


LigaSure hemorrhoidectomy versus the procedure for prolapse and hemorrhoids

A meta-analysis of randomized controlled trials

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Abstract

Background: LigaSure hemorrhoidectomy and the procedure for prolapse and hemorrhoids (PPH) are both relatively new treatments for managing symptomatic hemorrhoids. This review aimed to evaluate and compare their short-term outcomes.

Methods: We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials and the China National Knowledge Infrastructure database for randomized controlled trials comparing the LigaSure procedure and PPH published in any language from 1998 to October 2013.

Results: A total of 5 studies involving 397 participants were included in this review. Pooled analysis showed that the LigaSure procedure was associated with significantly lower recurrence rate [relative risk (RR)=0.21, 95% confidence interval (CI): 0.06 to 0.72, $P=.01$] and significantly shorter operating time [mean difference (MD)=−6.39, 95% CI: −7.68 to −5.10, $P<.001$]. The analysis showed no significant difference in postoperative pain between the two techniques (MD=0.55, 95% CI: −0.15 to 1.25, $P=.12$) or in time off work or away from normal activity [standard MD=0.13, 95% CI: −1.80 to 2.06, $P=.9$]. The two techniques did not show significant differences in postoperative complications or other patient-related outcomes ($P>.05$).

Conclusions: Our review indicates that both LigaSure hemorrhoidectomy and PPH are safe alternatives for the management of hemorrhoids. Available evidence suggests that the LigaSure technique is associated with shorter operating time and lower hemorrhoid recurrence rate, but these conclusions should be further confirmed in large, multicenter randomized controlled trials with long-term follow-up.

Abbreviations: CI = confidence interval, FEM = fixed effect model, MD = mean difference, PPH = procedure for prolapse and hemorrhoids, RCTs = randomized controlled trials, REM = random effect model, RR = relative risk, SMD = standard mean difference, VAS = visual analogue scale.

Keywords: hemorrhoids, LigaSure, meta-analysis, PPH

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This meta-analysis does not require an ethics approval as it does not collect any primary data from patients.

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The datasets generated during and/or analyzed during the present study are available from the corresponding author on reasonable request.

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1. Introduction

Hemorrhoids are a physiological component of the anal canal consisting mainly of vascular tissue and supported by smooth muscle and connective tissue.^[1] The hemorrhoidal cushions, which provide additional compression to close the anus completely, are found predominantly at three positions of the anal canal: left lateral (3 o'clock), right anterolateral (7 o'clock) and right posterolateral (11 o'clock).^[2] Hemorrhoid disease, a term that usually refers to hypertrophy of the hemorrhoidal plexus and pathological changes in the anal cushions,^[3] is one of the most common anorectal disorders, with a prevalence of 4.4% to 86% according to various studies.^[4–7] The age distribution of the disease shows a Gaussian distribution with a peak incidence between 45 and 65 years.^[8] The prevalence may be underestimated since only about one-third of patients with the disease turn to physicians for advice.^[8,9] Though men are more likely to seek treatment than women, the incidence of the disease is similar in both genders.^[10] Hemorrhoid disease invariably results in such symptoms as rectal bleeding, painful defecation, inflammation, mucosal prolapse or protrusion, and pruritus ani.^[11] Risk factors for the disease include a low-fiber diet, prolonged straining, constipation, diarrhea and hard stool.^[11]

Hemorrhoidectomy is recommended as the definitive treatment for grade III and IV hemorrhoidal disease.^[12] Indeed, most

surgeons rely on hemorrhoidectomy to manage symptomatic hemorrhoids. Both open^[13] and closed^[14] techniques are widely used, and both are associated with similar postoperative pain outcomes and complications.^[15,16] Postoperative pain is usually substantial, and complications include urinary retention, bleeding and subcutaneous abscess anal fissure, anal stenosis, incontinence, fistula, and hemorrhoid recurrence.^[17,18] As a result, significant efforts have been made to develop new treatment approaches.

