. Conversely, Carvajal Lopez et al. found pain scores to be lower in those treated with HAL-RAR versus those by excisional haemorrhoidectomy,

particularly during the first 15 days [30]. Additionally, absence of pain (VAS = 0) was achieved earlier in the HAL group. Similarly, Tsunoda et al. found pain scores to be significantly lower in the HAL group versus that of ultrasonic scalpel haemorrhoidectomy in the earlier follow-up period (5 days) [61]. This difference was not sustained beyond the first week. Similar results were seen in the study by Titov et al., showing significantly reduced postoperative pain score, lower narcotic use, and shorter return to work in the HAL group versus Harmonic scalpel [35].

Roervik et al. found no difference in average pain scores between minimally open haemorrhoidectomy (MOH) versus HAL, and pain tended to last longer in the MOH group [67]. In comparison to excisional (harmonic scalpel) haemorrhoidectomy, HAL had a mean postoperative pain score that was significantly lower (2.5 vs 4.8, p <0.01) [35]. There was less pain when compared to PPH postoperatively and 2 weeks post (2.2 vs 2.8 p=0.03, 1.3 vs 1.9 p=0.013) in the Lehur et al study [64]. In contrast, there was no significant difference in pain scores between HAL and PPH in days 1-7 postoperatively in the Leung et al study (3.68 vs 3.38, p=0.090) [34]. In the Giarratano study, postoperative pain was significantly higher in the HAL group, and showed a faster improvement in the PPH group (22 HAL vs 44 THD between a score of 0-3 (p=0.000), 22 HAL vs 6 SH between a score of 4-7 (p=0.000), 6 HAL vs 0 SH between a score of 8-10 (p=0.01) [68]. In comparison to a Vessel-Sealing device technique, there was no significant difference in average pain between groups in the first or second postoperative weeks (week 1: HAL 3.79 vs VSH 3.71, p=0.900; week 2: HAL 2.73 vs VSH 5.54, p=0.206) [31]. However, on analysis of postoperative analgesics, it showed significantly less use of pain medication by the HAL group. When compared to suture mucopexy alone, DGHAL with suture mucopexy interestingly resulted in less pain particularly in the first two weeks, but this was not statistically significant and this difference decreased thereafter [37]. There was no significant difference seen between HAL vs. suture mucopexy in the study by Zhai et al. [62]. Interestingly, HAL was found to be more painful than RBL at day 1 postoperatively (4.6 vs 3.4, p=0.0002), and day 7 postoperatively (3.1 vs 1.6, p<0.0001), but did not differ at 21 days or 6 weeks [36].

When comparing mucopexy-alone to classical DGHALm, there was no significant difference seen in recurrence rates between groups in either studies by Aigner et al. (Grade III only, 10% DGHALm vs. 5% mucopexy-alone, p=0.274) or Zhai et al (Grade III only, 11.1% DGHALm vs. 4.5% mucopexy-alone, p=0.450) [37,62].

Table 6. Study Results 2

Study	F/U (months)	Total Complication Rate (%)	Complications				Symptoms at F/U			Reoperation Rate (%)
			Incontinence (%)	Retention (%)	Thrombosis (%)	Anal Stenosis (%)	Bleeding (%)	Pruritis (%)	Prolapse (%)	
Perivoliotis et al.	1									6.7
	1									0
Rørvik et al.	12		0	6		0	(12mo) 34	(12mo) 59	(12mo) 59	8
Trenti et al.	1	(30d) 12.8		5						
Shehata et al.	6	6.7 grade II, 0 grade III					Grade II (6mo) 6.7 grade III - 0		Grade II (6mo) 0 Grade III (6mo) 10	0
Carvajal López et al.	15 (12-27)		(6mo) 16.6	10			(6mo) 5.2	(6mo) 14.2	(6mo) 5.5	10
Venara et al.	12	(90d) 24.3	8.5	23	2				(12mo) 13.9	(12mo) 9.7
Giarratano et al.	33.7 (7.6)						2		(~33.7mo) 16	
Tsunoda et al.	31 (9.8)	31.8		13.6	13.6		(3mo) 4.54	(3mo) 0	(3mo) 0	4.5
Leung et al.	12	2.5	0	2.5	0	0				2.5
Zhai et al	24		0	10		0	(12mo) 2.2 (24mo) 4.8		(12mo) 8.9 (24mo) 19	
Titov et al.	1.5	7.5		3.3			(1.5mo) 1.7		(1.5mo) 1.7	
Lehur et al.	12	(3mo) 24 (12mo) 14	2.4	5.6		0.5				(12mo) 8
Brown et al.	12	7		1						(12mo) 14
Aigner et al.	12						(1mo) 11.1% (6mo) 33% (12mo) 33%			

