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Vaginal cuff dehiscence following total laparoscopic hysterectomy by monopolar cut vs coagulation mode during colpotomy: A randomized controlled trial

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ABSTRACT

Objectives: To assess the effect of monopolar coagulation vs cut mode during colpotomy at total laparoscopic hysterectomy on vaginal cuff dehiscence.
Study design: We conducted this randomized controlled trial at a university hospital's department of obstetrics and gynecology from September 2016 through January 2018. Enrolled women were randomized 1:1 to monopolar coagulation or cut modes during colpotomy. We followed up 100 participants in the coagulation arm and 99 in the cut arm for ongoing data collection for 12 weeks after surgery. Exclusion criteria were suspicion of pregnancy, previous radiation therapy, uterine size exceeding 20 weeks' gestation, contraindication for high intraabdominal pressure, clinical advanced stage malignant disease, and conversion to laparotomy before completion of colpotomy. Differences between groups for categorical variables were analyzed by chi-square test and the comparisons of continuous variables between groups were analyzed by Student's *t*-test
Results: The study groups were comparable regarding demographics and perioperative parameters. The rate of vaginal cuff dehiscence in coagulation group (1%) was similar to that of cut group (0%) ($p = 0.995$). The other vaginal cuff related complication rates were also similar.
Conclusion: Monopolar coagulation and cut modes during colpotomy at total laparoscopic hysterectomy have similar vaginal cuff dehiscence rates and both energy modes seem acceptable for colpotomy.

Introduction

Vaginal cuff dehiscence (VCD) after hysterectomy is characterized by partial or complete separation of the vaginal cuff. It's a rare event but may result in major morbidities like prolapse of intraabdominal content and intestines. Intestinal evisceration can lead to serious sequelae such as peritonitis, intestinal injury and/or necrosis, and sepsis. The overall incidence of VCD has been reported less than 1% in large series [1–5]. However, the incidence of VCD was highest in women who had total laparoscopic hysterectomy (TLH). In a 15-year retrospective analysis, VCD rates were reported as 0.64% after TLH, 0.2% after abdominal hysterectomy, and 0.13% after vaginal hysterectomy [1]. Total laparoscopic hysterectomy-related dehiscence was significantly increased compared with other modes of hysterectomy, with a risk ratio of dehiscence after TLH of 9.1 (95% CI 4.1–20.3) compared with total abdominal hysterectomy, risk ratio of 17.2 (95% CI 3.9–75.9) compared with total vaginal hysterectomy, and risk ratio of 4.9 (95% CI 1.1–21.5) compared with laparoscopy assisted vaginal hysterectomy [2].

The most commonly proposed risk factors other than mode of surgery are previous pelvic radiation, vaginal atrophy, chronic steroid use, sexual intercourse, cigarette smoking, pelvic organ prolapse, postmenopausal status, low body mass index, chronic conditions increasing intraabdominal pressure, and other factors affecting wound healing.

Thermal damage induced by electrosurgical instruments during colpotomy, inappropriate suturing technique of vaginal cuff due to inexperience in laparoscopic suturing and deceptive effect of enlarged view may increase risk of VCD after TLH. In addition, several risk factors such as suture materials used, learning curve, local antiseptics and antibiotics during surgery, suture technique (one or two layer), and closure technique (continuous or interrupted) have also been proposed as risk factors [3,6,7]. However, there's still no consensus on the exact impacts of those possible risk factors.

Electrosurgery induced thermal injury during colpotomy and the mode of energy were proposed as the main reasons for higher

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rates of VCD after TLH [2,8]. However, there is no exact data to prove whether using energy or mode of energy increase the risk of VCD. Our hypothesis was that using cut or coagulation currents for colpotomy during TLH are not associated with increased risk of VCD. This randomized controlled trial investigates the effects of two monopolar current modes, coagulation and cut, during colpotomy on postoperative vaginal cuff complication rates. The primary outcome was VCD detected by vaginal examination.

Materials and methods

The present study, a randomized controlled trial (Clinicaltrials.gov registry number NCT02879487), was conducted at a university hospital's department of obstetrics and gynecology, from September 2016 through January 2018. The institutional Ethical Committee approved the study (approval number: 12-562-16) and the paper is written according to the CONSORT statement.

