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Original Article

Vaginal Cuff Thermal Injury by Mode of Colpotomy at Total Laparoscopic Hysterectomy: A Randomized Clinical Trial

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ABSTRACT **Study Objective:** To evaluate if the use of Valleylab mode ("V mode") (Covidien, Mansfield, MA) electrothermal energy for colpotomy during total laparoscopic hysterectomy (LH) results in a smaller margin of thermal injury to the upper vagina compared with traditional cut/coagulate (cut/coag) electrothermal energy.
Design: Prospective randomized clinical trial (Canadian Task Force classification I).
Setting: University medical center.
Patients: A total of 101 subjects who underwent LH between June 2010 and August 2012.
Interventions: Subjects were randomized to colpotomy by V mode electrothermal energy or cut/coag electrothermal energy.
Measurements and Main Results: The primary end point was the median depth of thermal injury measured in millimeters. The secondary end points included the proportion of subjects who developed granulation tissue, induration, infection, or dehiscence at the vaginal cuff at 4 weeks, 3 months, or 6 months postoperatively. There was no significant difference in the median depth of thermal injury in the cut/coag and V mode arms (anterior margin: 0.68 mm vs 0.63 mm [p = .94], posterior margin: 0.66 mm vs 0.70 mm [p = .87], respectively). Twenty-seven percent of subjects in each arm developed at least 1 of the clinical end points at 4 weeks, 3 months, or 6 months postoperatively (granulation tissue: 6%–18% vs 8%–21%, induration: 0%–2% vs 4%–5%, infection: 0%–4% vs 0%–10%, dehiscence: 2% vs 0% in the cut/coag and V mode arms, respectively), with no difference between arms (p = 1.0).
Conclusion: The V mode does not reduce the depth of thermal injury compared with cut/coag electrothermal energy when used for colpotomy incision during total laparoscopic hysterectomy (Clinical Trials.gov ID: NCT02080546). Journal of Minimally Invasive Gynecology (2015) 22, 227–233 © 2015 AAGL. All rights reserved.

Keywords: Electrothermal injury; Total laparoscopic hysterectomy; Vaginal cuff dehiscence

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Total laparoscopic hysterectomy (LH) is a minimally invasive procedure that has been used for benign gynecologic surgery for almost 30 years. It has become increasingly popular in gynecologic oncology surgery since the presentation of the LAP2 study results in 2006. LAP2 was a randomized clinical trial comparing laparoscopic endometrial cancer staging (hysterectomy, bilateral salpingo-oophorectomy, bilateral pelvic and para-aortic lymphadenectomy) to open endometrial cancer staging. This study showed that minimally invasive hysterectomy and staging techniques were a feasible and safe alternative to staging via laparotomy for the surgical

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treatment of endometrial cancer [1]. The advantages of LH over TAH include decreased blood loss, earlier return of bowel function, fewer wound complications, shorter hospital stay, faster return to normal activities, and improved quality of life [1–6]. However, several authors have reported increased vaginal cuff dehiscence rates among patients undergoing LH compared with TAH or vaginal hysterectomies (VHs) [7–10]. Although this is a rare adverse event, with an incidence of <5% in most series, it can be complicated by evisceration of the bowel through the vagina requiring immediate surgical repair and may also result in vaginal cellulitis, vaginal cuff abscess, and chronic pain.

There are multiple known risk factors for vaginal cuff dehiscence including smoking, infection (vaginal cuff cellulitis or abscess), chronic steroid use, immunocompromised states, increased intra-abdominal pressure, low body mass index (BMI), chemotherapy, radiation therapy with a vaginal cylinder, vaginal atrophy, and early intercourse after hysterectomy [8,9,11–14]. The use of electrothermal energy for colpotomy and/or insufficient tissue incorporation during closure of the vaginal apex at the time of hysterectomy have been hypothesized as reasons for the increase in vaginal cuff dehiscence reported in LH [8,9,12,13,15–18]. Unlike other hysterectomy procedures in which a knife or scissors without an energy source is used to amputate the cervix from the upper vagina, the colpotomy incision in LH is often accomplished using electrothermal energy to minimize blood loss, which can obscure the laparoscopic surgical field. Animal studies have shown delayed wound healing with the use of electrothermal energy compared with the use of a scalpel [19,20], and it has been hypothesized that the thermal injury to the adjacent tissue caused by electrothermal energy at the time of colpotomy may weaken the vaginal cuff and potentially compromise any closure that is performed [8–11,13,17].

