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Comparison of three different hemostatic devices in laparoscopic myomectomy

Original Article

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Abstract

Background: To compare conventional electrosurgery, LigaSure (Valleylab, Boulder, CO), and Harmonic scalpel (Ethicon Endosurgery, Cincinnati, OH) in terms of perioperative and postoperative outcomes during laparoscopic myomectomy (LM).

Methods: We retrospectively studied 817 women with symptomatic fibroids who underwent LM between January 1997 and September 2015. Three different instruments were used separately during surgery. The number and weight of removed fibroids, blood loss, operative time, postoperative decrease in the hemoglobin level, and length of hospital stay were measured for statistical analysis.

Results: No significant increase in complications was found in the three groups. Patients in the LigaSure and Harmonic scalpel groups had more numbers of removed fibroids, heavier fibroids removed, and higher rate of pretreatment with GnRH agonist (p < 0.001). These patients also had higher amount of intraoperative bleeding (p = 0.003) and longer operative time (p < 0.001) than those in the conventional electrosurgery group. However, no worse postoperative clinical outcome but shorter length of hospital stay was found in the LigaSure and Harmonic scalpel groups (2.1 ± 0.6 , 2.0 ± 0.4 vs 2.5 ± 0.8 days, p < 0.001).

Conclusion: The use of all three devices is feasible in LM. LigaSure and Harmonic scalpel can reduce the length of hospital stay without worse surgical outcomes.

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Keywords: Electrosurgery; Laparoscopy; Myomectomy; Ultracision vessel sealing

1. Introduction

Laparoscopic myomectomy (LM), which was first reported in 1979,¹ is a common surgery for the treatment of benign uterine fibroids. Based on the advantages of laparoscopy such as smaller incision wound or shorter length of hospital stay,² LM is an adequate intervention choice for women with symptomatic fibroids who want to preserve their fertility.

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However, some problems still cannot be neglected in LM. Compared with abdominal myomectomy, difficulty in bleeding control, uterine defect closure, uterine fibroid extraction after myomectomy, or smaller operative visual field makes operation time longer.^{3–5}

Conventional electrosurgery was used during laparoscopic surgery since the 1970s.⁶ This instrument coagulates tissue with high-frequency electric energy between two electrodes and makes hemostasis during operation easier. Operative laparoscopy has widespread use since the introduction of electrosurgery. However, smoke generation, frequent instrumental changes during surgery, and complications attributed to thermal spread make surgeons and researchers look for safer and more efficient instruments.

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Bipolar sealing device (LigaSure; Valleylab, Boulder, CO) can help in tissue dissection and performing sealing with a combination of pressure, and electric energy is automatically adjusted. Ultrasonic device (Harmonic scalpel; Ethicon Endosurgery, Cincinnati, OH) coagulates and cuts tissue by denaturing tissue protein resulting from ultrasonic energy. Good efficiency in hemostasis and less time spent in changing different instruments make these advanced power devices become more popular in laparoscopic surgery. The use of both LigaSure and Harmonic scalpel has been reported in many kinds of gynecologic surgery, such as simple and radical hysterectomy, and they have shown good surgical outcomes.^{7–10}

A previous study comparing the use of Harmonic scalpel and conventional bipolar electrosurgery system in LM demonstrated that the use of Harmonic scalpel leads to better surgical outcome.^{11,12} However, to our knowledge, no study has shown the difference in LM performed using different kinds of advanced power devices. Hence, we tried to compare three different instruments, including LigaSure, Harmonic scalpel, and conventional electrosurgery, in LM and evaluated the differences in surgical outcomes and complications.

