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ORIGINAL CONTRIBUTION

Partial Stapled Hemorrhoidopexy Versus Circumferential Stapled Hemorrhoidopexy for Grade III to IV Prolapsing Hemorrhoids: A Randomized, Noninferiority Trial

Hong-Cheng Lin, M.D.[1–3] • Qiu-Lan He, M.D.[4] • Wan-Jin Shao, M.D.[5]
Xin-Lin Chen, M.D.[6] • Hui Peng, M.D.[1–3] • Shang-Kui Xie, M.D.[1–3]
Xiao-Xue Wang, M.D.[1–3] • Dong-Lin Ren, M.D.[1–3]

1 Department of Coloproctology, The Sixth Affiliated Hospital of Sun Yat-sen University (Gastrointestinal & Anal Hospital of Sun Yat-sen University), Guangzhou, China
2 Guangdong Provincial Key Laboratory of Colorectal and Pelvic Floor Diseases, The Sixth Affiliated Hospital of Sun Yat-sen University, Guangzhou, China
3 Guangdong Institute of Gastroenterology, The Sixth Affiliated Hospital of Sun Yat-sen University, Guangzhou, China
4 Department of Anaesthesiology, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, China
5 Department of Colorectal Surgery, The Nanjing University of Chinese Medicine Hospital, Nanjing, China
6 School of Basic Medical Science, The Guangzhou University of Chinese Medicine, Guangzhou, China

BACKGROUND: Long-term outcomes and efficacy of partial stapled hemorrhoidopexy are not known.

OBJECTIVE: The purpose of this study was to compare the long-term clinical efficacy and safety of partial stapled hemorrhoidopexy with circumferential stapled hemorrhoidopexy.

DESIGN: This was a parallel group, randomized, noninferiority clinical trial.

SETTINGS: The study was conducted at a single academic center.

PATIENTS: Patients with grade III/IV hemorrhoids between August 2011 and November 2013 were included.

INTERVENTIONS: Three hundred patients were randomly assigned to undergo either partial stapled hemorrhoidopexy (group 1, n = 150) or circumferential stapled hemorrhoidopexy (group 2, n = 150).

MAIN OUTCOME MEASURES: The primary outcome was the rate of recurrent prolapse at a median follow-up period of 5 years with a predefined noninferiority margin of 3.75%. Secondary outcomes included incidence and severity of postoperative pain, fecal urgency, anal continence, and the frequency of specific complications, including anorectal stenosis and rectovaginal fistula.

RESULTS: The visual analog scores in group 1 were less than those in group 2 ($p < 0.001$). Fewer patients in group 1 experienced postoperative urgency compared with those in group 2 ($p = 0.001$). Anal continence significantly worsened after both procedures, but the difference between preoperative and postoperative continence scores was higher for group 2 than for group 1. Postoperative rectal stenosis did not develop in patients in group 1, although it occurred in 8 patients (5%) in group 2 ($p = 0.004$). The 5-year cumulative recurrence rate between group 1 (9% (95% CI, 4%–13%)) and group 2 (12% (95% CI, 7%–17%)) did not differ significantly ($p = 0.137$), and the difference was within the noninferiority margin (absolute difference, –3.33% (95% CI, –10.00% to 3.55%)).

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Correspondence: Dong-Lin Ren, M.D., Department of Coloproctology, The Sixth Affiliated Hospital of Sun Yat-sen University, 26 Yuancun Erheng Rd, Guangzhou 510655, China. E-mail: Rendl111@163.com

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LIMITATIONS: The study was limited because it was a single-center trial.

CONCLUSIONS: Partial stapled hemorrhoidopexy is noninferior to circumferential stapled hemorrhoidopexy for patients with grade III to IV hemorrhoids at a median follow-up period of 5 years. However, partial stapled hemorrhoidopexy was associated with reduced postoperative pain and urgency, better postoperative anal continence, and minimal risk of rectal stenosis. See **Video Abstract** at http://links.lww.com/DCR/A790.

Trial registration (chictr.org) identifier is chiCTR-trc-11001506.

KEY WORDS: Circumferential stapled hemorrhoidopexy; Partial stapled hemorrhoidopexy; Prolapsing hemorrhoids; Rectal compliance; Rectal stricture; Rectovaginal fistula; Tissue selecting technique.

The circumferential stapled hemorrhoidopexy (CSH) technique was first introduced for the management of symptomatic hemorrhoids by Longo in 1998.[1] Our previous systematic review and meta-analysis had reported that the CSH technique is an effective procedure for reducing the principle hemorrhoidal symptoms, although there is a reported higher rate of symptomatic prolapse over time compared with conventional hemorrhoidectomy.[2]

Although CSH procedures are associated with less postoperative pain compared with the conventional hemorrhoidectomy, a small but significant number of patients have unrelenting discomfort.[3] It is postulated that excessive fibrosis around the staples may be an important cause of persistent proctalgia.[4] Functional issues, including new-onset fecal urgency and difficulty in defecation, are probably a result of the inflammatory response to staple deployment, whereas in some cases a fixed fibrotic element led to significant postoperative anorectal stenosis.[5] Rarely, a rectovaginal fistula may develop secondary to the occurrence of hematoma within the rectovaginal septum.[6]

Our group had first reported the safety and feasibility of a new procedure called *tissue-selecting technique*, which is a partial or segmental stapled hemorrhoidopexy. Therefore, it is also referred to as *partial stapled hemorrhoidopexy* (PSH).[7] Using this technique, PSH was performed by preserving the mucosal bridges.[7,8] This approach is anticipated to preserve the compliant tissue because fewer staples are deployed,[9] thereby potentially reducing some of the morbidities associated with the conventional CSH procedure, including anastomotic stenosis, rectovaginal fistula, and defecatory dysfunction. Our unit has previously reported similar clinical results with the PSH technique compared with open hemorrhoidectomy in patients with grade III/IV hemorrhoids,[10] a finding recently confirmed by Wang et al.[11] We reported shorter operative time, less postoperative pain, and reduced hospital stay with minimal functional disturbance over a 12-month follow-up with the PSH. Our preliminary data had shown similar clinical efficacy between the PSH and CSH procedures for advanced hemorrhoidal prolapse over a medium-term follow-up with less postoperative pain and fewer cases of initial fecal urgency in the PSH-treated patients.[12] The PSH procedure showed little impact on anorectal physiology with low complications, consistent with the finding by Soares et al.[13] Favorable outcomes with PSH have been reported in short-term follow-up case series.[13–15] However, a head-to-head comparison between PSH and CSH in randomized trial has not been made, and information on long-term outcomes is lacking. Our choice of a noninferiority trial design was based on the expectation that the PSH procedure is noninferior to CSH with fewer postoperative complications. The current study is an expansion of our recent work comparing the clinical efficacy and safety of the PSH and CSH techniques for patients with symptomatic grade III and grade IV hemorrhoids over a long-term follow-up (5 y).

