Original Article

Short Term Outcomes after the Introduction of Ligasure Hemorrhoidectomy Technique to a Regional Hospital

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Key Words

Regional hospital; Ligasure hemorrhoidectomy; Surgical outcomes **Purpose.** Milligan-Morgan and Ferguson techniques are well-established standards of hemorrhoidectomy and were referred as traditional methods. Many reports suggest that the Ligasure hemorrhoidectomy has comparable results, with numerous benefits. We designed and implemented a trans-hospital training program to teach surgeons in a regional hospital to perform Ligasure hemorrhoidecotmy.

Methods. A surgical team in another hospital experienced with Ligasure hemorrhoidecotmy was invited as trainer. The training program had three phases: pre-training (phase I), live demonstration and on-line counseling (phase II), and independent practice (phase III). The surgical and clinical outcomes in each phase were analyzed.

Results. A significant increase in case numbers was recorded in phase III. The mean admission days decreased from 2.09 in phase I to 1.21 in phase II, but rebounded to 2.00 in phase III. This change in admission days achieved statistical significance. The mean and maximum visual analog pain scores on the operation day progressively decreased over the training phases (p = 0.00081 and 0.00051, respectively). Three high-risk patients experienced massive postoperative wound bleeding in phase II.

Conclusions. The introduction of LigaSure hemorrhoidectomy technique can improve postoperative pain, the complication rate, number of admission days. An increase of patient numbers was observed of surgeons learned and performed Ligasure hemorrhoidectomy. Massive postoperative wound bleeding can happen after LigaSure hemorrhoidectomy in patients with large-sized hemorrhoid piles, liver cirrhosis, or rectal prolapse. [J Soc Colon Rectal Surgeon (Taiwan) 2019;30:70-76]

Hemorrhoid disease is one of the most common conditions faced by colorectal and general surgeons. Surgical procedures are often indicated for grades III and IV hemorrhoids. Since the last century, the Milligan-Morgan and Ferguson techniques have been well-established standards of hemorrhoidectomy, and are referred to as conventional hemorrhoidectomy.^{1,2} The LigaSure vessel-sealing system is an electrothermal device for vascular and tissue sealing, commonly used in abdominal surgeries. Its usage in hemorrhoidectomy has been reported by many authors, after a pioneering study which was published in 2001 by Sayfan and colleagues.³ Numerous reports have shown that Ligasure hemorrhoidectomy has

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comparable results to conventional methods in terms of safety and effectiveness, with the benefits of less postoperative pain,⁴⁻⁷ decreased operative time,^{4,5,7-9} less intraoperative blood loss,^{7,8,10,11} and a faster to return to normal activity.^{4,7,10} Furthermore, a recent Cochrane review of conventional versus Ligasure hemorrhoidectomy reported that the Ligasure technique results in less early postoperative pain, without any increase in postoperative morbidity or rate of incontinence.¹²

Several randomized studies have compared the surgical outcomes between Ligasure and conventional diathermy hemorrhoidectomy; however, the results were not univocal.^{4-6,8-10} Currently, colorectal or general surgeons in Taiwan still perform hemorrhoidectomy using various types of energy devices according to their own preference. To our knowledge, there is no report in the literature recommending that surgeons experienced in traditional hemorrhoidectomy should change to the Ligasure hemorrhoidectomy.

In our institution, a regional hospital with annual hemorrhoidecotmy case numbers ranging from 160 to 180, all surgeons had never performed Ligasure hemorrhoidecotmy until this technique was introduced through a training program implemented since December 2017. Herein, we report the short term surgical and clinical outcomes.