2. Methods

We retrospectively studied 817 patients who underwent LM performed by one of the authors (CJW) at Chang Gung Memorial Hospital at Linkou for symptomatic uterine fibroids (e.g., menorrhagia, abdominal pain, and bulk-related symptoms) between January 1997 and September 2015. We introduced LigaSure and Harmonic scalpel for LM in 2010. However, we did not routinely use this system as daily practice because this needed extra fee for a patient based on the insurance policy in our country. The indications for surgery in these patients included menorrhagia, abdominal pain, bulkrelated symptoms (urine frequency or rectosigmoid compression), and infertility. All patients underwent preoperative assessments before surgery, including detailed medical history, pelvic examination, and ultrasonography. Patients with sexual experience were screened for the absence of cervical malignancy. Diagnostic hysteroscopy was performed to exclude pathologic lesions in the uterine cavity for patients with menometrorrhagia and anemia. The surgical risks were explained to the patients, including the potential need to switch to laparotomy during the procedure and the risks of intraoperative bleeding, transfusion, and adhesion. Gonadotropin-releasing hormone (GnRH) agonist was not routinely administered preoperatively. For premenopausal women with main fibroid size ≥ 9 cm or presence of more than 3 fibroids \geq 5 cm, the surgeon will consider pretreatment with 3 intramuscular injections of leuprolide acetate 3.75 mg (Leuplin; Takeda, Rome, Italy) 4 weeks apart and operation was performed 4-5 weeks after the final administration. Written informed consent was obtained from all subjects. All women had bowel preparation in the morning of surgery. Intravenous cephalosporin prophylaxis was administered just before surgery.

Preoperative clinical and demographic characteristics including age, body mass index (BMI), weight of excised fibroids in grams, number of cesarean deliveries, and pretreatment with GnRH agonist were summarized. Similarly, operating time, number of fibroids removed, main fibroid size, estimated blood loss, decreased hemoglobin level, length of postoperative stay, blood transfusion requirement, and any perioperative complications (fever, bowel injury, or genitourinary tract injury) were recorded. The study was approved by the Institutional Review Board of Chang Gung Memorial Hospital (201600374B0).

2.1. Operative procedures

The patient was placed in the dorsolithotomy Trendelenburg position, with both legs protected by elastic bandages, and a Foley catheter was inserted for constant urine drainage. After induction of general anesthesia, 1-g intravenous cephalothin was administered as prophylaxis. LM was performed following the procedures described by Wang et al.¹³ In brief, laparoscopic examination of the pelvis and lower abdomen was performed first to determine accessibility of the surgical field and spaces between the rectum and cervix and the parametrium and ureter. Four trocars were routinely used.

After identifying the location of all fibroids, a conventional unipolar electrode was used to incise transversely on the serosa overlying the largest tumor until its pseudocapsule was reached. A myoma screw or second puncture was then inserted into the fibroid to apply traction and countertraction movements after the identification of the cleavage plane. The unipolar electrode and bipolar forceps, harmonic scalpel (5 mm), or LigaSure (5 mm) was used to dissect the pseudocapsule attachment further. Additional fibroids located at the same area were removed through the same incision. However, creating a new incision was necessary for nonadjacent fibroids. The uterine defect was irrigated after fibroid removal. Bleeding points were identified and controlled with bipolar diathermy, harmonic scalpel, or LigaSure.

The uterine surgical defect was closed in two layers with a zero monofilament poliglecaprone 25 (Monocryl, Ethicon Inc., Somerville, NJ, USA), continuous nonrunning-lock suture, and intracorporeal knots. Specimens were extracted through posterior colpotomy routinely. The colpotomy incision was closed with a 2-0 polyglycolic acid suture after removal of all fibroids. If the specimen had to be removed from the abdominal wall (for women with no prior sexual activity), a 15-mm electromechanical morcellator (Ethicon Endosurgery, Cincinnati, OH, USA) was used to ease extraction of the specimen. Pneumoperitoneum was reestablished at this time, and the peritoneal cavity was irrigated and lavaged until the fluid was clear. After achieving complete hemostasis, all port sites were sutured with a 3-0 polyglycolic acid suture at the level of the fascia to prevent herniation. The skin was approximated by a sterile adhesive tape.

