

LigaSure versus Conventional Suture Ligature for Vaginal Hysterectomy: a Randomized Controlled Trial

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Abstract

Introduction: Vaginal hysterectomy is considered to be the method of choice for removal of the uterus. Of particular concern for the vaginal surgeon is the ability to access, visualize, and ligate structures while maintaining adequate hemostasis. Surgical hemostasis can be secured by a variety of methods, including mechanical means (sutures) or vessel coagulation (diathermy). Electro-surgical vessel sealing (LigaSure) is a new hemostatic system based on the combination of pressure and bipolar electrical energy and is able to seal vessels up to 7 mm in diameter.

Objective: To assess the safety and efficacy of using the LigaSure vessel sealing system for securing the pedicles during vaginal hysterectomy in comparison with the conventional method of securing the pedicles by suture ligation.

Design: Prospective randomized controlled trial.

Setting: Obstetrics and Gynecology departments (Al-Kharj University Hospital- KSA, Enjab Hospital - UAE and Gulf Medical College and Research Centre- UAE).

Methods: 80 patients undergoing vaginal hysterectomy for benign conditions were randomized to either LigaSure group (n=40) or Suture group (n=40).

Main outcome measures: The primary outcome measures were the operative time and blood loss while the secondary outcome measures were the hospital stay and intra- and post-operative complications.

Results: Patients in the LigaSure group had a significantly reduced operating time (37.1 ± 8.9 min vs. 63.8 ± 10.9 min; $P < 0.001$), operative blood loss (125.5 ± 33.2 mL vs. 264.6 ± 70.4 mL; $P < 0.001$), requirement of surgical sutures (1.2 ± 0.4 units vs. 8.2 ± 0.4 units; $p < 0.001$), pain status (2.0 ± 0.6 vs. 3.7 ± 0.7 ; $P < 0.001$), and hospital stay (30.3 ± 2.5 h vs. 45.7 ± 10.5 h; $P < 0.001$) compared to the control group. The overall complication rate in the study was 10 % (8/80), and did not differ between patients of the LigaSure and control group.

Conclusion: The use of LigaSure device can reduce operative time. It allows faster, safe and effective hemostasis compared with the conventional suture ligature. It also reduces the operative blood loss, pain status and hospital stays.

Key Words: LigaSure (Electro-surgical vessel sealing).

Introduction

Vaginal hysterectomy is considered to be the method of choice for removal of the uterus (Richardson *et al* 1995 & Doucette *et al* 2001). Although it has been shown to be associated with significantly fewer complications, shorter

hospital stay and faster recovery than abdominal hysterectomy, recent studies have shown that less than one-third of hysterectomies are performed vaginally (Maresh *et al* 2002 & Farquhar *et al* 2002).

A number of pre-existing clinical conditions are generally accepted as contraindications to vaginal hysterectomy as nulliparity or no prior vaginal delivery and adnexal diseases or the indication to oophorectomy (Doucette *et al* 2001). Moreover, vaginal hysterectomy is not frequently performed in patients with large uterine size (Unger *et al* 1999). This could be because the vaginal route offers relatively limited space for surgical access to vascular pedicles and thus surgeons have greater confidence in operating via the abdominal route (Dorsey *et al* 1995 & Kovac *et al* 2000).

Of particular concern for the vaginal surgeon is the ability to access, visualize, and ligate structures while maintaining adequate hemostasis. Surgical hemostasis can be secured by a variety of methods, including mechanical means (sutures) or vessel coagulation (diathermy). Electro-coagulation diathermy is unreliable for vessels larger than 2 mm in diameter (Kennedy *et al* 1998). Therefore; suture ligation is preferred for securing larger vascular pedicles. However, it can be time-consuming as the pedicles need to be clamped, cut, and ligated.

Electro-surgical vessel sealing (LigaSure Valleylab, Boulder, CO) is a new hemostatic system based on the combination of pressure and bipolar electrical energy and is able to seal vessels up to 7 mm in diameter. The current delivered to achieve hemostasis takes between 2 and 7 seconds, and hence, can be relatively faster compared with suture ligation. The electrosurgical vessel sealing systems had been used in a range of non gynecologic surgical procedures, (Palazzo *et al* 2002 & Horgan 2001), in abdominal hysterectomy (Petrakis 2005) and in vaginal hysterectomy (Hefni *et al* 2005 & Zubke *et al* 2004) with encouraging results.