We assessed eligibility of potential participants who were scheduled for hysterectomy either for benign or malignant conditions prior to surgery. Potential participants received standardized counseling about the coagulation and cut modes for colpotomy at TLH. Written informed consent was obtained from each patient. The inclusion criteria were women scheduled for hysterectomy due to benign or malignant gynecologic reasons, and agreed to randomization for the present study. Exclusion criteria were as follows: suspicion for a pregnancy, uterine size exceeded 20 weeks' gestation to constitute a more standardized cohort, previous radiation therapy, contraindication for Trendelenburg position and/or high intraabdominal pressure, clinical advanced stage malignant disease, conversion to laparotomy before completion of colpotomy incision and detachment of uterus from the vagina. Demographic data, indications for surgery, intra- and postoperative data were recorded were recorded along with primary and other outcome parameters.

Following application of inclusion and exclusion criteria the enrolled participants were randomized to one of the following two groups: monopolar coagulation mode vs monopolar cut mode at the stage of colpotomy. Randomization was performed using sealed envelopes. At the beginning of the study 210 envelopes were prepared, 105 for each group, according to the sample size calculation. The envelopes were kept in the operating room and an envelope was selected randomly at the stage of colpotomy and the surgeon was notified of the randomization assignment. All surgeries were performed by the same surgeon (S.T.) with assistance of a fellow.

The participants were blinded to the technique performed. In addition, the outcome adjudicator was blinded to the colpotomy technique. All patients were evaluated by the same author (S.T.) at 6 and 12 weeks following surgery.

All patients underwent TLH using a standardized approach. The operation was performed under general anesthesia in lithotomy position and a single dose of prophylactic antibiotic was given. After perineal and vaginal disinfection with polyvinylpyrrolidone iodine 10% (Batticon®, Adeka, Samsun, Turkey) the cervix is grasped with Pozzi tenaculum forceps and a uterine manipulator was inserted to assist the surgery. A 10-mm, 0-degree laparoscope was used in all cases. Vessel sealing was performed using conventional bipolar graspers (RoBi rotating bipolar forceps, Karl Storz, Tuttlingen, Germany) or advanced bipolar devices (e.g., LigaSure, Covidien-Medtronic, Dublin, Ireland).

Colpotomy was performed by circumferential vaginal incision with monopolar hook using a 35 W pure cut or coagulation current (ForceTriad Energy Platform, Medtronic, MN) according to randomization. While 30–40 W is the most commonly used setting for gynecologic laparoscopy worldwide, we preferred 35 W for all participants for standardization. Bipolar energy set at 40 W (ForceTriad Energy Platform, Medtronic, MN) applied with laparoscopic bipolar forceps was used to stop brisk arterial bleeding from the vaginal cuff. The uterus was removed vaginally in all of the operations. If the uterus was too big to remove vaginal morcellation was performed by using a scalpel.

The vaginal cuff was closed using barbed size 0 suture with unlocked fashion (V-Loc, Covidien, USA). Vaginal cuff suturing was initiated from the right side and attachment of uterosacral ligament to upper posterior vagina was included to the first bite. Full thicknesses of posterior and anterior vaginal walls were also included and suturing was continued to the left uterosacral ligament and then the suture was turned back (towards the medial part of vaginal cuff) with 2 additional bites. Barbed suture was cut at the level of vaginal cuff to avoid suture related complications (Movie clip S1).

Patients were informed about sexual intercourse abstinence for 6 weeks after surgery. All participants were examined twice during the follow-up period, at 6 and 12 weeks. Patients were asked for their complaints; vaginal cuff was visualized by speculum examination and transvaginal ultrasound was performed to detect any cuff related lesions such as hematomas or abscesses.

The primary end point of our study was to compare the rate of VCD between two study groups. Secondary end points were postoperative vaginal cuff abscess, hematoma, blood loss, postoperative hemoglobin drop and duration of hospital stay.

This study was performed as a non-inferiority trial, designating cut, the commonly used method for cuff opening, as the comparison for the effects of coagulation toward vaginal cuff dehiscence. The incidence of vaginal cuff dehiscence was calculated as 0.2% according to the data obtained from our previous surgeries. The number of patients required for each group was determined on the basis of the non-inferiority hypothesis. For non-inferiority of the coagulation group versus cut group, a maximum difference of 1.5% (margin of non-inferiority) on the incidence of vaginal cuff dehiscence was considered as acceptable. Therefore, we calculated that a study with 95 patients per group would have at least 80% power, with one-sided type I error of 0.05. Taking into consideration of the 10% dropout rate, we decided to enroll 105 patients in each group.