2.2. Statistical analysis

Statistical evaluation of the three groups was performed by one-way analysis of variance (ANOVA) with Bonferroni test

	Electrosurgery $(n = 481)$	Harmonic $(n = 80)$	LigaSure $(n = 256)$	р
Age (years)	$37.6 \pm 5.9 (20-56)$	$38.0 \pm 5.9 (23-49)$	$38.9 \pm 6.5 (24 - 59)$	0.017
Parity	$1.2 \pm 1.2 (0-6)$	$0.8 \pm 1.0 \ (0-3)$	$0.9 \pm 1.1 \ (0-4)$	0.005
Body Mass Index (kg/m ²)	$23.0 \pm 3.5 \ (16.0 - 36.5)$	$23.0 \pm 3.9 (15.6 - 38.1)$	$22.8 \pm 3.6 (16.3 - 41.5)$	0.824
Cesarean delivery	$0.3 \pm 0.6 \ (0-3)$	$0.3 \pm 0.6 \ (0-3)$	$0.2 \pm 0.6 \ (0-3)$	0.870
Largest fibroid size (cm)	$7.4 \pm 2.1 (5-18)$	$7.7 \pm 1.7 (5-12)$	$8.4 \pm 2.2 (5-17)$	< 0.001
Preoperative GnRHa treatment	43 (8.9)	30 (37.5)	98 (38.3)	< 0.001

Table 1 Clinical characteristic of 3 groups.

GnRHa = gonadotropin-releasing hormone agonist.

Values are mean \pm standard deviation or number (%).

for post hoc analysis. Continuous data are summarized as mean \pm standard deviation. Probability values < 0.05 were considered statistically significant. All analyses were performed by SPSS Version 18 software (Chicago, IL, USA).

3. Results

All laparoscopic procedures were performed uneventfully, without any conversion to laparotomy. Bleeding control procedures such as uterine artery ligation (permanent or temporal) or vasopressin injection were not used in this study. When comparing the parameters among the three groups, no significant differences were found in the BMI and cesarean section history (Table 1). However, a trend of increasing age and main fibroid size from the electrosurgery to LigaSure group was observed. The oldest patients and largest fibroid were found in the LigaSure group, and the youngest patients and smallest fibroid were found in the electrosurgery group. The difference was statistically significant between the LigaSure and electrosurgery groups $(38.9 \pm 6.5 \text{ vs } 37.6 \pm 5.9 \text{ years}, p = 0.013;$ 8.4 ± 2.2 vs 7.4 ± 2.1 cm, p < 0.001). Parity was significantly higher in the electrosurgery group than in the Harmonic scalpel and LigaSure groups $(1.2 \pm 1.2 \text{ vs } 0.8 \pm 1.0, p = 0.046; 1.2 \pm 1.2)$ vs 0.9 ± 1.1 , p = 0.026). Besides, the proportion of patients undergoing pretreatment with GnRH agonist in the LigaSure group was also significantly higher than that in the electrosurgery group (38.3% vs 8.9%, p < 0.001).

Thirty-seven, 11, and 35 patients in the electrosurgery, Harmonic scalpel, and LigaSure groups, respectively, underwent concomitant adnexal surgery, and 11, 3, and 10 patients in the electrosurgery, Harmonic scalpel, and LigaSure groups, respectively, underwent hysteroscopic removal of endometrial lesion. Otherwise, no additional procedures were performed.

Table 2							
Clinical	findings	related	to	3	different	energy	devices.

The outcomes of the three groups are summarized in Table 2. The number of fibroids removed was significantly less in the electrosurgery group compared with the other two groups. The total weight of fibroids in the LigaSure group was significantly higher than that in the electrosurgery group $(243.3 \pm 174.9 \text{ vs})$ 175.9 ± 149.5 g, p < 0.001). The shortest and longest operating times were shown in the electrosurgery and Harmonic scalpel groups, respectively (p < 0.001). The mean decrease in hemoglobin level, blood transfusion rates, and complications were not found to differ between the three groups; however, the estimated intraoperative amount of blood loss was found to be significantly higher in the Harmonic scalpel group compared with the electrosurgery group (245.8 ± 208.3) vs 175.4 ± 173.0 mL, p = 0.003). The mean length of postoperative stay was significantly less in the Harmonic scalpel group compared with the other two groups.

