

COMPARISON OF EFFICACY OF BIPOLAR ELECTROSURGICAL VESSEL SEALING WITH CONVENTIONAL SUTURING IN SECURING VASCULAR PEDICLES DURING VAGINAL HYSTERECTOMY

Vinita B Agrawal¹, Ashish Agrawal², Sangeeta B Agrawal³

¹ Department of Obstetrics & Gynaecology, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India

² Department of Surgery, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India,

³ Department of Anaesthesiology, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India

Correspondence to: Sangeeta B Agrawal (sagarwal2111@gmail.com)

DOI: 10.5455/ijmsph.2014.020820144

Received Date: 03.07.2014

Accepted Date: 02.08.2014

ABSTRACT

Background: During vaginal hysterectomy, pedicles are usually secured by conventional suturing but it may be difficult many a times. Electrosurgical bipolar vessel sealing in vaginal hysterectomy is safe and effective alternative for securing pedicles.

Aims & Objectives: Aim of the study is to compare the efficacy of vessel sealing for securing pedicles in vaginal hysterectomy as compared to conventional suturing in terms of operating time, perioperative blood loss, postoperative pain and short-term surgical complications.

Materials and Methods: This was a randomized controlled trial study done in our institute during a period of one year. Two groups were formed, one was control group I (total 60 patients), wherein, conventional suturing was done and other was study group II (total 65 patient) where Ligasure vessel seal was used for securing pedicles, irrespective of age and parity. Data of patients were collected and statistical analysis was performed using SPSS version software.

Results: Group II shows significant reduction in operative time compared to control group ($p = 0.0001$). There was significant difference between 2 groups in operative blood loss ($p = 0.0001$) and post-operative pain ($p = 0.0001$). None of the patients had major surgical complications.

Conclusion: The Ligasure vessel sealing system is a safe alternative for securing pedicles in vaginal hysterectomy when compare with conventional suture ligation.

Key Words: Ligasure; Pedicle; Vaginal Hysterectomy

Introduction

Vaginal hysterectomy is considered the preferred methods for hysterectomy in the absence of gross pelvic disease and it can be carried out in most patients.^[1-4] However, it is sometimes difficult to maintain adequate haemostasis during the vaginal approach as results of difficulties in visualizing and ligating sutures through a small opening.^[5] Surgical haemostasis can be secured by a variety of methods including suturing or vessel coagulation. Electro coagulation diathermy is unreliable for vessels larger than 2 mm in diameter.^[6]

Energy based vessel sealing devices allow for rapid sequential tissue and vessel sealing (vessels up to 7 mm diameter) coagulation and transaction of the pedicles in one handheld tool.^[7] There are numerous devices available for energy based vessel sealing. Ligasure is a new haemostatic system based on the combination of pressure and bipolar electric energy. It delivers a controlled high power current with low voltage to melt the collagen and elastin within the tissue 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 to existing bipolar instruments as energy is automatically switched off when tissue impedance reaches a critical level.^[6,8]

The Ligasure system has been used in a range of non-gynecological surgical procedures with encouraging results. The objective of this study is to compare vaginal hysterectomy performed with standard techniques versus the one performed with Ligasure, in terms of operating time, perioperative blood loss, postoperative pain and short-term surgical complications.

Materials and Methods

This study was randomized prospective controlled trial which was done after taking approval from the hospital ethical committee and explained consent from patients. The study was conducted during a period of one year from December 2012 to November 2013 in our institute. Out of 208 patients admitted for vaginal hysterectomy, 125 were recruited for the study. Informed and written consent was obtained from patients. Exclusion criteria were: uterine size greater than 14 weeks, suspected uterine cervical or ovarian malignancy, severe endometriosis and previous three caesarean sections.

Table-1: Indications for hysterectomy (total n=125)

Control group (I) (n = 60)	Ligasure group (II) (n = 65)
Uterovaginal prolapse (n = 33)	Uterovaginal prolapse (n = 32)
DUB (n = 18)	DUB (n = 20)
Fibroid (n = 19)	Fibroid (n = 13)

Table-2: Visual analog pain scale

10 - Agonizing (unbearable distress)
8 - Horrible
6 - Dreadful
4 - Uncomfortable
2 - Annoying
0 - No distress

The patients were randomized to either using Ligasure procedure or conventional suturing using a list of computer generated random number. Patients were blinded to treatment methods. Indication for hysterectomies were shown in table no 1.

Concomitant procedures performed at time of vaginal hysterectomy such as vaginal repair and oophorectomy were performed similarly in both groups. The mean age in group I was 52 years, and in group II, it was 51 years. Antibiotic prophylaxis in the form of single dose of metronidazole and 1.5 gm cefuroxime intravenously were given at the time of induction of anesthesia. All operations were performed under spinal anesthesia in lithotomy position. The operative field was cleaned with a standard antiseptic agent and 0.20 ml of 1:200000 adrenaline in normal saline was infiltrated under vaginal mucosa.

A circular incision was made around the cervix, the pouch of Douglas was opened posteriorly and the bladder was separated from the uterus. In group II, Ligasure was used, the electrodes on the hand piece were placed across the hysterectomy pedicles, 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 placed in the tightest ratchet position. The coagulation foot pedal was pressed until a characteristics two tone sound from the machines confirmed complete coagulation of tissue. After the feedback control of response system has delivered the appropriate amount of energy required to seal the tissue, the flow of current was automatically halted to minimum heat transmission to surrounding tissue. The foot pedal was then relaxed, the coagulated tissue cut, and electrode released by squeezing the handle of handset until it was unlocked. When the suturing technique was used, the pedicles were clamped, cut, transfixed and doubly ligated using vicryl no. 1 suture (polygalactin). Closure of vaginal cuff was identical in both study groups. The posterior cuff closed with running whipstitch of vicryl no 1,

incorporating the cardinal complex at each angle. The round ligament pedicles were attached to anterior vaginal uterosacral mucosa and the mucosa was closed side to side and attached to utreo-sacral cordinal complex – thus closing the pubo-cervical ring. Operative time was measured form the initial incision to complete closure of the vaginal cuff with satisfactory haemostasis. Operative blood loss was measured by evaluating the amount of blood collected in the perineal pouch and weighing the swabs used during the surgery. A 4 by 4 gauge fully soaked amounts to 10 cc of blood. Postoperative pain was measured by visual analog score as shown in table no 2.

