



Original Article

A case-controlled study comparing harmonic versus electrosurgery in laparoscopic myomectomy

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ABSTRACT

Objective: To compare the safety and effectiveness of the harmonic scalpel and conventional electrosurgery in laparoscopic myomectomy (LM).**Materials and Methods:** We performed a retrospective chart review of 591 women with symptomatic uterine fibroids who underwent LM. Thirty-three cases of LMs with harmonic scalpel (LMH) were compared with a matched control group that underwent conventional electrosurgery (LME). Outcome measures for both groups were studied comparatively in terms of the amount of blood loss, requirement of blood transfusion, length of operative time, cost, and hospital stay.**Results:** There was no incidence of switching to abdominal laparotomy. Length of postoperative stay was significantly lower in the LMH group than in the LME group (2.0 ± 0.4 days vs. 2.5 ± 0.7 days, $p < 0.001$), but the hospital charges were significantly higher in the LMH group than in the LME group ($39,207.7 \pm 9315.0$ new Taiwan dollar vs. $24,078.4 \pm 11,051.3$ new Taiwan dollar, $p < 0.001$). Four minor complications were noted in the LME group; two developed lower-grade febrile morbidity, one had urinary tract infection, and one had subcutaneous ecchymosis at the left ancillary port site. Length of operation, blood loss, hemoglobin decrease, and requirement of blood transfusion were not significantly different between the two groups.**Conclusion:** Harmonic scalpel is as safe and effective as conventional electrosurgery, and may offer an alternative option for patients undergoing LM. Harmonic scalpel has advantage over conventional electrosurgery in less postoperative hospital stay but disadvantage in higher cost.© 2017 Taiwan Association of Obstetrics & Gynecology. Publishing services by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

For surgically dealing with symptomatic uterine fibroids, hysterectomy provides a permanent resolution if childbearing is complete and uterine preservation is not important to the individual. As many women today have delayed marriage, myomectomy is a reasonable approach for women who desire future fertility and conservative therapy. Laparoscopic instruments and techniques have improved remarkably in the past two decades and

laparoscopic myomectomy (LM) is now a feasible and safe alternative to open myomectomy [1,2].

Three major aspects were involved in LM: enucleation of myomas, repair of uterine defect, and removal of specimens. Therefore, LM is still considered a time-consuming, bloody, and skillful procedure. Unipolar and bipolar electrocautery are most commonly used for energy generation in LM. Unipolar diathermy offers good cutting function but produces much plume and indeterminate dispersion of current. Bipolar forceps provide effective coagulation but uncontrolled thermal spread and charcoal formation [2,3]. Although the relationship between surgical smoke and health risk is still unclear, at least five carcinogenic compounds could be detected when using an electrocautery device in laparoscopic surgery [4]. Bleeding of LM usually occurs during incision of the myometrium and can be controlled by effective uterine defect

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repair. Because mastering the laparoscopic suture skills cannot be achieved in one step, it is necessary to investigate the evolutionary energy device providing same cutting and coagulating functions as traditional electrosurgery devices while preventing the aforementioned drawbacks.

Based on an ultrasonically activated shear, vibrating at 55,500 cycles/s and generating sound waves, the harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) can coagulate and cut simultaneously. The hemostatic seal is approved for vessels up to 5 mm in diameter [5,6]. Furthermore, the ultrasonic shears do not permit electric transference through the patient as well as diminish the generation of smoke and minimize lateral thermal damage [5,7,8].

A search of the literature showed few published studies discussing the ultrasound energy, although it had already been used in laparoscopic and open surgeries [5,9–11]. The purpose of this study was to compare the results of LM performed using harmonic scalpel with a matched control standard LM performed with conventional electrosurgery.

Materials and Methods

This study consisted of 33 women (age range, 23–49 years; mean, 38.4 ± 6.3 years) with different indications scheduled to undergo LM with harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, OH, USA) performed by one of the authors (C.J.W.) at Chang Gung Memorial Hospital at Linkou between February 2010 and August 2014. Five hundred fifty-eight women receiving LM with conventional electrosurgery (LME) performed by the same surgeon (C.J.W.) were also retrospectively studied to avoid specific clinical bias. We introduced harmonic scalpel for LM since 2010. However, we did not routinely use this system in daily practice because this needed extra charge for patients according to the insurance policy in our country. The indications for surgery in these patients included menorrhagia, abdominal pain, bulk-related symptoms (urine frequency or rectosigmoid compression), and infertility. Before the surgery, all patients underwent preoperative assessments, including detailed medical history, pelvic examination, and ultrasonography. Patients with sex experience were screened for the absence of cervical malignancy. Diagnostic hysteroscopy was performed to exclude pathologic lesion in the uterine cavity for patients who suffered from menometrorrhagia and anemia. The risks of surgery were explained to the patients, including the potential need to switch to laparotomy during the operation and the risks of intraoperative bleeding, transfusion, and adhesion. Written informed consent was obtained from all patients. All women had bowel preparation in the morning of surgery. Intravenous cephalosporin prophylaxis was given just before surgery.