The aim of the present study was to evaluate the safety and efficacy of the LigaSure device for securing the pedicles at vaginal hysterectomy.

Patients and methods

This prospective study was conducted between June 2008 to May 2011, at the Obstetrics and Gynecology departments (Al-Kharj University

Hospital- KSA, Enjab Hospital- UAE and Gulf Medical College and Research Centre- UAE).

The study protocol was approved by Hospital Ethics Committee in each setting. Eighty women admitted for vaginal hysterectomy for benign disease were participated in the study and enrolled after informed and written consent. The exclusion criteria were: uterine size greater than 14 weeks, suspected uterine, cervical or ovarian malignancy and/or obliteration of pouch of Douglas due to severe endometriosis.

Patients who participated in the study were randomized to either using the LigaSure procedure (study group = 40) or conventional suturing (control group = 40) during vaginal hysterectomy. Randomization was performed using a list of computer-generated random numbers and participants were assigned to their groups using sealed envelopes that were opened just before starting the procedure. Sample size was calculated as 40 subjects in each group (total 80) to give the study 80% power to detect a 20% difference in procedure times between the two groups. The 20% difference in times was chosen as this was the percentage of reduction in a previous randomized controlled trial Cronje *et al* 2005. According to our protocol, each patient received single dose of a prophylactic antibiotic agent (1.5 gm Cefuroxime and 500 mg Metronidazole) intravenously at induction of anesthesia and low molecular weight subcutaneous heparin prophylaxis against thromboembolism.

Surgical technique

All patients were given general anesthesia. The woman was placed in the gynecologic position, with her thighs at an angle of 90 degrees. The patient's buttocks were positioned at the edge of the table. The operative field was cleaned with a standard antiseptic agent. A urinary catheter was left in place during the operation. Four retractors were positioned into the vagina to expose the cervix that was firmly grasped. Twenty milliliters of 1:200,000 adrenalin in normal saline was infiltrated under the vaginal mucosa. A circular incision was made around the cervix, the pouch of Douglas was opened posteriorly and anteriorly, and the bladder was separated from the uterus. After this step,

either the LigaSure device or conventional 'clamp, cut and suture' technique was used for securing the hysterectomy pedicles.

The LigaSure device consists of a bipolar radio-frequency generator, a reusable hand-piece and disposable electrodes. The generator delivers a low voltage high power current, using continuous feedback and computerized algorithm that recognizes vessel sealing by alterations in tissue impedance. The electrodes on the hand-piece were placed across the hysterectomy pedicles (uterosacral-cardinal, uterine and ovarian and round ligaments) so that the tissue was interposed between the jaws of the hand-piece in the centre of the electrode. The handle was then closed until it latched in place in the tightest ratchet position. The coagulation foot pedal was pressed until a characteristic two-tone sound from the machine confirmed complete coagulation of tissue. After the feedback-controlled response system had delivered the appropriate amount of energy required to seal the tissue, the flow of current was automatically halted to minimize heat transmission to surrounding tissues. The foot pedal was then released, the coagulated tissue cut and the electrode released by squeezing the handle of the handset until it unlocked.

When the suturing technique was used, the pedicles were clamped, cut, transfixed and doubly ligated using Vicryl No. 1 sutures (Polyglactin, Ethicon, Edinburgh, UK). In most cases, three pedicles were needed on each side (occasionally four in cases of enlarged uterus). Closure of the vaginal cuff was identical in both study groups. The posterior cuff was closed with a running whipstitch of polyglycolic acid suture incorporating the uterosacral-cardinal complex at each angle. The round ligament pedicles were attached to the anterior vaginal mucosa, and the mucosa was closed side to side and attached to the uterosacral-cardinal

complex, thereby closing the pubocervical ring.

The primary outcome measures were the operative time and blood loss while the secondary outcome measures were the hospital stay and intra- and post-operative complications.

Definition

Procedure time was measured from the initial incision to the complete closure of the vaginal cuff with satisfactory hemostasis. Operative blood loss was estimated by weighing the swabs (by the anesthetist and auxiliary theatre staff). Concomitant procedures had separate calculation of operative time and blood loss. The post-operative hemoglobin and hematocrit were measured for all participants at 24 h after the procedure. Complications were reported, e.g. the need for blood transfusion, urinary bladder injury or conversion to laparotomy.

