Original Article *นิพนธ์ต้นฉบับ*

Comparison of Conventional Suture versus Electrosurgical Bipolar Vessel Sealing in Abdominal Hysterectomy: A randomized Control Trial

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Abstract Electrosurgical bipolar vessel sealing has been used in many fields of surgery. This presented trial was randomized controlled trial comparing the effects of conventional suturing and electrosurgical bipolar vessel sealing (BiClamp) in women undergoing abdominal hysterectomy for benign conditions. Sixty patients undergoing abdominal hysterectomy (with or without salpingo-oopherectomy) for benign conditions were performed. The patients were randomized to conventional suture (n = 30) or BiClamp (n = 30). Demographic data showed no statistical difference between the two groups. The mean operative time in conventional suture group was 92.3, SD26.54 minutes versus 70.03, SD 21.06 minutes for Biclamp group ($p<0.001$). Mean intraoperative blood loss in conventional suture group was 357, SD 245.34 ml versus 248.33, SD 154.52 ml for Biclamp group (p 0.04). The requirement of surgical sutures was highly significant lower in BiClamp group than in conventional suture group (mean 7.27 units versus 10.77 units, $p<0.001$). No significant differences in number of blood transfusion units, length of hospital stay, perioperative and postoperative complications were found in both groups. Postoperative pain was no different between the two groups in the first 12 hours after surgery but highly significant lower in the BiClamp group than in the conventional suture group at 24 hours after surgery. In conclusion, EBVS is an expensive but convenient instrument. The use of BiClamp in abdominal hysterectomy can reduce operative time, blood loss and postoperative pain,it allows faster but is equally safe compare with conventional suture ligature. Furthermore this procedure needs less suture materials that can overcome an expensive cost if used in the regional hospital that have high volume of patients.

Key words: **BiClamp, abdominal hysterectomy, bipolar vessel sealing**

Introduction

During the past few years, a variety of energy-based techniques for vessel ligation have been developed. Electrosurgical bipolar vessel sealing (EBVS) has become established in both open and laparoscopic surgery. A variety of studies have indicated that the technique is capable of safely sealing vascular structures with diameters up to 7 mm. by denaturing col-

lagen and elastin within the vessel wall and in the surrounding connective tissue.[1-3] Several experimental studies have proven that vessel sealing provides an excellent seal, resistant to supra physiological (burst) pressure (601 mmHg at 4-5 mm. vessels and 442 mmHg at 6-7 mm. vessels), with little lateral thermal tissue damage.[2-7] The system has been used in thoracic surgery[8], hemorrhoidectomy[9], biliary surgery and gastric cancer resection.[10] Several advantages of the use of EBVS during vaginal hysterectomy such as less blood loss, reduced postoperative pain, and shorter admission stay were documented.[11-15] Only few randomized trials have compared conventional suturing and EBVS in patients undergoing abdominal hysterectomy for benign conditions. Hagen et al. had reported trial in 2005 that no differences with respect to duration of surgery, amount of blood loss, and complications between the two methods.[16] This trial included only 30 patients (15 for each arm). The use of vessel sealing during abdominal hysterectomy for benign conditions associated with reduced postoperative pain and faster recovery had been reported.[17] The study had been conducted in 2 teaching hospitals by ten different surgeons. Therefore a randomized controlled trial was conducted to assess the benefit of new technology; electrosurgical bipolar vessel sealing (ERBE VIO 300D BiClamp (Erbe, Tubingen, Germany)) versus conventional suturing in women undergoing abdominal hysterectomy for benign conditions.