PATIENTS AND METHODS

Patient Selection

The study was a single-center, parallel group clinical study. We recruited 300 consecutive adult patients with a minimum of 6 months of symptoms from grade III/IV hemorrhoids referred to the Department of Coloproctology of The Sixth Affiliated Hospital of Sun Yat-Sen University. Patients with acute hemorrhoidal complications (thrombosis or strangulation), previous hemorrhoid surgeries, or active anorectal diseases (fistula, abscess, or fissure); those on anticoagulant therapy; and those with IBD or colorectal carcinoma were excluded. Patients were allocated at a ratio of 1:1 to receive either PSH or CSH and blinded to the procedure. Blocked randomization with a fixed block size of 4 (2 in PSH group and 2 in the CSH group) was performed by a statistician who had no clinical involvement in the study using computer-generated coding in sealed envelopes. The study was approved by the local hospital ethics committee, and all of the patients provided written informed consent to participate in the trial.

Surgical Procedure

All of the procedures were performed by specialist colorectal surgeons with a minimum experience of 30 PSH procedures. CSH was performed according to the technique as described by Longo et al.[1] The details of the PSH technique have been reported previously.[7,8] After removal of the stapler, staple-line bleeding was controlled with absorbable 3/0 Vicryl Z sutures. Skin tag excision was performed at the surgeon's discretion. Postoperative management was standardized and

consisted of basic nursing care, dietary modifications, sitz baths, and conventional postoperative analgesia.

Intraoperative data included the operative time (time between the beginning of the operation and the application of the dressing, recorded with a digital timer and accurate to the minute) and the intraoperative blood loss (based on the number of gauzes used, where each gauze represented 5 mL of blood loss). The mean vertical height of the resected specimen in PSH cases and the height of the resected doughnut in the CSH cases were recorded. All of the resected specimens were examined histologically. The primary outcome measured was the rate of recurrent prolapse at the median follow-up of 5 years. Secondary outcomes included incidence and severity of postoperative pain, fecal urgency, anal continence, and the frequency of specific complications, including rectal stenosis and rectovaginal fistula. If recurrence was reported by the patients, they were examined by 2 senior surgeons to rule out skin tags or thrombosed hemorrhoids. Postoperative pain was assessed at 12 hours and then at 1, 2, 3, and 7 days postoperatively, as well as during the first defecation, using a visual analog scale (VAS), where 0 = no pain and 10 = the most severe pain. Urgency was determined at the same time points and was considered present if patients were unable to defer defecation for >15 minutes.[16] *Rectal stenosis* was defined as the loss of compliant natural elasticity of the anal opening, which then became abnormally tight and fibrous.[17] *Outlet-obstructed constipation* (as distinct from anorectal stenosis) was defined as difficulty in defecation after stapled hemorrhoidopexy because of the reduced rectal compliance caused by the circumferential stapled anastomosis rather than by rectal stenosis.[8] Continence was assessed with the Jorge-Wexner incontinence score before surgery and at 1 and 3 postoperative months.

Patients were assessed by a physician at 1 week after the surgery and then at 1, 2, 6, and 12 months, and finally at 2 years after surgery. Patients who could not attend follow-up visits were contacted via the telephone for interview. Follow-up interviews were performed by telephone after the 2-year office visit until up to 5 years. Additional follow-up visits were performed for significant symptoms, including severe pain, severe urgency, or difficulty in defecation. Patients were considered as having recurrence if the symptoms occurred after a minimum of a 2-month symptom-free postoperative period.

All of the patients in the study (both men and women) were surveyed at 3 months postsurgery regarding the broad effect of the surgery on sexual function using a questionnaire that assessed whether the surgery influenced patient sexual activities, the patients experienced anal pain, or the patients experienced abdominal pain after intercourse. At the 1-year follow-up visit, based on the presence and severity of these specific symptoms, a postoperative rating was created including *excellent* if no symptoms were present, *good* if ≥1 moderate symptom was present, and *poor* if >1 severe symptom was present.

Statistics

Statistical analyses were performed in the intent-to-treat population. Data with normal distribution were recorded as mean and standard, and those with non-normal distribution were recorded as medians and interquartile ranges. The 2-sample *t* test or the Mann-Whitney *U* test was used to compare quantitative variables between the groups where appropriate. The χ^2 or Fisher exact test was used for qualitative variables. The log-rank test was used to assess the difference between the 2 groups. Recurrence was analyzed by calculation of cumulative incidence. Univariate analysis was performed to identify significant predictors of recurrence in both arms. Multivariate analysis with a Cox proportional hazards model via stepwise selection was used to identify independent predictive factors for time-to-event outcomes. The generalized estimating equation method was used to examine longitudinal associations of outcome with several variables measured repeatedly (eg, fecal urgency, postoperative pain, and anal continence). Because postoperative pain and anal continence are continuous variables, we specified Gaussian distribution for the family along with an identity link and an unstructured correlation matrix in the model. In addition, fecal urgency is a binary variable, so that binary logistic distribution was indicated. The published recurrence rate after CSH for hemorrhoidal disease is 25%,[18] and the recurrence rate of the PSH procedure in the pretest to treat hemorrhoids is ≈15% based on our database containing 3000 cases (unpublished data, Dong-Lin Ren, et al.). This resulted in a magnitude of the noninferiority margin of 0.0375 (ie, 15%[19] × 25% = 0.0375) with an α value of 0.025 and a power value of 0.80, mandating that a sample size of 133 patients was required for each group. Taking into account an anticipated dropout rate of 10%, a total of 300 patients overall was recruited. A 2-sided p value < 0.05 was considered statistically significant. Statistical analyses were conducted using SPSS version 13.0 (SPSS Inc, Chicago, IL) and R language version 3.4.2 (www.r-project.org).

RESULTS

In this study, 738 patients were screened between August 2011 and November 2013, and 438 patients were excluded because of nonconsent, alternative surgeries, hemorrhoidal management procedures, or other reasons (Fig. 1). The average follow-up time in this study was 63.5 months (range, 48–75 mo) in the PSH group and 60 months (range, 48–75 mo) in the CSH group. Baseline characteristics are summarized in Table 1, showing that the 2 groups were well matched in age, sex, duration of disease (rounded to the half year), degree of severity of the hemorrhoids, and preoperative Jorge-Wexner incontinence score.