Statistical analysis

Statistical analysis was performed using SPSS version 15 software. The results are shown in percentages, means and standard deviation for the quantitative characteristics. Data were evaluated by Chi-Square test and Student's t-test. A probability level (P) of less than 0.05 was considered significant.

Results

Eighty patients were included in the study. The LigaSure device was used in 40 patients (group I) and conventional suture ligation used in 40 patients (control group). The two groups were similar with respect to age ($p = 0.257$), parity ($p = 0.445$), body mass index ($p = 0.277$), previous caesarean section ($p = 0.762$) and indications for surgery (Table 1). The mean preoperative hemoglobin in both groups were 11 g/dl and hematocrit were 34.2%.

Table 1: Baseline patient characteristics in both groups

	LigaSure Group (N= 40)	Conventional Suture Group (N= 40)	P value
Age	53.3 ± 7.4	55.1 ± 7.3	0.257
Parity	4.7 ± 1.6	4.9 ± 1.6	0.445
Previous C.S	7 (17.5%)	6 (15%)	0.762
BMI (Kg/m²)	24.5 ± 3.7	23.7 ± 2.9	0.277
Indication for surgery			
• Dysfunctional uterine bleeding	22 (55%)	19 (47.5%)	0.502
• Utero-vaginal prolapse	11 (27.5%)	13 (32.5%)	0.625
• Fibroid uterus	7 (17.5%)	10 (25%)	0.412

Patients in the LigaSure group had a significantly shorter mean operating time compared with the control group (37.1 ± 8.9 min vs. 63.8 ± 10.9 min; $p < 0.001$). The mean operative blood loss was significantly decreased in the LigaSure group (125.5 ± 33.2 mL vs. 264.6 ± 70.4 mL; $p < 0.001$). The requirement of surgical sutures was lower in the LigaSure group (1.2 ± 0.4 units vs. 8.2 ± 0.4 units; $p < 0.001$). Patients of the LigaSure group presented reduced pain status (2.0 ± 0.6 vs. 3.7 ± 0.7; $p < 0.001$) and hospital stay (30.3 ± 2.5 h vs. 45.7 ± 10.5 h; $p < 0.001$) compared to the control group. Post-operative hemoglobin was significantly higher in LigaSure group (10.1 ± 0.6 vs. 9.1 ± 0.8; $p < 0.001$). Post-operative hematocrit values were significantly higher in LigaSure group (32 ± 2.5% vs. 29.2 ± 1.4%; $p < 0.001$). There was no significant difference in the type of concomitant procedures performed in the two groups (Table 2).

Table 2: Outcome of surgery in both groups

	LigaSure Group (N= 40)	Conventional Suture Group (N= 40)	P value
Operative time (min)	37.1 ± 8.9	63.8 ± 10.9	< 0.001
Operative blood loss (ml)	125.5 ± 33.2	264.6 ± 70.4	< 0.001
Surgical sutures (n)	1.2 ± 0.4	8.2 ± 0.4	< 0.001
Operative complications			
• Major vessels injury	0 (0%)	2 (5%)	0.152
• Bladder injury	1 (2.5%)	1 (2.5%)	1.00
• Bowel injury	0 (0%)	0 (0%)	
• Labial burn	1 (2.5%)	0 (0%)	0.314
Conversion to laparotomy	0 (0%)	2 (5%)	0.152
Concomitant vaginal repair	19 (47.5%)	14 (35%)	0.256
Concomitant oophorectomy	10 (25%)	13 (32.5%)	0.459
Postoperative hemoglobin	10.1 ± 0.6	9.1 ± 0.8	< 0.001
Postoperative hematocrit	32.0 ± 2.5	29.2 ± 1.4	< 0.001
Days in hospital (h)	30.3 ± 2.5	45.7 ± 10.7	< 0.001
Pain score (0-10)	2.0 ± 0.6	3.7 ± 0.7	< 0.001
Postoperative complication			
• Urinary tract infection	1 (2.5%)	2 (5%)	0.556
Overall complication	3 (7.5%)	5 (12.5%)	0.456