Materials and Methods

A trans-hospital training program was designed and implemented to train all colorectal surgeons in our hospital to perform Ligasure hemorrhoidectomy. The trainer team was invited from a hospital where Ligasure hemorrhoidectomies were performed routinely. And a surgeon who had more than 3000 cases of Ligasure hemorrhoidectomy experience, with multiple papers published regarding this surgical technique was assigned as head trainer.¹³⁻¹⁵

The training program was divided into three phases: phase I, pre-training; phase II, live demonstration and on-line counseling; and phase III, independent practice. For establishing a baseline data, a time period (from 1/1/2017 to 31/11/2017) before the introduction of Ligsure hemorrhoidectomy technique was chosen and defined as pre-training phase (phase I). The live demonstration and on-line counselling phase (phase II, from 1/12/2017 to 28/2/2018) started with a oneday workshop with a live demonstration of ten consecutive Ligasure hemorrhoidectomies performed. A free discussion session followed the live demonstration session: all questions regarding the surgical principles, technical details, and perioperative care were discussed and answered. After the workshop, every patient who planned to undergo hemorrhoidectomy at our hospital were provided choices in the hemorrhoidectomy method. Patients and their families were preoperatively informed of the potential complications, cost and effectiveness, and surgical outcomes reported in the Ligasure hemorrhoidectomy literature. The patients could then decide to undergo conventional diathermy hemorrhoidectomy or the Ligasure hemorrhoidectomy, according to their preference. During phase II, critical photos were taken of problems that emerged during the Ligasure hemorrhoidectomies, which were collected and sent to the trainer team via the internet. Then the head trainer would comment, answer questions, and share experiences for every difficulty and complication experienced.

During the independent-practice phase (phase III, from 1/3/2018 to 31/7/2018), surgeons in our hospital performed the Ligasure hemorrhoidectomy using the procedures that had been optimized during phase II. The problems faced during this phase were managed independently, without comments from the trainer team.

All patients underwent hemorrhoidectomies in our hospital accept intravenous plus local anesthesia. Patients taking Aspirin for other medical diseases were asked to hold the drug 5 days before the surgery. The routine postoperative oral form analgesics was Diclofenac 25 mg four times per day. And intramuscular injection of Ketorolac would be considered for severe wound pain.

Patient characteristics, case numbers, admission days, visual analog pain scores (VAS), complications, re-admissions, patient's choice of surgical procedures, and operative times were recorded for each phase. Considering that some surgeons in our hospital still refused to perform Ligasure hemorrhoidectomy after the trainging program, only patients of surgeons who did perform Ligasure hemorrhoidectomy after the training were included in the analysis.

Statistical analysis

The Pearson's Chi-square test was used to compare quantitative data among phases. A two-tailed p-value < 0.05 was considered statistically significant. R version 3.5.1 software (R Foundation for Statistical Computing, Vienna, Austria) was used to manage patient data and perform statistical analyses.

Results

The total case numbers of hemorrhoidectomies performed at our hospital were presented in Table 1. The percentage of patients included in the analysis of each phases ranging from 86.7 to 90.5%.

The case numbers and patient sex are summarized in Table 2. The male-to-female ratio did not significantly differ between phases I and II (0.70 and 0.67, respectively). However, a reversal in the male-to-female ratio was observed during phase III (1.45).

The numbers of hemorrhoidectomies performed by the surgeons involved in this study in the most recent three years and during the three phases of the pro-

 Table 1. Case numbers of hemorrhoidectomies performed in our hospital

Phase	Overall cases, n	Included cases*, n	Percentage
I: 1/2017-11/2017	135	117	86.7%
II: 12/2017-2/2018	39	35	90.1%
III: 3/2018-7/2018	84	76	90.5%

* Patients of surgeons refused to perform Ligasure hemorrhoidectomy were excluded.

Table 4. Prevalence of the Ligasure hemorrhoidectomy

gram are provided in Table 3. The average monthly case numbers decreased slightly during phase I (10.6/ month) compared to that in 2015 (11.3/month) and 2016 (11.7/month), then increased slightly during phase II (11.7/month) and increased greatly during phase III (15.2/month).

