

Safety and efficacy of using the LigaSure vessel sealing system for securing the pedicles in vaginal hysterectomy: randomised controlled trial

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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 Randomised controlled trial.

Setting Gynaecology Department, Benenden Hospital, Kent.

Population One hundred and sixteen women undergoing vaginal hysterectomy were prospectively randomised to either LigaSure (Group I) or suture ligation (Group II) for securing the pedicles.

Methods Data of patients were collected prospectively. Statistical analysis was performed using the Mann–Whitney U test, χ^2 and Fisher's exact test as appropriate.

Main outcome measures Operating time, operative blood loss and peri-operative complications.

Results The operating time was significantly shorter in the LigaSure group compared with the control group ($P < 0.04$). There was no statistical significant difference between the two groups in operative blood loss ($P = 0.433$), but peri-operative haemorrhagic complications were less frequent in the LigaSure group (0% vs 6.8%, $P = 0.057$). Four patients in the control group required either conversion to laparotomy because of bleeding, return to theatre for immediate post-operative haemorrhage or readmission for vault haematoma, whereas none in the LigaSure group had bleeding from unsecured pedicles.

Conclusion The LigaSure vessel sealing system is a safe alternative for securing pedicles in vaginal hysterectomy when compared with conventional suture ligation. Larger studies are required to determine its place in gynaecological surgery.

INTRODUCTION

Despite the introduction of endometrial ablation techniques, hysterectomy remains the most common major gynaecological operation performed in the UK.¹ One in five women in the UK will have hysterectomy by the age of 55² and nearly one in three women in the USA will have undergone hysterectomy by the age of 60.³

Vaginal hysterectomy is considered to be the method of choice for removal of the uterus and, in the absence of gross pelvic disease, can be carried out in most patients.^{4–7} 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.^{8,9} This could be due to the fact that 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.^{10,11}

Surgical haemostasis can be secured by a variety of methods, including mechanical means (sutures) or vessel coagulation (diathermy). Electrocoagulation diathermy is unreliable for vessels larger than 2 mm in diameter.¹² 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. LigaSure (Autosuture, Valleylab, Boulder, Colorado, USA) is a new haemostatic system based on the combination of pressure and bipolar electrical energy and is able to seal vessels up to 7 mm in diameter (Fig. 1). The device delivers a controlled high power current at low voltage to melt the collagen and elastin in the tissue leading to permanent fusion of the vascular layers and obliteration of the lumen. The collagen and elastin within the tissue reform to create a 'seal zone' which appears as a distinctive, translucent area and has plastic resistance to deformation. In addition, the vessel sealing mechanism produces significantly reduced thermal spread compared with existing bipolar instruments, as energy is automatically switched 'off' when tissue impedance reaches a critical level.^{12,13} The current delivered to achieve

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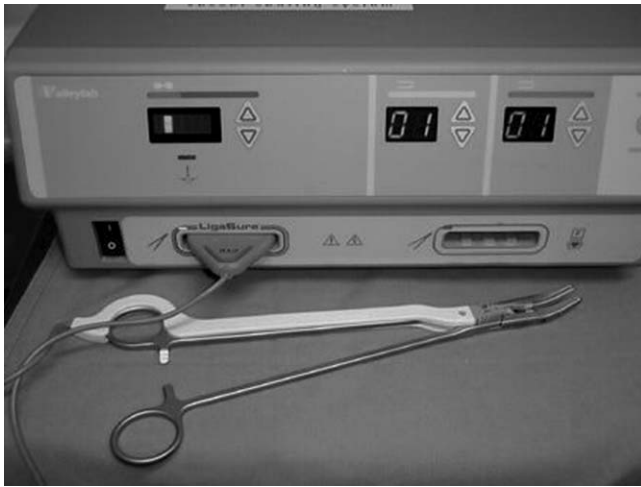


Fig. 1. LigaSure clamp and LigaSure vessel sealing generator.

haemostasis takes between 2 and 7 seconds, and hence, can be relatively faster compared with suture ligation.

The LigaSure system had been used in a range of non-gynaecological surgical procedures with encouraging results.^{14–18}

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

METHODS

This study was conducted from January 2001 to December 2002. Approval was obtained from our local Research Ethics Committee. Patients admitted for vaginal hysterectomy during this period were invited to participate in the study and enrolled after informed and written consent. During this period, out of 261 women were admitted for vaginal hysterectomy, 116 were recruited for the study. The exclusion criteria were: uterine size greater than 14 weeks, suspected uterine, cervical or ovarian malignancy, obliteration of pouch of Douglas due to severe endometriosis or pelvic inflammatory disease and/or refusal to participate in the study (Fig. 2).