Preoperative clinical and demographic characteristics including age, body mass index, weight of excised fibroids (g), number of cesarean delivery, and pretreatment with gonadotropin-releasing hormone agonist (GnRHa) were abstracted. Similarly, operating time, number of fibroids removed, main fibroid size, estimated blood loss, hemoglobin decrease, postoperative stay, requirement of blood transfusion, and any perioperative complications (e.g., fever, bowel injury, or genitourinary tract injury) were recorded. Total hospital charges (this amount does not include the cost covered by the National Health Insurance) were obtained from hospital financial records. The study was approved by the Institutional Review Board of Chang Gung Memorial Hospital.

LM technique

The patient was placed in the dorsolithotomy Trendelenburg position with both legs protected by elastic bandages, and a Foley

catheter was inserted for constant urinary drainage. After induction of general anesthesia, intravenous cephalothin (1 g) was administered as prophylaxis. LM was performed following procedures as described by Wang et al [2]. 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 transverse elliptical incision was made on the serosa overlying the largest tumor by conventional unipolar electrosurgery or harmonic scalpel (5 mm in size) until its pseudocapsule was reached. Additional fibroids located at the same area were removed through the same incision. However, for removal of nonadjacent fibroids, creating a new incision was necessary. A myoma screw, or a second puncture, was then inserted into the fibroid to apply traction and countertraction movements. The unipolar electrode or harmonic scalpel was used to dissect pseudocapsule attachments further. After fibroid removal, the uterine defect was irrigated. Bleeding points were identified and controlled with electrocoagulation (bipolar diathermy or harmonic scalpel). 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. After removal of all fibroids, the colpotomy incision was closed with 2-0 polyglycolic acid suture (Ethicon Inc., Somerville, NJ, USA). If the specimen had to be removed from the abdominal wall (for women with no prior sexual activity), a 15-mm electromechanical morcellator (Ethicon Endo-Surgery, Cincinnati, OH, USA) was used to ease extraction of the specimen. Pneumoperitoneum was re-established at this time, and the peritoneal cavity was irrigated and lavaged until fluid was ran clear. After achieving hemostasis completely, all port sites were sutured with 3-0 polyglycolic acid suture (Ethicon Inc., Somerville, NJ, USA) at the level of the fascia to prevent herniation. The skin was approximated by sterile adhesive tape.

Statistical analysis

Continuous variables were compared with Student *t* test and categorical values with Pearson χ^2 analysis and Fisher exact test. To reduce the effects of confounding by some covariates, the propensity score was used, which is a statistical matching technique that attempts to select a set of patients who have similar distribution of measured baseline covariates between patients of two different treatments. Multiple logistic regression was used to estimate the likelihood of undergoing a LM with harmonic scalpel (LMH) for all patients based on age, body mass index, the number of cesarean delivery, specimen weight, and pretreatment with GnRHa. The logistic model produces a zero to one propensity score based on the predicted probability of undergoing LMH versus LME, which was dependent on differences in patient demographic and preoperative clinical characteristics [12]. These propensity scores were then used to measure selection bias. Patients undergoing LME with low scores would have been unlikely to undergo an LMH, and therefore were excluded them from comparative analysis.

Six clinical outcomes (number of fibroids removed, main fibroid size, estimated blood loss, hemoglobin decrease, incidence of blood transfusion, and perioperative complications) and three efficiency outcomes (operating time, postoperative stay, and hospital charges) were compared between groups. We compared a propensity score-matched sample of 93 LME patients with the 31 LMH patients using a “nearest neighbor” approach. In this approach, each LMH patient was matched to three LME patients with the closest propensity scores. Differences in outcomes by procedure

type were tested by linear regression with log transformations or Student *t* test and logistic regression or Pearson χ^2 analysis and Fisher exact test for categorical outcomes. All analyses were performed with SPSS version 18 software (Chicago, IL, USA).

Results

Table 1 shows the multiple logistic regression analysis of variables associated with case selection for LMH. Patients with LMH were more likely to receive pretreatment with GnRHa. The propensity score model had a relatively high classification accuracy (c statistic = 0.7).

