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Original Article

Improved hemostasis with plasma kinetic bipolar sealing device in the vaginal steps of laparoscopic-assisted vaginal hysterectomy

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ABSTRACT

Objective: During the vaginal steps of laparoscopic-assisted vaginal hysterectomy (LAVH), excessive bleeding occurs if the vascular pedicles are not securely clamped. Accordingly, this study investigates if an advanced bipolar sealing device (PlasmaKinetics [PK] Sealer), compared to conventional sutures, could improve the efficacy and safety in the vaginal steps of LAVH.
Material and methods: The medical records of 101 women who underwent LAVH for a non-malignant condition between June 2014 and August 2017 were retrospectively reviewed. Among the women, 60 received LAVH using conventional sutures (control group), while 41 using the PK Sealer during vaginal steps (PK group).
Results: A 35% reduction (76.1 vs. 117.3 mL) in the blood loss was observed in the PK group. The natural logarithm (*ln*) of the blood loss was significantly lower in the PK group than in the control group (P = .045). The percentage of cases which achieved the minimal blood loss goal (<50 mL) was significantly higher in the PK group than in the control group (61 vs. 48%, P = .044). After adjusting for confounding factors, the PK group still exhibited a significantly lower *ln* intraoperative blood loss (OR -0.477, P = .002) than the control group.
Conclusion: The PK bipolar sealing device provides a safe and effective alternative in reducing blood loss in the vaginal steps of LAVH.

Introduction

During laparoscopic-assisted vaginal hysterectomy (LAVH), excessive intraoperative bleeding occurs in approximately 2.7% of women, and typically comes from a loose vascular pedicle [1]. If the pedicle cannot be reclamped vaginally, laparoscopy, or even laparotomy, must be performed to locate and control the profuse bleeding. Several studies have reported on the use of bipolar electrosurgical sealers based on vapor-focused pulses (SuperPulses) of energy for hemostasis in vaginal hysterectomy [2,3]. In general, these studies have shown that such devices (e.g. the Gyrus ACMI PlasmaKinetic (PK) SuperPulse Generator are safer than conventional bipolar devices due to a well-controlled thermal margin around the application site, and reduced rebleeding due to tissue sticking to the instrument [4,5].

Some case-controlled studies have been published to compare the blood loss, operative time and propensity for perioperative complication in LAVH surgeries with bipolar electrosurgical sealers and conventional sutures, respectively [6–8]. But they all focused on laparoscopic instruments in laparoscopic steps of LAVH, and perform vaginal steps of LAVH by conventional clamping, cutting and ligation with sutures. Accordingly, this study performs a retrospective investigation into the operative outcomes of cases receiving LAVH with and without PK instrument application in vaginal steps of LAVH, respectively.

Materials and methods

The medical records of patients with indication of LAVH who visited National Taiwan University Hospital, a tertiary medical institution in Taiwan, between June 2014 and August 2017 were examined. Women undergoing hysterectomy were considered eligible if the uterus was less than 20 cm in size on the basis of preoperative imaging and examination. Moreover, women undergoing simple hysterectomy for pre-malignant conditions (e.g. atypical endometrial hyperplasia) were regarded as eligible for

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LAVH if their disease was apparently confined to the uterus. Cases with more than stage II uterine prolapse were excluded and received vaginal hysterectomy directly. We also excluded women with known bleeding tendency (i.e. recent anticoagulation use, von Willebrand disease, etc.). No restrictions on eligibility were imposed based on body mass index (BMI) or the number of prior abdominal surgeries.

One hundred and one women received LAVH in the considered period, of which 60 cases self-assigned to the "control group" (i.e., received LAVH with conventional vaginal sutures), while 41 cases to the "PK group" (i.e., received LAVH using the PK SuperPulse Generator, curved open forceps, Fig. 1) after well-explained the cost and potential benefit if PK sealer. Specifically, vaginal steps included the ligation and cutting of the uterosacral ligaments, cardinal ligaments, and uterine vessels. All of the surgeries were performed by a team composed of the corresponding author (Bor-Ching Sheu, with 15 years of experience in laparoscopic surgery) and senior fellows. The LAVH surgeries were all American Association of Gynecologic Laparoscopists Classification Type I, with the bilateral uterine artery ligated vaginally. Laparoscopic steps of LAVH, including coagulation and cutting the round ligaments, opening the broad ligament, cauterizing and incising the pedicles of adnexae, were performed with LigaSure™ (Valleylab Inc., Boulder, CO, USA) laparoscopic vessel sealing instruments.

