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Long-term outcomes for different vaginal cuff closure techniques in robotic-assisted laparoscopic hysterectomy: A randomized controlled trial

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ABSTRACT

Objective: This randomized controlled trial aimed to evaluate the outcomes of different vaginal cuff closure techniques in robotic-assisted total laparoscopic hysterectomy.
Study design: Ninety women undergoing robotic-assisted total laparoscopic hysterectomy for benign disease were randomized to three vaginal cuff closure techniques: running 2.0 V-Lock™ (Arm 1), 0 Vicryl™ figure-of-eight (Arm 2), and running 0 Vicryl™ with Lapra-Ty® (Arm 3). Patients' records were reviewed for age, body mass index, smoking status and relevant co-morbidities. Operative times for vaginal closure and total length of surgery, estimated blood loss, and peri-operative complications were collected. Patients were evaluated at 2 and 6 weeks post-operatively, and interviewed 1 year following surgery by a telephone survey. Outcomes evaluated were vaginal cuff dehiscence, pain, dyspareunia and bleeding.
Results: The study arms did not differ with respect to estimated blood loss (50 mL in each arm; $p = 0.34$), median vaginal cuff closure time (14.5, 12 and 13 min, respectively; $p = 0.09$) or readmission ($p = 0.55$). In the 1-year follow-up (54/90 respondents; 60%), there were no significant differences among study arms for vaginal bleeding, cuff infection or dyspareunia. Only women belonging to arm 3 reported vaginal pain (0%, 0% and 23%, respectively; $p = 0.01$). No cases of vaginal cuff dehiscence were observed.
Conclusions: The type of closure technique has no significant impact on patient outcomes. In the absence of a clear advantage of one technique over the others, the decision regarding the preferred method to close the vaginal cuff in robotic-assisted total laparoscopic hysterectomy should be based on surgeons' preference and cost effectiveness.

Introduction

The surge of minimally invasive hysterectomy in recent years has been associated with reports of impaired vaginal cuff healing [1–3]. These studies documented vaginal cuff dehiscence (VCD) rates of 1.3%–4.9% for laparoscopic and robotic-assisted laparoscopic total hysterectomy (RTH), compared to 0.29% and 0.12% for vaginal and abdominal hysterectomy respectively [1–3]. Electrosurgical colpotomy resulting in necrosis and tissue breakdown of the cuff has been hypothesized to contribute to VCD [1,2]. However, histopathologic studies do not show a consistent relationship between specific energy sources and extent of thermal damage; nor do retrospective clinical trials demonstrate an association between specific energy sources and VCD rate [4–9].

Other studies ascribe increased VCD to laparoscopy in general, wherein the technical difficulty achieving adequate tissue capture and secure knots may result in compromised tissue approximation [8,10]. The introduction of barbed sutures has been shown to reduce operative time, blood loss and vaginal dehiscence rates during laparoscopic or robotically-assisted hysterectomy [7,9,11].

Few studies have evaluated the effects of different vaginal cuff closure techniques on long-term outcomes in RTH. Only three randomized controlled trials assessed this clinically important aspect, focusing mostly on short-term outcomes. We therefore

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conducted a randomized controlled trial to evaluate the short- and long-term clinical outcomes of different vaginal closure techniques described in the literature. Our hypothesis was that suturing technique does not impact rates of adverse events of vaginal cuff closure after RTH. The primary objective of this study was to evaluate the occurrence of VCD. We compared barbed suture to interrupted and continuous braided sutures, up to one year post-operatively. The secondary clinical outcome measures were vaginal cuff closure time, peri-operative bleeding and other complications, continuous pain, dyspareunia and vaginal bleeding or discharge.

Additionally, we conducted a cost analysis of the different vaginal closure techniques and materials, as a system-based practice outcome.

Material and methods

Trial design and participants

All women scheduled for RTH at Henry Ford West-Bloomfield Hospital, an affiliated teaching hospital, Henry Ford Health System, Detroit, Michigan were invited to participate. The enrollment period was October 2010–April 2012. Patients who were scheduled for concomitant uro-gynecological procedures or had RTH due to non-benign indications were excluded. The study was approved by the institutional review board (IRB# 6297, September 4, 2010) and registered at clinicaltrials.gov (registration number NCT02696239). All women who agreed to participate in the study gave written informed consent.