Patients who participated in the study were randomised to either using the LigaSure procedure or conventional suturing (control group) during vaginal hysterectomy (Fig. 2). Randomisation was performed using a list of computer-generated random numbers. All operations were performed by or under supervision of consultants. The operating surgeon was informed of the method to use just before the start of surgery and this information did not influence which surgeon was to operate. The patients were blinded to treatment method. Concomitant procedures performed at the time of vaginal hysterectomy (such as sacrospinous colpopexy, vaginal repair and oophorectomy) were performed similarly in both groups. Sacrospinous colpopexy

was carried out in patients with procidentia, enterocele or in second degree uterovaginal prolapse where the vault lies at the level of the hymenal ring after vaginal hysterectomy. The method, results and follow up of sacrospinous colpopexy at the time of vaginal hysterectomy have already been described previously.¹⁹

Antibiotic prophylaxis in the form of a single dose of 500 mg metronidazole and 1.5 g cefuroxime intravenously were given at induction of anaesthesia.

All operations were performed under general anaesthesia in the lithotomy position. Twenty millilitres of 1:200,000 adrenaline in normal saline was infiltrated under the vaginal mucosa. A circumferential vaginal incision was made around the anterior portion of the cervix between the transverse cervical ligaments and extended posteromedially in a V-shaped manner. The bladder was then dissected off the vagina anteriorly and the pouch of Douglas was opened posteriorly. 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 computerised algorithm that recognises vessel sealing by alterations in tissue impedance. The electrodes on the hand-piece were placed across the hysterectomy pedicles (uterosacral–cardinal, uterine

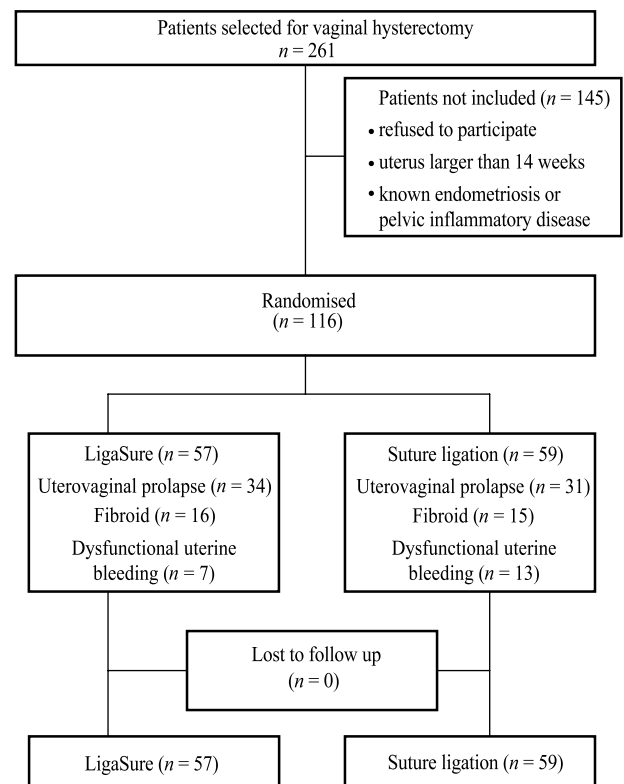


Fig. 2. Flow diagram of participants through trial.

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 minimise 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).

If indicated, bilateral oophorectomy was performed after hysterectomy. The LigaSure device was used for the oophorectomy in the LigaSure group. In the control group, oophorectomy was performed using one of the methods previously described by the authors.²⁰

The vault was closed similarly in both groups in a manner previously described by the authors.²¹ In brief, it started posteriorly in a vertical fashion using an interlocking continuous suture. The peritoneum was included in the suture until the uterosacral ligaments were reached. After that, closure was completed using the vaginal skin alone. Other procedures, such as sacrospinous colpopexy, colporrhaphy and oophorectomy were then performed as indicated using conventional suture ligation in all patients in both groups.

Operative blood loss was calculated by evaluating the amount of blood collected in the perineal pouch and weighing the swabs used during surgery. Also, changes in haemoglobin level were calculated by comparing pre-operative haemoglobin level with that obtained on the second day after surgery.

Data were collected prospectively using Epi-INFO version 6 software package (CDC, Atlanta, Georgia, USA). Patient demographics, operative details including operating time, operative blood loss, peri-operative drop in haemoglobin level and post-operative adverse events such as haemorrhage, infection, need for re-operation or readmission following discharge were recorded.

