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Stapled Hemorrhoidectomy: 6-Year Experience in Thai Patients

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Abstract

Background: Hemorrhoidal disease is one of the most common anorectal disorders worldwide. Stapled hemorrhoidectomy (SHD) is a relatively new technique introduced in 1998. Nowadays, there are sufficient evidences of its benefits. There are 25 randomized clinical trials comparing SHD with open hemorrhoidectomy and 6 randomized clinical trials comparing SHD with closed hemorrhoidectomy (CHD). There are also 5 systematic reviews of randomized trials comparing SHD and conventional hemorrhoidectomy. We have previously studied and retrospectively compared hemorrhoidectomy by stapled technique (n = 88) and closed hemorrhoidectomy (n = 88).

Objective: The aim of this study was to analyze the results of our 6-year experience of SHD in Thai patients and to compare with our previous study.

Patients and Methods: From January 2004 to December 2006, 116 patients underwent SHD using PPH-03. We compared these data including 88 SHD using PPH-01 performed between October 2000 and December 2003 with 88 CHD from our previous study. All procedures were performed under spinal anesthesia and in jackknife position.

Results: In SHD group (N = 204), 96 were male (47%) and 108 were female (53%) with median age of 51 years (20-80 years). In CHD group (N = 88), 36 were male (41%) and 52 were female (59%) with median age of 47 years (22-79 years). SHD group required less analgesic consumption than CHD group (58.3% vs 100%; p <0.05). Mean operative time was shorter in SHD than CHD group (17 vs 35 minutes; p <0.05). Postoperative hospitalization for one day was more common in SHD than CHD group (81.9% vs 20.4%; p <0.05). Postoperative complication rates especially urinary retention were lower in SHD than CHD group (36.8% vs. 62.5% and 32.8% vs. 55.7%; p <0.05; respectively). Overall recurrent hemorrhoidal symptoms were similar between the two groups after median follow-up period of 34 months (3-77 months). SHD group developed less recurrent bleeding than CHD group (1.5% vs 9.1%; p <0.05). No serious complications after SHD were found.

Conclusions: Our results confirm that SHD is simple (shorter operative time), safe (less postoperative pain and less complications) and effective (low recurrent symptoms). Stapling technique also reduces the length of hospital stay. There are no serious complications. This study demonstrates that the previously published favorable results of SHD can be reproduced in Thai patients. The keys of success are proper patient selection and good surgical technique. Because of the rather high urinary retention rate, SHD should not be performed under spinal anesthesia as a day-case surgery.

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INTRODUCTION

Hemorrhoidal disease is one of the most common anorectal disorder worldwide.¹ From practice parameters for the management of hemorrhoids in 2005, ten million Americans complained of hemorrhoids.²

Conventional hemorrhoidectomy is considered a painful operation and postoperative pain is still the most common reason for patients avoiding surgery.^{3,4}

Stapled hemorrhoidectomy (SHD) is a relatively new technique introduced in 1998 by Longo⁵ and Milito et al.⁶ from Italy. The rationale of the procedure is to reset the hemorrhoids in their normal position without damaging the sensitive anal mucosa and to decrease the blood flow to hemorrhoids. In contrast to the traditional hemorrhoidectomy, it does not remove the hemorrhoids. As a result, the excision occurs above the dentate line, thus it avoids a painful wound in the somatically innervated anoderm.

Initially, SHD gained widespread acceptance throughout Europe, despite the lack of significant clinical data to support its use. In 2000, Cheetham et al estimated that 50,000 SHD operations had already been performed in Europe.⁷ This procedure is rapidly popular because of the short operative time, slight postoperative pain, shorter hospital stay and earlier return to daily activities and work. From 1998 to 2003, approximately 350,000 SHD procedures have been performed worldwide.⁴

Nowadays, however, there are sufficient evidences of its benefits. There are 25 prospective randomized controlled trials comparing SHD with open hemorrhoidectomy;^{3,8-31} 19 trials from Europe,⁸⁻²⁶ 5 trials from Asia (Singapore 3,²⁷⁻²⁹ India 1,³⁰ China 1³) and one trial from Egypt.³¹ There are 6 prospective randomized controlled trials comparing SHD with closed hemorrhoidectomy (Ferguson technique), 2 trials from Europe,^{32,33} 2 trials from Asia (Singapore 1,³⁴ China 1³⁵) and one trial each from the United States⁴ and Mexico.³⁶ There is also one prospective randomized controlled trial comparing SHD with rubber band ligation from Singapore.³⁷