Data analyses were performed by using SPSS Version 21.0 (IBM Corporation, Armonk, NYC, USA). Shapiro-Wilk test was used to test distribution of normality. Differences between groups for categorical variables were analyzed by chi-square test and the comparisons of continuous variables between groups were analyzed by Student's *t*-test according to results of their normality tests. *P* value less than 0.05 was considered statistically significant.

Results

From September 2016 through January 2018 we assessed a total of 217 women for eligibility. Seven of them excluded from the study because of clinical advanced stage malignancy (n = 3), extremely large uterus (n = 3) and lung disease preventing high intraabdominal pressure (n = 1). Then, 210 participants were enrolled and randomized during the study period, 105 to each group (Fig. 1). During the post-operative follow-up period five from coagulation arm and six from cut arm were lost to follow-up within the first 12 weeks. All patients who could not be followed-up indicated that they lived in another city at a long distance. Finally, we analyzed results of 100 participant in coagulation arm and 99 participants in cut arm. The mean age and BMI of the trial population were 52.1 ± 9.0 years and 29.1 ± 4.0 kg/m^2, respectively. Patient characteristics and indications for surgeries are shown in Table 1. There were no statistically significant differences between the study groups regarding demographics. The indications for surgery were similar between the groups. The rate of premalignant or malignant indications were similar between the groups (48% vs 44.4%, P = 0.670). Fifty-eight patients had previous abdominal or

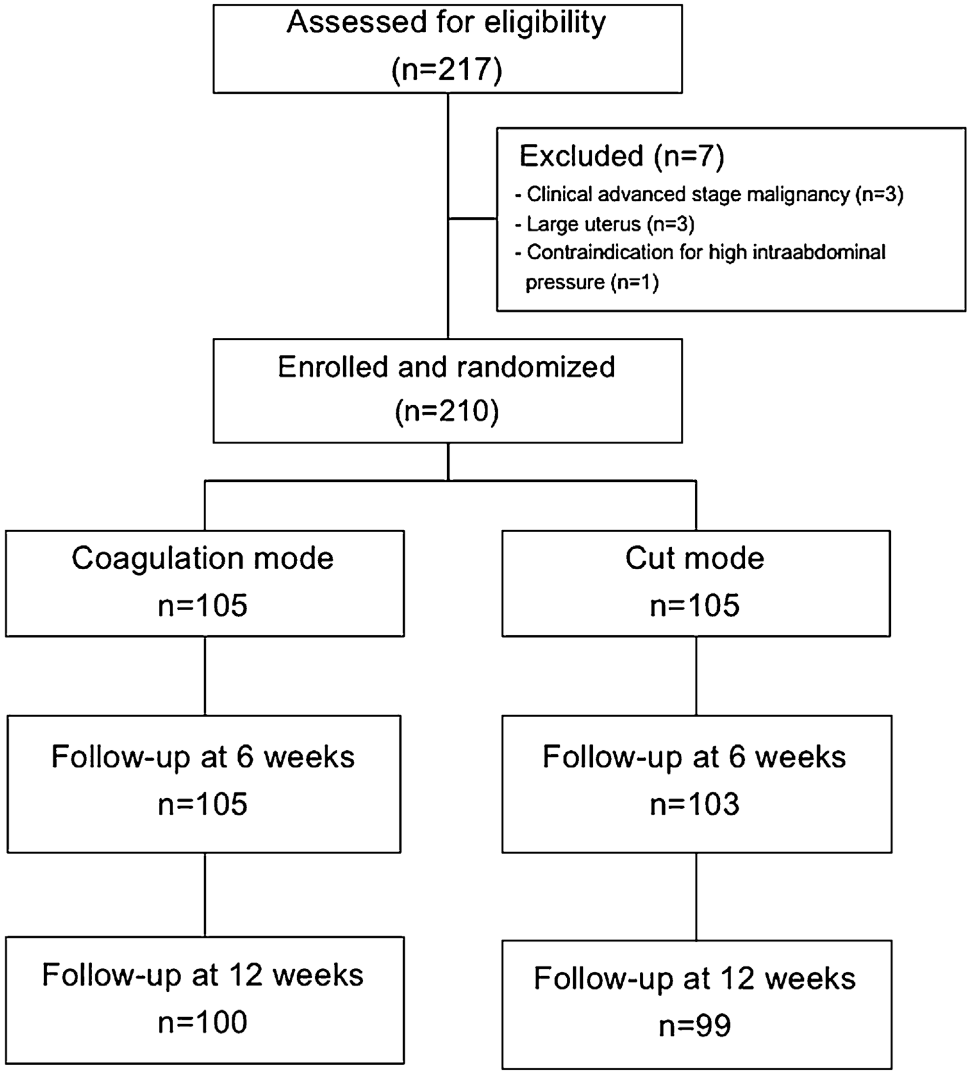

Fig. 1. Flowchart of the study.

