



A novel technique for the treatment of stages III to IV hemorrhoids

Homemade anal cushion suspension clamp combined with harmonic scalpel

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Abstract

To compare the efficacy of homemade anal cushion suspension clamp combined with harmonic scalpel (ACS) and Milligan–Morgan hemorrhoidectomy combined with electric knife (MMH) in the treatment of stages III to IV hemorrhoids. We conducted a retrospective study of 99 patients with stages III to IV hemorrhoids hospitalized from January to December in 2013. Among them, 51 patients were treated with ACS, while 48 patients received MMH. Data from clinical recording and follow-up included operative time, intraoperative blood loss, hospitalization information, postoperative pain, and postoperative complications. Operative time, intraoperative blood loss and hospitalization time in ACS group were significantly less than those in MMH group (P<.05). Compared with MMH group, ACS group had a lower postoperative static pain score from days 1 to 14 (P<.01). The patients in ACS group exhibited less postoperative defecation pain scores from days 3 to 20 than those of MMH group (P<.05). The incidence of postoperative anal edema and delayed wound healing in ACS group was lower than that in MMH group (P<.05). Compared with MMH, our novel technique ACS was more effective and had fewer postoperative complications in the treatment of stages III to IV hemorrhoids.

Abbreviations: ACS = anal cushion suspension clamp combined with harmonic scalpel, MMH = Milligan-Morgan hemorrhoidectomy combined with electric knife.

Keywords: harmonic scalpel, hemorrhoids, homemade anal cushion suspension clamp, Milligan-Morgan hemorrhoidectomy, novel technique

1. Introduction

Hemorrhoids are structures of submucosal arteriovenous sinusoids, belonging to the part of normal anorectum. [1] The incidence of hemorrhoids is around 44% among the population, and the common symptoms are bleeding, pain, prolapsing, and itch. [2–3] A number of effective treatments are available for hemorrhoids, ranging from rubber band ligation, infrared coagulation and nonoperative sclerotherapy along with diet intervention, but as to the stages III to IV ones, surgery still remains the first choice. Milligan–Morgan hemorrhoidectomy combined with electric knife (MMH) is the classical and well-developed technique, [4] which has been widely adopted in treating hemorrhoids. However, MMH is usually associated with significant postoper-

ative complications, including pain, bleeding and anal stricture, ^[5] which stimulates surgeons to develop novel techniques. Our department has invented a novel surgical technique named anal cushion suspension clamp combined with harmonic scalpel (ACS) to treat stages III to IV hemorrhoids. Here, we compared the efficacy of ACS and MMH and discussed the advantages of

2. Materials and methods

2.1. Study subjects

A total of 99 patients with stages III to IV hemorrhoids, who had received surgical treatment in our department from January to December 2013, were enrolled in this study. All patients consenting to participate in this study were recruited in order to minimize the selection bias. The patients comprised 55 men and 44 women aged between 30 and 65 years old without any other anal disease like anal fistula, anal fissure, or special infection. Among them, 51 patients were treated with ACS, while 48 patients received MMH. Clinical data were obtained through medical records and follow-up materials were collected by telephone or questionnaire surveys. The average follow-up time was 1.5 years.

2.2. Homemade anal cushion suspension clamp

The homemade anal cushion suspension clamp (Chinese National Patent no.: ZL02251536.4), invented by our group, is a novel surgical tool for the management of hemorrhoids (Fig. 1A and B). It mainly consists of 5 parts: ring handle, shank,

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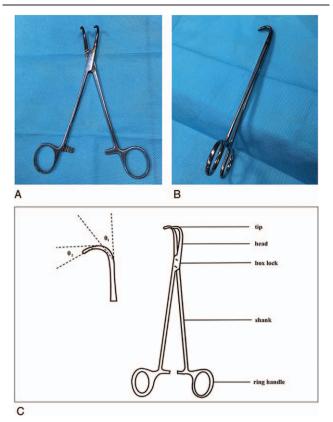


Figure 1. The product picture and schematic of the homemade anal cushion suspension clamp. (A) and (B) The product picture of the homemade anal cushion suspension clamp; (C) the schematic of the homemade anal cushion suspension clamp.

box lock, head, and tip (Fig. 1C). The clamp is made from a hemostatic clamp (Product no. J31180) and the detailed clamp-making process is as follows: first, the head and the tip of a hemostatic clamp are heated to turn red by the hot air welding machine. Then, by using another clamping tool, the heated clamp head is vertically bent into an arc shape at the angle of θ_1 degree (30°–60°) and the hot clamp tip is bent into an inverted hook shape at the angle of θ_2 degree (25°–45°). The major advantage of this novel clamp is that it can horizontally clamp the mucosa to suspend the cushion, which is quite different from the longitudinal way the regular clamp uses.