There are also 5 systematic reviews of randomized trials comparing SHD and conventional hemorrhoidectomy by Sutherland et al in 2002,³⁸ Nisar et al in 2004,³⁹ Lan et al in 2006,⁴⁰ Cochrane Database systematic review in 2006¹ and Tjandra & Chan in 2007.⁴¹

According to a recently published consensus among experts, the technique has been standardized and is widely accepted in different countries. The indications, contraindications, and operative technique have been defined.⁴²

We have previously studied and retrospectively compared hemorrhoidectomy by stapled technique (n = 88) and closed hemorrhoidectomy technique (n = 88).⁴³

The purpose of this study was to analyze the results of our 6-year experience regarding the safety and effectiveness of SHD in Thai patients and to compare the results with our previous and first study in Thai patients.⁴³

PATIENTS AND METHODS

Medical records of patients with hemorrhoids who underwent stapled hemorrhoidectomy (SHD) by one surgeon (CE) from January 2004 to December 2006 in the Department of Surgery, Ramathibodi Hospital, Mahidol University, were analyzed retrospectively. There were 116 cases during this 3-year period. Including 88 cases from our previous study⁴³, a total of 204 cases of SHD were available for this study (Diagram 1). Patients older than 18 years with third-degree hemorrhoids or combined internal and external hemorrhoids in at least three quadrants were eligible for SHD. Our exclusion criteria for SHD included fourth-degree hemorrhoids, hemorrhoids with large external components, large fibrotic skin tag, hemorrhoids with only one or two sites and hemorrhoids with associated anorectal pathologies.

Patients were followed at 2 weeks after surgery and then at 1, 3 and 6 months and then once every year. The median follow-up duration was 34 months (range 3-77 months).

For the control group of patients, conventional closed hemorrhoidectomy (CHD) in 88 patients from our previous study was compared.⁴³ CHD with only one or two sites or emergency cases were excluded. Both procedures were carried out under spinal anesthesia.

In SHD group, 96 were male (47%) and 108 were female (53%) with median age of 51 years (range 20-80 years). In CHD group, 36 were male (41%) and 52 were female (59%) with median age of 47 years (range 22-79 years) (Table 1).

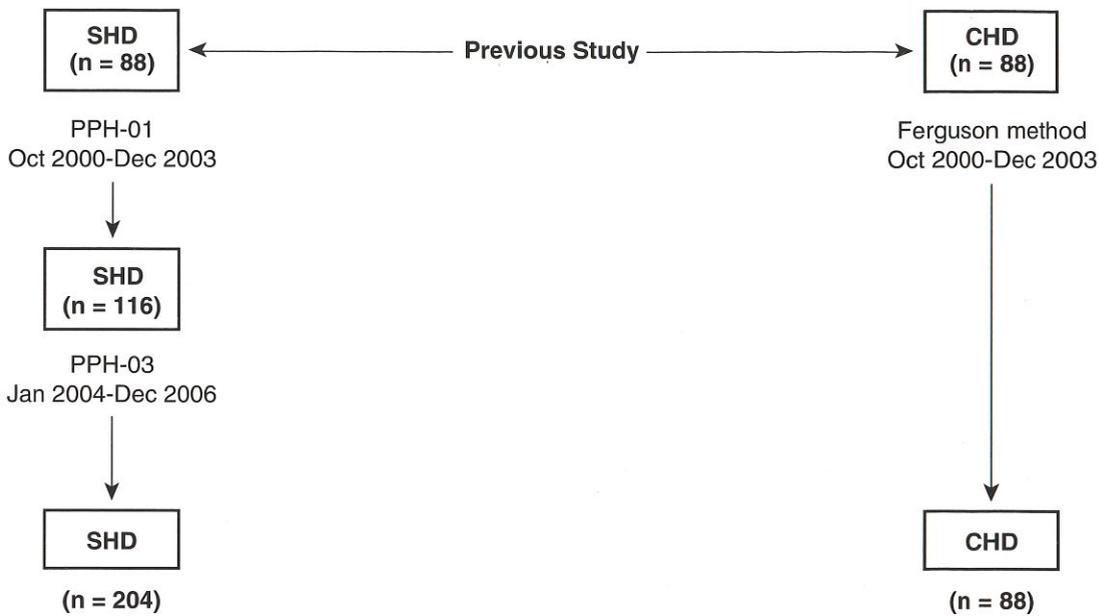


Diagram 1 Intent-to-Treat analysis population

Table 1 Gender and age

	SHD (n = 204)	CHD (n = 88)
Male : Female	96:108 (47% vs 53%)	36:52 (41% vs 59%)
Median age (years)	51 (20-80)	47 (22-79)