The clinical parameters, including the patient age, surgical indications, BMI, prior abdominal surgeries, major medical disease, procedure type, uterine weight, estimated blood loss (by independent anesthesiologist), total operative time (defined as initial skin incision to skin closure), length of hospital stay, and perioperative complications were collected retrospectively from the medical records. Minimal blood loss goal was defined as an estimated blood loss of less than 50 mL. Perioperative complications included major hemorrhage (>500 mL), the need for blood transfusion, gastrointestinal or urologic tract injury, postoperative fever (>38.5 °C), and recurrent vaginal bleeding after discharge. All of the parameters were intact, and no one was excluded.

Statistical analysis

The data were analyzed using commercial SAS software (SAS Institute, Version 9.4). Chi-square tests and independent t-tests were used to detect differences between the two groups. All of the p-values were two-sided. Moreover, $P < .05$ was considered to be statistically significant. Linear regression analysis was used to examine the relationships among the parameters and delineate the trends. Finally, multivariate analysis was used to account for the possible effects of confounding factors, e.g., the patient age, parity, and uterine weight.

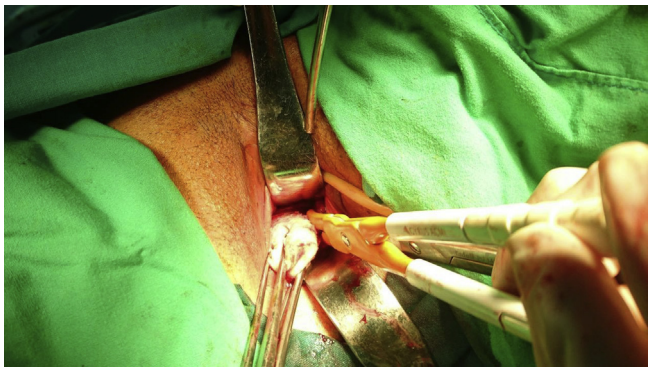

Fig. 1. Intraoperative photo of the PK group. Coagulation of the left uterine artery with plasma kinetic bipolar sealing device.

Ethics statement

The ethics committee waived the requirement for informed consent in this retrospective research. We followed the ethical standards established in the Declaration of Helsinki.

Results

As shown in Table 1, the indications for operation included uterine myoma, adenomyosis, endometrial hyperplasia, and high-grade cervical dysplasia. Besides, previous abdominal surgeries included Cesarean section, laparoscopic or laparotomic ovarian cystectomy, appendectomy, tubal ligation, and myomectomy. Significant differences ($P < .05$) existed in the mean age and parity of the PK and control groups. In particular, the PK group was younger and had lower parity. No significant differences were observed between the two groups in terms of the BMI, percentage of previous abdominal surgery, major medical disease, hemoglobin level and coagulation profile before surgery.

The uterine weight, concomitant adnexectomy, total operative time, length of hospital stay and perioperative complications were not significantly different between the two groups (Table 2). Furthermore, none of the surgeries required conversion to laparotomy. However, two patients experienced moderate vaginal bleeding after discharge, namely one patient in the PK group at postoperative day 12 and another patient in the control group at postoperative day 16. Both reported having vigorous sexual intercourse before bleeding, even though all of the subjects were instructed to avoid heavy lifting, sexual intercourse and tampon insertion for the first 6 weeks after surgery. One additional complication of major hemorrhage (intraoperative blood loss of 800 mL) occurred in the control group for an individual with a 10-cm cervical myoma, who subsequently received 4 units of packed red blood cell transfusion. There was one patient experience postoperative fever in each group, and both subsided spontaneously in 2 days.

Since the original intraoperative blood loss data were substantially skewed and the sample size was at most moderate ($n = 101$), natural logarithm (*ln*) transformation was applied prior to further analysis. A 35% reduction (76.1 vs. 117.3 mL) in the blood loss was observed in the PK group compared to the control group (Table 2). The natural logarithm of the blood loss was significantly lower in the PK group than in the control group ($P = .029$). Furthermore, the percentage of cases achieving the minimal blood loss goal (i.e., <50 mL) was significantly higher in the PK group ($P = .003$).

In the multivariate analysis (Table 3), a higher uterine weight had a significant effect on the *ln* intraoperative blood loss ($P = .001$). Specifically, women with a larger uterus were found to have a greater blood loss. After adjusting for the effects of confounding factors, i.e. the uterine weight, age and parity, the PK group still exhibited a significantly lower *ln* intraoperative blood loss (OR -0.477, $P = .002$) than the control group. As shown in Fig. 2, the *ln* blood loss was also reduced when using the PK instrument. Notably, the rates of increase of *ln* blood loss with increasing uterine weight were lower in the PK group than in the control group.