Complications

Complication rates can be seen in Table 6 for urinary retention, incontinence, anal stenosis and thrombosis for HAL as reported, and range from 0-24.3%. In the study assessing HAL vs RBL, there were no statistically significant differences between patients with grade III haemorrhoids in terms of postoperative complications [4% HAL (minor bleeding) vs. 16% RBL (4% minor bleeding, 12% severe pain)] [60]. Brown et al. found overall complications in 7% of HAL vs 1% of RBL, but they found this relatively similar [36]. Overall complications occurred in 7.5% vs. 15.8% of HAL and EH (harmonic scalpel) respectively [35]. At postoperative day 90, DGHAL and SH respectively had an overall complication rate of 24% vs 26% respectively (p = 0.70) [64]. No patients in the study by Zhai et al in either group developed faecal incontinence or anal stenosis [62].

Urinary Retention

Overall, 10 of 14 studies reported urinary retention as a complication, with rates ranging from 1-23% (Table 6). This was the most commonly reported adverse event of those studied. Titov et al. describe urinary retention occurring in 3.3% vs 9.1% between HAL and harmonic scalpel respectively [35], and 13.6% versus 4.5% of HAL vs ultrasonic Scalpel techniques in another study [61]. 1% of patients in the HAL group versus 0 in the RBL group in the HuBbLe trial had urinary retention [36]. Only 2.5% developed urinary retention in the HAL group versus 0 in the PPH group in the study by Leung et al, with no other significant postoperative complication reported [34]. Rates were similar between HAL vs PPH groups in the study by Lehur et al. [64]. 5 (10%) developed urinary retention in the HAL group versus 7 (15%) of those who underwent suture fixation only in the study by Zhai et al. [62].

Incontinence

6 studies reported incontinence, ranging from 0-16.6%. Incontinence was seen in 4% versus 0% in MOH vs. HAL respectively, one of which requiring referral to a specialist center [67]. Carvajal Lopez et al found 30% (HAL) vs. 35% (EH) experienced incontinence in the first 7 days, but of these patients their symptoms lasted in only 16.6% and 14% respectively [30]. No differences were found between groups regarding continence alterations P=NS [68]. In comparison to PPH, there were less patients who suffered from incontinence including 4 from the HAL versus 13 from the CSH group, but exact proportions could not be calculated [33]. Incontinence or urgency was reported in 13 (6.6%) PPH vs. 4 (2%) HAL at 3mo, 7 (3.6%) PPH, 0 HAL at 12mo [64]. No differences were found between HAL and ultrasonic scalpel groups [61].

Anal Stenosis

There was no difference in the number of overall complications seen in Roervik et al's study between MOH and HAL, however they did find a 6% anal stenosis rate in the MOH group (one of which requiring reoperation) versus 0% in HAL [67]. Anal stenosis, described as "fibrotic narrowing of the anal canal" in their study, arose in 2.5% of patients in the MOH group, vs 0 in HAL62. 0 patients had anal stenosis at 3-month follow up of either HAL vs Ultrasonic scalpel [61], versus 2.5% of patients following US HE [35]. There was only one reported anal stenosis following HAL between the 2039 patients studied in this review [64].

External Haemorrhoid Thrombosis

3 studies reported haemorrhoidal thrombosis rates, ranging from 0-13.6% Both groups in Titov's study had experienced external haemorrhoid thrombosis as a postoperative complication in 2.5% [35]. Thrombosis was seen in 3% of patients who underwent HAL versus 0 in the PPH arm of the study by Venara et al. [33]. 3 patients of 22 HAL patients (13.6%) vs 1 of 22 (4.5%) ultrasonic scalpel patients developed a thrombosed haemorrhoid [61].