These medical records were analyzed for operative time, postoperative pain (analgesics consumption), duration of postoperative hospitalization, complications such as urinary retention and urinary catheterization, bleeding, thrombosed or inflamed skin tag, infection (foul-smelling discharge with oral antibiotics administration), incontinence, anal stricture, fecal impaction (need enema or evacuation), and recurrent hemorrhoidal symptoms.

Surgical technique of SHD

The Ethicon PPH-03 set was used in these new 116 cases. The PPH-01 set was used in our 88-previously reported cases. The PPH-03 is a new enhanced version of the PPH-01 stapler and the operative technique is essentially similar to that used with PPH-01. The PPH kit consists of 33-mm hemorrhoidal circular stapler, circular anal dilator and obturator, purse-string anoscope and suture threader.

All operations were performed without conventional bowel preparation. Only simple bowel preparation consisting of two phosphate enema was needed.

All operations were performed under spinal anesthesia, with patients in prone jackknife position and by one surgeon (CE). With this position, a superior view of the anal canal is obtained that allows comfortable access for operating surgeons as well as surgical assistants. Because of the dependent drainage of the submucosal and venous complex, the hemorrhoidal plexus tend to be less congested and therefore less voluminous.

The detail of the procedure was reported elsewhere.⁴³ In brief, in a prone jackknife position, a circular anal dilator with obturator is gently inserted and secured into the anus. The obturator is then removed and replaced with a purse-string anoscope. A purse-string suture of 2/0 polypropylene is placed about 3-4 cm above the dentate line by rotating the gap in the anoscope. Care must be taken to include only mucosa and submucosa. The number of suture bites is irrelevant. However, to obtain a band-like specimen (as opposed to an undulating specimen), it is of importance to avoid large suture gaps on the luminal surface; the suture should therefore be placed almost at the same point where the preceding stitches come out. The purse-string anoscope is then removed and

the widely open hemorrhoidal circular stapler is introduced into the circular anal dilator with the distal anvil beyond the purse-string suture. The purse-string suture is tied snugly around the staple shaft. Both free ends of the suture are pulled through both side holes of the stapler using suture threader and knotted externally. With moderate traction on the suture, the stapler is closed and tightened to the maximum. The purpose of this traction is to pull the loose anorectal tissue into the stapler housing to maximize the tissue resection. The stapler is kept closed for at least 2 minutes to ensure hemostasis. Before firing the staples in female, it is imperative to perform a vaginal examination to ensure that the posterior vaginal wall has not been incorporated into the staple line. The purse-string anoscope is reintroduced and rotated to visualize the staple line for bleeding and proper hemostasis. Bleeding points could be easily controlled with electric cauterization. A piece of Gelfoam is left in the anal canal at the end of the procedure. The tissue doughnut is checked for completeness and sent for histopathologic examination routinely.

No attempt is made to excise the external components and perianal skin tags because it will result in postoperative pain similar to conventional techniques, hence the benefit of using stapled procedure is diminished. We have observed regression of external hemorrhoids in most patients at one year after surgery. The external hemorrhoids and perianal skin tags tend to shrink in size and the large majority of the patients will not required additional treatment.

Statistic analysis

Two by two table with chi-square test was used for statistic analysis. Statistically significant difference was considered if p-value was less than 0.05.

RESULTS

Operative time

The average duration of the operation was 17 minutes (ranged 12-30 minutes) in SHD group and 35 minutes (ranged 25-60 minutes) in CHD group ($p < 0.05$) (Table 2).

Hospital stay

The mean postoperative hospitalization was 1.2 days (ranged 1-4 days) in SHD group with 167 cases (81.9%) staying for only one night after surgery. The mean postoperative hospitalization was 2.6 days (ranged 1-5 days) in CHD group with 18 cases (20.4%) staying for only one night after surgery ($p < 0.05$) (Table 2).

Postoperative pain

Due to the retrospective type of study, postoperative pain was evaluated by analgesics consumption.