In 1998, Longo^[19] introduced a novel procedure referred to as stapled hemorrhoidectomy, hemorrhoidopexy, or the procedure for prolapse and hemorrhoids (PPH). Several early randomized controlled trials (RCTs) showed PPH to be less painful than traditional excisional surgery.^[20–27] More recently, the LigaSure vessel sealing system, designed initially for abdominal surgery, has proven effective at reducing post-hemorrhoidectomy pain significantly below that of conventional hemorrhoidectomy.^[28–30] The LigaSure technique allows complete coagulation of vessels up to 7 mm in diameter such that thermal spread and tissue charring are minimized.^[31,32] In fact, the technique restricts thermal spread to within 2 mm of the adjacent tissue, helping to minimize anal spasm and pain.^[29,30]

LigaSure and PPH are relatively new procedures and we are unaware of systematic attempts to compare their safety and efficacy. Such comparisons may prove invaluable for helping clinicians decide which approach to use when managing symptomatic hemorrhoids. Therefore we carried out a meta-analysis of RCTs analyzing short-term outcomes of the two treatments.

2. Materials and method

2.1. Search strategy

This meta-analysis does not require an ethics approval as it does not collect any primary data from patients. We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials and the China National Knowledge Infrastructure databases without language restrictions from 1998, the year when Longo^[19] first reported stapled hemorrhoidectomy, until October 2013. We used the following search terms: hemorrhoid, haemorrhoid, pile, PPH, longo, stapl*, random*, and Ligasure. The reference lists in relevant studies were manually searched to identify additional potential studies. We also searched in the clinical trial registries at ClinicalTrials.gov (www.clinicaltrials.gov) and in the Meta Register of Controlled Trials (mRCT) (www.controlled-trials.com).

2.2. Inclusion and exclusion criteria

Only prospective RCTs comparing LigaSure and PPH for treating hemorrhoids were eligible for the review. All patients with symptomatic hemorrhoids who underwent either procedure were eligible for inclusion, irrespective of age, gender or hemorrhoid grade. Patients who underwent hemorrhoidectomy with the LigaSure vessel sealing device were assigned to the LigaSure group. Patients who underwent hemorrhoidectomy with a custom-designed stapler were assigned to the PPH group. Retrospective and non-randomized comparative studies, cohort studies, case series and case reports were excluded. When two or more studies showed substantial overlap of participants, study duration, authors or institutions, we included only the most recent or highest-quality study.

2.3. Study selection and data extraction

Two reviewers independently performed primary screening of potentially eligible studies based on the title, abstract and MeSH terms. All articles selected through primary screening were then read in full to ensure study eligibility. Any disagreements were resolved by discussion with a third reviewer. Data on baseline information and outcomes were extracted from the final set of included studies using specially designed tables. If studies were found to report insufficient information, attempts were made to contact authors.

2.4. Outcome measures

Primary outcomes were postoperative pain, recurrence rate, and time off work or away from normal activity. Secondary outcomes included postoperative complications (hemorrhage, urinary retention, stenosis, itching, difficult defecation, and incontinence), and other patient-related results (hospital stay, need for analgesics, and operating time).

2.5. Quality assessment

The quality of included RCTs was assessed using the five-point Jadad scale.^[33] Studies with a score of less than three were regarded as low quality, while trials with a score of three or more were regarded as high quality. We used GradePro 3.6^[34] designed by the Cochrane Collaboration to further evaluate the strength of evidence for primary outcomes.

2.6. Patient and public involvement

Patients and the public were not involved in this meta-analysis.