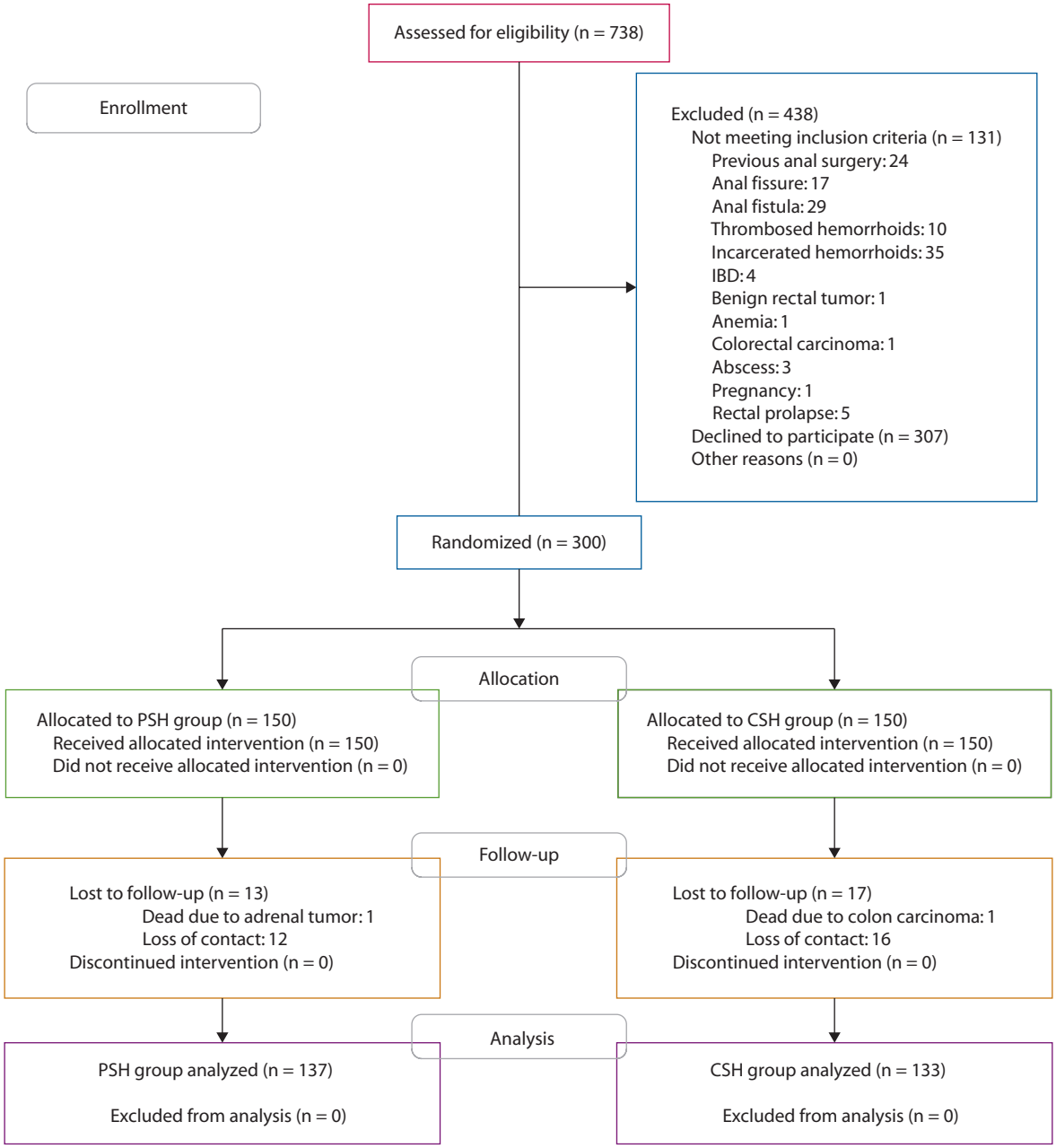

FIGURE 1. Participant enrollment and follow-up (CONSORT flow diagram). PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

Early Postoperative Outcomes in Patients Receiving PSH and CSH

The median operative time was comparable between the groups (20 min (range, 8–60 min) in the PSH group vs 20 min (range, 5–60 min) in the CSH group; $p = 0.705$). Of the total patients in each study arm, the incidence of intraoperative bleeding from the staple line requiring hemostatic sutures was significantly lower in the PSH group (12% (18/150)) compared with the CSH group (75% (112/150); $p = 0.001$). There was a slight but significant difference in estimated blood loss between the 2 groups (PSH group, 10 mL (range, 5–25 mL) vs 20 mL (range, 5–100 mL); $p = 0.001$). The length of the resected rectal tissues was 4.00 cm (range, 3.00–5.50 cm) in the PSH group and 3.25 cm (range, 3.00–5.00 cm) in the CSH group ($p = 0.001$). Skin tags were removed in 125 patients (83%) in the PSH group and 112 (75%) in the CSH group ($p = 0.065$). No squamous epithelium was evident in the rectal resected tissue from either group, although smooth muscle was found in all of the rectal resected specimens from both groups.

There was no significant difference in VAS values measured at 12 hours and 1 day after surgery ($p > 0.05$). Compared with VAS values at 12 hours postsurgery, these

TABLE 1. Demographic and clinical features of patients undergoing either PSH or CSH

Characteristics	*PSH (N = 150)*	*CSH (N = 150)*	*p*
Age, y	40 (21–78)	42 (19–80)	0.745
Men/women	88/62	85/65	0.815
Symptom duration, y	5 (0.5–40.0)	3 (0.5–35.0)	0.071
Grade III [a]	99 (66%)	110 (73%)	0.209
Grade IV [a]	51 (34%)	40 (27%)	
Preoperative incontinence scores[b]	1 (0–3)	1 (0–3)	0.206

PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.
[a]Percentages are shown in parentheses for grade of hemorrhoids.
[b]Data show the Jorge-Wexner incontinence score, median (range).

scores increased at 2 days ($p < 0.001$) and decreased at 3 days and 7 days after surgery ($p < 0.001$). The VAS values in the PSH group were smaller compared with the CSH group ($p < 0.001$; Table 2); the model-based estimates of VAS at different times are shown in Table 3 and Figure 2. In addition, the patients in the PSH group experienced less pain than those in the CSH group during first defecation (2 (1–3) vs 3 (2–3); $p = 0.010$). Compared with 12 hours after surgery, the ORs of fecal urgency were 0.474, 0.409, 0.296, and 0.175 at 1, 2, 3, and 7 days after surgery, which suggested that this symptom risk ameliorates with time. The risk of fecal urgency in the PSH group was lower than that in the CSH group (OR = 0.24; $p < 0.001$; Table 4), and the model-based percentages for postoperative recorded fecal urgency between groups are shown in Table 5 and Figure 3. Fourteen patients (4 from the PSH-treated group and 10 from the CSH-treated group) experienced significant postoperative bleeding. All of the cases of postoperative hemorrhage were successfully managed by local inward pressure and the use of a local noradrenaline enema (noradrenaline 4 mg diluted with ice normal saline to 200 mL) without the need for reoperation. Twenty-one patients (14%) in the PSH-treated group complained of gaseous incontinence compared with 35 patients (23%) in the CSH-treated group ($p = 0.038$). Compared with the preoperative Jorge-Wexner incontinence scores, the score increased at 1 and 3 months after surgery ($p < 0.001$). The Jorge-Wexner incontinence