Return to Work/Normal activities

Return to work/normal activities was reported by 8 of 14 studies and ranged from 1.58 – 19.75 days on average for those who underwent a HAL procedure. The average time tended to be longer in those studies which were European [64,67,68]. Sick leave in HAL on average was less than that required for PPH (12.4 +/- 8.2 vs. 14.8 +/- 7.3, p= 0.045). There was no statistical difference between TST and HAL groups [34].

Operative Time

Operative time was significantly shorter in those who underwent pudendal nerve (and no doppler) block versus those who underwent spinal (plus doppler) (16.7 vs. 35.03 minutes, p<0.0001) [65]. Operative time was significantly longer in those who underwent HAL versus those in MOH (57.6 vs. 29.0, p<0.001) [67]. In addition, operative time was longer in HAL versus EH group (41 vs 25 minutes, p = 0.001) [30]. A similar result was seen when compared to PPH (44 vs 30 mins, p<0.001),[64] and (28.7 vs 22.2, p=0.000) [68]. Mean operating time was also longer than that of the ultrasonic scalpel group (35.9 vs. 19 mins, p=0.0001) [61]. There was no significant difference between TST and HAL in terms of operative time (38.6 vs. 38.9, p=0.633) [34].

Discussions

Haemorrhoidal disease is a benign condition that has been treated with classical excisional forms of haemorrhoidectomies for nearly a century. As a result, patients have endured relatively painful and complicated postoperative periods and thus these methods have been challenged with newer, more tolerable forms of treatment. There have been over 14 new methods described, ranging from alternative excisional to completely non-excisional techniques. Two forms of treatment, PPH and HAL, have

gained particular popularity in the last 20 years, particularly as they promised an alternative to the pain associated with the Milligan-Morgan or Ferguson techniques. PPH is effective and less painful, but has been associated with an increased recurrence rate and complications that many colorectal surgeons deem unacceptable [19,69,70]. There was a systematic review performed in 2013 by Pucher et al. on the clinical outcomes of DGHAL, but this featured limited evidence including only six RCTs of between 38 and 169 patients [25]. There have been two recent meta-analyses assessing HAL versus PPH, including six and eight RCTs each, finding a HAL had significantly higher recurrence rate in both studies, less pain and bleeding post-operatively, but no significant differences between overall postoperative outcomes, complication rates, length of hospital stay, or patient satisfaction [71,72]. As surgical practice evolves and new treatments emerge, this updated systematic review was performed to assess how DGHAL performs in current practice as a surgical treatment for grade II-III haemorrhoids. The ideal treatment for haemorrhoids is one that features a balance of the lowest complication rates, lowest recurrence, earliest time back to normal activities, and ideally the lowest cost [68].

Recurrence

Minimally invasive techniques have been very effective for low-grade haemorrhoidal disease. High recurrence rates with HAL have been linked to the degree of prolapse, as recurrence tends to worsen with increasing grade. As a result, other reviews have not recommended HAL, with or without mucopexy, for treatment for grade IV haemorrhoids [25]. Apart from a few of the included studies, rates of recurrence were not stratified by grade, making it difficult to make the same recommendation. With a total pooled recurrence rate of 18.9%, and excluding those without 12 month follow up at 23.65%, this reflects similarly to previous pooled rates [25]. Only four studies stratified by grade III haemorrhoids. Their pooled recurrence was 10.34%. The only recurrence rate stratified for grade IV haemorrhoids was 21% [67], and for grade II ranged from 0-18% [60,67]. Of those who discussed up to grade IV haemorrhoids, their overall recurrence rates ranged from 0-60% but had small patient cohorts (<45 patients each) and were likely of small statistical value. Titov et al. had a relatively low recurrence rate of 1.7% at 1.5 months in grade III and IV haemorrhoids, but this may be related to their shorter follow-up period [35]. Given this, it is difficult to make a recommendation on the use of HAL in grade IV haemorrhoids. Thus, a call is made for future RCTs to report their stratified results by grade of haemorrhoid for proper assessment.