Discussion

There were abundant of literature in gynecologic field trying to elucidate the advantages and short comings of several kinds of advanced bipolar devices, including Ligasure, Pk gyrus, and Enseal™ (Ethicon Endo-surgery, US, LLC), comparing them to conventional bipolar device or in between [9–12]. Different instruments has various characteristics in efficiency of vessel sealing, cooling rate, condition of lateral thermal spread, and production of smoke plume. Most authors agreed improved surgical outcomes

Table 1
Patient characteristics.

	PK (n = 41)	Control (n = 60)	P-value
Patient age (y)	46.1 (31–59)	49.1 (34–66)	0.03
Parity	1.3 (0–5)	2.1 (0–7)	<0.001**
Body mass index (kg/m^2)	22.7 (17–31)	23.4 (17–35)	0.33
Indications for operation			
Uterine myoma	17 (43%)	27 (45%)	
Adenomyosis	12 (29%)	17 (28%)	
Endometrial hyperplasia or clinically early-staged endometrial cancer	11 (26%)	14 (23%)	
High-grade cervical dysplasia	1 (2%)	2 (3%)	
Previous abdominal surgery	14 (34%)	16 (27%)	0.43
Total number of previous abdominal surgery	20	17	
Cesarean section	9 (45%)	5 (29%)	
Ovarian cystectomy	5 (25%)	5 (29%)	
Appendectomy	3 (15%)	2 (12%)	
Tubal ligation	1 (5%)	2 (12%)	
Myomectomy	2 (10%)	1 (6%)	
Others	0 (0%)	2 (12%)[a]	
Major medical disease [b]	28 (68%)	37 (62%)	0.27
Hemoglobin before surgery	11.8 (7.4–14.6)	12.4 (7.6–15.6)	0.10
PT INR before surgery	0.94 (0.92–0.96)	0.95 (0.92–0.97)	0.40
PTT before surgery	27.6 (26.5–28.9)	28.3 (26.9–29.1)	0.11

* p < 0.05.
** p < 0.01.
Data is presented as n (%) or mean (range).
[a] One is laparoscopic colectomy, and the other is transvaginal uterine suspension.
[b] Include: Breast cancer, lung cancer, colon cancer, thyroid cancer, hypo- or hyperthyroidism, hypertension, diabetes mellitus, dyslipidemia, thalassemia, asthma, end-stage renal disease under hemodialysis, Sjogren syndrome, rheumatoid arthritis.

Table 2
Operative parameters and outcomes.

	PK (n = 41)	Control (n = 60)	P-value
Uterine weight (g)	246.7 (53–620)	241.8 (29–870)	0.864
Concomitant adnexectomy	38 (93%)	55 (92%)	0.762
Operative time (min)	135.6 (70–225)	140.7 (83–239)	0.483
Intraoperative blood loss (mL)	76.1 (30–500)	117.3 (30–800)	0.052
ln intraoperative blood loss (mL)[a]	3.93 (3.4–6.2)	4.34 (3.4–6.7)	0.045*
Minimal blood loss (<50 mL)	25 (61%)	29 (48%)	0.044*
Length of hospital stay (day)	3.5 (2–7)	3.8 (2–8)	0.816
Perioperative complications[b]	2 (4.9%)	3 (5.0%)	0.978

* p < 0.05.
Data is presented as n (%) or mean (range).
[a] Because the original data is substantially skewed and the sample size is at most moderate, natural logarithm transformation (*ln*) is applied before analysis.
[b] Perioperative complications: Major hemorrhage (>500 mL), need of blood transfusion, gastrointestinal or urologic tract injury, postoperative fever and recurrent vaginal bleeding after discharge.

Table 3
Multivariate analysis of the outcome.

Parameter	*ln* intraoperative blood loss (mL)	
	OR [95% CI]	P-value
Age	0.021 [−0.001, 0.043]	0.064
Parity	−0.019 [−0.147, 0.108]	0.763
PK use	−0.477 [−0.771, −0.184]	0.002*
Uterine weight	0.002 [0.0006, 0.003]	0.001*

* p < 0.05.

with advanced bipolar devices to conventional bipolar instruments at least from reduction of “instrument traffic” during laparoscopy, and neither one had been proven to be superior.