The overall complication rate in all study groups was 10 % (8/80). One patient in each group sustained a bladder injury. The patients who had bladder injuries in both groups had one previous caesarean section and significant bladder adhesions to the anterior peritoneum, both bladder injuries

were recognized and repaired vaginally during the primary surgery. A conversion from the vaginal to the abdominal route occurred in two patients in the control group due to major intra-operative bleeding (> 500ml) to achieve hemostasis. In the LigaSure group, one patient sustained a second degree unilateral labial burn when the hand-piece came in contact with the labia inadvertently. The injury was immediately detected and managed conservatively. No ureteric injuries, readmission for bleeding or return to the operating room occurred in either arm of the trial. Three patients experienced post-operative complications. Urinary tract infection occurred in two patients in the control group and one in the LigaSure group, and was treated with oral antibiotics (Table 2). The pathological diagnoses in both groups are reported in (Table 3).

Table 3: Pathological diagnoses in both groups

	LigaSure Group (N= 40)	Conventional Suture Group (N= 40)	P value
Weight of uterus after removal (gm)			
• < 80	28 (70%)	23 (57.5%)	0.245
• 80-150	8 (20%)	15 (37.5%)	0.084
• >150	4 (10%)	2 (5%)	0.396
Pathological reports			
• Endometrial hyperplasia	21 (52.5%)	17 (42.5%)	0.370
• Fibroid uterus	7 (17.5%)	10 (25%)	0.412
• Fibroid with adenomyosis	5 (12.5%)	7 (17.5%)	0.531
• Endometrial polyp	4 (10%)	2 (5%)	0.396
• Others	3 (7.5%)	4 (10%)	0.692

Table 4: Comparative data from relevant RCTs

	Levy and Emery (27)			Cronje and Coning (16)			Hefni et al. (15)			M. Elhao et al. (29)			Present study		
	L G	SG	P	L G	S G	P	L G	S G	P	L G	S G	P	LG	SG	P
Patient No.	30	30		37	31		57	59		50	53		40	40	
Operative time (min)	39.1	53.6	0.003	32	40	<0.001	57	66	0.04	52.5	90	<0.001	37.1	63.8	<0.001
Operative blood loss (ml)	68.9	126.7	0.005	100	160	0.36	100	100	0.43	230	360	<0.001	125.5	264.6	<0.001
Surgical sutures (n)	NR			1	7	<0.001	NR			NR			1.2	8.2	<0.001
Hospital stay (days)	0.1	0.33	0.03	2	2	0.03	NR			2	2	-	1.3	1.9	<0.001
Postoperative pain	NR			Less in BVSS group			NR			NR			Less in LigaSure group		
Complications	In BVSS group: right leg weakness (n=1) and cystitis (n=1). In conventional suture group: femoral neuropathy (n=1) and pelvic abscess (n=1).			No intra-operative or post-operative complications.			One patient in the BVSS group sustained a small first degree labial burn.			In BVSS group: bladder injury (n=1), blood transfusion (n=2) and vault hematoma (n=1). In conventional suture group: conversion to Laparotomy (n=1), bladder injury (n=1) and blood transfusion (n=1).			In LigaSure group: bladder injury (n=1), second degree labial burn (n=1) and UTI (n=1). In conventional suture group: conversion to Laparotomy (n=2), UTI (n=2) and bladder injury (n=1).		

Note: LG- LigaSure group, SG- Suture group, NR- not reported; BVSS- bipolar vessel sealing system.

Discussion

It is every surgeon's goal to adopt the least invasive, fastest, least complicated, and most effective operative techniques necessary for the shortest hospital stay at the lowest cost. Despite clearly meeting this goal, the vaginal approach is used in only 20% to 25% of the women who undergo hysterectomy (Deval *et al* 2003), perhaps because gynecologic

surgeons do not think they are adequately trained. Uterine enlargement, previous pelvic surgery, absence of uterine descent, and the need for oophorectomy should no longer be considered as contraindications to vaginal hysterectomy (Darai *et al* 2001).

Therefore, it is important to investigate alternatives in surgical technique, which might make the procedure technically easier, and be associated with a lower risk of complications and ultimately encourage more surgeons to operate vaginally.