One hundred and nineteen patients (58.3%) in SHD group required analgesics. Parenteral analgesics was used in 52 patients (25.5%); Pethidine in 26 patients, Dynastat in 15 patients, Voltaren in 8 patients, Morphine in 2 patients and Tramal in 1 patient. The average parenteral analgesics requirement was 0.3 dose/case. The average use of oral paracetamol was 0.8 tab/case.

While 85 patients (41.7%) in SHD group did not require analgesics, all patients (100%) in CHD group required analgesics.

In CHD group, parenteral analgesics were used in 27 patients (30.8%); Pethidine in 18 patients, Morphine in 7 patients and Tramal in 2 patients. The average parenteral analgesic requirement was 0.5 dose/case. The average use of oral paracetamol was 4.4 tabs/cases (Table 3).

Table 2 Operative time and hospital stay

	Total SHD (n = 204)	SHD with		CHD (n = 88)	p-value (total SHD vs CHD)
		PPH-03 (n = 116)	PPH-01 (n = 88)		
Mean operative time (minutes)	17 (12-30)	15 (12-20)	20 (15-30)	35 (25-60)	<0.05
Postoperative hospitalization (days)	1.2 (1-4)	1.1 (1-3)	1.5 (1-4)	2.6 (1-5)	
Postoperative hospitalization for 1 day	167 (81.9%)	105 (90.5%)	62 (74.5%)	18 (20.4%)	<0.05

Table 3 Postoperative analgesics requirement

	SHD (n = 204)	CHD (n = 88)	p-value
Postoperative analgesic requirement	119 (58.3%)	88 (100%)	<0.05
● Parenteral analgesic requirement	52 (25.5%)	27 (30.8%)	
● Average dosage of parenteral injection (dose/case)	0.3	0.5	
● Average dosage of oral paracetamol (dose/case)	0.8 (1.8 tabs)	2.2 (4.4 tabs)	

Table 4 Postoperative complications

	Total SHD (n = 204)	SHD with		CHD (n = 88)	p-value (total SHD vs CHD)
		PPH-03 (n = 116)	PPH-01 (n = 88)		
Postoperative complications	75 (36.8%)	39 (33.6%)	36 (40.1%)	55 (62.5%)	<0.05
● Urinary retention	67 (32.8%)	32 (27.6%)	35 (39.7%)	49 (55.7%)	<0.05
● Postoperative bleeding					
- Minor bleeding	9 (4.4%)	2 (1.7%)	7 (7.9%)	4 (4.5%)	
- Major bleeding	1 (0.5%)	1 (0.9%)	0	0	
● Thrombosed/inflamed skin tag	10 (4.9%)	2 (1.7%)	8 (9%)	9 (10.2%)	
● Infection (minor)	11 (5.4%)	9 (7.7%)	2 (2.2%)	5 (5.7%)	
● Anal stricture (mild)	4 (2%)	1 (0.9%)	3 (3.4%)	0	
● Incontinence	0	0	0	0	
● Fecal impaction	0	0	0	0	

Complications

Postoperative complications were recorded in 75 cases (36.8%) of SHD group. The most common complication was urinary retention (67/204 cases or 32.8%) which occurred in 40 males (59.7%) and 27 females (40.3%). Other postoperative complications in SHD group included minor bleeding that were treated conservatively in 9 cases (4.4%), major bleeding from partial anastomotic dehiscence that needed reoperation to re-suture in one case (0.5%), thrombosed or inflamed skin tag in 10 cases (4.9%), infection in 11 cases (5.4%), and mild anal stricture that resolved after digital dilatation in 4 cases (2%). No incontinence, fecal impaction or serious complications were recorded in SHD group.

Postoperative complications were recorded in 55 cases (62.5%) of CHD group. The most common complication was urinary retention (49/88 cases or 55.7%). There were 30 males (61.2%) and 19 females (38.8%). Other complications in CHD group included minor bleeding in 4 cases (4.5%), thrombosed or inflamed skin tag in 9 cases (10.2%), and infection in

5 cases (5.7%). No anal stricture, incontinence, fecal impaction, or serious complications were recorded in CHD group (Table 4).

Recurrent hemorrhoidal symptoms

Nine cases (4.4%) in SHD group developed recurrent symptoms after the median follow-up period of 34 months (ranged 3-77 months). These included 3 cases (1.5%) of rectal bleeding after defecation and 6 cases (2.9%) of hemorrhoidal prolapse. All cases were treated successfully with non-operative approach.

