

Ligasure Vessel Sealing System versus Conventional Suture Ligation Method in Vaginal Hysterectomy

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ABSTRACT

Objective: To compare the efficiency of ligasure vessel-sealing system with conventional sutures ligation method in vaginal hysterectomy.

Methods: A randomized clinical trial (RCT) was conducted at the Department of Obstetrics and Gynecology at King Hussein Medical Centre in Jordan between March 2010 and May 2012. A total of 100 patients for vaginal hysterectomy were recruited in this study: ligasure vessel sealing system was used for 52 patients and a conventional suture ligation method was used for 48 patients. The patients were re-evaluated two weeks, two months, and six months after the procedure.

Results: The operating time (min) was significantly shorter at a 95% confidence level in ligasure group than the conventional suture group ($p = 0.000$). Operative blood loss (ml) and the reduction in hemoglobin level (gm/dL) were significantly lower in ligasure group in comparison to the conventional suture group ($p = 0.000$). The hospitalization (days) of ligasure group was also significantly lower than the conventional suture group ($p = 0.002$). No statistically significant difference was found between the two groups in major intra-operative and immediate postoperative complications, whereas, the pain score was significantly higher in the conventional suture group compared with ligasure group ($p = 0.01$).

Conclusion: Ligasure vessel sealing system is a preferred and a safe alternative method when compared with the conventional suture ligation method in vaginal hysterectomy. It has the advantages of shorter operating time, reduced blood loss, less reduction level of hemoglobin, shorter time of hospitalization, and lower pain score.

Key words: Conventional sutures, Blood loss, Ligasure vessel sealing system, Vaginal hysterectomy.

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Introduction

Hysterectomy is considered the most common gynecological operation worldwide as it is done for 30% of women during their lifetime.⁽¹⁻⁵⁾ The operative site for hysterectomy can be abdominal, vaginal or laparoscopic. Abdominal hysterectomy has the advantage of good intra-operative field, but the disadvantages are an abdominal wall scar and the long time for recovery.^(6,7) Vaginal

hysterectomy was first operated by Lagenbeck in 1813, since that time it had gained some popularity for both benign gynecological conditions and for uterovaginal prolapse.⁽⁸⁾ The advantages of vaginal hysterectomy include less perioperative morbidity, shorter hospitalization, and early return to normal activity.⁽⁶⁾ Despite these advantages of vaginal hysterectomy, only one third of hysterectomies are done vaginally

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because of the limited surgical planes for securing the vascular pedicles^(3,4,6) and the risk for bladder injury.⁽⁹⁾

Vascular pedicles during hysterectomy can be secured using usual mechanical ways (sutures, clips or staples), or by vessel coagulation (high frequency electrocautery, ultrasound or laser).^(10,11) To replace the usual methods of hemostasis, the ligasure vessel sealing apparatus was launched by Valleylab (Boulder, CO, USA).^(2,12) It is operated by recognizing the type of tissue to pass the right dose of pressure and energy. This dose alters the collagen and elastin in the vessels to be sealed with minimal lateral thermal injury.^(2,6,11,12)

Ligasure is becoming more popular in many operative procedures as thyroidectomy, splenectomy, and urology procedures.⁽¹²⁾ It is more suitable for difficult operative cases because it can abandon the need for vessel traction and the shorter time needed for hemostasis.^(1,6,10) The efficacy of ligasure in gynecological procedures was found to be comparable to clips and ultrasound vessel sealing.⁽¹⁰⁾

The Ligasure Vessel Sealing System (LVSS) was developed for sealing vessels and tissue bundles up to 7mm in diameter by using a controlled high power current at low voltage to melt the tissue's collagen and elastin. This technique is associated with reduced thermal spread in comparison with unipolar cautery.^(1-13,14) Previous studies found that employing the LVSS in thyroid surgery is easy that a surgeon is able to acquire it within the first operation. It is also safe as complications are minimal.⁽¹⁵⁾ LVSS is relatively faster compared with suture ligation as the current delivered to achieve haemostasis takes between 2 and 7 seconds.⁽⁶⁾

The purpose of the current study is to compare the efficiency of ligasure vessel sealing system with conventional sutures ligation method in vaginal hysterectomy using different parameters: the operating time, operative blood loss, hemoglobin level, the hospitalization, and the intra-operative and immediate postoperative complications.