Table 1
Baseline characteristics of the study groups.

	Coagulation (n = 100)	Cut (n = 99)	P value
Age, years	51.9 ± 9.2	52.3 ± 8.8	0.723
BMI, kg/m^2	28.7 ± 3.9	29.6 ± 4.1	0.136
Postmenopausal, n (%)	45 (45)	47 (47.4)	0.309
Previous abdominal surgery, n (%)	30 (30)	28 (28.3)	0.229
Systemic diseases, n (%)	50 (50)	47 (47.5)	0.722
Smoking, n (%)	14 (14)	11 (11.1)	0.669
Indications for surgery, n (%)			0.670
Benign Disorders	52 (52)	55 (55.5)	
Fibroid	32	34	
Ovarian cyst / Adnexal mass	4	3	
Abnormal uterine bleeding	10	11	
Endometriosis	6	5	
Tuboovarian abscess	1	0	
Premalignant or Malignant Disorders	48 (48)	44 (44.4)	
Endometrial cancer	33	31	
Endometrial hyperplasia	10	9	
Uterine leiomyosarcoma	1	0	
Placental site trophoblastic tumor	0	1	
Cervical cancer stage Ia1	2	1	
Cervical carcinoma in situ	1	1	
Borderline ovarian tumor	1	1	

Note: BMI: body mass index.

pelvic surgery including cesarean section (n = 24), cholecystectomy (n = 12), appendectomy (n = 11), cesarean section and cholecystectomy (n = 3), cholecystectomy and appendectomy (n = 3), diagnostic laparoscopy (n = 2), myomectomy (n = 1), endometriosis surgery (n = 1) and laparoscopic tubal ligation (n = 1).

Perioperative data and follow-up outcomes are presented in Table 2. The rate of participants who underwent bilateral pelvic (±paraaortic) lymph node dissection in addition to TLH were comparable between the groups (32% vs 32.4%, P = 0.123). The number of adjuvant radiotherapies were also similar between the groups. In addition, the groups were comparable regarding the duration of operation, estimated blood loss, and duration of hospitalization. The rate of VCD in the coagulation group (1%) was similar to that of the cut group (0%). The only VCD was a partial one and it was a 1 cm defect at the left corner of the cuff. It was vaginally sutured by local anesthesia. There was no complete separation. The other vaginal cuff related complication rates were also similar between the groups.

Comment

This randomized controlled trial demonstrated that the coagulation and cut modes during colpotomy were similar to

Table 2
Perioperative factors and outcome parameters.

	Coagulation (n = 100)	Cut (n = 99)	P value
Surgical intervention, n (%)			0.123
TLH + salpingectomy	8 (8)	9 (9.1)	
TLH + BSO	60 (60)	58 (58.5)	
TLH + BSO + BP(P)LND	32 (32)	32 (32.4)	
Antibiotic prophylaxis, n (%)			0.658
Cefazoline	97 (97)	97 (98)	
Metronidazole and Ciprofloxacine	3 (3)	2 (2)	
Radiation therapy within 3 months, n (%)			0.679
Vaginal radiotherapy	12	10	
External pelvic and vaginal radiotherapy	2	1	
Chemotherapy and vaginal radiotherapy	0	1	
First intercourse postoperatively, n (%)			0.870
<6th week	3 (3)	2 (2)	
6th -12th weeks	55 (55)	53 (53.5)	
Abstinence within 12 weeks	42 (42)	44 (44.4)	
Duration of operation, min.	94 ± 30	92 ± 31	0.702
Estimated blood loss, ml	188 ± 95	174 ± 92	0.322
Hemoglobin drop after surgery, g/dL	0.8 ± 0.4	0.7 ± 0.5	0.349
Bipolar energy during colpotomy, n (%)	17 (17)	24 (24.2)	0.224
Blood transfusion, n (%)	2 (2)	3 (3)	0.682
Duration of hospitalization, days	1.7 ± 1.6	1.9 ± 0.9	0.389
Vaginal cuff dehiscence, n (%)	1 (1)	0 (0)	0.995
Vaginal cuff hematoma, n (%)	0 (0)	1 (1)	0.996
Vaginal cuff abscess, n (%)	1 (1)	0 (0)	0.995

Note: TLH: total laparoscopic hysterectomy; BSO: bilateral salphingo-oophorectomy; BP(P)LND: bilateral pelvic (para-aortic) lymph node dissection.

each other regarding VCD. The incidences of VCD were similar in the study arms and it does not support the thoughts that using monopolar energy, particularly coagulation current, is associated with increased VCD risk after TLH. In addition, we also failed to show any effect of monopolar energy mode on other vaginal cuff related complications.