One of the most important advances in HAL procedures has been the use of a plication “mucopexy” suture that reduces and fixes the prolapsed haemorrhoidal tissue. It has been postulated that the ligation suture used in HAL acts to halt arterial supply, thereby shrinking the haemorrhoidal tissue while the mucopexy suture specifically restores the prolapse of tissue, acting in a complementary fashion [73]. All but one of the included studies in this review used the mucopexy technique [60]. However, Brown et al. used mucopexy sutures variably, without reporting the proportion [36]. When comparing mucopexy-alone to classical DGHALm, there was no significant difference seen in recurrence rates between groups in either study by Aigner et al. or Zhai et al. [37,62]. Long-term two-year outcomes by Zhai et al. would suggest suture-fixation mucopexy even performed better in terms of incidence of recurrence. This suggests that rather than previously accepted as a mechanism behind the success of treatment, arterial ligation may not be key to success, contradictory to the vascular theory by Thomson et al. [74]. Due to high recurrence rates in the past of DGHAL alone, it is felt its use is inappropriate for use in grade IV haemorrhoids as a result [21]. It appears that mucopexy itself, returning the haemorrhoidal plexus and tissue to original position above the dentate line, may be the key to successful treatment of prolapsed haemorrhoids. Alternatively, Thomson’s sliding theory may be more likely true of haemorrhoids [74]. This stated that haemorrhoids are the result of sliding of the anal mucosa of the vascular cushions, perpetuated by the gradual destruction of the collagen at the ligament of Treitz with prolonged and repeated passage of constipated stools. Zhai et al. proposed this laxity of the cushions’ supporting ligaments and resultant prolapse is the aim of their suture fixation technique, and in the mucopexy technique in general [75]. As an added benefit, the sutures may naturally decrease flow to haemorrhoids contributing to further shrinkage, without exact arterial ligation. Further long-term and larger RCTs are required to confirm this.

Recurrence rate of HAL was compared to several additional techniques in the RCTs of this review. Perivoliotis et al had an overall recurrence rate of 33.3% at one month for HAL-RAR; 50% in those who underwent DGHAL-RAR under spinal anaesthetic, versus 16.7% in those who underwent non-doppler HAL-RAR under pudendal nerve block, but these were not stratified by grade [65]. This indicates that the use of doppler may actually relate to a higher recurrence rate, following similar results in the literature [37,43]. Indeed, the use of doppler has also been associated with a higher risk of pain postoperatively, which as proposed, is related to the more frequent use of ligations thus aggravating local adverse effects and pain rates [37,42,43]. Perivoliotis et al. found this to be true but their results were not significant [65].

In assessment of RBL vs HAL in grade II and III haemorrhoids, unsurprisingly HAL had a superior recurrence rate [60,36]. Of note, neither of these studies

used mucopexy techniques routinely in their HAL groups. The rate of recurrence for RBL seemed to be relatively higher in the results of Brown et al. than previously reported, which they attribute to relying on patient-reported recurrence. In addition, they felt due to the nature of RBL, many clinicians would classify recurrence only after a "course" of RBL versus a single treatment. This may have increased their recurrence rate, but further delineation is required to define recurrence in RBL.

Out of the three studies comparing HAL with PPH, only one study found PPH was superior in terms of recurrence (4% vs. 16%, p=0.04), but this was a small study of only 50 patients per arm [68]. The two other studies suggested equivalency [64,33]. Similarly, previous literature in recent years has shown recurrence rates of 14% in HAL vs 7.1% in the PPH group, whereas others found a recurrence of 6.3% in HAL groups [76]. There has been no consensus on which of the two perform best in terms of recurrence, and this review follows this. In stratifying their results by the instrument used (A.M.I. HALO device vs. THD), there was no significant difference found between outcomes in the Venara et al. study. The only significant difference between groups were that there were more ligations and mucopexies performed in the A.M.I. group versus THD device groups. This suggests the number of ligations made has no significant impact on recurrence outcomes, similar to what was found previously [54]. Through the use of the PPH stapler device, the prolapsed, damaged tissue is excised, whereas in the HAL technique the tissue remains in the rectum, theoretically causing a risk of recurrence. Giarratano et al. suggest PPH may be more effective due to the physical resection of the damaged rectal wall, but this was only seen in the results of one, albeit small study [68]. The newer Tissue Selecting Technique (TST), which acts as a modified, more controlled PPH, may promise a future in surgical treatment of haemorrhoids. Recurrence rates of TST in this study are similar to that of conventional haemorrhoidectomy, and similarly significantly lower than HAL at one year [34,50]. To note, the recurrence in this study may have been underestimated due to their definition of recurrence being the requirement for an additional procedure during the follow-up period.