2.7. Statistical methods

All statistical analyses were performed using Review Manager 5.1, designed by the Cochrane Collaboration. Pooled dichotomous data were analyzed using the risk ratio (RR) with 95% confidence intervals (CIs). Pooled continuous data were analyzed using the mean difference (MD) if outcomes were measured in the same way among trials, or the standard mean difference (SMD) if outcomes were reported in different units. Heterogeneity among trials in each analysis was assessed using the I^2 statistic.^[35] We defined heterogeneity as substantial when I^2 was more than 50%, in which case pooled data were analyzed using a random effect model (REM); otherwise, if I^2 was less than 50%, data were analyzed using a fixed effect model (FEM).

2.8. Sensitivity analysis

The robustness of results was tested by sensitivity analyses in which the outcomes from the REM and FEM were compared; robust results should not be affected by changing the model. Outcomes were presented descriptively when meta-analysis could not be carried out.

3. Results

3.1. Characteristics of included studies

Our literature search identified 97 potentially relevant studies (Fig. 1). Most studies could be eliminated during the primary screening of titles, abstracts and keywords. The full text of the

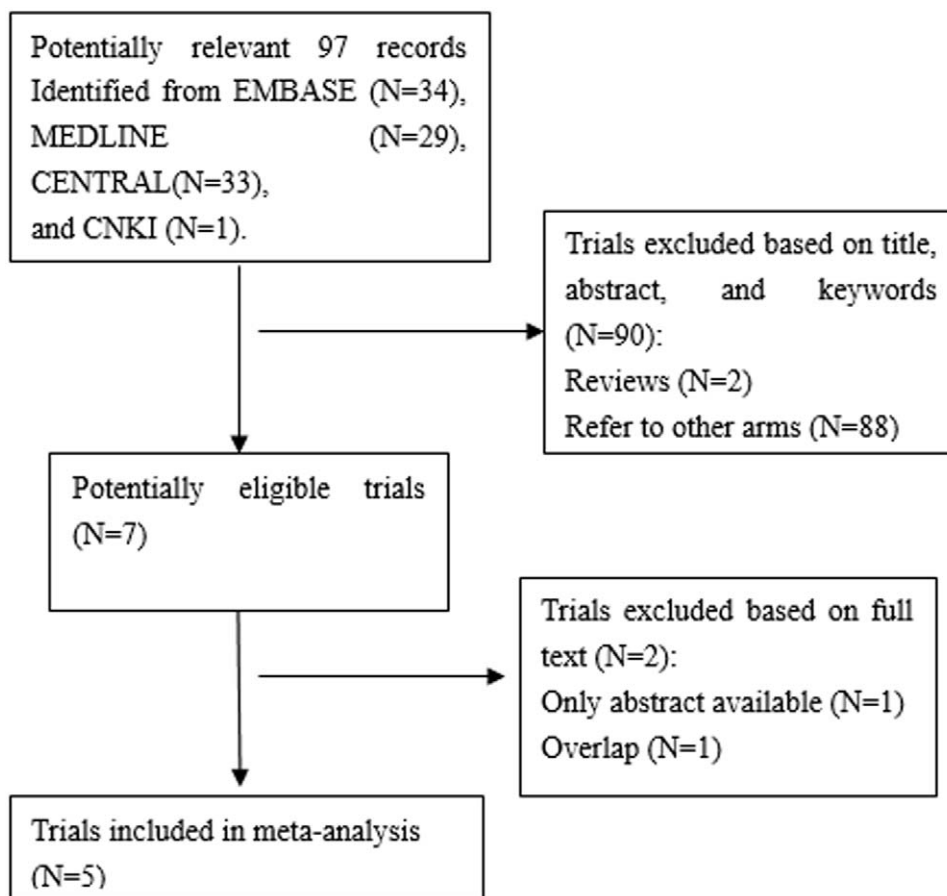


Figure 1. Flow chart of study selection.

remaining 7 trials was read. One study was excluded because only the abstract was available,^[36] while another was excluded because of overlap.^[37] Finally, 5 studies^[38–42] involving 397 participants were found to be eligible for this review. The sample size of included studies ranged from 50 to 98. Demographic data were reported in all included studies and were statistically comparable (Table 1).