Nine cases (10.2%) in CHD group developed recurrent hemorrhoidal symptoms. There were 8 rectal bleeding after defecation (9.1%) and one hemorrhoidal prolapse (1.1%) (Table 5).

Histopathology

Histopathologic examination of the excised doughnut tissue showed no squamous mucosa nor smooth muscle fibers. Incomplete doughnut was found in one patient (0.5%) without postoperative complication. The patient developed recurrent hemorrhoidal

Table 5 Recurrent hemorrhoidal symptoms

Symptoms	SHD (n = 204)	CHD (n = 88)	p-value
Total recurrence	9 (4.4%)	9 (10.2%)	
● Rectal bleeding	3 (1.5%)	8 (9.1%)	<0.05
● Hemorrhoidal prolapse	6 (2.9%)	1 (1.1%)	

prolapse 10 months after surgery which responded to one rubber band ligation.

DISCUSSION

In this report, we studied the safety and effectiveness of 204 SHD procedures performed by a single surgeon (CE) during a 6-year period and compared it with the results from our previous study.⁴³

We previously reported the outcomes of a retrospective comparative study of patients treated with SHD using PPH-01 stapler (n = 88) compared with patients treated with CHD (n = 88) during October 2000 and December 2003.⁴³

The PPH-03 kit was introduced at Ramathibodi Hospital in 2004 and had been used in 116 SHD procedures during January 2004 and December 2006. The new features are that of a more ergonomic design, tighter closed stapled height of 0.75 mm for better hemostasis, and a quicker close knob which allow for less turns for opening and closing.

Median operative time was shorter in SHD group than CHD group (17 vs 35 minutes; $p < 0.05$), especially in SHD using PPH-03 (15 vs 20 minutes) (Table 2). Antonio Longo himself reported the very short operative time of 6 minutes but others reported from 12.7-30 minutes.^{1,3,4,10,12,13,16,18,23,28,29,33-35,44,45}

Due to retrospective evaluation in this series, we used analgesic consumption instead of visual analogue scale to assess the intensity of postoperative pain. Patients in SHD group had significant less postoperative pain than CHD group. While 41.7% of patients in SHD group did not require analgesic, all of the patients in CHD group required analgesics after surgery ($p < 0.05$). The use of oral paracetamol and parenteral analgesics tended to be less in SHD group, but without statistically significant difference (Table 3). The finding of less postoperative pain was also reported in nearly all

randomized studies that compared SHD with conventional hemorrhoidectomy.^{4,8-36} The reduction in pain and absence of perianal wound undoubtedly help in the more rapid recovery.

Concerning the duration of hospitalization, mean postoperative hospital stay was shorter in SHD group (1.2 vs 2.6 days). Most of the patients in SHD group (81.9%) stayed in the hospital for only one night after surgery while most of the CHD group (79.6%) stayed in the hospital for more than one night (Table 2). This resulted from less postoperative pain and no specialized wound care was needed in SHD group. We have no policy to perform hemorrhoidectomy as a day-case surgery.

Since the initial description of SHD, 31 randomized clinical trials have been published in English literatures.^{3,4,8-36} There are 25 studies comparing SHD with open hemorrhoidectomy^{3,8-31} and only 6 studies comparing SHD with closed (Ferguson) hemorrhoidectomy,^{4,32-36} including one multicenter study from the United States.⁴ This may be due to the slower take-up rate of SHD technique in the United States, where Ferguson technique is most commonly practiced. Most of these randomized studies have consistently shown that the stapling technique decreases postoperative pain,^{3,4,8-13,15-18,20-27,29,31-36} reduces the operative time^{8-16,18-20,23,26,27,29,31-33,35,36} and reduces the length of hospital stay.^{3,8,10,11,16,24,25,29,31} Only two randomized studies^{21,28} demonstrated a shorter operative time in open hemorrhoidectomy than in SHD group; one study compared with Miligan-Morgan technique (11.4 vs 17.5 minutes)²⁸ and one study compared with LigaSure technique²¹ (13 vs 15 minutes). To date, the largest single center experience published in 2005 was from Singapore General Hospital.⁴⁴ They reported 3,711 SHD and have shown that SHD is safe and effective for the treatment of hemorrhoids.