Patients with morbid obesity, significantly enlarged uteri, narrow vaginal canals, and contracted pelvises continue to pose a surgical challenge. Placing sutures high in the pelvis, under and around a narrow pubic arch, is difficult and often quite frustrating. Not only it is difficult to see in these regions, but also accurately placing a stitch and retrieving the needle is problematic. These difficulties may lead to increase blood loss, necessitating conversion to laparoscopic or abdominal approaches. Electrosurgical bipolar vessel-sealing technology seems uniquely suited for vaginal surgery. The surgical steps other than placement of suture are identical to those used during standard vaginal hysterectomy. Pedicles can be controlled rapidly and effectively with this device, virtually eliminating the need for suture except for reconstruction of the vaginal vault. Although in skilled hands vaginal hysterectomy may be performed using standard techniques even in difficult patients, the electrosurgical bipolar vessel sealer technology should permit the less experienced vaginal surgeon an opportunity to expand the indications for vaginal hysterectomy. (Davies *et al* 1998).

In the present study the LigaSure group presented a lower pain status which may be the cause of the reduced hospitalization. Cronje and Coning were the only other study that evaluated post-operative pain status in women submitted to VH using LigaSure and found similar results (Cronje *et al* 2005). This technique delivers a precise amount of energy with thermal spread limited to an area less than 1.5 mm beyond the tissue bundle or vessel. Thus, minimized injury to adjacent tissues decreases the inflammatory response and the post-operative pain (Kennedy *et al* 1998).

Experimental studies comparing electrosurgical bipolar vessel sealing system (EBVS), monopolar, bipolar and ultrasonic coagulation demonstrated histologically that BVSS had the mildest side thermal injury and the fastest healing process (Diamantis *et al*

2006). A porcine model showed that BVSS is associated with less thermal damage to the media of the vessels (Person *et al* 2008). The EBVS creates seals that are stronger than the seals obtained with other energy-based ligation methods, and similar in strength to those obtained with mechanical ligation techniques (Kennedy *et al* 1998).

The current study shows no significant difference between the two groups as regards the rate of occurrence of surgical complications. The overall complication rate in the present study (10%) is comparable with the 8.0% to 16.1% complication rates after vaginal hysterectomy reported in larger series. Makinen *et al* 2001 & Garry *et al* 2004. The use of LigaSure, however, was associated with a reduced risk of hemorrhage-related complications. In the control group, major intra-operative bleeding (>500 mL) occurred in two patients requiring conversion to laparotomy to achieve hemostasis. Such bleeding usually occurs due to difficulty in securing the pedicles with sutures in the limited space available vaginally. Similar complications did not occur in the LigaSure group attesting to the efficacy of LigaSure in achieving hemostasis in spaces with limited surgical access. Unlike the seal provided by conventional suturing which is subject to slippage and dislodgement, seals created by the LigaSure device resist dislodgement because they are intrinsic to the vessel wall structure (Segupta *et al* 2001). In present study, the bladder injury was occurred one in each group, and occurred in a patient with a previous cesarean section and significant bladder adhesions. There is no association between the use of EBVS and higher complication rates (Levy *et al* 2003 & Person *et al* 2008).

One RCT and one observational study reported no complications in either group (Levy *et al* 2003 & Person *et al* 2008), and two studies described a variety of minor problems which appeared unrelated to the operative technique (Hefni *et al* 2005 & Cronje *et al* 2005). Two studies reported minor skin burns in the LigaSure group early in their experience (Cronje *et al* 2005 & Clave *et al* 2005).

These findings are in agreement with seven studies that evaluated the use of LigaSure

technology in VH. Four of those were RCTs (Hefni *et al* 2005, Cronje *et al* 2005, Levy *et al* 2003 and Elhao *et al* 2009), while the others were prospective case-control studies (Clave *et al* 2005, Zubke *et al* 2004 and Ding *et al* 2005). Using the LigaSure technique significantly decreases the operative blood loss; a desirable effect in patients undergoing hysterectomy for menorrhagia as they often suffers from iron deficiency anemia. Lower blood loss in LigaSure procedures reached statistical significance in only three studies, (Hefni *et al* 2005, Ding *et al* 2005 & Elhao *et al* 2009), determined by changes in the hemoglobin level and the 'surgeons' estimate of the volume lost during the procedure. No difference was found in two studies, (Cronje *et al* 2005 & Levy *et al* 2003), where authors attributed that to having already established a good surgical technique with conventional sutures.