Method

This randomized clinical trial (RCT) was conducted between March 2010 and May 2012 in

King Hussein Medical Centre. It was approved by the Ethical Committee of Jordanian Royal Medical Services after providing a proposal which included the title of the study, literature review, the objectives, the significance, the methodology, the procedures of maintaining confidentiality, and the risks/benefits. A total of 100 patients participated in this study. Ligasure method was used for 52 patients and conventional suture method was used for 48 patients.

Simple randomization was the procedure of randomizing the participants of the study. Patients awaiting hysterectomy were prospectively randomized. Approximately 25 appointments for hysterectomy were available every six months during the time of the study. The patients were indicated for vaginal hysterectomy due to benign gynecological problem (dysfunctional uterine bleeding, and myoma) and uterovaginal prolapse. The patients who had previous pelvic surgery, pelvic inflammatory disease, endometriosis, uterine size more than twelve weeks, and genital malignancy were excluded from the study. The investigator called each eligible patient to inquire if she was willing to participate in the project after giving her full information about the study orally on the phone. Such information included details about the purpose of the study, the procedures, and the significance. Out of 103 eligible patients who were called, 100 patients gave verbal approval to participate (Fig.1).

The patients were assigned identification numbers to ensure confidentiality. These numbers were entered into International Business Machines Corporation Statistical Product and Service Solutions (IBM SPSS) software. Ligasure procedure was coded as number 1 and conventional suture ligation was coded as number 2. Random number generator was run for simple randomization to either using the Ligasure procedure or conventional suture ligation during vaginal hysterectomy. This method of randomization prevented the selection bias in allocating the patients to two different procedures of treatment. Before the surgery, the participants signed the consent form and they had the right to withdraw from participating in the study at any time. The same surgeon operated all surgeries. The surgeon and the patients were blinded to the method of surgery.

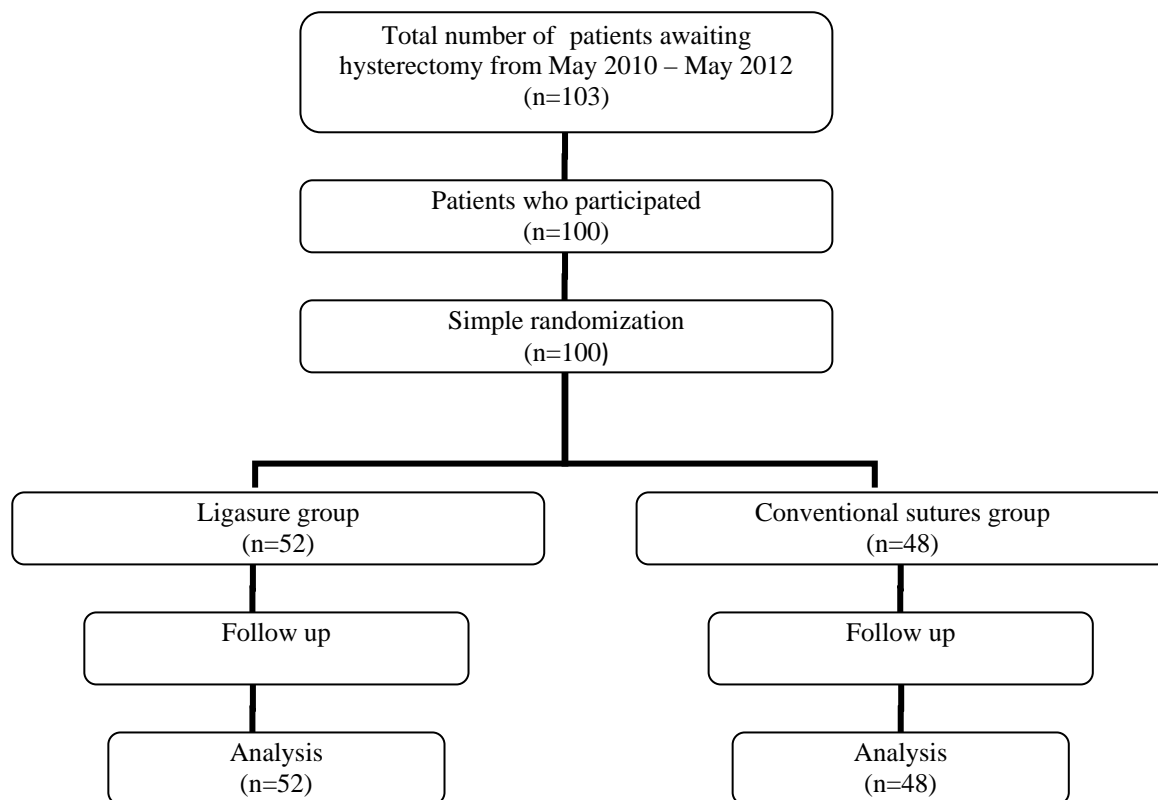


Fig. 1: Flow diagram of participants in the RCT

This blinding of the study subjects and the surgeon helped avoid the performance bias by ensuring that the compared groups received a similar amount of attention, treatment and diagnostic investigations.