A pilot study of 10 cases of vaginal hysterectomy using LigaSure was conducted in year 2000. The study showed a 31% reduction in the mean blood loss of the LigaSure group (110 [96] mL, range 20–340) compared with that in 66 consecutive patients who had vaginal hysterectomy using the conventional suture technique during the same period (161 [145] mL, range 25–750). Therefore, it was noted that there was about 25% reduction in blood loss due to the use of LigaSure. This is felt to be clinically relevant. Based on this, a sample size of 56 patients in each arm was

required for 80% power of detection at the 5% significance level. Statistical analysis was performed using Epi-INFO version 6 software package (CDC). Using a value of less than 0.05 as significant, the Mann–Whitney *U* test was used to establish the statistical significance of the difference between the two groups with respect to the duration of operation, operative blood loss and reduction in day two haemoglobin levels. χ^2 test (Yates corrected as appropriate) was used to assess the significance of the difference in the incidence of complications, except when the cell count was below 5, in which case Fisher's exact test was used.

RESULTS

One hundred and sixteen patients were included in the study. The LigaSure device was used in 57 patients (group I) and conventional suture ligation used in 59 patients (control group). The two groups were similar with respect to age, parity, incidences of previous pelvic surgery and caesarean section and indications for surgery (Table 1). There was no significant difference in the mean number (1.2 operation/patient in both groups) or type of concomitant procedures performed in the two groups (Table 1). Patients in the LigaSure group had a significantly shorter mean operating time, 57 (SD 20) minutes compared with the control group, 66 (SD 25) minutes, $P < 0.04$.

The overall complication rate in the study was 11.2% (13/116). One patient in each group sustained a bladder injury and one patient in the LigaSure group had a rectal injury. The bladder injury in the control group had a previous laparoscopic sterilisation prior to the vaginal hysterectomy. The patient in the LigaSure group who had bladder injury had previously had augmentation cystoplasty (for detrusor hyperreflexia due to traumatic spinal cord injuries) and Burch colposuspension. Both bladder injuries were repaired vaginally. The rectal injury in the LigaSure

Table 1. Baseline patients' characteristics and concomitant surgery. Values are given as *n* (%) or mean [SD].

	LigaSure group (<i>n</i> = 57)	Control group (<i>n</i> = 59)
Age (years)	51 [11.4]	52 [11.6]
Previous pelvic surgery	33 (57.9)	35 (59.3)
Previous caesarean section	5 (8.8)	5 (8.5)
Indications for surgery		
Uterovaginal prolapse	34 (59.6)	31 (52.5)
Fibroid	16 (28.1)	15 (25.4)
Dysfunctional uterine bleeding	7 (12.3)	13 (22.0)
Concomitant procedures performed*		
Sacrospinous colpopexy	23 (40.4)	20 (33.9)
Vaginal repair	24 (42.1)	29 (49.1)
Bilateral oophorectomy	22 (38.6)	23 (39)

* Some patients underwent more than one procedure.

group occurred while attempting to open the pouch of Douglas in a patient whose pouch of Douglas was obliterated due to unrecognised rectovaginal septum endometriosis. These visceral injuries occurred during the initial steps of the operation (i.e. dissection of the bladder from the cervix or opening of the pouch of Douglas) and were unrelated to the haemostatic control method. All injuries were recognised and treated during the primary surgery and all healed without delaying recovery. No ureteric injuries occurred in the study.

The mean operative blood loss was not significantly different in the two groups [146 (SD 110) mL in the LigaSure group vs 168 (SD 172) mL in the control group, mean difference (95% CI) -22 (-75 to 32) mL, $P = 0.433$], but the incidence of peri-operative haemorrhagic complications was lower in the LigaSure group [0/57 (0%) vs 4/59 (6.8%, 95% CI 0.3% to 13.2%), $P = 0.057$] (Table 2). In the control group, four patients had peri-operative bleeding from unsecured pedicles; two patients required conversion to laparotomy to achieve haemostasis, the third patient required return to theatre because of haemorrhage in the immediate post-operative period due to bleeding from one of the hysterectomy pedicles, which necessitated re-clamping and ligation. Haemostasis was achieved vaginally. The fourth patient in the same group required readmission six days following hospital discharge due to vaginal bleeding. Clinical and ultrasound examination confirmed the presence of a vault haematoma. Blood transfusion was given and the patient was managed conservatively.

In the LigaSure group, one patient sustained a small (<1 cm) first degree unilateral labial burn when the hand-piece came in contact with the labia inadvertently. The injury was immediately detected and managed conservatively. Healing occurred promptly with no scarring.

Table 2. Outcome of surgery. Values are presented as mean [SD], n (%) or median (range).