No recurrences were seen in either the HAL or EH group in the study by Carvajal Lopez et al by the mean 15 month follow up. This likely reflects the small size of the study (20 patients per group) [30]. In the assessment of HAL vs. a newer minimally open haemorrhoidectomy (MOH) by Roervik et al., where a small portion of the haemorrhoid is left to remain intra-anally, versus completely excised in conventional techniques, recurrence rates remained lower than those experienced by patients who underwent HAL (p=0.008) [67]. Additionally, reoperation rates for recurring disease also remained lower in the MOH group (p=0.013). This suggests MOH performs similarly to other excisional techniques, holding a more favourable recurrence rate, and intriguingly a higher patient satisfaction as well. This may be related to the fact this study had a higher grade of grade IV haemorrhoids (48% MOH, 62% THD) of which have been related to poorer outcomes when treated with HAL and is described as best treated with excisional techniques.

Symptoms of recurrence were reported in various studies to varying degrees. The reporting of recurrence symptoms across studies tended to increase in parallel with increasing follow-up periods, and were particularly low in those with follow-up periods of 1-3 months [61,62]. Bleeding was the most reported symptom of recurrence, featuring in 8 of the 14 studies. When reported at 12 months, the pooled bleeding rate was 18%, which is significantly higher than the rate of 9.7% in the review performed by Giordano et al. in 2009 [24]. The highest was found in the patients of Roervik et al, who reported a 34% bleeding rate at 12 months follow-up, [67] next to 33% in Aigner et al. [37]. These were both relatively small studies of 36 and 20 patients at analysis in each respectively and may represent sampling bias. We recommend for future studies longer periods of follow-up, plus standardized follow-up periods (e.g. 12 months, 18 months and 24 months, and so on) therein minimizing sources of sampling error.

In conclusion to presented data, open or conventional haemorrhoidectomy techniques still remain the better option for patients when the concern is recurrence rates. Mucopexy-alone has comparable results to DGHALm, thus questioning the success of arterial ligation in reducing haemorrhoids. This technique may have potential as an effective and affordable treatment option in those with grade III haemorrhoids. PPH has been seen to offer a small advantage in terms of recurrence, but other studies found this was not significant. As a modified PPH, TST has promising results regarding recurrence. Ultrasonic scalpel and DGHAL have similar results. In comparison to RBL, HAL has better recurrence rates, but there is a requirement for further definition of what a true course of RBL is.

Pain

Pain was measured on a numerical scale from 0 (minimal pain) to 10 (being the worst pain) (e.g. Visual Analog Scale/VAS). HAL was associated with an overall pain score ranging from 2.5-6.33/10 within 24 hours postoperatively, and 1.3-4.53/10 taken within the first week.

Both HAL and PPH have been regarded both as having a relatively lower pain score, particularly when compared to open excisional techniques. OH is classically associated with a long-lasting, significant pain that poses significant strain on patients for a relatively small operation [12]. There were variable results in our study regarding HAL vs.

PPH in terms of postoperative pain. HAL's pain was seen to be significantly less postoperatively and at 2-weeks in one study [64], were relatively the same in another [34], and even higher than PPH in another [68]. Consistent with previous evidence, there is still no clear consensus regarding which procedure is more pain-free. Further examination of these two procedures in larger trials are required to evaluate whether the improvement of 0.6 on the VAS for pain make up for these downfalls. Both techniques have been regarded as relatively pain-free in comparison to excisional techniques, partly due to HAL's non-excisional nature, and most surgical activity taking place above the sensate area distal to the dentate line in both. However, to determine which performs best will likely require larger-scale comparative trials.

There were also no significant differences seen between HAL and TST, but satisfaction rates were significantly greater in the TST group ($p<0.0001$), which may mirror the results as just described in comparing PPH. Characterized by a segmental targeting of haemorrhoids which consequently leaves mucosal bridges intact, Lin et al. in 2008 proposed the TST method as an alternative to PPH that aims to avoid the feared risks of anal stenosis and rectovaginal fistulas [77]. In a noninferiority trial by the same group in 2019, they were able to show TST had significantly reduced pain, urgency symptoms, incontinence, and rectal stenosis (0 vs. 5%) when compared to PPH, without altering recurrence rates by 5-year follow-up [78]. Despite a relatively equivalent pain score, better patient satisfaction, less risk of the serious adverse events associated with PPH, and a significantly lower recurrence rate (often equivalent to conventional excisional techniques), the TST promises a successful technique in the future of haemorrhoidal surgery when compared to HAL.