Our study showed that SHD developed less postoperative complications than CHD (36.8% vs 62.5%; p

<0.05). The most common complication was urinary retention in both groups. Urinary retention was significantly higher in CHD group than in SHD group (55.7% vs 32.8%; $p < 0.05$). The reason may be due to less postoperative pain in SHD group. But our findings demonstrated a rather high percentage of patients with urinary retention in both groups. Others reported an incidence of 0-22.2% of urinary retention after SHD^{13,16,33,45-48} and 4-50% after conventional hemorrhoidectomy.^{1,4,13,16,24,29,33,44,45} The risk factors of urinary retention in these patients may include spinal anesthesia and perioperative intravenous fluid administration.^{46,47} All of our patients underwent hemorrhoidectomy under spinal anesthesia, unlike other reports that included patients who underwent surgery under general or local anesthesia. This finding suggested that SHD should not be performed under spinal anesthesia as day-case surgery and perioperative intravenous fluid should be restricted.

Other complications including bleeding, thrombosed or inflamed skin tag and infection were not significantly different in both groups. Minor bleeding rates were less in SHD using PPH-03 than in SHD using PPH-01 (1.7% vs 7.9%) (Table 4). This may be due to an increase in compression on rectal tissue and blood vessels of PPH-03. The closed staple height is 0.75 mm and 1 mm in PPH-03 and PPH-01, respectively. There were 4 cases (2%) of mild anal stricture at the staple line in the SHD group, which were easily treated by digital dilatation at the out-patient department. Anorectal stricture is a known complication after SHD, with a reported incidence of about 0.4-5%.^{1,4,35,44} It has been postulated that the occurrence of stricture is due to the low placement of the purse-string. Most stricture formation occurred early in the postoperative period. Digital dilation can be easily performed because the fibrous tissue forming the stricture are soft and easily disrupted at that time.

Some randomized clinical trials reported less complications in SHD group^{27,34} and some reported no difference in complication rates between SHD and conventional hemorrhoidectomy.^{3-4,13,16,18,22,25,32-33,36}

After a median follow-up of 34 months (ranged 3-77 months), there were no statistically significant difference in overall recurrent hemorrhoidal symptoms between the two groups. Considering specific type of recurrent symptoms, SHD group developed less recurrent bleeding (1.5% vs 9.1%; $p < 0.05$) (Tables 5).

Concerning effectiveness of SHD procedure, two systematic reviews concluded that SHD is associated with a higher long-term risk of recurrent hemorrhoidal prolapse than conventional hemorrhoidectomy.^{1,39} But the recent systematic review in 2007 which included 25 randomized studies with 1,918 procedures concluded that the long-term effectiveness is similar to conventional procedure.⁴¹

Rare but serious complications after SHD have been reported in the literature⁴⁹ including pelvic sepsis,⁵⁰⁻⁵³ Fournier's gangrene,^{54,55} rectovaginal fistula,⁵¹⁻⁵⁶ rectal perforation,^{57,58} acute intestinal obstruction from closure of the rectum,⁵⁹ retroperitoneum and pneumomediastinum,⁵⁸ severe intraabdominal bleeding,^{60,61} and persistent severe pain and fecal urgency.⁷ In our study, there were no serious complications after SHD. This supports the view that serious complications probably occur as a result of inappropriate surgical techniques. It is probably more dependent on operator skills than previously believed.²⁴ Even though the technique seems simple and relatively straightforward, only strict adherence to its principles will avoid serious complications and preserve the previously described benefit of this method. The presence of squamous mucosa or smooth muscle fibers was not found in histopathologic examination of the stapled doughnut in this study.

Current limitation of the use of stapled technique in developing countries is the high cost of the stapler. However, there are few studies that have analyzed the cost of SHD over the conventional hemorrhoidectomy and have concluded that SHD is more cost-effective on the basis of shorter length of hospital stay and earlier return to work.^{3,28,29,62,63}

CONCLUSIONS

SHD is a simple, safe and effective procedure for the treatment of hemorrhoids. This study supports the evidence that SHD is a less painful and more rapid procedure compared with CHD. Stapling technique also reduces the length of hospital stay; furthermore, the long-term outcome is good. There are no serious complications. This study demonstrates that the previously published favorable results of SHD can be reproduced in Thai patients. The keys of success are proper patient selection and good surgical techniques.

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