Patients were randomized using a computer-generated list. Prior to each case, a sealed envelope distributed to the surgical team contained the vaginal closure technique to be implemented: barbed suture (V-lock; V-Lock™ 90 absorbable wound closure device, Covidien, Mansfield, MA; http://www.medtronic.com/covidien/products/wound-closure/barbed-sutures), interrupted (Vicryl) suture (Vicryl™; Ethicon Endosurgery, Cincinnati, OH; http://www.ethicon.com/healthcare-professionals/products/wound-closure/absorbable-sutures/coated-vicryl-polyglactin-910-suture), or continuous suture (Vicryl™ suture with Lapra-Ty®; Ethicon Endosurgery; http://www.ethicon.com/healthcare-professionals/products/wound-closure/suture-assist/lapra-ty). Each group consisted of 30 patients. Three attending surgeons in the division of minimally invasive gynecologic surgery, well-versed in RTH surgeries, performed the procedures (Fig. 1).

Surgical techniques

All groups underwent robotic hysterectomy using monopolar scissor and advanced vessel sealer during the dissection. Colpotomy was performed with monopolar scissors using a radio-frequency energy setting of 35 W over a colpotomy cup attached to a uterine manipulator. For the barbed suture group, two 9-in. V-Lock™ sutures anchored to each angle of the vaginal cuff by the loop at the end of each suture, were run to the midline and back to

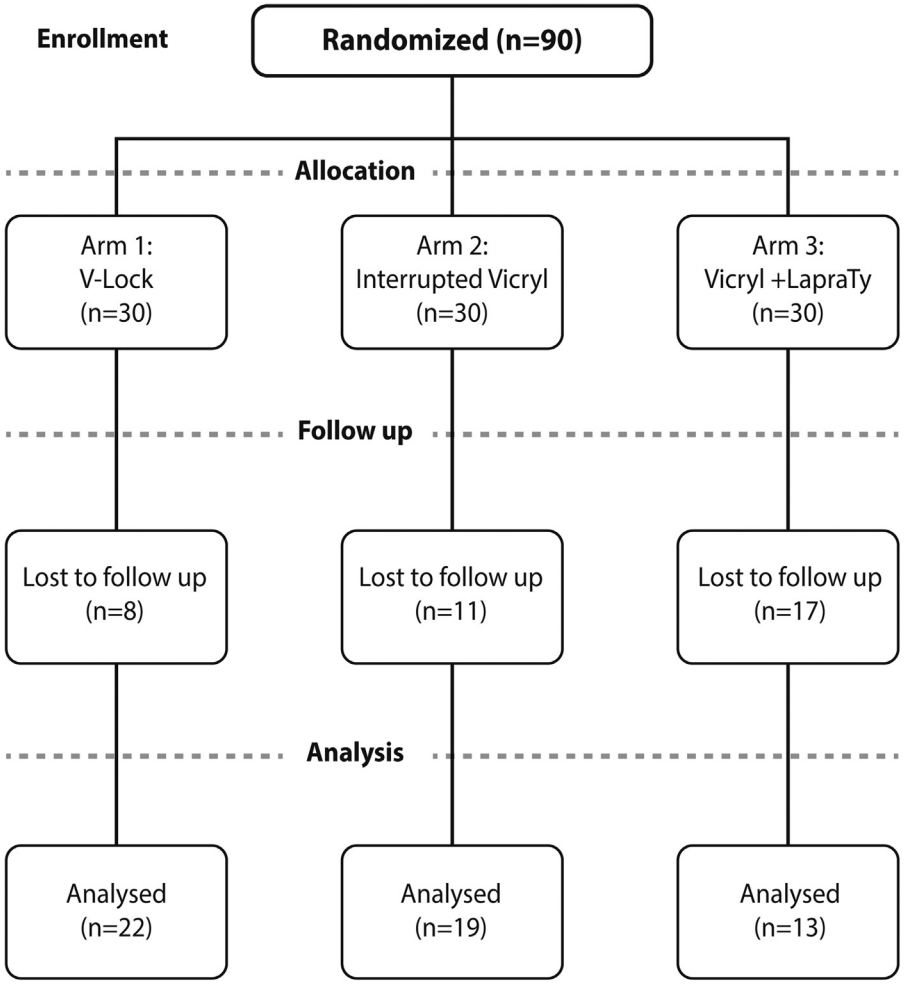

Fig. 1. The study flow diagram.