One third of our patients underwent lymphadenectomy and some of them received postoperative radiotherapy. Although intraabdominal lymphatic leakage and radiotherapy suggested as predisposing factors for VCD, there were no vaginal cuff related complications even in those cases in our study population [9]. Furthermore, while the ratio of malignant cases and adjuvant therapies were similar between the two study groups, this situation could not affect the results.

There were no randomized trials comparing monopolar cut and coagulation for VCD risk. In a retrospective study, VCD rate was reported 4.1% and 0.4% by using coagulation or cut modes, respectively, after robotic hysterectomy [10]. The median thermal damage distance from colpotomy border was reported as 0.7 mm (range: 0.2 to 1.6 mm) with monopolar currents and there were no differences for thermal damage distance and vaginal cuff complications including VCD for monopolar v-mod and cut/coagulation arms [11]. We believe in that suturing of vaginal cuff from few millimeters from vaginal edge including full thickness of vaginal wall and mucosa, as described, could be enough to overcome the risk of thermal damage on VCD after TLH.

Vaginal cuff dehiscence risk was reported 3–17 times higher after TLH [1]. However, this risk become equal to other hysterectomy types if vaginal cuff was closed vaginally [12]. These results suggest that inexperience in laparoscopic vaginal cuff suturing may lead to higher VCD rates after TLH. Hur et al. reported 2.76% VCD rate after TLH between 2001 and 2005 and this rate was decreased to 0.76% between 2006 and 2009 [2]. There is an inverse correlation between VCD rate and surgeons' experience in endoscopic suturing [2]. Uccella et al. found lower VCD rate after laparoscopic closure of vaginal cuff by experienced surgeons compared to transvaginal closure (1% vs 2.7%) [13]. In addition to that, our results also suggest that standardized and proper laparoscopic suturing of vaginal cuff may decrease or avoid VCD. Minimally invasive surgeons should improve their laparoscopic suture skills. Until gaining enough skill, vaginal visualization of the cuff and when necessary additional suture through vagina might be feasible.

In addition to experience, the suturing technique was also assessed for VCD risk. Recently, Zhou et al. reported that vaginal cuff closure by unidirectional barbed suture had some advantages over interrupted vicryl suturing such as less granulation tissue, shorter operation time, and lower estimated blood loss [14]. However, they could not show a statistical difference in cuff healing time, VCD or cellulitis [14]. On the other hand, continuous suturing of the cuff was reported to have a lower risk of VCD [3]. Another important factor studied was the type of suture material. Although barbed sutures have been associated with shorter operation time and less intraoperative blood loss, the overall postoperative complication rates seem to be similar with conventional suturing [15]. However, two recent studies reported a dramatic decrease of VCD by using barbed sutures [16,17].

Although there are concerns about increased risk of VCD by using coagulation mode for colpotomy, less bleeding during colpotomy incision may provide clearer laparoscopic view and can make vaginal cuff closure easier. Also, according to our clinical observations, less smoke by coagulation mode may be advantageous during colpotomy. As mentioned above there were no unfavorable effects of these two methods on VCD and our results also showed that there were no significant adverse effects in terms of other intra- and post-operative outcomes.

The standardization of all surgical steps by a single surgeon, except using cut or coagulation current for colpotomy, was the most important strength of our study. As a limitation of our study, effects of different powers of monopolar energy was not evaluated. In addition, although VCD mostly occurs within three months postoperatively, the follow-up period of 12 weeks might be short and VCD incidence could have change with longer follow-up as it can occur even years after hysterectomy [8,13,18]. Another limitation was the design of monocentric survey with only one surgeon. Performing a multicentric study could possibly be more advantageous.

In conclusion, using cut or coagulation mode during colpotomy at TLH does not seem to be a risk factor for VCD. We suppose that VCD can be avoided by proper and standardized vaginal cuff closure technique regardless of the energy mode used for colpotomy. Future studies should focus on the quality of laparoscopic closure as a variable in VCD occurrence.

Conflicts of interest

The authors have no conflicts of interest.

Acknowledgements

None.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ejogrb.2018.12.034.

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