2.3. Surgical procedures

Subarachnoid anesthesia was used for all patients. In ACS group, patients were placed in the lithotomy position (Fig. 2A). Anoscope was introduced into anal canal and left lateral rectal mucosa was clamped and tightened by the tissue clamp at 2.0 cm above the dentate line. Then, with the homemade anal cushion suspension clamp, we horizontally clamped the bottom of tightened rectal mucosa (including partial internal hemorrhoids) (Figs. 2B and 3A). After that, we withdrew the 2-lobe anoscope and ligated the clamped rectal mucosa with double strand 7-0 suture in the middle of upper edge of the suspension clamp (Figs. 2C, D and 3B). Usually, we excised the distal clamped mucosa by leaving an around 0.5-cm stump. Similar processes were repeated to right lateral and anterior rectal mucosa. External hemorrhoids were tightened with the tissue clamp and cut by the harmonic scalpel (Fig. 2E).

In MMH group, patients were also placed in the lithotomy position. Prolapsed hemorrhoids were clamped, followed by a V-shape incision under the skin of external hemorrhoids using electric knife. The incision was radially extended across the

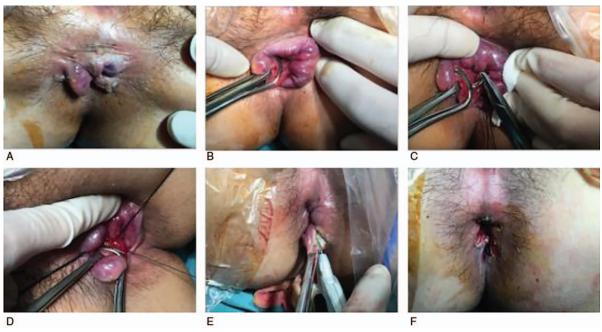


Figure 2. Surgical procedures of homemade anal cushion suspension clamp combined with harmonic scalpel in the treatment of stages III to IV hemorrhoids. (A) Preoperative status; (B) the mucosa was tightened by the tissue clamp (left) and homemade anal cushion suspension clamp (right); (C) the surgical needle passes through the clamped mucosa; (D) ligation of mucosa with 7-0 suture; (E) external hemorrhoids were excised by harmonic scalpel; (F) postoperative status.

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dentate line and then we stripped external hemorrhoid vein plexus to 0.5 cm above the dentate line. The surgical incision was closed with 7-0 suture, followed by stripping the mucosa of external and internal hemorrhoids.

2.4. Data collection

The following clinical data were collected: First, operative time and intraoperative blood loss. Second, hospitalization time and wound healing time. Wound healing time means time interval from the surgical day to the day when the wound was completely healed. Third, postoperative static pain and defecation pain. Using visual analog scoring system to assess pain, the scores from 0 to 10 represents different degrees of pain. The score 0 represents no pain, 1 to 3 represent mild pain, 4 to 6 represent moderate pain, 7 to 10 represent severe pain. [5,6] Fourth postoperative complications, including postoperative bleeding, urinary retention, anal itch, anal stricture, anal incontinence, anal edema, and delayed wound healing and recurrence.

2.5. Statistics

All the statistical analyses were performed by SPSS 22 (IBM Inc., North Castle, NY). Quantitative data and categorical data were respectively analyzed through t test or χ^2 test. P < .05 indicated that the difference was statistically significant.

3. Results

3.1. Baseline characteristics

The baseline characteristics of the included subjects were presented in Table 1. There was no significant difference in age, gender, disease duration, or stage between 2 groups (P > .05).