Concomitant vaginal procedure indicated for each patient included anterior and posterior colporrhaphy, sacrospinous fixation, or anti-incontinence procedure. The anesthesia was either general or regional depending on the patient's condition and decision of the anesthetist. Vaginal hysterectomy in both groups was done in steps including circumcision of the cervix, opening of the posterior vaginal wall to access the pouch of Douglas, dissection of bladder and opening of anterior peritoneal cavity. Steps of securing and division of vascular pedicles were followed. After that, other concomitant procedures were done according to indication. All patients were asked to score their pain post-operatively on a 0 to 10 visual scale (0=no pain; 10=unbearable pain).

All patients received anti coagulation in the form of low molecular weight heparin (Inohep

from Leo pharmaceutical), second-generation cephalosporin antibiotics (cefotixin one gram) preoperatively were given. Analgesia in the form of pethidine and nonsteroidal was given as indicated by the visual analogue pain score of the patient.

The primary investigator used a written sheet to collect information about operation time for the vaginal hysterectomy, operative blood loss, reduction in hemoglobin level, staying at the hospital, intra-operative complications, and immediate postoperative complications. Patients were re-evaluated after two weeks, two months, and six months after the procedures looking for early (Hemoglobin changes), intermediate and late complications, such as prolapse recurrence..

Statistical analyses were performed using IBM SPSS Statistics version 21.0. All statistical tests were conducted at the 95% confidence level.

Results

Vaginal hysterectomy was operated for one hundred patients. Ligasure method was used for 52 patients and conventional suture method was

Table I: Participants characteristics

Characteristic	Ligasure group Mean \pm SD (n=52)	Conventional sutures group Mean \pm SD (n=48)	p-value
Age (years)	47 \pm 4	49 \pm 5	0.3
Parity	3.8 \pm 1	3.5 \pm 1	0.6
Height (cm)	160 \pm 5	162 \pm 2	0.5
Weight (kg)	71 \pm 11	74 \pm 9	0.2
BMI*	25 \pm 3	26 \pm 5	0.5

BMI = Body mass index

Table II: Independent sample t-tests for comparison of operating time, blood loss, hospitalization and reduction in hemoglobin level of both groups

Parameter	Ligasure group Mean \pm S.D. (n= 52)	Conventional suture group Mean \pm S.D. (n= 48)	t-value	p-value
Operating time (vaginal hysterectomy) (min)	40 \pm 8	65 \pm 10	4.05	< 0.00
Operative blood loss (mL)	75 \pm 13	137 \pm 17.3	17.3	< 0.00
Reduction in hemoglobin (gm/dL)	1.1 \pm 0.4	1.9 \pm 0.9	5.3	0.001
Hospitalization (days)	1.5 \pm 0.6	4.2 \pm 0.8	19.2	0.002

used for 48 patients. The mean of follow-up was four months. The basic characteristics of the patients in ligasure and conventional groups were similar, including mean of age 47 and 49 respectively as presented in Table I. There was no significant statistical difference regarding parity, height, weight, and BMI in both groups.

Independent sample t-tests were run to compare ligasure group and conventional suture group using different parameters. In the ligasure group, the operative time for vaginal hysterectomy was significantly shorter than the conventional suture group. The operative blood loss and drop of hemoglobin were significantly lower in the ligasure group than the conventional group. Regarding hospitalization, the number of days for staying in the hospital for ligasure group was significantly less than the conventional suture group. These results are shown in Table II. No significant difference was found between the two groups in major intra-operative complications. For example, there were no cases of blood vessels injury, ureteric injury, rectal injury, vulvar burns, or the need for laparotomy for operative difficulties or uncontrolled bleeding in both groups. There was only one case of bladder injury and two cases of soft tissue hematomas in the conventional sutures group.

The immediate post-operative period was assessed for complications including the pain scores using a visual analogue score from 0-10. Pried sample t-test results indicated a statistically significant lower score in ligasure group compared with conventional sutures group, the p value, and t value were equal 0.03, and 5.5, respectively. The mean of pain score in the conventional suture group was 6 in the comparison with the mean of 4 for the ligasure group. No cases were reported for wound infection and blood transfusion in both groups. There was only one case with fever and one case of urinary tract infection (UTI) in the conventional suture group.