Methods

This was a prospective randomized controlled trial study, approved by Vachira Phuket hospital medical ethics and research committee. In all, 60 patients aged 30-80 years were undergoing abdominal hysterectomy (with or without salpingo-oopherectomy) for benign conditions in Vachira Phuket Hospital between November 2010 and December 2011 were enrolled. The surgery were performed by two experienced gynecologists. Exclusion criteria included coagulation defect, severe underlying diseases and patients whose diagnoses or type of operations were changed after surgery. Primary outcome was operative time. Secondary outcomes were intraoperative blood loss, blood transfusion requirement, intraoperative complications, postoperative complications, length of hospital stay and postoperative pain. A priori calculation to determine sample size was based on historical data from the Division of Obstetrics and Gynecology Vachira Phuket Hospital. With a power of 80 percent and α level of 0.05, the calculated sample size necessary was 56 (28 in each group). So this sample size was designed 30 cases per group or 60 cases in total. After the patients had given informed consent, assignment to treatment arms was determined based on a computer-generated randomization table. Block randomization was performed to certify that both interventions were equally distributed over two operating surgeons. Thirty patients for each surgeon were assigned into two groups (15 in conventional suture group and 15 in BiClamp group). An assignment of treatment was known only to surgeon. The patients and nursing staff were blinded for treatment allocation. Preoperative physical examination, counseling and preoperative laboratory tests were performed before admission. Patients were admitted in the hospital one day before surgery. Baseline characteristics (age, BMI, parity, menopausal status, previous abdominal surgery, incision and indication) were obtained. Others parameters such as operative time, intra operative blood loss, unit of blood transfusion, number of suture required, intraoperative complications, postoperative complications, length of hospital stay and visual analogue scale (VAS) pain scores were recorded during and after surgery. Visual analogue scale (VAS) pain scores is a 10 cm scale with anchor points at 0-10 cm (0 = no pain and 10 = worst possible pain) were recorded 1,2,6,12

and 24 hour at rest after surgery by nurses who did not know the type of operation. Patients who had VAS pain scores more than 5 or requesting medication for pain, morphine 0.1 mg/ Kg intramuscular every 6 hour were provided. Intraoperative blood loss were assessed by anesthesiologists.

Surgical Technique

General anesthesia with endotracheal intubation were employed in all patients. One gram of ampicillin was given intravenously as an prophylaxis antibiotic at 30 minutes before operation. In conventional suturing, total abdominal hysterectomy with or without salpingo-oophorectomy was performed according to a standardized surgical technique.[18]

If the procedure was performed using EBVS, BiClamp was used to seal the pedicle by double seals and cut in the middle of these 2 seals instead of clamp cut and suture ligated. After the uterus was removed, the cuff is closed by interrupted stitches. The angle of vaginal cuff was sutures with uterosacral and cardinal ligament to ensure hemostasis and support of the vaginal cuff as in conventional suture method. The peritoneum was sutured by continuous stitch. Abdominal wall was closed layers by layers.

Statistical analysis

Statistical analysis was done and presented in mean, standard deviation (SD) and percentage. The patients' characteristics, surgical outcomes and VAS pain scores between the two groups were compared. Comparative data from each group were analyzed by using student's t-test, Fisher's exact test and chi's squre test. Statistical significance was defined when $p<0.05$.

Results

A total of 60 patients were enrolled and randomized equally to both the Biclamp and the conventional suture groups. Baseline characteristics of the randomized patients are summarized in Table 1 which showed no statistical differences between the two groups.

Mean operative time for hysterectomy with the conventional suture group was significantly longer than the BiClamp group (92, SD 26.54 minutes vs 70.03, SD21.06 minutes; $p<0.001$).

Intraoperative blood loss as assessed by anesthesiologists was lower in the BiClamp group compared to the conventional suture group (248.33, SD 154.52 ml vs 357.00,SD 245.34 ml; p 0.04), as shown in Table 2.

The blood transfusion requirement were not different between both groups. Only two patients in the BiClamp group and three patients in the conventional suture group required blood transfusion.

Need of suture material, as expected, was significantly lower in the BiClamp group than in the conventional suture group (7.27, SD1.14 units vs 10.77, SD 1.57 units; $p<0.001$). The difference may be cost effective in high volume hospital in which more patients underwent operation with BiClamp.