3.2. Quality assessment of included studies

All the included studies were single-center RCTs with moderate Jadad scores. All studies had scores of 3, except one study^[41] with a score of 4 because it reported single blinding. We assessed the strength of evidence about primary outcomes using GradePro. The strength of evidence about recurrence rate was high; about postoperative pain, low; and about time off work, very low.

Table 1

Key characteristics of studies included in the systematic review.

Study	Country	LigaSure/PPH (N)	Male:female (N), LigaSure/PPH	Age, yr*	Hemorrhoid grade	Follow up	Jadad score
Arslani 2012 ^[40]	Croatia	52/46	23:29, 21:25	50 (18–78) 52 (17–72)	III	24 mo.	3
Sakr 2010 ^[41]	Egypt	34/34	19:15, 21:13	39.33 52 (17–72)	III, IV	18 mo.	4
Chen 2007 ^[42]	China	42/44	24:18, 26:18	46 (23–85) 48 (25–81)	III	6 mo.	3
Kraemer 2005 ^[38]	Germany	25/25	13:12, 14:11	58 (28–72) 58 (40–71)	III, IV	6 wk	3
Basdanis 2005 ^[39]	Greece	45/50	NR	NR	III, IV	24 mo.	3

NR=not reported, PPH=procedure of prolapse and hemorrhoids.

* Reported as mean or as median (range).

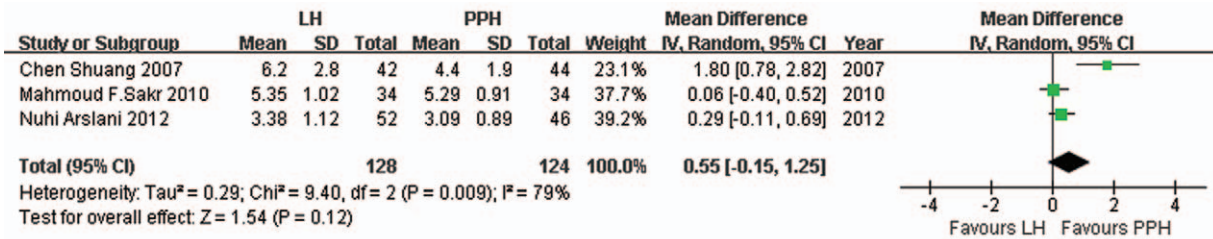


Figure 2. Comparison of postoperative pain following LigaSure hemorrhoidectomy or PPH. PPH=procedure of prolapse and hemorrhoids.

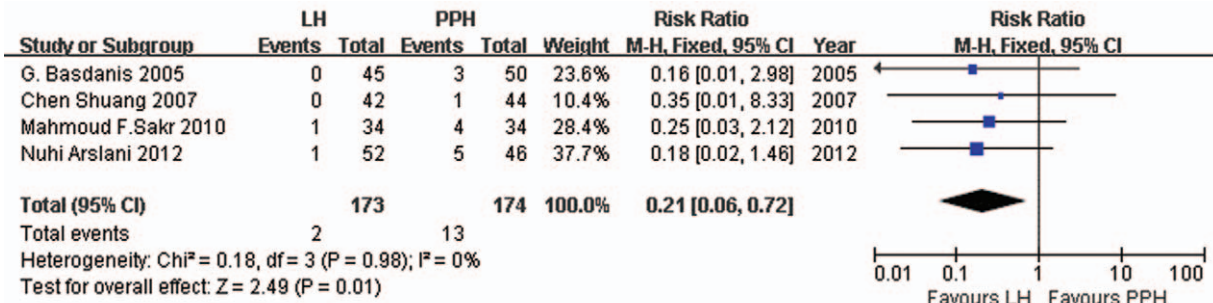


Figure 3. Comparison of hemorrhoid recurrence rate following LigaSure hemorrhoidectomy or PPH. PPH=procedure of prolapse and hemorrhoids.