Electrothermal energy has traditionally consisted of a surgeon's choice between "cut" (continuous low-voltage, high-current) and "coagulate" ("coag," pulsed high-voltage, low-current) modes. However, the newer Valleylab mode ("V mode") (Covidien, Mansfield, MA) combines real-time tissue sensing technology with a modified lower mean voltage coag waveform to reduce the amount of thermal spread to the tissue without sacrificing hemostasis during monopolar electrothermal procedures. We hypothesized that the use of V mode electrothermal energy for colpotomy would reduce thermal injury at the upper vagina. The goals of this randomized clinical trial were to evaluate if the use of V mode for colpotomy during LH results in a smaller margin of thermal injury to the upper vagina and to evaluate the effects on the formation of granulation tissue, vaginal cuff induration and infection, and vaginal cuff dehiscence.

Materials and Methods

A prospective randomized clinical trial was designed to compare the use of cut/coag with V mode for colpotomy incision during LH. The study was approved by the Duke University Institutional Review Board. The primary outcome of the study was the histologically measured total depth of thermal injury at the vaginal cuff margin of the hysterectomy specimen. Secondary end points were the presence of granulation tissue, induration, infection, and vaginal cuff dehiscence. Subjects who were scheduled to undergo LH for benign or malignant indications were randomized 1:1 using a permuted block design to colpotomy using traditional cut/coag or colpotomy using V mode. Patients undergoing robotic-assisted LH were excluded from participation in the study because cut and V mode were not available using the institution's robotic platform during the study time period of accrual. Additionally, patients were excluded from analysis if they had been diagnosed with a pelvic infection within 30 days before surgery or if the procedure was converted to laparotomy before the creation of the colpotomy incision. All surgeries were performed at a single large academic institution by 1 of 5 gynecologic oncologists or a single gynecologist in the Division of Minimally Invasive Gynecologic Surgery. All participants in the study provided a written informed consent that was approved by the Duke University Institutional Review Board.

Randomization was performed, and surgeons were informed of the randomization on the day before the scheduled procedure. The recommended electrothermal energy settings were 35 to 40 W for cut, coag, and V mode due to individual surgeon preference. In the cut/coag arm, colpotomy incision was made by applying a single layer of electrothermal energy using the coag mode circumferentially followed by the application of electrothermal energy using the cut mode until the cervix was completely separated from the vagina, as is the standard practice at our institution to optimize hemostasis while decreasing thermal spread. Subjects in the V mode arm had the entire colpotomy incision made with application of V mode electrothermal energy. The technique and suture for closure of the vaginal cuff were left to the discretion of the surgeon to achieve optimal cuff closure using the technique most familiar to the surgeon, and this information was collected. Subjects were instructed not to lift anything weighing greater than 10 lb for 6 weeks and to refrain from sexual intercourse for a minimum of 8 weeks after surgery.

The study pathologist was blinded to the mode of electrothermal energy used. To determine the depth of thermal injury, anterior and posterior vaginal cuff blocks from the hysterectomy specimen were examined by a single blinded gynecologic pathologist. Hematoxylin-eosin staining was performed to identify areas of thermal injury. Sections of the specimen were then stained with picrosirius red dye (Poly Scientific, Bay Shore, NY) to confirm the area of thermal injury. Under polarized light, the intact collagen fibers are birefringent, whereas the degraded or injured collagen fibers appear dark (Fig. 1) [21]. Thermal injury was measured from the cut edge in millimeters. The greatest depth of injury for each specimen was recorded in millimeters, and the median depth was calculated for each mode of energy.