3.2. Comparison of hospitalization information and postoperative pain

Operative time, intraoperative blood loss, and hospitalization time of ACS group were all significantly less than those of MMH group (P < .05). For postoperative static pain score from days 1 to 14, ACS group is significantly lower than MMH group (P < .01). Similarly, the score of postoperative defectaion pain from days 3 to 20 in ACS group is remarkably lower than that in MMH group (P < .05) (Table 2).

3.3. Comparisons of postoperative complications

Both groups had no anal stricture and incontinence. As to postoperative bleeding, urinary retention, anal itch, and recurrence, there were no statistically significant differences between 2

Table 1
The comparison of general information between 2 groups.

Group	ACS (n=51)	MMH (n=48)	P
Gender, female/male	21/30	23/25	.500
Age, y	40.1 ± 5.7	42.3 ± 6.4	.074
Disease duration, y	4.2 ± 1.3	5.1 ± 3.7	.106
Stage, III/IV	24/27	27/21	.360

ACS = anal cushion suspension clamp combined with harmonic scalpel, MMH = Milligan-Morgan hemorrhoidectomy combined with electric knife.

Table 2

The comparison of hospitalization information and postoperative pain between 2 groups.

	ACS (n=51)	MMH (n=48)	Р
Operative time, min	13.4 ± 0.8	17.5 ± 2.3	<.001
Intraoperative blood loss, mL	3.8 ± 0.5	7.3 ± 1.5	<.001
Hospitalization time, d	7.0 ± 0.8	7.5 ± 1.3	.023
Postoperative static pain			
Day 1	6.9 ± 1.2	7.5 ± 0.9	.006
Day 3	4.7 ± 1.6	6.6 ± 1.8	<.001
Day 7	3.4 ± 0.6	4.7 ± 0.9	<.001
Day 14	0.8 ± 0.3	1.3 ± 0.9	<.001
Postoperative defecation pain			
Day 3	7.5 ± 1.2	8.0 ± 1.3	.049
Day 7	4.3 ± 1.2	5.6 ± 1.0	<.001
Day 14	1.3 ± 0.7	2.1 ± 0.3	<.001
Day 20	0.5 ± 0.3	0.7 ± 0.6	.037

 $\label{eq:action} ACS = \text{anal cushion suspension clamp combined with harmonic scalpel}, \ MMH = \ Milligan-Morgan \\ \text{hemorrhoidectomy combined with electric knife}.$

groups (P > .05). The incidence of anal edema in ACS group (3.9%) was notably less than that in MMH group (20.8%) (P = .010). ACS group had a less incidence of delayed wound healing (5.8%) than MMH group (16.7%) (P = .028) (Table 3).

4. Discussion

Current surgical treatments of hemorrhoids consist of 2 commonly performed interventions: traditional excisional surgery (or hemorrhoidectomy) and stapled hemorrhoidopexy. Compared with hemorrhoidectomy, stapled hemorrhoidopexy had less invasiveness and postoperative pain. However, the latest study from *Lancet* demonstrated that overall quality of life in the hemorrhoidectomy group is better than that in stapled hemorrhoidopexy group and it was recommended that hemorrhoidectomy should be considered over stapled hemorrhoidopexy for the treatment of stages II to IV hemorrhoids.^[7]

Hemorrhoidectomy was thought to be the most painful surgery in the world, but recently it has been improved through following ways: using analgesics in the perioperative period, improving the operation methods, and choosing new operation devices. [8] One breakthrough was the development and popularization of new surgery devices such as electric knife, harmonic scalpel, and Ligasure. Harmonic scalpel uses ultrasonic vibrations to cut and cauterize soft tissue. [9] Compared with electric knife, harmonic scalpel exhibited less damage to surrounding tissue, less

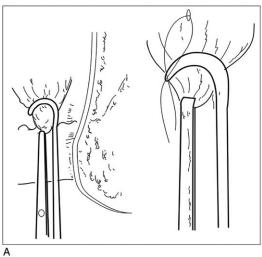
Table 3

The comparison of postoperative complications between 2 groups.