Table 3 shows the results of patients pretreated with GnRH agonist. No significant differences were found in the number of fibroids removed, operating time, intraoperative blood loss, blood transfusion requirement, and complication incidence. The main fibroid size in the LigaSure group was significantly larger than that in the electrosurgery group ($9.3 \pm 2.3 \text{ vs } 8.1 \pm 2.0 \text{ cm}$, p = 0.009). The total weight of fibroids in the LigaSure group was significantly higher than that in the electrosurgery group ($324.9 \pm 193.7 \text{ vs } 252.5 \pm 160.0 \text{ g}$, p < 0.026). In addition, the mean postoperative stay was also significantly less in the Harmonic scalpel group compared with the other two groups.

4. Discussion

Laparoscopic myomectomy is a common surgery performed by gynecologists currently. However, bleeding during myometrium incision remains a major problem, particularly in

Clinical indings related to 3 different energy devices.						
	Electrosurgery $(n = 481)$	Harmonic $(n = 80)$	LigaSure ($n = 256$)	р		
Fibroids removed (no.)	$2.6 \pm 2.7 \ (1-24)$	$3.5 \pm 3.2 \ (1-16)$	$3.7 \pm 3.6 (1-23)$	< 0.001		
Fibroid weight (g)	$175.9 \pm 149.5 (33 - 1370)$	$202.5 \pm 120.6 (34 - 493)$	243.3 ± 174.9 (32-841)	< 0.001		
Operating time (min)	$100.1 \pm 43.2 \ (30-320)$	$130.8 \pm 48.7 \ (45-270)$	$115.7 \pm 42.9 \ (45 - 330)$	< 0.001		
Blood loss (mL)	$175.4 \pm 173.0 \ (10 - 1100)$	245.8 ± 208.3 (10-1050)	$201.0 \pm 178.2 \ (10-800)$	0.003		
Hemoglobin decrease (mg/dL)	$1.4 \pm 0.8 \ (0.1 - 4.1)$	$1.4 \pm 0.7 \ (0.1 - 3.6)$	$1.5 \pm 0.8 \ (0.2 - 4.9)$	0.285		
Blood transfusion	18 (3.7)	4 (5.0)	13 (5.1)	0.658		
Complication	10 (2.1)	1 (1.3)	4 (1.6)	0.922		
Postoperative stay (d)	$2.5 \pm 0.8 \ (1.0 - 10.0)$	$2.0 \pm 0.4 \ (1.0 - 3.0)$	$2.1 \pm 0.6 (1.0 - 8.0)$	< 0.001		

Values are mean \pm standard deviation or number (%).

Table 3 Clinical findings related to pre-operative gonadotropin-releasing hormone agonist treatment.

	Electrosurgery $(n = 43)$	Harmonic $(n = 30)$	LigaSure $(n = 98)$	р	
Fibroids removed (no.)	$4.9 \pm 4.4 (1-20)$	$4.6 \pm 3.9 (1-16)$	$4.9 \pm 4.5 (1-23)$	0.949	
Largest fibroid size (cm)	$8.1 \pm 2.0 (5-13)$	$8.0 \pm 1.6 (5-11)$	$9.3 \pm 2.3 (5-17)$	0.001	
Fibroid weight (g)	$252.5 \pm 160.0 (44 - 779)$	$227.5 \pm 125.2 \ (40-471)$	$324.9 \pm 193.7 \ (60 - 841)$	0.009	
Operating time (min)	$135.7 \pm 53.9 \ (60 - 300)$	$143.8 \pm 51.4 \ (45-270)$	$133.6 \pm 51.9 (50 - 330)$	0.645	
Blood loss (mL)	294.7 ± 281.0 (30-1100)	$221.3 \pm 120.6 (40 - 500)$	$249.5 \pm 218.8 \ (20 - 800)$	0.353	
Hemoglobin decrease (mg/dL)	$1.9 \pm 0.8 \ (0.5 - 3.9)$	$1.4 \pm 0.7 \ (0.2 - 3.6)$	$1.6 \pm 0.9 \ (0.2 - 4.9)$	0.092	
Blood transfusion	5 (11.6)	0 (0.0)	10 (10.2)	0.138	
Complication	2 (4.7)	0 (0.0)	2 (2.0)	0.498	
Postoperative stay (d)	$2.6 \pm 0.8 \ (2.0-5.0)$	$2.1 \pm 0.3 (2.0 - 3.0)$	$2.1 \pm 0.8 \ (1.0 - 8.0)$	0.003	

Values are mean \pm standard deviation or number (%).

patients who have larger uterine fibroids or more fibroid numbers.³⁻⁵ To choose an adequate device to minimize intraoperative bleeding and reduce surgical complications, we compared three different power devices, which were all widely used in various gynecologic surgeries.