TABLE 2. Visual analog pain scores associated with PSH and CSH in the early postoperative period

Parameter	*β*	*SE*	*95% CI*	*p*
Day 1 vs 12 h	0.01	0.06	−0.11 to 0.14	0.836
Day 2 vs 12 h	0.39	0.07	0.25 to 0.52	<0.001
Day 3 vs 12 h	−0.39	0.07	−0.53 to −0.25	<0.001
Day 7 vs 12 h	−0.63	0.06	−0.75 to −0.51	<0.001
PSH vs CSH	−0.31	0.04	−0.39 to −0.23	<0.001

The generalized estimating equation parameter estimates with Gaussian distribution.
PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

TABLE 3. The model-based estimates of visual analog scores at different times

	CSH			*PSH*		
Time	*Estimate*	*SE*	*95% CI*	*Estimate*	*SE*	*95% CI*
12 h	2.47	0.05	2.37–2.57	2.22	0.05	2.12–2.33
Day 1	2.48	0.05	2.39–2.58	2.24	0.05	2.13–2.34
Day 2	2.86	0.06	2.75–2.97	2.61	0.06	2.50–2.72
Day 3	2.08	0.05	1.98–2.19	1.84	0.05	1.74–1.94
Day 7	1.84	0.04	1.75–1.93	1.59	0.04	1.51–1.68

PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

score in the PSH group was lower compared with that in the CSH group at 1 month ($p < 0.001$). However, there were no significant differences between the 2 groups at 3 months ($p > 0.05$; Table 6); the model-based estimates of Wexner scores at different times are shown in Table 7 and Figure 4. There were 3 cases identified with anastomotic polyps in the PSH group and 2 cases in the CSH group ($p = 1.0$). The reported sexual satisfaction assessment is shown in Table 8, 52 patients (35%) reporting some perceived influence of the operative procedure with PSH treatment compared with 92 patients (61%) treated by CSH ($p < 0.001$). Of the PSH-treated patients, 21% experienced anal pain after intercourse compared with 32% of CSH-treated patients ($p = 0.037$). No patient reported vaginal bleeding after intercourse. Comparative costs analysis showed that there was no significant difference in cost between PSH ($2045 (range, $2150 to $2741)) and CSH ($2020 (range, $2266 to $2686); $p = 0.767$).

Outcomes of Patients Receiving PSH and CSH at 5-Year Follow-Up

During the follow-up, there were 13 patients (9%) in the PSH group and 17 (11%) in the CSH group lost to follow-up. Two deaths (1%) occurred during the follow-up period, and they were unrelated to the surgery. One death occurred 6 months after surgery because of an adrenal tumor (PSH) that was asymptomatic at the time of randomization; the other was because of colon carcinoma, which was diagnosed 4 years postoperatively (CSH). One patient treated with PSH developed an anal fissure requiring surgical excision.

During follow-up, 9% of patients (13/150 (95% CI, 4%–13%)) were confirmed to have recurrent hemorrhoidal prolapse in the PSH group, whereas 12% of patients (18/150 (95% CI, 7%–17%)) were confirmed in the CSH group. This difference in the recurrence rate did not reach significance ($p = 0.137$). The estimated HR was 1.707 ($p = 0.137$ (95% CI, 0.835–3.486)), indicating that there was no significant difference of risk of recurrence between the 2 groups. No significant difference was found in the cumulative recurrence rate between the 2 groups ($p = 0.137$; Fig. 5A); the number of patients

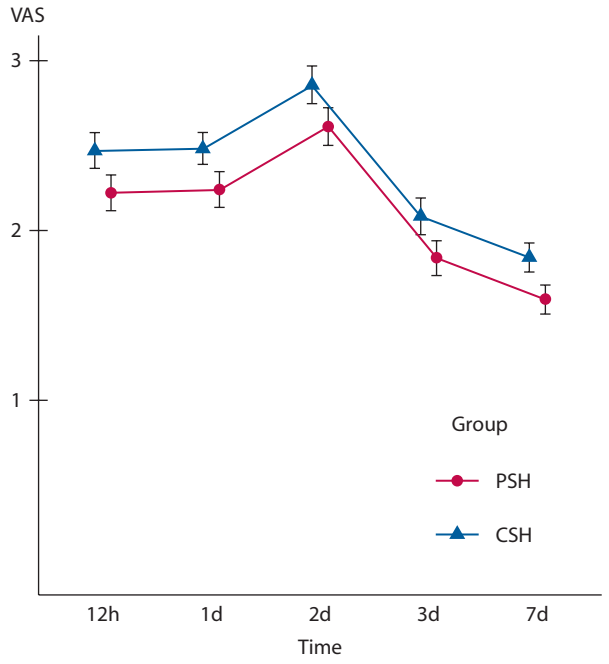

FIGURE 2. Model-based visual analog scale (VAS) scores by treatment groups and time on study with error bars indicate 2-sided 95% CIs. PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

remaining at risk at 5 years was 93 in the PSH group and 99 in the CSH group. However, the cumulative recurrence rate in patients who initially presented with grade III hemorrhoids (8%; 14/183) was significantly lower than that in patients with grade IV hemorrhoids (20%; 17/87; $p = 0.001$; Fig. 5B), both in the PSH group and the CSH group (PSH: $p = 0.002$; CSH: $p = 0.039$; Fig. 5C). Furthermore, older patients (>43 y) were found to have a higher cumulative recurrence rate than younger patients (≤43 y; $p = 0.041$; Fig. 5D). With a univariate analysis, factors significantly associated with a higher cumulative recurrence rate were grade IV hemorrhoids (HR = 3.099 (95% CI, 1.525–6.298); $p = 0.002$) and age >43 years (HR = 2.089 (95% CI, 1.014–4.303); $p = 0.046$). In the subsequent multivariate analysis, only the grade of hemorrhoids was confirmed as an independent predictor for further recurrence, with an HR of 3.099 (95% CI, 1.525–6.298; $p = 0.002$). The 5-year cumulative recurrence rate difference between