3.3. Sensitive analysis

We performed the sensitive analysis of all the pooling results by changing the effect model, and all the findings were stabilized and shown under the appropriate effect model.

3.4. Postoperative pain

Three studies^[40–42] reported mean results for postoperative pain and found no significant difference between LigaSure and PPH (MD=0.55, 95% CI: -0.15 to 1.25, $P = .12$, REM; heterogeneity, $I^2 = 79\%$, $P = .009$; Fig. 2). Another study^[38] reporting mean results (without data of standard deviation) on postoperative pain came to a similar conclusion. One study^[39] reported postoperative pain results but it could not be included in the pooled analysis because it reported outcomes as medians and ranges. Median visual analogue scale (VAS) scores (range) were significantly lower for PPH than for LigaSure at various follow-

up points: after 8 hours, 3 (2–6) vs 5 (3–8), $P < .01$; after 24 hours, 3 (1–6) vs 6 (3–7), $P < .01$; after the first defecation, 5 (3–8) vs 7 (3–9), $P < .001$.

3.5. Hemorrhoid recurrence rate

Four studies^[39–42] reported data on hemorrhoid recurrence. Pooled analysis showed that the recurrence rate was significantly lower for LigaSure than for PPH (RR=0.21, 95% CI: 0.06 to 0.72, $P = .01$, FEM; heterogeneity, $I^2 = 0\%$, $P = .98$; Fig. 3).

3.6. Time off work or away from normal activity

Three studies reported data about time off work or away from normal activity.^[39–41] This outcome did not differ significantly between the two techniques (SMD=0.13, 95% CI: -1.80 to 2.06, $P = .9$, REM; heterogeneity, $I^2 = 98\%$, $P < .001$; Fig. 4).

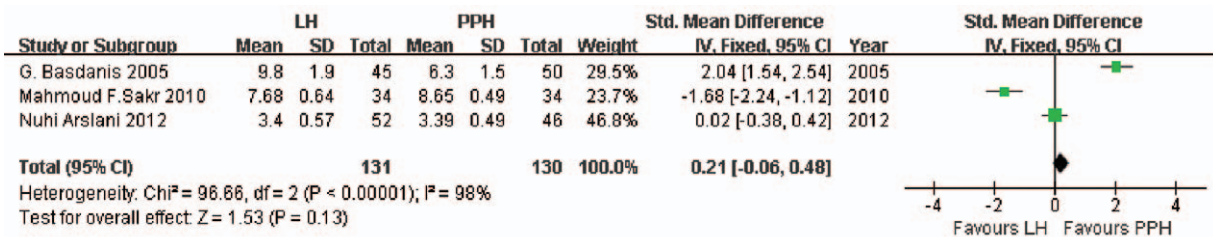


Figure 4. Comparison of time off work or away from normal activity following LigaSure hemorrhoidectomy or PPH. PPH=procedure of prolapse and hemorrhoids.