The propensity score-matched analysis is presented in Table 2. The total weight of fibroids, size of main fibroid, mean blood loss, requirement of blood transfusion, hemoglobin decrease, and duration of operation were similar in both groups. Five patients suffered from intraoperative blood loss of more than 500 mL, two in the LMH group (285 g and 391 g) and three in the LME group (80 g, 460 g, and 550 g). The extreme blood loss was mainly caused by multiple uterine incision wounds (>5) in two patients (285 g and 550 g) and removal of large intramural tumor (>9 cm) in two patients (391 g and 460 g). In one patient (80 g), blood loss was attributed to malfunction of instrument and lack of proficient collaboration of the surgical assistant. All these patients recovered uneventfully after blood transfusion with 4 units to 8 units of whole blood and packed red blood cell and administration of cefamezine (1 g) every 6 hours for 2 days. Although the complication rate was significantly greater in the LME group, there were no major complications, such as ureteric injury, bladder injury, or bowel injury in any of the cases. Two patients in the LME group developed low-grade fever (<38.5°C) and made full recovery after fluid challenge and antibiotic therapy with cefamezine (1 g) administration every 6 hours and gentamicin (60 mg) administration every 8 hours for 3 days to 4 days. One patient in the LME group was found to have urinary tract infection and was able to void after intravenous cefamezine (1 g) administration for 6 hours for 3 days. Another patient in the LME group had subcutaneous ecchymosis at the left ancillary port site, which also resolved spontaneously after 2 weeks. Hospital charges for the LMH group were significantly higher than for the LME group.

Five patients in the LMH group and 33 in the LME group required electric morcellator for extraction of specimens. All the remaining cases had specimens removed from vagina smoothly. Histologic examination of the resected tissue showed leiomyomatous tissue in all patients. Fifteen specimens had hyaline degeneration and two had myxoid degeneration. One specimen was atypical leiomyoma. Two patients had adenomyosis concomitantly. No sarcomatous change was observed. Four women had uterine cavity broken during operation and control hysteroscopy performed 4 weeks postoperatively showed no intrauterine adhesion.

The correlations between operating time and specimen weight are plotted in Figure 1. There was a significant linear correlation between operating time and specimen weight in both groups.

Discussion

LM requires meticulous procedures, including incision of the uterine wall, retraction of the fibroids, repair of uterine wound, and extraction of surgical specimens. The incision and retraction steps lead to operative blood loss and remain a challenge for laparoscopists. Some evidence-based methods with requirement of additional steps have been utilized to reduce blood loss, including local injection of diluted vasopressin into the uterus and bilateral uterine artery ligation [13,14]. With improvements in laparoscopic instruments, alternative energy source was introduced to achieve the purpose of facilitating operative procedures, maintaining the safety and efficacy, and controlling operative blood loss. Harmonic scalpel is one of the newly developed energy sources for laparoscopic procedures [15].

The blade of harmonic scalpel moves back and forth at an imperceptible frequency of 55,000 cycles/s. This movement vibrates the tissues and thus breaks the hydrogen bonds in the tissue to denature protein. Therefore, the harmonic scalpel executes hemostasis, incision, and excision simultaneously, saving procedures of instrument change [5,10]. Besides, harmonic scalpel generates limited heat (approximately 80°C) during operation. By contrast, conventional electrosurgery usually heats tissues to above 100°C and even 150°C, which causes smoke, odor, and tissue charring. Instead of electrical current, harmonic scalpel uses mechanical vibration to divide tissues and seal vessels, thus minimizing the thermal damage and reducing smoke generation [7,8]. Unintentional or accidental thermal damage can cause substantial injury to surrounding tissues and even mortality [16]. Surgical smoke obscures the operating field and might contain gaseous by-products with aerosols that have detrimental effects on the human body [4]. That is the rationale we used ultrasound energy instead of conventional electrocautery to perform LM.

The percentage of pretreatment with GnRHa was significantly higher in the LMH group (33.3% vs. 7.4%, $p < 0.001$). Nevertheless, there was a trend of bigger fibroids in the LMH group. These results insinuated, in the LMH group, larger uterine size before medical hormone suppression and supposed more difficult preconditions. GnRHa may provide some short-term advantages such as decreasing blood loss and shrinking uterine size in patients undergoing myomectomy, but enhanced the hardness of surgery for blurred fibroid capsules [17]. This predisposed difficulty prolonged surgical time in the LMH group compared with the LME group (119.7 ± 37.1 minutes vs. 106.0 ± 48.4 minutes, $p = 0.154$); however, there was no significant difference between the two groups.

In this study, length of postoperative stay was significantly lower in the LMH group but the hospital charges were significantly higher in the LMH group. The harmonic scalpel uses no electrical current, and therefore, does not induce the electric stimulation of nerve and muscle. Furthermore, consequential transient paralysis or numbness of nearby organs or structures can be diminished. This probably explains the shorter postoperative hospitalization of patients in the LMH group. However, the harmonic scalpel is a

Table 1

Comparative patient characteristics for laparoscopic myomectomy with either harmonic or electrosurgery: Logistic regression results for propensity score model.