Conventional electrosurgery system and LigaSure both coagulate tissue and seal vessels with electric energy. Conventional electrosurgery induced the highest local temperature elevation and most lateral thermal injury.^{14,15} In contrast, the output power of LigaSure can be adjusted automatically according to the tissue impedance to deliver the appropriate amount of energy for desired tissue effect. Therefore, less postoperative pain has been reported for LigaSure compared with conventional electrosugery.^{8,16} A combination of pressure and electric energy also provided good efficacy of vessel sealing due to tissue collagen, and elastin was transformed into a permanent fusion zone. Besides, it has an additional blade to dissect tissue; therefore, time wasted in instrument change can be reduced. Harmonic scalpel coagulates tissue by the energy from the active jaw with 55,500 cycles/s vibration, which generates heat and causes protein denaturation. It is characteristic of relatively less lateral thermal injury and smoke.17

In our study, both LigaSure and Harmonic scalpel groups had more amount of intraoperative bleeding and longer operative time than the conventional electrosurgery group. However, patients in these two groups had more numbers of fibroids removed, heavier fibroids removed, and higher rate of pretreatment with GnRH agonist. It is probably the reason why surgeons tend to choose advanced power devices during operation to deal with more complicated cases. However, no worse postoperative clinical outcome but shorter length of hospital stay was found in the LigaSure and Harmonic scalpel groups. A previous study showed Harmonic scalpel resulted in lesser pain 24 h after surgery other than the conventional electrosurgery systems.¹¹ Compared with the conventional electrosurgery system, lesser incidence of lateral neural injury due to electric current and lateral spread due to Harmonic scalpel might be the reasons for less operative pain.^{14,17} Thus, the length of postoperative hospital stay can be reduced. Previous studies had also reported that LigaSure has faster sealing time and lower failure rate in vessel sealing than

Harmonic scalpel.^{17,18} Compared with Harmonic scalpel and LigaSure groups, this trend correlated with our findings.

Preoperative treatment with GnRH agonist may provide the benefits of a decrease in fibroid size, correction of anemia preoperatively, and decrease in the amount of operating blood loss.^{3,19} Obscuring the tissue plane between the fibroid and the normal myometrium may occur because of the drug effect and make enucleation of fibroids more difficult compared with no preoperative GnRH agonist therapy.¹⁹ In this study, the medical effect of obscuring the surgical plane was observed, but had no influence on fibroid enucleation. The LigaSure group had the largest and heaviest fibroids; however, no significant differences were found in operating time, amount of intraoperative blood loss, blood transfusion requirement, and complication incidence among the three groups. In addition, the length of postoperative stay was also significantly less in Harmonic scalpel and LigaSure groups compared with electrosurgery groups. This finding reflects that the newly developed device might be more efficiently used to deal with complicated cases.

The limitation of our study is that this is a retrospective study, and we have only compared perioperative and postoperative outcomes between these three devices. Patients in these three groups have no similar background. We also did not record postoperative pain score and analyze the reason of different lengths of hospital stay. Minor postoperative pain might lead to less analgesic use and hospital stay. In contrast, we included a large number of cases, all of which underwent the procedure by the same surgical group at a single institution. Therefore, the difference between surgeons and operative room setting would be minimized.

In conclusion, the use of all three devices is feasible in LM. LigaSure and Harmonic scalpel can reduce the length of hospital stay without increasing the incidence of worse surgical outcome. Besides, these two advanced power devices are more user-friendly and can reduce surgeon work load. However, LigaSure and Harmonic scalpel cost more and are not covered by public health insurance in Taiwan. Therefore, using these instruments still needs a valid reason based on stronger evidence. Hence, further investigation with a randomized control study is needed to guide surgeons in choosing adequate instruments during surgery for better surgical outcomes.

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