Intraoperative and postoperative complications were not different in the two groups. One patient in the BiClamp group sustained a bladder injury due to previous caesarean section and significant bladder adhesion to the anterior peritoneum. The bladder lesion was recognized and repaired during the primary surgery. However the injury was not related with the vessel sealing procedure. There was no serious intra and postoperative complications reported in both groups.

The length of hospital stay in the BiClamp group was slightly shorter than that in the conventional suture group (4.13, SD 0.35 days vs 4.4, SD 0.67 days), but did not reach statistical significance.

Postoperative pain was not different in both groups in the first 12 hours after surgery. However after 24 hours, patients who underwent operative procedure with BiClamp reported a significant less pain

Table 1 Baseline characteristics of patients undergoing abdominal hysterectomy assigned to conventional surgery or vessel sealing

	conventional (n=30 cases)	**BiClamp (n=30 cases)**	**p-value**
age(year) mean, SD (range)	43.97, 5.57 (34-59)	46.00, 7.73 (38-75)	0.24*
parity(n) mean, SD (range)	1.8, 1.54 (0-5)	1.6, 1.43 (0-6)	0.6*
postmenopausal (n,%)	2, 6.67	5, 16.67	0.42**
BMI (kg/m^2) mean, SD (range)	25.19, 5.41 (17.8-39)	24.67, 3.08 (18.4-29)	0.65*
previous abdominal surgery			0.66***
No (n,%)	20, 66.67	20, 66.67	
TR (n,%)	5, 16.67	7, 23.33	
Explore Laparotomy (n,%)	5, 16.67	3, 10	
incision			0.59***
Low midline (n,%)	18, 60	20, 66.67	
Pfannenstiel (n,%)	12, 40	10, 33.33	
indication			0.48***
Myoma (n,%)	23, 76.67	21, 70	
Adenomyosis (n,%)	4, 13.33	6, 20	
Endometriosis (n,%)	3, 10	1, 3.33	
Endometrial hyperplasia (n,%)	0, 0	1, 3.33	
adnexal mass (n,%)	0, 0	1, 3.33	

BMI = body mass index; TR = tubal resection
**student's t-test*
***Fisher's exact test*
****chi-square test*

Table 2 Comparison of surgical outcomes

	Conventional (n=30 cases)	**BiClamp (n=30 cases)**	**p-value**
operative time (min) mean, SD (range)	92.3, 26.54 (46-160)	70.03, 21.06 (40-140)	< 0.001*
blood loss (ml) mean, SD (range)	357.00, 245.34 (50-1000)	248.33, 154.52 (50-700)	0.04*
blood transfusion (unit) mean, SD (range)	0.23, 0.68 (0-3)	0.1, 0.4 (0-2)	0.36*
surgical suture (unit) mean, SD (range)	10.77, 1.57 (8-15)	7.27, 1.14 (5-9)	< 0.001*
intra op complication			
bladder injuries (n,%)	0, 0	1, 3.33	1**
post op complication			
infected wound (n,%)	2, 6.67	1, 3.33	1**
infected vaginal stump (n,%)	1, 3.33	1, 3.33	1**
length of hospital stay (day) mean, SD (range)	4.4, 0.67 (4-6)	4.13, 0.35 (4-5)	0.06*

**student's t-test*
***Fisher's exact test*

Table 3 VAS of postoperative pain

Postoperative Vas pain score	conventional (n=30 cases)	BiClamp (n=30 cases)	p-value
at 1 hr	4.21, 2.26 (0-10)	5.17, 2.26 (0-8)	0.11*
at 2 hr	4.9, 2.28 (0-10)	4.33, 2.20 (0-10)	0.33*
at 6 hr	5.5, 1.48 (2-10)	5.17, 1.78 (1-10)	0.43*
at 12 hr	5.03, 1.90 (0-10)	4.2, 1.52 (1-8)	0.07*
at 24 hr	4.93, 1.05 (3-8)	3.53, 1.14 (1-5)	<0.001*

remark : data reported in mean, SD (range)
**student's t-test*

than those in the conventional suture group. One of the explanation may be from lower reaction from suture material. However this was not related to shorter period in the hospital stay.