	LigaSure group ($n = 57$)	Control group ($n = 59$)	P
Operative time (minutes)	57 [20]	66 [25]	0.04
Operative blood loss (mL)	100 (10–600)	100 (20–1000)	0.4338
Reduction in haemoglobin level (g/dL)	1.2 [0.98]	1.5 [1.1]	0.735
Visceral injury	2 (3.5)	1 (1.7) ^a	
Febrile illness*	1 (1.8)	1 (1.7) ^a	
Urinary infection	–	3 (5.1) ^a	
Labial burn	1 (1.8) ^a	–	
Peri-operative haemorrhagic complications	0	4 (6.8)	0.0571
Conversion to laparotomy	–	2 (3.4)	
Return to theatre	–	1 (1.7)	
Readmission for bleeding	–	1 (1.7)	

^a Numbers are too small to allow for a meaningful statistical comparison.

* Temperature >38°C on two occasions 6 hours or more apart excluding the first 24 hours.

DISCUSSION

Several studies have emphasised that vaginal hysterectomy should be the primary method of uterine removal. Uterine enlargement, previous pelvic surgery, absence of uterine descent and the need for oophorectomy should no longer be considered as contraindications to vaginal hysterectomy.^{4,6,7} Nevertheless, fewer than 30% of all hysterectomies in the UK are currently performed via the vaginal route.⁸ This could be due to lack of training or experience in vaginal surgery.^{22,23} 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.

This is the first randomised study to investigate the use of the LigaSure device during vaginal hysterectomy. It showed that LigaSure is associated with a shorter operating time than conventional clamping and suture ligation of vascular pedicles. This finding concurs with the results of two randomised studies, which reported reduction of around 50% in the mean operating time for haemorrhoidectomy with the use of LigaSure^{14,15} as well as a retrospective study of radical prostatectomies¹⁶ where LigaSure led to a significant reduction in operating time from 135 minutes to 113 minutes ($P < 0.01$).

The overall complication rate in the present study (11.2%) is comparable with the 8.0% to 16.1% complication rates after vaginal hysterectomy reported in larger series.^{8,24,25} The use of LigaSure, however, was associated with a reduced risk of haemorrhage-related complications. In the control group, major intra-operative bleeding (>500 mL) occurred in two patients requiring conversion to laparotomy to achieve haemostasis. A third patient from the same group returned to theatre because of post-operative bleeding from a hysterectomy pedicle, but the bleeding was controlled vaginally. 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 haemostasis 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.¹⁶

The LigaSure vessel sealing system melts the collagen and elastin in the vessel wall to form a seal zone. This process is operator independent, whereas the haemostasis achieved by conventional suture ligation is skill and operator dependent. The training curve for LigaSure is minimal. During the study, vaginal hysterectomy was done by doctors in various grades of training, most of whom had no or minimal experience with LigaSure. It is a relatively easy device to learn and use.

Besides randomisation, one of the main strengths of the present study is the fact that trainees as well as consultants

performed the surgery. Knowing that over 50% of hysterectomies performed in the National Health Service are done by doctors in training grades,⁸ our results provide the necessary reassurance from a clinical governance perspective that the LigaSure technique is safe and effective in the hands of trainees and relatively less experienced surgeons as much as more experienced ones. We did not encounter any situation where it was not possible to apply the LigaSure device on hysterectomy pedicles, even though the uterine weight in the LigaSure group was on average larger than that in the control group (148 g vs 117 g, respectively, $P = 0.1$).

The reduction in blood loss associated with the use of the LigaSure device in the present study was not statistically significant. This could be due to two reasons. Firstly, our technique of vaginal hysterectomy is characterised by limited blood loss (average 173 mL, unpublished audit data). Secondly, many patients in both groups had additional procedures performed, thus influencing total blood loss during surgery. Limiting the study to patients who require vaginal hysterectomy only without any additional procedures or those without uterovaginal prolapse would probably demonstrate the difference in blood loss, but would also extend the study period to an unacceptable length of time.

Finally, one patient in the LigaSure group sustained a small first degree labial burn. This is the first report of such a complication, highlighting the importance of ensuring that the activated hand-piece or the hand-piece that is still hot after use does not come in contact with the patient's skin. We emphasise that when not in use, the hand-piece should be placed in a holster or a clean, dry, non-conductive and visible area away from the patient.

CONCLUSION

We have found the LigaSure device to be a safe and effective alternative for securing vascular pedicles during vaginal hysterectomy when compared with conventional suture ligation. The technique is easy to learn and use. Larger randomised studies are required to determine its place in securing pedicles in gynaecological surgery.

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