The prevalence of Ligasure hemorrhoidectomy is provided in Table 4. During phase II, 54.3% of patients chose Ligasure hemorrhoidectomy. Three months later, during phase III, 80.3% of patients chose Ligasure hemorrhoidectomy, reflecting a statistically significant increase in the number of patients choosing the Ligasure method (p = 0.00459).

The admission days and operative times of all patients in phase I and those who underwent Ligasure hemorrhoidectomy in phases II and III are provided in Table 5. The mean admission days decreased from 2.09 days in phase I to 1.21 days in phase II, but rebounded to 2.00 days in phase III; this change reached statistical significance. Phase II had a shorter mean operative time for the Ligasure hemorrhoidectomy

 Table 2. Case numbers and patient sex according to the training phase

Phase	Case number, n	Male, n	Female, n	Male/female ratio
I: 1/2017-11/2017	117	48	69	0.70
II: 12/2017-2/2018	35	14	21	0.67
III: 3/2018-7/2018	76	45	31	1.45

Pearson's Chi-squared test, p = 0.03151.

Table 3. Patient numbers of included surgeons* in recent years

Year	Case number, n	Cases per month
2015	136	11.3
2016	140	11.7
1/2017-11/2017	117	10.6
12/2017-2/2018	35	11.7
3/2018-7/2018	76	15.2

* Surgeons agreed to perform Ligasure hemorrhoidectomy.

Phase	All cases of hemorrhoidectomy, n	Cases of Ligasure hemorrhoidectomy, n	Prevalence
II: 12/2017-2/2018	35	19	54.3%
III: 2/2018-7/2018	76	61	80.3%

Pearson's Chi-squared test, p = 0.00459.

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(16.6 min) than that recorded in phase III (20.5 min); however, this difference failed to reach significance.

Between phases II and III, the surgical procedure underwent modification. In phase II, surgeons did not perform any suturing during the Ligasure hemorrhoidectomy. However, after experiencing 3 cases of massive postoperative wound bleeding during phase II (Table 8), we modified the procedure by adding transfixing suture-ligation of the feeding vessels of each removed hemorrhoid pile. This suturing was standardized as routine in the Ligasure hemorrhoidectomy in phase III, during which there were no more massive postoperative bleedings.

The mean and maximum visual analog pain scores on the operation day (VAS0 mean and VAS0 max) and postoperative day 1 (VAS1 mean and VAS1 max) are provided according to phase in Table 6. The VAS0 max and VAS0 mean showed a significant progressive decrease over phases I, II, and III (VAS0 max: 3.50, 3.11, and 2.43, p = 0.00081; VAS0 mean: 2.02, 1.87, and 1.52, p = 0.00051, respectively). Although the VAS1 max and VAS1 mean were lower in phase II (1.90 and 1.54) than in phase III (2.57 and 1.78), the

Table 5. Number of admission days and operative times

Phase	Admission days	Operative time (min.)
I: 1/2017-11/2017	2.09	19.2
II: 12/2017-2/2018 Ligasure method	1.21	16.6
III: 3/2018-7/2018 Ligasure method	2.00	20.5
All cases of hemorrhoidectomy	1.91	19.0
All cases of Ligasure method	1.81	19.6

Data are means.

Pearson's Chi-squared test.

Admission days with Ligasurevs pre-training (phase 1): p = 0.268. Operative time with Ligasurevs pre-training (phase 1): p = 0.468. Admission days with Ligasure, phase: p = 0.00166. Operative time with Ligasure, phase: p = 0.289.

differences failed to reach statistical significance. However, all pain scores (operation day and postoperative day 1) of the patients who underwent Ligasure hemorrhoidectomy were lower than those recorded in phase I.

The case numbers and percentage of patients discharged on the next morning after the Ligasure hemorrhoidectomy (i.e. overnight discharge) are shown according to phase in Table 7. The highest (89.5%) overnight discharge rate was found in the patients who underwent LigaSure hemorrhoidectomy during phase II. However, only 44.3% of patients accepted an overnight discharge during phase III, which was similar to the rate in phase I. This fluctuation in the overnight discharge rate achieved statistical significance (p = 0.000184).