Discussion

Electrosurgical vessel sealing was demonstrated to have more advantage than conventional suturing method in its convenience. In the early study, EBVS did not showed its benefit over conventional suturing method in abdominal hysterectomy for benign conditions. However during that period, in which EBVS was just introduced, the experience of surgeon was one of the obstacles.[16] Even with the problem of experience, in vaginal hysterectomy, EBVS still showed some of the benefit such as less operative time and blood loss than in the conventional suture group.[12,14,15] EBVS was introduced to Thailand some years ago and was used for surgery in many benign conditions. With the workload in surgical services, EBVS is used as the standard procedure in many surgical procedures due to surgeon's beliefs in its convenience in sealing method without suture. Several questions were addressed during its introduction period. Most frequent questions are the doubts in its efficiency in sealing procedure against the conventional suturing ligation and complications of this new vessel sealing method. However, because of its convenience to use, EBVS is still used in many operations including abdominal hysterectomy. This study was therefore conducted to assess the efficacy of EBVS. The study performed in abdominal hysterectomy by two experienced surgeons who had extensive experiences in both methodologies of surgical methods.

This study demonstrated that with the equal experiences in both methods, EBVS was easier to use therefore it ended up with significant less operative time than the conventional method. In term of complications, EBVS group showed less blood loss than conventional suture group. This finding is contrary to the earlier study in which EBVS was just introduced and the experiences of users were still limited.[16,17] However during that time in the complicated cases such as in vaginal hysterectomy, EBVS still showed benefit in less blood loss than the conventional method.[12,14,15] However this finding did not show any differences in blood transfusion, intraoperative and postoperative complications, and length of hospital stay. One important parameter that indicated an indirect benefit of EBVS is less pain in this group. In the first, second, sixth and twelfth hours, no significant differences in pain report in both groups. However after 24 hours, the pain score in the conventional group was much higher. The possible mechanism is less healing reaction in EVBS group due to less injury to surrounding tissue during operating process performed

by EBVS. An earlier study demonstrated that heat production from EBVS effected nearby tissue surrounding sealing point within less than 1.5 millimeters from that point.[3] Whereas in conventional suturing method the injury occurs may include tissue and nerve compression from clamping and suturing during operative procedure. Patients underwent EBVS sealing procedure require less recovery period than those in the conventional suture group.[17] All of these procedures and effects may contribute to delay in pain from tissue reaction. After follow up period up to 1 month, some minor complications such as stump and wound infections were found equally in both groups. Last but not least, concerning the economical aspect, EBVS does not need suture material during sealing vessels procedure. Yet in small hospital, the benefit is not large enough to cover the investment cost of this instrument. On the contrary, in a regional hospital with large volume of patients, the benefit may be significant enough to render such investment cost-effective.

In conclusion, EBVS is an expensive but convenient instrument that can be used in varieties of surgical procedures. With more experiences, EBVS demonstrates more benefits than conventional suturing methods in many ways for abdominal hysterectomy. The method provides a convenient procedure for vessels sealing resulting in less operative time, less blood loss and less postoperative pain. Furthermore this procedure needs less suture materials that can overcome an expensive cost if use in hospitals with high volume of patients. Even expensive, but its convenience and other direct and indirect benefits can overcome its disadvantage on high price. Therefore EBVS is suitable to be used for abdominal hysterectomy without serious complications in a regional hospital.