	Harmonic (n = 33)	Electrosurgery (n = 558)	Odds ratio (95% CI)	p
Fibroid weight (g)	219.6 ± 114.3	158.6 ± 153.6	1.00 (1.00–1.00)	0.166
Age (y)	38.4 ± 6.3	37.8 ± 5.8	1.02 (0.96–1.09)	0.495
Body mass index (kg/m ²)	23.4 ± 4.2	22.9 ± 3.4	1.02 (0.93–1.13)	0.633
Cesarean delivery	0.27 ± 0.7	0.23 ± 0.6	1.17 (0.67–2.03)	0.577
Pre-op GnRHa administration	11 (33.3)	41 (7.4)	5.88 (2.60–13.30)	<0.001

Values are presented as mean ± standard deviation or n (%).

CI = confidence interval; GnRHa = gonadotropin-releasing hormone analogs; pre-op = pre-operative.

Table 2

Propensity score-matched (3:1) comparison of outcomes after laparoscopic myomectomy with harmonic scalpel versus with electrosurgery.

	Harmonic (n = 31)	Electrosurgery (n = 93)	p
<i>Clinical outcomes</i>			
Fibroids removed (n)	3.1 ± 2.8	3.0 ± 3.5	0.902
Main fibroid size (cm)	7.6 ± 1.9	7.6 ± 2.1	0.942
Blood loss (mL)	300.0 ± 230.6	214.7 ± 215.7	0.063
Hemoglobin decrease (mg/dL)	1.2 ± 0.84	1.5 ± 0.9	0.109
Blood transfusion	5 (16.1)	3 (3.2)	0.571
Complication	0	4 (4.3)	0.023
<i>Efficiency outcomes</i>			
Operating time (min)	119.7 ± 37.1	106.0 ± 48.4	0.154
Postop stay (d)	2.0 ± 0.4	2.5 ± 0.7	<0.001
Hospital charges (NTD)	39,207.7 ± 9315.0	24,078.4 ± 11,051.3	<0.001

Values are presented as mean ± standard deviation or n (%).

NTD = new Taiwan dollar.

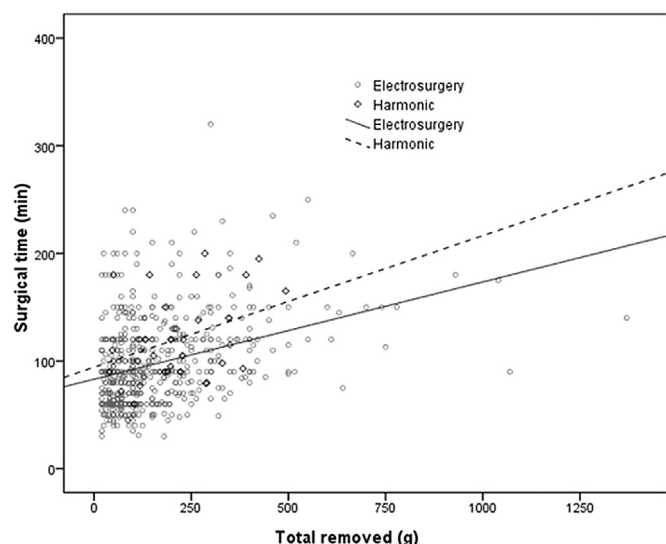


Figure 1. A significant linear regression between specimen weight and operating time could be seen in laparoscopic myomectomy performed with harmonic scalpel [operating time (minutes) = $94.3 + 0.12 \times$ specimen weight (g); $p < 0.001$] and laparoscopic myomectomy performed with electrosurgery [operating time (minutes) = $83.1 + 0.09 \times$ specimen weight (g); $p < 0.001$].

disposable device, and the extra self-payment made for this device will mask the real reduction in cost by shortened hospital stay. Therefore, surgeons need to be aware of the additional cost.

The limitations of this study include its retrospective design and absence of any documentation on postoperative pain comparison if there was a difference in pain between the two groups. In a prospective randomized study by Litta et al [10], which compared pain scores between groups receiving LM with harmonic scalpel and LM with electrosurgery, the electrosurgery group had higher pain scores at 24 hours after surgery compared with the harmonic scalpel group. In both groups, there was no difference in surgical difficulty and pain at 48 hours after surgery [10]. A larger prospective study on this topic is still warranted to further confirm the benefits of using harmonic scalpel in LM.

In conclusion, we find that the use of the harmonic scalpel in LM is associated with lower postoperative hospital stay, less postoperative sequels, but higher cost. Although harmonic scalpel may require a slightly longer operating time, in the hands of experienced surgeons, both conventional electrosurgery and harmonic scalpel can be used safely and effectively in LM. The decision on

which method to use would be based on cost, facility, and surgeon experience.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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