Group	ACS (n=51)	MMH (n=48)	P
Postoperative bleeding	0 (0.0%)	3 (6.0%)	.220
Urinary retention	5 (9.8%)	6 (12.5%)	.670
Anal itch	2 (3.9%)	4 (8.3%)	.618
Anal stricture	0 (0.0%)	0 (0.0%)	_
Anal incontinence	0 (0.0%)	0 (0.0%)	_
Anal edema	2 (3.9%)	10 (20.8%)	.010
Delayed wound healing	1 (1.7%)	8 (16.7%)	.028
Recurrence	1 (1.7%)	6 (12.5%)	.098

 $\mbox{ACS} = \mbox{anal cushion suspension clamp combined with harmonic scalpel}, \mbox{ MMH} = \mbox{Milligan-Morgan hemorrhoidectomy combined with electric knife}.$

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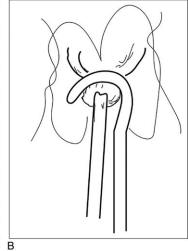


Figure 3. Schematic drawings of major surgical procedures. (A) The mucosa was tightened by the tissue clamp and the homemade anal cushion suspension clamp; (B) the clamped mucosa was ligated with double-strand suture.

intraoperative blood loss, wider surgical view, more safety, lower risk of infection and faster wound healing; therefore, it has been gradually introduced into the treatment for anorectal diseases. [10,11] That was why we chose harmonic scalpel as energy device in this study.

Based on previous clinical experience, we developed a homemade anal cushion suspension clamp and invented a novel surgical method named ACS which was a modified type of hemerroidectomy. The advantages of ACS in stages III to IV hemorrhoid treatment were as follows: First, Compared with vertical ligation in traditional hemorrhoidectomy (like MMH), horizontal ligation and excision of rectal mucosa (including partial internal hemorrhoids) above the dentate line in ACS enlarged the ligation surface, enhanced anal cushion and reduced the size of external hemorrhoids. Meanwhile, the surgical incision caused by harmonic scalpel would be small and easily healed. Second, blocking varicose veins of hemorrhoids in ACS reduced the flow of blood to anal cushion and decreased anal cushion pressure, leading to the shrink of hemorrhoids. At the same time, ligation suture induced sterile and chronic inflammation which promoted local fibrosis and connection between the submucous layer and the muscle layer. This would help the reposition and fixation of the prolapsed anal cushion.

However, following points should be paid attention to during surgery: If the clamped mucosa is quite large, a multiple-segment ligation is preferred; to avoid anal stenosis, no more than 3 internal hemorrhoids in the same plane should be ligated; to avoid rectal ulcer, no more than 1 mL of hardener should be injected into each hemorrhoid; use linear incision during ultrasonic knife resection of external hemorrhoids and keep the anal skin intact between 2 incisions to avoid anal stenosis.

Our study found that the score of postoperative static pain and defecation pain in the ACS group were significantly lower than those in MMH group. Postoperative pain was correlated with local inflammation and surgical methods. [12] Moreover, ACS group had less incidence of postoperative anal edema than MMH group, which we supposed was attributed to the enhancement of anal cushion by the homemade suspension clamp and the excision of varicose vein through the harmonic scalpel. Besides, as to the incidence of delayed wound healing, the ACS group was

significantly lower than MMH group. Only 1 patient in ACS group got delayed wound healing, which might be associated with short resting time and inadequate postoperative care. During the follow-up phase, we also observed that 1 patient in ACS group recurred because of alcohol abuse and 3 patients in MMH group occurred with bleeding owing to hard stool and forced defecation. Furthermore, there was no significant difference between 2 groups in the incidence of postoperative urinary retention which might be related with anesthesia method and surgery position. [13]

Originated from Rubber band ligation^[14] and sclerotherapy, ^[15] the idea of ACS, accord with the concept of minimally invasive surgery, had the advantage of preventing prolapse and shrinking hemorrhoid through the formation of submucous scar, as well as minimizing pain and reducing bleeding by the combined use of harmonic scalpel. Up to now, we have performed ACS method on approximately 2000 patients in the past 10 years. Considering its simple procedure, recyclable devices, few complications and low cost, ACS method might take place of tissue-selecting therapy stapler^[16] in less developed areas in the future. Given that this study was a retrospective cohort analysis, further randomized controlled trials are needed to validate our findings.

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