HAL had better pain outcomes than the ultrasonic scalpel group in both studies comparing the two in this review [35,61]. As a modified version of an OH, this ultrasonic technique may be associated with relatively lower pain than more conventional techniques and thus a similar VAS score by the first week postoperatively [64]. This is likely due to the nature of ultrasonic devices theoretically causing a smaller heat-related injury to tissue [79].

As another form of modified OH, the VSH (Ligasure) groups were comparable to HALm postoperatively in terms of pain scores in the first two weeks, but significantly more patients were taking analgesics postoperatively in the VSH groups which would be in keeping with higher levels of pain. HALm and MOH performed similarly with no significant difference between in terms of pain, pruritis or bleeding postoperatively.

Not surprisingly, HAL as a more invasive technique was more painful than RBL at days one and seven postoperatively ($p=0.002$, $p<0.001$) but had resolved beyond the first week in the large scale HubBLe trial [36]. In addition, the pain described was minimal and could be relieved with oral analgesia. As described in literature and within studies in this review, it appears HAL patients tend to experience pain in the first week that dissipates afterwards [49]. Pain scores were found to be equivalent in the smaller Shehata et al. study which likely reflects a sampling bias [36,60]. Notably, symptom scores, complications and continence scores were comparable between single-RBL and HAL procedures in addition. The decision should be made between the patient and healthcare provider knowing the pitfalls and strengths of both procedures, as some patients might be more inclined to undergo multiple RBLs if less painful, whereas others might elect for the procedure that is more promising for success.

Complications

As mentioned, PPH had fallen out of fashion from many colorectal surgeons due to the risks deemed unacceptable including rectovaginal fistulas, anal stenosis and perforation. DGHAL is not without complications, but serious complications (e.g. rectal perforation with subsequent peritonitis) are scarcely reported [80]. The complication rates for HAL in this review can be seen in Table 6. Particular complications were tabulated, including external haemorrhoidal thrombosis, urinary retention, faecal incontinence, and anal stenosis.

Despite the common concept of HAL being associated with less risk than a PPH procedure, Lehur et al. concluded that HAL does not produce a significantly higher risk than PPH, but significant complications of the procedure do exist. In our review there was a range of incidence of incontinence after HAL from 0.0-16.6%, retention in 1.0-23%, external haemorrhoid thrombosis in 1.0-23.0%. There was only one reported anal stenosis following HAL between the total 2039 patients studied in this review, confirming the scarcity of this complication following HAL [64]. Overall morbidity has been cited to be as high as 18% [81].

Most complications after MOH and HAL were mild and transient, but there was still a 6% rate of anal stenosis after MOH, one patient of which requiring referral to a specialist center [67]. Despite a more simple procedure, Suture-mucopexy alone successfully had 0 patients with strictures or faecal incontinence alongside their HAL comparative [37,62]. Complications were comparable between HAL and RBL groups [36]. We believe the similar rate of complications between HAL and EH groups in the study by Carvajal Lopez et al. are related to sampling bias with only 20 patients each cohort [30]. Previous larger trials have seen a significantly higher rate of chronic complications arise from EH, including anal strictures and incontinence [44,50]. Many non-invasive techniques are

designed to avoid these late and chronic complications often associated with EH [61]. Titov et al. experienced an anal stenosis rate of 2.5% of EH by ultrasonic technique, by only three months postoperatively, consistent with this.

Retention was the most commonly reported complication, which was mild and resolved quickly, and has rates comparable with conventional haemorrhoidectomy techniques, but could be related to anaesthesia and not the surgical type at all [61]. Of note, external haemorrhoid thrombosis was recorded in three studies, ranging from 0-13.5% and may be related to the localized vascular changes at the site caused by HAL. Thrombosis is a significant complication as it often requires a further procedure and should not be dismissed.