TABLE 4. Postoperative recorded fecal urgency between groups

Variables	*β*	*SE*	*OR*	*95% CI*	*p*
Day 1 vs 12 h	–0.75	0.11	0.47	0.38–0.59	<0.001
Day 2 vs 12 h	–0.90	0.11	0.41	0.33–0.51	<0.001
Day 3 vs 12 h	–1.22	0.12	0.30	0.23–0.38	<0.001
Day 7 vs 12 h	–1.75	0.15	0.18	0.13–0.23	<0.001
PSH vs CSH	–1.41	0.22	0.24	0.16–0.37	<0.001

Data show the generalized estimating equation parameter estimates.
PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

TABLE 5. Model-based percentages for postoperative recorded fecal urgency between groups

Time	*CSH*	*PSH*
12 h	75.6%	44.4%
Day 1	59.3%	27.3%
Day 2	55.6%	24.4%
Day 3	47.7%	19.0%
Day 7	35.1%	12.2%

PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

the PSH and CSH groups was –3.33% (95% CI, –10.00% to 3.55%). The CI lies wholly to the left of Δ and includes 0, which indicates that PSH is noninferior but not shown to be superior (Fig. 6). One patient in the PSH group who developed recurrence was retreated with stapled hemorrhoidopexy (CSH) with good outcome. All of the remaining patients with recurrent hemorrhoidal prolapse were managed successfully without surgery.

Adverse events in the present study were also detailed in Table 9. Of these, rectal stenosis developed in 8 patients (5%) in the CSH group and none in the PSH group ($p = 0.004$). One of these cases was successfully managed by operative division of the anastomotic staple line, and all of the others were managed by dilatation alone. Three patients in the CSH group and none in the PSH group ($p = 0.246$) developed outlet-obstructed constipation. One patients with outlet-obstructed constipation was treated with bilateral incision of the anastomotic ring, and the

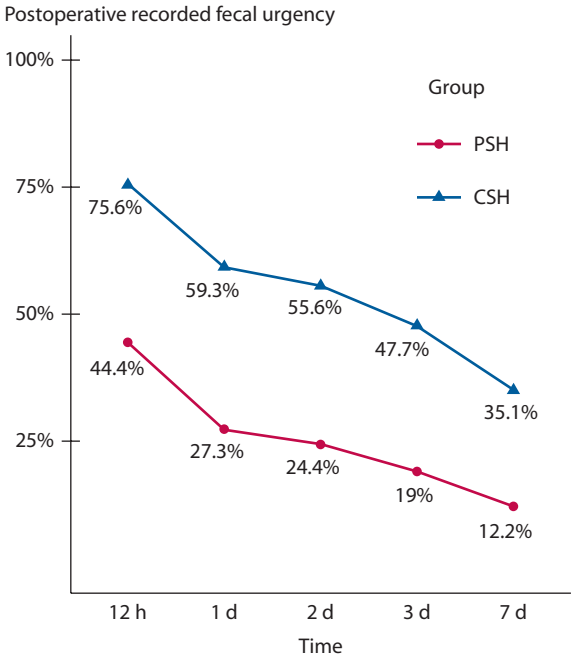

FIGURE 3. Model-based percentages for postoperative fecal urgency by treatment groups and time on study. PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

TABLE 6. Comparison of preoperative and postoperative Wexner scores between PSH and CSH

Parameter	*β*	*SE*	*95% CI*	*p*
Postoperative 1-mo vs preoperative	1.64	0.10	1.44 to 1.84	<0.001
Postoperative 3-mo vs preoperative	0.37	0.06	0.26 to 0.49	<0.001
PSH vs CSH	−0.14	0.11	−0.36 to 0.08	0.210
Postoperative 1-mo group	−0.67	0.13	−0.92 to −0.42	<0.001
Postoperative 3-mo group	−0.13	0.08	−0.28 to 0.02	0.094

The generalized estimating equation parameter estimates with Gaussian distribution.
PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

other 2 were successfully treated with digital anal dilation. Two patients experienced blood-stained stool or long-term fecal urgency in the CSH group, which resolved after treatment with agraffectomy (removal of visible staples with or without repeat resection of the stapled anastomosis and manual reanastomosis). No persistent pain was reported by patients in either group. When satisfaction with treatment was surveyed, 82% of patients in the PSH group and 79% of patients in the CSH group rated excellent, and 18% in the PSH group and 20% in the CSH group rated moderate ($p = 0.310$).

DISCUSSION

This study found that PSH, a procedure that preserves mucosal and submucosal anodermal bridges, had comparable efficacy as CSH for symptomatic grade III/IV hemorrhoids at a median follow-up of 5 years but with less postoperative pain and fecal urgency compared with CSH. There was a moderate incidence of anal discomfort during sexual intercourse in the postoperative period in both groups. Also, a significant number of patients noted that their sexual activity was adversely affected by the surgery. The incidence of serious postoperative complications with both techniques was extremely low.

In the management of grade IV hemorrhoids, the incidence of recurrent prolapse with both techniques at 12 months was lower than the 58.9% of patients reported by Zacharakis et al[20] in our study. In the PSH study arm of the present trial, the cumulative recurrence rate in patients with grade IV hemorrhoids was higher than patients with grade III hemorrhoids, and a similar finding was noted in the CSH study arm, suggesting that both PSH and CSH resulted in an insufficient resection in patients presenting with more advanced hemorrhoids. Similar findings have been reported by Fueglistaler et al,[21] where one third of patients with manifestation of hemorrhoidal prolapse preoperatively experienced persistent prolapse-related symptoms after a CSH procedure. By contrast, the height of the resected specimen was slightly greater in the PSH group compared with the CSH group, suggesting that PSH has a better longitudinal resection. This may be potentially advantageous for grade III prolapsing hemorrhoids over a conventional CSH procedure. Conflicting results concerning the incidence of postoperative hemorrhoidal prolapse might be a result of misdiagnosis, where patient-reported symptoms of recurrent prolapse were not confirmed clinically in many cases. Moreover, patients were often unable to differentiate between remnant prolapsed piles and skin tags from recurrent prolapse, and, therefore, recurrent prolapse could be overestimated. In our study, the patients reporting recurrence were examined by 2 senior surgeons to exclude remnant piles or skin tags.