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บทคัดย่อ **การเปรียบเทียบผลการผ่าตัดมดลูกทางหน้าท้องระหว่าง วิธีเย็บผูกหลอดเลือดแบบปกติและการใช้คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า : การวิจัยแบบสุ่มมีกลุ่มเปรียบเทียบ**

ชาญชัย สุประสงค์สิน, มนตรี บุญยกิตานนท์

กลุ่มงานสูติ-นรีเวชกรรม โรงพยาบาลวชิระภูเก็ต

วารสารวิชาการสาธารณสุข **2555; 21:415-22.**

ในการผ่าตัดหลายสาขาได้ใช้คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้าอย่างแพร่หลาย การศึกษาแบบสุ่มมีกลุ่มเปรียบเทียบนี้ เปรียบเทียบผลของการผ่าตัดมดลูกออกทางหน้าท้องโดยใช้วิธีเย็บผูกหลอดเลือดแบบปกติและใช้คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า ในภาวะที่ไม่ใช่มะเร็ง แบ่งผู้ป่วยที่ได้รับการรักษาโดยการผ่าตัดมดลูกทางหน้าท้อง (อาจร่วมกับการตัดปีกมดลูกและรังไข่) 60 ราย เป็นสองกลุ่มโดยการสุ่ม คือ กลุ่มที่ใช้วิธีเย็บผูกเส้นเลือดแบบปกติจำนวน 30 รายและกลุ่มที่ใช้คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า จำนวน 30 ราย ข้อมูลพื้นฐานทั่วไปไม่แตกต่างกันระหว่างสองกลุ่ม ค่าเฉลี่ยของเวลาที่ใช้ในการผ่าตัดในกลุ่มเย็บผูกหลอดเลือดแบบปกติ คือ 92.3, SD 26.54 นาที เทียบกับ 70.03, SD 21.06 นาที ในกลุ่มคีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า ($p < 0.001$) ค่าเฉลี่ยของจำนวนเลือดที่เสียไปในการผ่าตัดในกลุ่มเย็บผูกเส้นเลือดแบบปกติ คือ 357, SD 245.34 มิลลิลิตร เทียบกับ 248.33, SD 154.52 มิลลิลิตร ในกลุ่มคีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า (p 0.04) กลุ่มคีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า ใช้วัสดุผูกเย็บเส้นเลือดในการผ่าตัดน้อยกว่ากลุ่มเย็บผูกหลอดเลือดแบบปกติ (ค่าเฉลี่ย 7.27 หน่วย เทียบกับ 10.77 หน่วย, $p < 0.001$) ไม่พบความแตกต่างของจำนวนเลือดที่ให้ทดแทน ระยะเวลาการพักในโรงพยาบาล ผลข้างเคียงระหว่างการผ่าตัดและภายหลังการผ่าตัด ระหว่างสองกลุ่ม ความเจ็บปวดภายหลังการผ่าตัดไม่แตกต่างกันเมื่อเวลา 1 ชั่วโมง 2 ชั่วโมง 6 ชั่วโมง และ 12 ชั่วโมง แต่ในกลุ่มคีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้ามีความเจ็บปวดภายหลังผ่าตัด เมื่อเวลา 24 ชั่วโมง น้อยกว่าในกลุ่มวิธีเย็บผูกเส้นเลือดแบบปกติ สรุป คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้าเป็นเครื่องมือที่มีราคาแพงแต่สะดวกในการผ่าตัด การใช้คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้าในการผ่าตัดมดลูกทางหน้าท้องสามารถลดเวลาที่ใช้ในการผ่าตัด ลดการเสียเลือดระหว่างการผ่าตัด ลดความเจ็บปวดภายหลังการผ่าตัด วิธีนี้ทำให้การผ่าตัดเร็วขึ้น และปลอดภัยเทียบเท่าวิธีเย็บผูกเส้นเลือดแบบปกติ นอกจากนี้การใช้วัสดุผูกเย็บเส้นเลือดน้อยลงจะคุ้มค่ากับเครื่องมือราคาแพงนี้ถ้าใช้ในโรงพยาบาลศูนย์ ซึ่งมีผู้ป่วยจำนวนมาก

คำสำคัญ: **คีมเชื่อมปิดหลอดเลือดด้วยไฟฟ้า, การผ่าตัดมดลูกทางหน้าท้อง**