Discussion

Hysterectomy is a major gynaecological procedure, which is indicated in cases of abnormal uterine bleeding, uterine fibroid or genital prolapse.^(3,16) Vaginal hysterectomy is preferred over abdominal hysterectomy because of less perioperative morbidity and quicker recovery and return to normal activities.^(4,16) Also, nowadays combining oophorectomy with vaginal hysterectomy by experienced surgeons makes it a good alternative surgical procedure with lower risk of morbidity especially in the absence of

uterine prolapse.^(6,10) Ligasure sealing system makes the surgical field more accessible which may be reflected on increasing the indications of vaginal hysterectomy.⁽²¹⁾

Gynecologists are looking for less invasive and more effective operative techniques using the vaginal route.^(10,17) Ligasure vessel sealing system has the advantage of reducing the blood loss and achieving safe method of vessel sealing with lower rate of morbidity compared to conventional sutures in vaginal hysterectomy.^(10,18) It is also important to have shorter operation time and to reduce the use of conventional sutures as these will lower the morbidity and the cost of the operation.⁽¹⁹⁾

Performing vaginal hysterectomy needs experience and training especially in the absence of prolapse and for the ligation of the main vessels.⁽¹⁰⁾ In some studies vaginal hysterectomy was the main procedure in around 95% of benign gynaecological conditions.⁽¹⁾ With this wide spread use of vaginal route for hysterectomy, it is necessary to have the suitable instruments to encourage more surgeons to practice vaginal hysterectomy.⁽¹⁾ Ligasure unit is a blood vessel sealing system that can handle blood vessel up to 7 mm in diameter and decrease the loss of blood as safe alternative to other methods.^(10,20) It has been found that the operation time, operative blood loss and hospital stay are significantly lower when operating with the ligasure vessel sealing system and more effective compared to the conventional suturing method.⁽¹²⁾

It is well known that bleeding is one of the important drawbacks of hysterectomy. Using ligasure will give the surgeon a better and easier surgical field which will be reflected on the outcome including the bleeding, duration of surgery, and thrombotic complications.⁽¹²⁾

The strength of vessel seal obtained by ligasure is comparable to conventional methods and better than other energy dependent modes.⁽²¹⁾ Some studies did not show any statistical significance in reducing blood loss using ligasure method.^(10,19) The results of this study are in agreement with several previous studies^(1,12,18,21,22) that showed a significantly lower blood loss and less drop in hemoglobin in ligature group compared with conventional group.

Improving the accessibility of the surgical plane

in a limited space using the ligasure is reflected on shorter operative time and no need for space for the use of needles, in addition to reducing the risk of stings.^(4,21) The results of this study also showed a significant shorter operating time for vaginal hysterectomy of the ligasure group compared with conventional sutures group. This result is comparable to other studies that showed similar finding.^(6,12)

Some previous studies^(1,19,21) found that the period of hospitalization is shorter in the ligasure group compared with the conventional sutures group. The findings of these studies support the result of the current study about hospitalization. On the other hand, some other studies^(4,16) did not show any significant difference in the hospital stay between the two groups.

Several studies showed that the complication rate of using ligasure varies from 8.0% to 16.0%.⁽⁶⁾ There was no significant complication regarding intra-operative and immediate post-operative period with regard to major blood vessels injury, ureteric injury, and bladder injury. There was also no soft tissue hematoma, or a need for laparotomy for significant bleeding or vulvar burn. These results were found previously in the literature.^(6,23,24,25)

The post-operative pain is reduced after using ligasure because there is no foreign body in the form of ligature as ligasure system is giving certain current of energy which is confined to 1.5mm from the sealed vessel, this will cause less inflammation and less chance of fibrosis in the pelvis.^(12,21) Moreover, reducing the pain score enhances the possibility of early hospital discharge and reduce the operation cost.⁽¹⁰⁾ Furthermore, ligasure will cause less tissue pressure compared with the conventional methods.⁽¹⁹⁾ Significant lower post-operative pain score was found previously in the ligature group than the conventional group.^(3,22) This finding matches the result of this study about pain score in ligature group compared with conventional group.

Limitations of the study

The main limitation of the study was the relatively small sample size. In order to give more valuable results, further research is needed with larger sample size.

Conclusion

Ligasure vessel sealing system is a preferred and safe alternative method when compared with conventional sutures ligation method in vaginal hysterectomy. It has the advantages of shorter operating time, reduced blood loss, less reduction level of hemoglobin, shorter time of hospitalization, and lower pain score.

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