There are currently limited data concerning sexual function after hemorrhoidectomy. Our study showed that stapled hemorrhoidopexy (both PSH and CSH) commonly influences postoperative sexual satisfaction, with the CSH technique having a greater effect. Both groups reported a moderate incidence of anal pain after vaginal intercourse, although the incidence was higher in the CSH-treated group. Lin et al[22] reported a similar prevalence of sexual dysfunction symptoms, including desire, arousal, pain, orgasm, and sexual satisfaction assessments, after conventional hemorrhoidectomy. Additional prospective work is required in this area to determine the specific impact of stapled anal surgery. For women who have undergone a stapled hemorrhoidopexy, one highly undesirable complication is a rectovaginal fistula.[6] No patient in our series experienced this complication. In addition, the PSH procedure may offer additional protection by the

TABLE 7. The model-based estimates of Wexner scores at different times

	CSH			*PSH*		
Time	*Estimate*	*SE*	*95% CI*	*Estimate*	*SE*	*95% CI*
Pre	1.38	0.08	1.23–1.53	1.24	0.08	1.08–1.40
Pos 1	3.02	0.10	2.83–3.21	2.21	0.06	2.09–2.34
Pos 3	1.75	0.06	1.64–1.86	1.49	0.09	1.31–1.66

Pre = preoperative; POS 1: postoperative 1-month; Pos 3: postoperative 3-month; PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

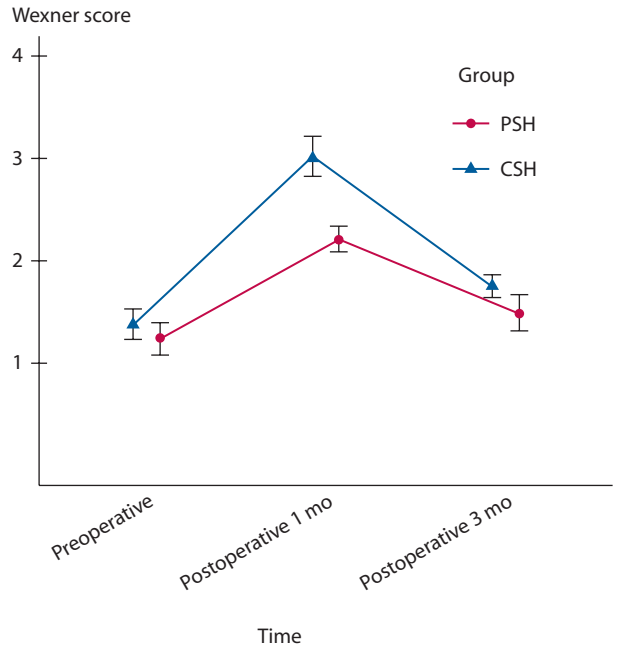

FIGURE 4. Model-based Jorge-Wexner incontinence scores by treatment groups and time on study with error bars indicate 2-sided 95% CIs. PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

placement of the plastic bridge directly against the septum as a protective barrier.

The postsurgery complication rate in our series was low with both techniques, with a substantially low risk of persistent postoperative pain. Of note, removal of skin tags is a favored practice among Chinese surgeons. Although this practice might contribute to postsurgery pain, we did not find an association between excessive postoperative pain and skin tag excision in our previous study.[12] In addition, the patients who underwent PSH experienced less pain than that in the CSH group, and this might be because the PSH involves fewer staples and better preservation of rectal compliance.[8] Others have reported a relatively high incidence of unrelenting pain after stapled hemorrhoidopexy either related to an inappropriately low deployment of the staples or possibly because of an excessive inflammatory response around the staple line.[4,23] Patients in our study did not experience this complication, although some studies have indicated that staple excision (agraffectomy) may be effective in selected cases.[24] Also, because of an excessive inflammatory response, the presence of a fixed, noncompliant circumferential staple ring will contribute in some patients to rectal stenosis. In our study, all 8 patients (5%) with delayed rectal stenosis were in the CSH group and none in the PSH group. The concept of partial resections designed to preserve some normal rectal bridging tissue is aimed at safeguarding rectal compliance and functional outcome.[8]

The incidence of gaseous incontinence was higher in the CSH group compared with the PSH group. Although the continence scoring improved significantly postsurgery in both groups, the scores overall were better in patients who were in the PSH study arm. The cause of soiling and urgency after stapled hemorrhoidopexy is multifactorial, and possibly a result of the dynamics of the anastomosis. Symptoms after some endoanal stapled surgeries, including cramping abdominal pain, fecal urgency, difficulty in defecation, and even incontinence, have been sufficiently specific as to be labeled by some a "stapled hemorrhoidopexy syndrome[25]" or a "postPPH syndrome.[26]" The pathogenesis of this cluster of symptoms is complex and most likely reflects excessive inflammatory responses to the staples combined with a reduced effective neorectal reservoir. These physical changes may be accompanied by subtle disturbances in rectal sensation and perceived distension, where a reduction in volume threshold with normal pressures would fit with reduced reservoir function.[27]

TABLE 8. Sexual satisfaction survey 3 months after surgery

	Total			*Men*			*Women*		
Questionnaire	*PSH*	*CSH*	*p*	*PSH*	*CSH*	*p*	*PSH*	*CSH*	*p*
Did the surgery influence your sexual activity?									
No influence	98	58	<0.001	66	36	<0.001	32	22	0.036
Some influence but with high sexual satisfaction	52	89		22	49		30	40	
Considerable influence with reduced sexual satisfaction	0	3		0	0		0	3	
Did you experience anal pain after vaginal intercourse?									
Yes	32	48	0.037	30	39	0.113	28	32	0.646
No	118	102		58	46		34	33	
Did you experience abdominal pain after intercourse?									
Yes	2	7	0.176	0	2	0.240	2	5	0.475
No	148	143		88	83		60	60	

PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

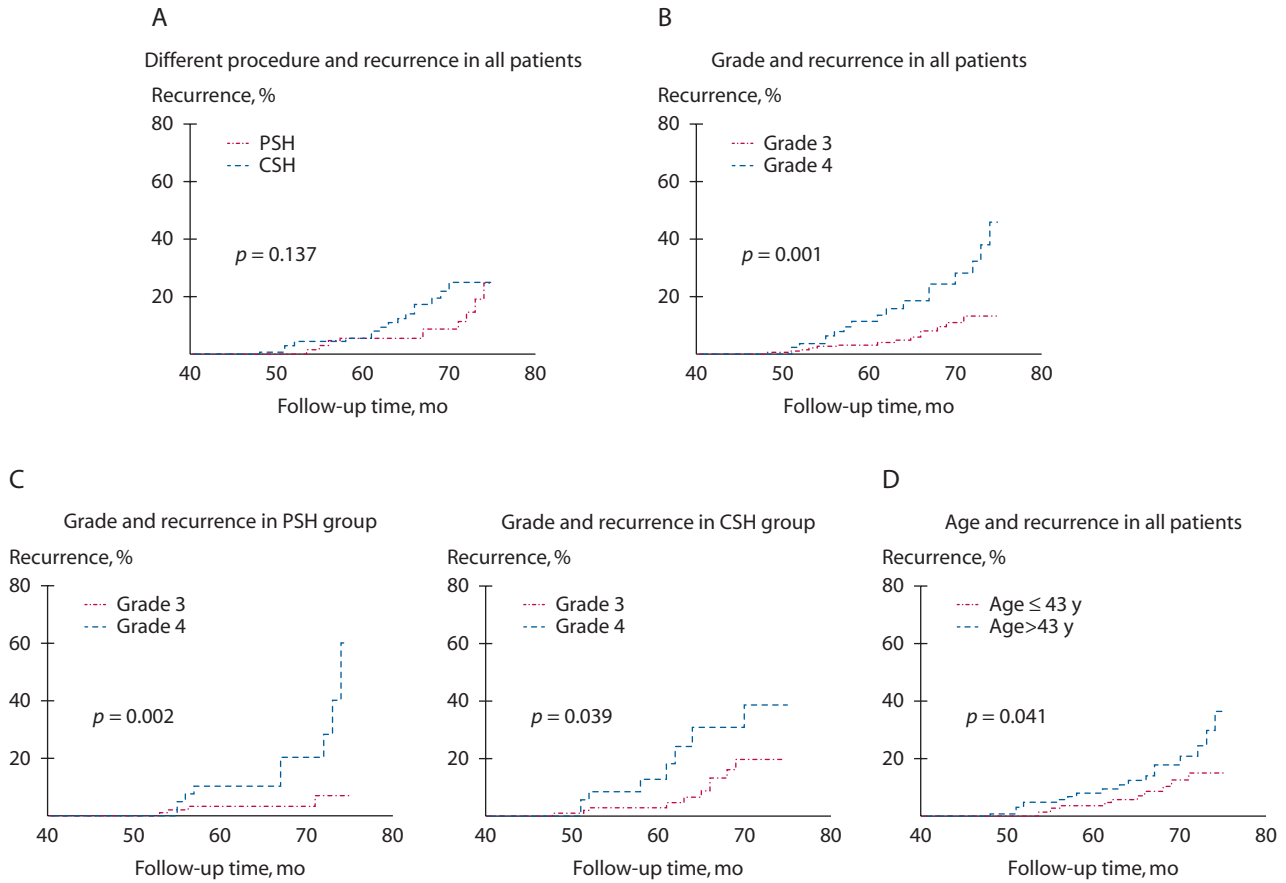

FIGURE 5. Cumulative recurrent rate stratified by (A) treatment group, (B) grade, (C) treatment group and grade, and (D) age. PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

Although not required in our patients for these symptoms, staple removal has been reported to be successful in alleviating such symptoms after CSH.[28] This operative revision needs to be particularly selective, avoiding those patients with coincident obstructed defecation or underlying psychological disturbance.[29] The present study aimed to evaluate the efficacy of PSH compared with the conventional CSH procedure. Because a 5-year recurrence rate is considered clinically meaningful by physicians in China, we chose the 5-year recurrence rate as the key parameter for the noninferiority comparison. We set the noninferiority margin at 3.75%, based on an earlier study that reported the recurrence rate of 25.0% after a CSH procedure.[18] However, in our study, the 5-year recurrence rate was 12%,

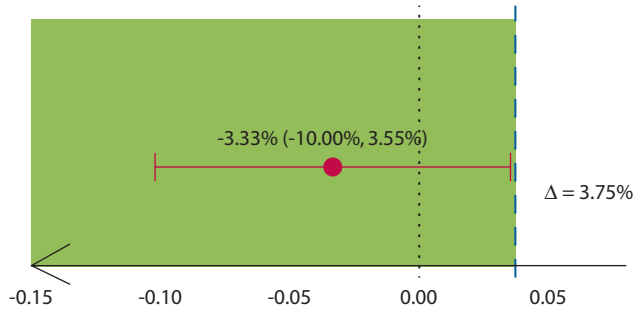

FIGURE 6. The 5-year cumulative recurrence rate difference and the noninferiority margin.

TABLE 9. Adverse events

Adverse events, n (%)	*PSH (N = 150) n (%)*	*CSH (N = 150) n (%)*
Total number of adverse events	61	108
Gaseous incontinence	21 (14)	35 (23)
Liquid incontinence	0	0
Solid stool incontinence	0	0
Postoperative bleeding	4 (3)	10 (7)
Anastomotic polyps	3 (2)	2 (1)
Anal fissure	1 (1)	0
Outlet-obstructed constipation	0	3 (2)
Blood-stained stool	0	1 (1)
Rectal stenosis	0	8 (5)
Long-term fecal urgency	0	1 (1)
Anal pain after intercourse	32 (21)	48 (32)
Vaginal bleeding following intercourse	0	0
Rectal perforation	0	0
Pelvic abscess	0	0
Rectovaginal fistula	0	0

PSH = partial stapled hemorrhoidopexy; CSH = circumferential stapled hemorrhoidopexy.

lower than the reported rate, indicating a possibly wide range of recurrence rates after CSH. Nevertheless, in the present study, we did not note a significant difference in 5-year recurrence rates between the PSH and CSH groups, although the PSH group showed a numerically lower recurrence rate. Overall, our results showed that the 5-year recurrence rates were comparable between PSH and CSH. More head-to-head comparisons between PSH and CSH are needed to confirm that PSH is noninferior to CSH.

Limitations of our study also include the fact that the work was conducted in a single center, which could introduce systemic errors and some biases in the analysis. In addition, all of the cases were local Chinese patients, and the benefits of PSH over other stapled procedures must be validated in other populations. Moreover, there was a lack of control for lifestyle modifications, such as eating habits, which might impact the long-term outcomes of the procedure. Furthermore, additional studies are needed to examine the impact of new devices and thereby provide a targeted approach to hemorrhoidal surgery, particularly in treating prolapse at advanced stages. In this respect, our team has collaborated with an Italian group (Naldini et al[30]) and reported the use of the STARR Plus stapler, which has a higher housing volume in a slightly larger-diameter stapler (36 mm) compared with the standard PSH and CSH device. This larger stapler may result in a larger resection and is mainly suitable for the cases of rectal intussusception and large prolapsing hemorrhoids with better clinical medium-term outcomes.[30] It is highly likely that PSH offers more benefits to selected cases of prolapsing hemorrhoids of lesser grade. However, the selected use of the STARR or double-stapled approach has been shown to be more effective than simple prolapsectomy in the management of advanced hemorrhoids.[31,32]

CONCLUSION

In summary, the 5-year recurrence rates were similar in patients with grade III to IV hemorrhoids treated with PSH or CSH. However, PSH was associated with reduced postoperative pain and urgency, better postoperative anal continence, and minimal risk of rectal stenosis. Additional analysis indicated that PSH is a clinically effective procedure, particularly in grade III hemorrhoids, with less efficacy in more advanced hemorrhoidal prolapse. New single-fire devices may provide better management for more extensive hemorrhoidal prolapse.