The complications and re-admissions are presented according to phase in Table 8. During phase II,

Table 6. Pain scores during admission

Phase	VAS0	VAS0	VAS1	VAS1
Thuse	max	mean	max	mean
I: 1/2017-11/2017	3.50	2.02	2.81	1.91
II: 12/2017-2/2018 Ligasure	3.11	1.87	1.90	1.54
III: 3/2018-7/2018 Ligasure	2.43	1.52	2.57	1.78
<i>p</i> value	0.00081	0.00051	0.112	0.139

Data are means.

VAS0: Visual analog pain score on operation day.

VAS1: Visual analog pain score on postoperative day 1.

Table 7. Case numbers and percentage of "overnight discharges"

Phase	OD cases, n	Total cases, n	Percentage
I: 1/2017-11/2017	45	117	38.5%
II: 12/2017-2/2018 Ligasure	17	19	89.5%
III: 3/2018-7/2018 Ligasure	27	61	44.3%

Pearson's Chi-squared test, p = 0.0001838. OD, overnight discharge.

Phase	AUR (%)	Re-admission, n	Bleeding, n	Other complications, n
I: 1/2017-11/2017	11/117 (9.4%)	2	0	RP, 1; SI, 1
II: 12/2017-2/2018 Ligasure	2/19 (10.5%)	3	3 (2 PBRO)	0
III: 3/2018-7/2018 Ligasure	4/61 (6.6%)	1	0	Abscess, 1
All Ligasure cases	6/80 (7.5%)	4	3	Abscess, 1

AUR, acute urine retention; RP, residual prolapsed; SI, stool impaction; PBRO, postoperative bleeding with re-operation.

3 patients experienced massive postoperative wound bleeding (blood loss of more than 1000 ml and transfusion of more than 4 units of PRBC), which had never occurred after hemorrhoidectomies at our hospital before the introduction of the Ligasure hemorrhoidectomy (phase I). As mentioned before, these bleeding complications prompted the surgeons to add suture-ligations to the feeding vessels of the hemorrhoidal piles removed by Ligasure, after which no massive postoperative wound bleeding was experienced. One patient experienced an abscess formation after the Ligasure hemorrhoidectomy during phase III. This patient was re-admitted and underwent an emergent operation with incision and drainage of the abscess. The postoperative acute urine retention (AUR) rate was 9.4% in phase I and 6.6% in phase III.

Discussion

Numerous reports have shown the benefits of the Ligasure hemorrhoidectomy.⁴⁻¹¹ Furthermore, several prospective, randomized studies also suggested the superiority of Ligasure hemorrhoidectomy over the conventional diathermy method.^{4,16} Additionally, a meta-analysis by Chen and colleagues in 2010 concluded that the Ligasure hemorrhoidectomy is superior to conventional diathermy in terms of the number of admission days, return to normal activities, bleeding amount, and operative time.¹⁷ However, performing hemorrhoidectomy demands a lot of personal experience of the surgeons. When attempting to evaluate the benefit for a surgeon to change from conventional hemorrhoidectomy to the Ligasure method, the previous experience and personal preference will influence the results. We found that some surgeons still refused to perform Ligasure hemorrhoidectomy even a training program were provided.

In our study, the benefit interms of admission days (Table 5), pain scores (Table 6), and rate of overnight discharge (Table 7) emerged rapidly and achieved statistical significance after the introduction of the Liga-Sure hemorrhoidectomy. An increase in the case numbers (Table 3) and a change in the sex ratio (Table 1) were also recorded. In a regional hospital located at rural area in southern Taiwan, this increase of case number was impressive. Furthermore, since most family incomes in the local area were earned by male workers, the reversal of the male-to-female ratio (Table 2) from 0.70 in phase I to 1.45 in phase III might suggests a change in the composition of the patient source. Furthermore, the prevalence of the Ligasure method significantly increased from 54.3% in phase II to 80.3% in phase III. This may be explained by improved subjective outcomes of the patients after the introduction of the LigaSure hemorrhoidectomy. Considering that a significant self-pay cost was demanded to patients who chose the Ligasure hemorrhoidectomy, the changes in the prevalence of Ligasure and sex ratio may also reflect the improvements in patient satisfaction and confidence regarding this surgical procedure.