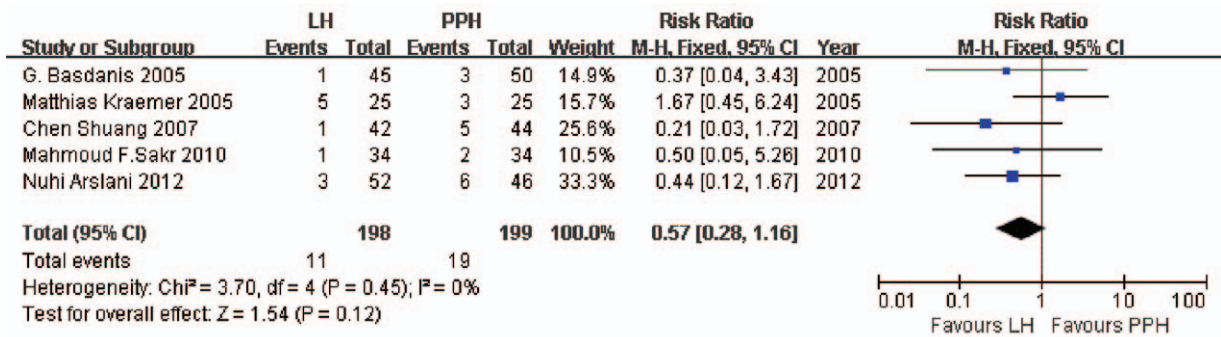


Figure 5. Comparison of hemorrhage occurrence following LigaSure hemorrhoidectomy or PPH. PPH=procedure of prolapse and hemorrhoids.

3.7. Postoperative complications

While not all the included studies reported data on the same postoperative complications, the available data showed no significant differences between LigaSure and PPH. All the included studies reported data about hemorrhaging, pooled analysis indicated no significant difference between the two techniques (RR=0.57, 95% CI: 0.28 to 1.16, P=.12, FEM; heterogeneity, I²=0%, P=.45; Fig. 5). Pooled analysis of urinary retention^[39-42] showed no significant difference (RR=0.88, 95% CI: 0.41 to 1.89, P=.74, FEM; heterogeneity, I²=0%, P=.73; Fig. 6). Similar results were obtained for stenosis^[38,40-41] (RR=0.80, 95% CI: 0.20 to 3.17, P=.75, FEM; heterogeneity, I²=0%, P=.63), itching^[38-39,42] (RR=1.58, 95% CI: 0.32 to 7.79, P=.57, REM; heterogeneity, I²=86%, P<.001), difficult defecation^[38-39,41-42] (RR=0.89, 95% CI: 0.46 to 1.69, P=.71, FEM; heterogeneity, I²=0%, P=.58), and incontinence^[38-41] (RR=0.50, 95% CI: 0.15 to 1.60, P=.24, FEM; heterogeneity, I²=0%, P=.99).

3.8. Other patient-related outcomes

Only two studies^[41-42] reported mean hospital stays; pooled analysis showed no significant difference between LigaSure and PPH (RR=0.82, 95% CI: -1.27 to 2.91, P=.44, REM; heterogeneity, I²=98%, P<.001). Similar results were obtained for the rate of patients needing analgesics in three studies^[38,40,42] (RR=1.06, 95% CI: 0.81 to 1.40, P=.65, REM; heterogeneity, I²=88%, P<.001). In contrast, pooled analysis of operating time^[41,42] showed a significantly shorter time for the LigaSure

procedure (MD=-6.39, 95% CI: -7.68 to -5.10, P<.001, FEM; heterogeneity, I²=0%, P=.52).

4. Discussion

This is, to our knowledge, the first meta-analysis comparing the safety and efficacy of LigaSure hemorrhoidectomy and PPH, two relatively new approaches to managing symptomatic hemorrhoids. Our meta-analysis shows that the LigaSure technique is associated with significantly lower hemorrhoid recurrence and shorter operating time. The two techniques are similar in terms of postoperative pain, time off work, hemorrhage, urinary retention, stenosis, itching, difficult defecation, incontinence, hospital stay, and the need for analgesics.

Therapies for hemorrhoid disease fall into three main categories:

- (1) conservative therapy, which seeks to alter bowel habits and ensure sufficient dietary fiber intake^[43];
- (2) medical therapy, including such techniques as sclerotherapy, rubber band ligation, cryotherapy, infrared coagulation, laser therapy and diathermy coagulation^[44]; and
- (3) surgical therapy, involving such techniques as conventional hemorrhoidectomy (open or closed), LigaSure hemorrhoidectomy, PPH, and Doppler-guided transanal hemorrhoidal de-arterialization. Hemorrhoidectomy is usually the final and effective choice for treating symptomatic hemorrhoids, but the conventional procedure is associated with substantial postoperative pain and various complications.