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REFERENCES

1. Longo A. Treatment of hemorrhoidal disease by reduction of mucosa and hemorrhoidal prolapse with a circular suturing device: a new procedure. In: *Proceedings of the 6th World Congress of Endoscopic Surgery*. Bologna, Italy: Monduzzi Editore; 1998:777–784.
2. Shao WJ, Li GC, Zhang ZH, Yang BL, Sun GD, Chen YQ. Systematic review and meta-analysis of randomized controlled trials comparing stapled haemorrhoidopexy with conventional haemorrhoidectomy. *Br J Surg*. 2008;95:147–160.
3. Pescatori M, Gagliardi G. Postoperative complications after procedure for prolapsed hemorrhoids (PPH) and stapled transanal rectal resection (STARR) procedures. *Tech Coloproctol*. 2008;12:7–19.
4. Garg P, Sidhu G, Nair S, et al. The fate and significance of retained staples after stapled haemorrhoidopexy. *Colorectal Dis*. 2011;13:572–575.
5. Naldini G. Serious unconventional complications of surgery with stapler for haemorrhoidal prolapse and obstructed defaecation because of rectocoele and rectal intussusception. *Colorectal Dis*. 2011;13:323–327.
6. McDonald PJ, Bona R, Cohen CR. Rectovaginal fistula after stapled haemorrhoidopexy. *Colorectal Dis*. 2004;6:64–65.
7. Lin HC, He QL, Ren DL, et al. Partial stapled hemorrhoidopexy: a minimally invasive technique for hemorrhoids. *Surg Today*. 2012;42:868–875.
8. Lin HC, Lian L, Xie SK, Peng H, Tai JD, Ren DL. The tissue-selecting technique: segmental stapled hemorrhoidopexy. *Dis Colon Rectum*. 2013;56:1320–1324.
9. Corsetti M, De Nardi P, Di Pietro S, Passaretti S, Testoni PA, Staudacher C. Rectal distensibility and symptoms after stapled and Milligan-Morgan operation for hemorrhoids. *J Gastrointest Surg*. 2009;13:2245–2251.
10. Lin HC, Luo HX, Zbar AP, et al. The tissue selecting technique (TST) versus the Milligan-Morgan hemorrhoidectomy for prolapsing hemorrhoids: a retrospective case-control study. *Tech Coloproctol*. 2014;18:739–744.
11. Wang ZG, Zhang Y, Zeng XD, et al. Clinical observations on the treatment of prolapsing hemorrhoids with tissue selecting therapy. *World J Gastroenterol*. 2015;21:2490–2496.
12. Lin HC, Ren DL, He QL, et al. Partial stapled hemorrhoidopexy versus circular stapled hemorrhoidopexy for grade III-IV prolapsing hemorrhoids: a two-year prospective controlled study. *Tech Coloproctol*. 2012;16:337–343.
13. Soares MB, Pitombo MB, Paulo FL, et al. Partial stapled hemorrhoidopexy: clinical aspects and impact on anorectal physiology. *Rev Col Bras Cir*. 2017;44:278–283.
14. Leung ALH, Cheung TPP, Tung K, et al. A prospective randomized controlled trial evaluating the short-term outcomes of transanal hemorrhoidal dearterialization versus tissue-selecting technique. *Tech Coloproctol*. 2017;21:737–743.
15. Jeong H, Hwang S, Ryu KO, et al. Early experience with a partial stapled hemorrhoidopexy for treating patients with grades III-IV prolapsing hemorrhoids. *Ann Coloproctol*. 2017;33:28–34.
16. Katdare MV, Ricciardi R. Anal stenosis. *Surg Clin North Am*. 2010;90:137–45, Table of Contents.
17. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum*. 1993;36:77–97.

18. Tjandra JJ, Chan MK. Systematic review on the procedure for prolapse and hemorrhoids (stapled hemorrhoidopexy). *Dis Colon Rectum*. 2007;50:878–892.
19. Chow SC, Song F. On selection of margin in non-inferiority trials. *J Biom Biostat*. 2016;7:301.
20. Zacharakis E, Kanellos D, Pramateftakis MG, et al. Long-term results after stapled haemorrhoidopexy for fourth-degree haemorrhoids: a prospective study with median follow-up of 6 years. *Tech Coloproctol*. 2007;11:144–147.
21. Fueglistaler P, Guenin MO, Montali I, et al. Long-term results after stapled hemorrhoidopexy: high patient satisfaction despite frequent postoperative symptoms. *Dis Colon Rectum*. 2007;50:204–212.
22. Lin YH, Stocker J, Liu KW, Chen HP. The impact of hemorrhoidectomy on sexual function in women: a preliminary study. *Int J Impot Res*. 2009;21:343–347.
23. Zhao Y, Ding JH, Yin SH, Hou XL, Zhao K. Predictors of early postoperative pain after stapled haemorrhoidopexy. *Colorectal Dis*. 2014;16:O206–O211.
24. Pescatori M, Gagliardi G. Agraffectomy after low rectal stapling procedures for hemorrhoids and rectocele. *Tech Coloproctol*. 2011;15:265–266.
25. Efthimiadis C, Kosmidis C, Grigoriou M, et al. The stapled hemorrhoidopexy syndrome: a new clinical entity? *Tech Coloproctol*. 2011;15(suppl 1):S95–S99.
26. Khubchandani I, Fealk MH, Reed JF 3rd. Is there a post-PPH syndrome? *Tech Coloproctol*. 2009;13:141–144.
27. De Nardi P, Corsetti M, Passaretti S, et al. Evaluation of rectal sensory and motor function by means of the electronic barostat after stapled hemorrhoidopexy. *Dis Colon Rectum*. 2008;51:1255–1260.
28. Mari FS, Nigri G, Di Cesare T, et al. Does the removal of retained staples really improve postoperative chronic sequelae after transanal stapled operations? *Dis Colon Rectum*. 2014;57:658–662.
29. Brusciano L, Ayabaca SM, Pescatori M, et al. Reinterventions after complicated or failed stapled hemorrhoidopexy. *Dis Colon Rectum*. 2004;47:1846–1851.
30. Naldini G, Martellucci J, Rea R, et al. Tailored prolapse surgery for the treatment of haemorrhoids and obstructed defecation syndrome with a new dedicated device: TST STARR Plus. *Int J Colorectal Dis*. 2014;29:623–629.
31. Boccasanta P, Venturi M, Roviaro G. Stapled transanal rectal resection versus stapled anopexy in the cure of hemorrhoids associated with rectal prolapse: a randomized controlled trial. *Int J Colorectal Dis*. 2007;22:245–251.
32. Naldini G, Martellucci J, Talento P, Caviglia A, Moraldi L, Rossi M. New approach to large haemorrhoidal prolapse: double stapled haemorrhoidopexy. *Int J Colorectal Dis*. 2009;24:1383–1387.