It is a rare occurrence for HAL to worsen continence scores. PPH tended to produce more incontinence overall in comparison to HAL but differences were often not significant [64,68]. It is thought resting anal sphincter tone and haemorrhoidal tissue together contribute to continence of faeces, liquid and gas [4,74,82]. Correction of prolapsed haemorrhoidal tissue tended to reduce mean continence scores [36], but due to an inconsistent use of scoring systems used for faecal incontinence, the reports of these were not recorded. There are over ten scoring systems available, but those most commonly used were the patient-subjective Wexner, Vaizey, and Faecal Incontinence Severity Index (FISI) systems. Some studies performed an incontinence investigation prior to treatment to determine pre-existing symptoms. Higher rates of incontinence in some studies may be explained by the lack of pre-treatment assessment and thus persistent incontinence cases. We recommend future studies to incorporate a standard subjective scoring system for more streamlined interpretation. The Wexner scale has been recommended above FISI, Vaizey and Rothenberger systems [83]. We suggest following this review that HAL remains a continence-preserving strategy of haemorrhoidal surgery.

Cost

In addition to optimizing patient care, there is a strong argument guiding optimal procedural choice in finding the most economical option for the overall healthcare system. This is one aspect where HAL may perform relatively poorly. Cost per patient of DGHAL has been estimated at roughly €400 [64]. It was originally suggested by Infantino et al. that DGHAL would be more cost-effective than PPH due to lower device costs and reduced hospital stay, but there was no robust data to support this [48]. In comparison to PPH, Lehur et al. performed an in-depth cost comparison assessing mean costs per procedure, including microcosting identifying all relevant cost components of the procedure and valued each component for all individual patients using procedure duration, staff, devices, and type of theatre as variables, as well as cost of medical devices at the manufacturer's rate (incl. mean of €400 for each doppler probe in DGHAL, and cost of histology of each donut in PPH) [64]. At 3 and 12 months, they had shown DGHAL to be more costly than SH at both time points by €198 ($p<0.001$) and €268 ($p<0.001$) respectively. Through their analysis they concluded at 3 months, DGHAL is 67% more likely to be more expensive but more effective (measured by the rate of patients with at least one postoperative complication or reoperation) than PPH, but this efficacy fell by 12 months, where DGHAL at this stage was 85% likely to be less efficient and more expensive. Despite shorter sick leave and less postoperative pain which would theoretically reduce cost, DGHAL was still more expensive. Notably, theatre times and operative times were on average 10 minutes longer in their study than in other centers using doppler-guidance, thus possibly impacting on increased costs in this study [35,48,65,68, 76]. Roervik also found DGHAL to be more expensive than MOH, finding operative time and device costs the likely cause [67]. There were no differences in postop recovery but the cost analysis did not include sick leave or post-op consultations. Despite adjusting for operative time, HAL was still on average €429 more expensive (95% CI, €525 to 368); $p < 0.001$). Not surprisingly, DGHAL with mucopexy was shown to be significantly more expensive than simpler suture-mucopexy alone (3,138±552 versus 4,020±673 Chinese Yuen, $p < 0.001$, or roughly €421 vs. €539), without any significant differences in length of hospitalisations [62]. In the HubBLe trial, in which a cost analysis (per quality-adjusted life-years (QALYs), including repeat procedures) was performed, they also found HAL to be significantly more expensive than RBL [36]. Trenti et al. noted surgical time of HAL vs VSD was nearly twice as long [28]. Despite not performing cost analysis with preliminary data, Trenti et al. plan on performing this with the data from their two-year follow-up, which is well awaited. Final cost-effectiveness is dependent on the surplus of charges in each recurrence, morbidity and additional procedure required per procedure failed. Of note, five of the 14 studies failed to report which anaesthetic technique was used for their procedure. This may have influenced operation/theatre time and thus cost and must be included in future studies for proper cost analysis.

Conclusions

Haemorrhoidal Artery Ligation with mucopexy or recto-anal repair is a potential treatment for second to fourth-degree haemorrhoids. In assessment of the randomized controlled trials published in the last five years, HAL has an acceptably low complication rate, and pain scores are comparable to other non-invasive techniques, and superior to other modified open techniques. Recurrence rates are still inferior to conventional techniques, but are comparable to other non-invasive techniques, and superior to RBL. DGHAL is more

costly than most. Newer modifications of previous techniques including the Suture-mucopexy alone technique and the Tissue Selecting Technique (TST) offer potential to be a superior treatment, as they are comparable in outcomes, while less costly, time intensive and are associated with less risk than their predecessors respectively. Further long-term studies with larger patient cohorts are required.