We chose PK device in vaginal steps of LAVH as to reduce lateral thermal spread and achieve the most rapid cooling rate, in order to minimize the complication of ureteral, bladder and bowel injury especially in relatively blind parts of the surgery. The results obtained in this retrospective study showed that the use of a PK instrument in the vaginal steps of LAVH was associated with a lower intraoperative blood loss and a shorter operative time. Besides, the PK instrument resulted in non-inferior low incidence of perioperative complication. The PK device uses plasma kinetic technology to deliver a high

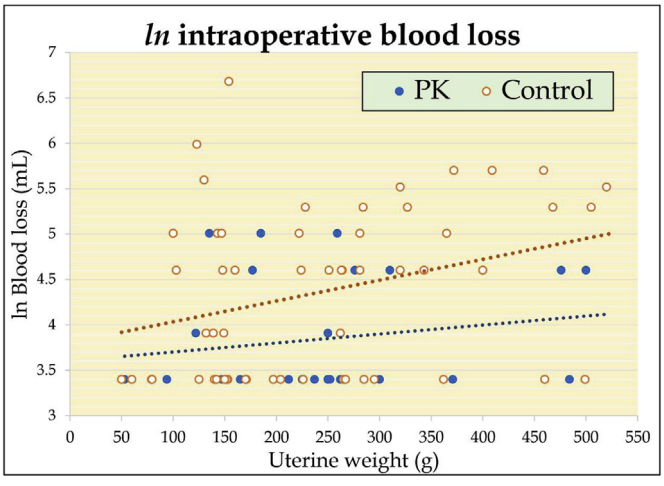

Fig. 2. Linear regression analysis results for relationship between natural log (*ln*) blood loss and uterine weight in PK group and control group. The ln blood loss is reduced when the PK instrument is used (blue solid line vs. orange dotted line). *ln* blood loss in control group (in mL) = uterine weight (in gram) × 0.002 + 3.8; ln blood loss in PK group (in mL) = uterine weight (in gram) × 0.00004 + 3.9. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

current and very low voltage to the tissue. The application of a series of rapid pulses with a cooling phase during coagulation leads to a better controlled lateral thermal spread and rebleeding due to tissue sticking [3]. It has been reported that vessel sealing with a pulsed bipolar system is more effective than using clips, sutures or staples [13]. This finding is consistent with the present results that showed that the PK group exhibited a 35% reduction in the intraoperative blood loss compared to the control group. Moreover, the PK group also showed a significantly greater percentage of cases achieving the minimal blood loss goal of less than 50 mL.

A previous retrospective study showed that, with regard to a shorter operative time and a lower blood loss, LAVH is preferable for a uterine weight of 350 g or more, whereas transvaginal hysterectomy is better for uteri weighing less than 350 g [14]. A large retrospective 9-year study showed a larger mean weight of the uterus in abdominal hysterectomy (518 g) than in LAVH (159 g) or vaginal hysterectomy (128 g) [15]. The present results showed a lower *ln* blood loss in the PK group than in the control group even for a uterus weight of more than 350 g (Fig. 2). These findings, combined with the previous experience, suggests that with the use of the PK instrument, large uteri (even those with a weight of 550 g) can be well managed by LAVH.

A case series in 2009 showed the PK instrument to be a safe and effective alternative to sutures in vaginal hysterectomy [2]. This study also revealed that the PK device had a fair security profile to previous studies in respect of a vaginal cuff healing (i.e., a comparable dehiscence complication rate of 1–2%) [16,17]. A lower incidence of urinary tract injury in the PK group compared to that in the control group (1.2–3%) suggests a more well-controlled thermal margin around the application site [18]. In short, we confirmed the practical advantages of the PK device as the designed theory.

Several limitations of the present study should be acknowledged. First, the study performed a retrospective investigation; not a double-blind randomized controlled trial. Consequently, the age and parity difference between the PK group and the control group could not be adjusted. Nevertheless, the placebo effect should be minimal due to the subjective recording of the blood loss and operative time. In addition, the PK device (with a cost of around 600 US dollars) is not supported by the national health insurance system in Taiwan. This represents a major limitation on the general accessibility of the device and is the main reason why a randomized controlled trial design could not be employed in the present study. Finally, the sample size of the PK group ($n = 41$) is rather small, and hence care must be taken in extending the findings to a larger group. Hence, overall, there is a need for further randomized controlled trials to confirm the present results and assess the cost-effectiveness of PK instrument use in LAVH. Also, to elucidate the pure effect of PK open forceps, we consider conduct a prospective study for the use of PK devise in vaginal total hysterectomy in the future.

Conclusions

Using the PK bipolar sealing device results in a relative low blood loss and similar post-operative complications and is therefore a safe and effective alternative to the conventional sutures in the vaginal steps of LAVH.

Conflicts of interest

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

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