There were three cases of massive bleeding in phase II. The recorded blood loss was more than 1000 cc in each of these cases. One patient was a normal 67-year-old lady without significant co-morbidity. Her bleeding stopped spontaneously after conservative treatment and transfusion. One patient experienced massive postoperative bleeding had liver cirrhosis and huge, persistantly bleeding hemorrhoid piles (the largest one was 5 cm in size). The third patient had large hemorrhoid piles, mild rectal prolapse, and coronary artery disease. He took long-term Aspirin for his heart disease. The latter two patients required surgery and suturing the bleeders to stop the bleeding. During the operations of check bleeding, the bleeders were always found to be located at the proximal tip of the wounds where hemorrhoid piles were removed during the Ligasure hemorrhoidectomy. Many studies in the literature that compared conventional and LigaSure hemorrhoidectomy reported decreased postoperative or delayed wound bleeding after Ligasure hemorrhoidectomy, which did not need re-operation.^{4,13,16-19} This scale of postoperative bleeding in our study after Ligasure hemorrhoidectomy has not been reported. Fortunately, once a routine suture-ligation to the feeding arteries of each of the removed piles during the LigaSure hemorrhoidectomies was added, there was no more massive bleeding.

Overall, the complication rate in the 61 patients

who underwent Ligasure hemorrhoidectomy in phase III was low (Table 8). The only complication was a perianal abscess in one patient. The AUR rate was 9.4% in phase I and 6.6% in phase III, which is consistent with the literature.^{16,19,20}

Conclusions

The introduction of Ligasure hemorrhoidectomy technique can improve postoperative pain, the complication rate, number of admission days. An increase of patient numbers was observed of surgeons who learned and performed Ligasure hemorrhoidectomy. Massive postoperative wound bleeding can happen after LigaSure hemorrhoidectomy in patients with large-sized hemorrhoid piles, liver cirrhosis, or rectal prolapse.

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<u>原 著</u>

區域醫院導入組織凝集儀痔瘡切除手術技術後 的短期成果分析

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目的 穆勒-摩根術式與佛格森術式是被廣泛接受的痔瘡切除手術方式,一般被稱為傳統方式。許多文獻已經顯示使用組織凝集儀進行痔瘡切除手術可以達到相同效果但是有許多優勢。本院設計並且實行了一個跨院訓練計畫教導區域醫院的外科醫師執行組織凝集儀痔瘡切除手術。

方法一個它院具有豐富的組織凝集儀痔瘡切除手術經驗的團隊被邀請擔任講師,訓練 計劃包含三個階段:訓練前期(第一階段)、示範及線上輔導期(第二階段)、與獨立運 作期(第三階段),各階段的臨床效益被加以分析。

結果 第三階段病案數明顯增加,平均住院日從第一階段的 2.09 日降到第二階段的 1.21 日,但是在第三階段回升到 2.00 日,此變化達到統計學上的意義。手術當日的最大與 平均疼痛指數隨著階段推進遞減 (p 值各為 0.00081 以及 0.00051),在第二階段有三個高 風險病人發生術後大量出血。

結論 導入組織凝集儀痔瘡切除手術技術可以改善手術疼痛、併發症率、與住院日數。學習並且執行該手術的外科醫師病患數目有增加,大型痔瘡、肝硬化、與直腸脫垂的病人有可能發生術後大量出血。

關鍵詞 區域醫院、組織凝集儀痔瘡切除手術、手術成果。