Several limitations exist within this review. Of note, the studies included were of overall small calibre, with only four studies having over 100 patients in each arm at analysis [33,35,36,64]. This posed significant bias in collecting our results, and was the result of a narrow timeframe of studies selected. Given the purpose of the review in assessing HAL practice in current practice, we felt this was an acceptable compromise.

A large issue we felt that existed between studies was that there was no standard definition for recurrence. Some studies defined this as the "onset of a new haemorrhoidal prolapse" based on the patient or surgeons assessment, whereas others define recurrence as the "requirement to undergo further treatment/operation", or "recurrence of symptoms associated with haemorrhoidal disease, including bleeding, itching or pain" [34,68]. Some defined recurrence dependent on pile grade (grade III+), whereas others regarded recurrence the presence of a pile regardless of the grade [64,65]. Additionally, follow-up period ranged from one month to 33.7 months in assessment for recurrence. It has been suggested to assess for recurrence at 12 months as most occur within the first year [50].

Lack of standardized postoperative care between and within studies may have been another source of error within the review. Despite most studies outlining they followed a standard postoperative care regimen; it may be worthwhile reporting their technique in future RCTs to minimize risk of bias. Titov et al. reported their two incidences of recurrent prolapse were due to the lack of stool softener and patient toileting advice they had failed to give during the early days of managing DGHALm patients [35]. The other study comparing HAL to ultrasonic scalpel found a non-significant recurrence rate of 4.5% in DGHAL group vs. 0% in their US group, but their follow-up period of 3 months limited the significance of this result [61]. We suggest a longer follow-up period is necessary to assess overall long-term outcomes which may be critical to determining the success of these procedures and should be incorporated to ensure the high-quality of future RCTs, although previous studies have suggested effects of HAL are longstanding [24].

Additionally, pain scores were assessed on 11-point scales ranging from 0-10, but may have been carried out differently between studies. In addition, this review did not record satisfaction rates or quality of life scores that were a common theme in assessing outcomes.

In contrast to previous reviews, we did not see significantly reduced pain in the HAL group compared to PPH, and instead were comparable and even more painful than PPH [25,72]. The change may reflect natural evolution of surgical technique since those reviews were performed.

Included in our further recommendations, is to stratify results of future studies per pre-operative grade of haemorrhoid. This will enable us to determine the answer to the controversial question of whether HAL is efficacious for grade IV haemorrhoids.

Highlights

- ✓ HAL is a safe surgical technique for the treatment of grade II to grade IV haemorrhoids. It still has a relatively low complication rate, and pain scores are comparable to other non-invasive techniques, and superior to open techniques.
- ✓ HAL still performs poorly in terms of recurrence rates. New modified procedures including suture-mucopexy only and tissue-selecting techniques promise better therapeutic potential.

Abbreviations

HAL	: Haemorrhoidal Artery Ligation
HALm	: Haemorrhoidal Artery Ligation with mucopexy
HAL-RAR	: Haemorrhoidal Artery Ligation with Recto-Anal Repair
DGHAL	: Doppler Guided Haemorrhoidal Artery Ligation
THD	: Transanal Haemorrhoidal Dearterialization
PPH	: Procedure for Prolapse and Haemorrhoids
SH	: Stapled Haemorrhoidopexy
OH	: Open Haemorrhoidectomy
CH	: Conventional Haemorrhoidectomy
MOH	: Minimally Open Hamorrhoidectomy
VAS	: Visual Analog Scale
NICE	: National Institute for Health and Clinical Excellence
RCT	: Randomized Controlled Trial
VSH	: Vessel Sealing Device Haemorrhoidectomy
TST	: Tissue Selecting Technique

Compliance with ethical standards

Any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

Conflict of interest disclosure

There are no known conflicts of interest in the publication of this article. The manuscript was read and approved by all authors.

Contributions

Both authors contributed to the conception and design of the work, acquisition, analysis and interpretation of data, drafting or revising the work, final version approval and agreement to accountability for work ensuring accuracy and/or integrity of the article.

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