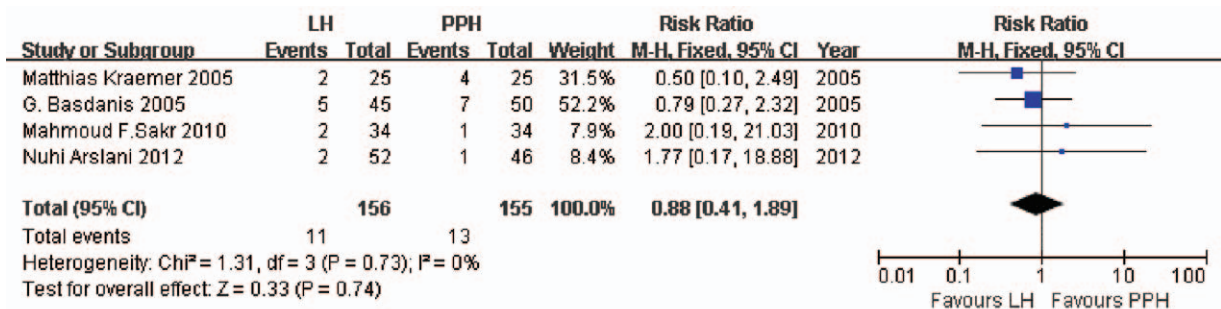


Figure 6. Comparison of urinary retention following LigaSure hemorrhoidectomy or PPH. PPH=procedure of prolapse and hemorrhoids.

All but one of the included studies were of moderate quality, with a Jadad score of 3. One study^[41] incorporated single blinding and therefore had a score of 4. All studies reported appropriate randomization methods, although none described allocation concealment. The strength of evidence about recurrence rate was evaluated as strong, suggesting that it should be taken into serious consideration during clinical decision-making. In contrast, the strength of evidence was low for results about postoperative pain and very low for results about time off work or away from normal activity.

The complications reported in the studies in our review were not so serious as those previously reported for PPH, which include pelvic sepsis,^[45–47] rectal obstruction,^[48] rectal perforation,^[49–50] rectovaginal fistula^[45], and staple line dehiscence.^[51] This may reflect PPH is relatively safe provided that we restrictively followed the operative indication and completed the operation with experienced skills. A Cochrane systematic review^[52] comparing PPH and conventional hemorrhoidectomy showed PPH to be associated with a higher long-term risk of hemorrhoid recurrence and similar postoperative pain. Our systematic review extends these findings by showing that PPH is also associated with a higher recurrence rate and similar postoperative pain as the LigaSure approach.

This systematic review suffers from several limitations. First, it is based on a small number of studies with relatively small samples. Second, most studies were not of high quality, with only one study describing any blinding and none of the studies describing allocation concealment. Third, incomplete reporting in the included studies prevented us from performing subgroup analyses based on hemorrhoid grade or length of follow-up. Fourth, we included only studies for which the full text was available, which may have introduced selection bias.

Our systematic review of the literature comparing LigaSure hemorrhoidectomy and PPH leads us to recommend that future RCTs be large, multi-centered, and double-blinded; that they include long-term follow-up and perform subgroup comparisons based on hemorrhoid grade; and that they take into account additional outcomes such as cost-effectiveness and postoperative quality of life.

5. Conclusion

Our review indicates that both LigaSure hemorrhoidectomy and PPH are safe options for treating hemorrhoids. Available evidence suggests that the LigaSure technique is associated with a lower recurrence rate and operating time, but these findings should be validated in larger, multi-center RCTs involving long-term follow-up.

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Software: Xiaofei Ma.

Validation: Wanchun Wang.

Visualization: Wanchun Wang.

Writing – original draft: Wu Zhong.

Writing – review & editing: Huirong Xiao, Wu Zhong.

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