In the present study, the total operative time was significantly shorter in the LigaSure group compared to the suture group. Significant reductions in procedure time when using EBVS were found in the four RCTs, (Hefni *et al* 2005, Cronje *et al* 2005, Levy *et al* 2003 & Elhao *et al* 2009) (Table 4). Variations in operating times reflect the variability in local procedures as well as surgeon and patient factors.

Using the electrosurgical bipolar vessel sealing technique (EBVS) significantly decreases operative blood loss and operating time without increasing the complication rate of vaginal hysterectomy procedures. The beneficial effect of LigaSure in reducing the operative blood loss seems to be more pronounced in patients who underwent a more difficult procedure.

Conclusion:

In conclusion, the use of LigaSure device can reduce operative time. It allows faster, safe and effective hemostasis compared with the conventional suture ligature, also reducing operative blood loss, pain status and hospital stay. The technique is to learn and use.

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مقارنة جهاز التخثر الحراري الجراحي بالوسائل التقليدية في خياطة الجروح في حالات استئصال الرحم عن طريق المهبل

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المقدمة : استئصال الرحم المهبلّي يعتبر الأسلوب المفضل لإزالة الرحم. خاصة للجراح حيث القدرة على الوصول، ورؤية الأنسجة والأوعية الدموية مع الحفاظ على وقف النزف الدموي أثناء الجراحة. يمكن تأمين العمليات الجراحية بمجموعة متنوعة من الطرق، بما في ذلك الوسائل الميكانيكية (خياطة الجروح) أو عن طريق جهاز التخثر (الحراري) الكهربائي الجراحي (ليجاسوري) وهو نظام جديد يقوم علي الجمع بين الضغط والطاقة الكهربائية بين القطبين، وهو قادر علي وقف النزف من الأوعية لدموية حتي قطر يصل إلى 7 مم .

الهدف: لتقييم سلامة وفعالية استخدام ليجاسوري أثناء استئصال الرحم المهبلّي بالمقارنة مع ال طريقة التقليدية. تصميم الدراسة: دراسة الخاضعة للرقابة العشوائية .

المواد والطرق : شملت الدراسة 80 من المريضات اللات يخضعن لعمليات استئصال الرحم المهبلّي لظروف حميدة وتم تقسيمهم الي مجموعتين مجموعة (40) مريضة تم استخدام الطريقة التقليدي في خياطة الجروح والمجموعة الاخرى (40) مريضة خضعن للطريقة الجديدة في خياطة الجروح تمت هذه الدراسة في أقسام التوليد وأمراض النساء (مستشفى جامعة الخرج-السعودية، مستشفى إنجاب-دولة الإمارات العربية المتحدة وكلية الخليج الطبية ومركز أبحاث -الإمارات العربية المتحدة).

النتائج: كان المرضى ليجاسوري وقت تشغيل حدث انخفاض ملحوظ في زمن العملية في المجموعة التي استخدمت النظام الجديد (8.9 ± 37.1 دقيقة مقابل 10.9 ± 63.8 دقيقة في المجموعة الاخرى)، كما حدث انخفاض في كمية الدم الذي فقد في نفس المجموعة (125.5 ± 33.2 مل مقابل 264.6 ± 70.4 مل)، ألم بعد العملية (0.6 ± 2.0 مقابل 0.7 ± 3.7 ؛ $p < 0.001$)، ومدة البقاء في المستشفى (30.3 ± 2.5 ح مقابل 45.7 ± 10.5 ح) مقارنة بمجموعة التحكم. نسبة المضاعفات في الدراسة هو 10% ($8/8$)، وأن لا تختلف فيما بين المرضى لمجموعة ليجاسوري والتحكم .

الاستنتاج : استخدام جهاز (ليجاسوري) التخثر الحراري الكهربائي يمكن تقليل الوقت اللازم للعمليات الجراحية كما يقلل من فقدان الدم ومن حدوث الام بعد الجراحة والي اقل فترة بقاء بالمستشفى. ، فإنه وسيلة آمنة وفعالة بالمقارنة مع الوسائل التقليدية.