Surgical complications included labial burn in two patients in Ligasure group and post-operative bleeding in one case in control group which required return to operation theatre for haemostasis.

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

Results

One hundred twenty-five patients were included in the study. The Ligasure device was used in 65 patients and conventional suture ligation technique was used in 60 patients. The two groups were similar with respect to age, parity and indications for surgery. Patients in Ligasure group had a significantly shorter mean operating time of 57.34 (SD=1.58) minutes compare to control group's 70.03 (SD=1.64) minutes as shown in table no 3.

Table-3: Comparison between groups

	Ligasure group n=65	Control group n=60	P value
Operation time (minutes)	57.34 (SD=1.58)	70.03 (SD=1.64)	0.0001
Operative blood loss (ml)	135.0 (SD=6.01)	191.23 (SD=7.19)	0.0001
Pain score	3.80 (SD=0.68)	5.88 (SD=0.66)	0.0001

Only two patient in Ligasure group suffered from complication of unilateral labial burn which was detected promptly and managed conservatively. The healing occurred without scarring.

The mean operative blood loss was significantly less in Ligasure group as compared to controlled group. In Ligasure group, the average blood loss was 135ml (SD=6.01) compared to 191.23 ml in control group (SD=7.19) with a p =0.0001 as shown in table no 3. In

conventional suturing group, one patient required return to operation theatre due to hemorrhage in immediate postoperative period due to bleeding from one of the hysterectomy pedicles, which required reclamping and ligation. Haemostasis was achieved vaginally. The visual analogue pain score shows significant difference between pain perceived by patient in both group. In Ligasure group, the average pain score was 3.80 (SD=0.68), and in conventional group, it was 5.88 (SD=0.66) as shown in table no 3.

Discussion

It has been emphasized that vaginal hysterectomy should be the primary method of uterine removal. Still less than 30% of all hysterectomies are currently performed via the vaginal route.^[9] This could be due to lack of experience in vaginal surgery.^[10,11] Patients with morbid obesity, significantly enlarged uterus, narrow vaginal canals and contracted pelvis continue to pose a surgical challenge. Placing suture high in the pelvis under and around a narrow pubic arch is difficult and quite frustrating. Not only it is difficult to see in these regions, but also accurately placing a suture and retrieving the needle is also problematic. These difficulties may lead to increased blood loss and necessitate conversion to laparoscopic or abdominal approach. Therefore it is important to investigate the alternative in surgical techniques which could make the procedure easier and associated with lower rate of complications. 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 sutures, except for reconstruction of vaginal vault. Although in skilled hands, vaginal hysterectomy may be performed using standard techniques even in difficult patients, the Ligasure technology permits less experienced vaginal surgeon an opportunity to expand the indication for vaginal hysterectomy. It has been shown that Ligasure is associated with a shorter operating time than conventional suturing clamping, and suture ligation of pedicles. Two randomized studies has reported reduction of around 50% in the mean operating time for hemorrhoidectomy with use of the Ligasure^[12,13] as well as in radical prostatectomy.^[14] Present study supports this fact as the mean operating time in control group was 70.03 minutes and in Ligasure group it was 57.30 minutes with $p=0.0001$.

The use of Ligasure was associated with a reduced risk of hemorrhage related complications. In the control group, one patient returned to OT because of postoperative bleeding from one pedicles – but bleeding was controlled vaginally. Ligasure vessel sealing system is operator independent whereas haemostasis achieved by conventional suturing is skill and operator dependent. Ligasure is easy device to learn and use. There was also a reduction in mean blood loss in Ligasure group (135.36 ml), as compare to control group (191.23 ml) with a $p=0.0001$. This is in accordance with six studies, which reported blood loss either by a change in haemoglobin (measure on postoperative day 2)^[15] or blood loss in millilitres.^[16-20] The postoperative pain score on visual analog scale also showed a significant difference in both groups. The score was 3.80 in Ligasure group and 5.88 in control group respectively with $p=0.0001$. In the present study, the Ligasure group presented at a lower pain status. Cronje and Coneney was only known other study that evaluated postoperative pain status in women submitted to vaginal hysterectomy using Ligasure, and they got similar result.^[16] 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 tissue decreases the inflammatory response and postoperative pain.^[6] Finally, two patients in Ligasure group sustained a small first degree unilateral labial burn. This highlighted the importance of noticing that activated hand piece remains still hot after use and should not come in contact with patient skin.

Conclusion

We have found that the Ligasure device is safe and effective alternative for securing vascular pedicles during vaginal hysterectomy, compared to conventional suture ligation. It is not only easy to learn and use but also leads to decrease in operative time, blood loss and pain.

References

1. Richardson RE, Bournas N, Magos AL. Is laparoscopic hysterectomy is a waste of time? *Lancet* 1995;345:36-41.
2. Kovac SR. Hysterectomy outcomes in patients with similar indications. *Obstet Gynecol* 2000;95:783-93.
3. Darai E, Soriano D, Kimata P, Laplace C, Lecuru F. Vaginal hysterectomy for enlarged uteri with or without laparoscopic assistance: randomized study. *Obstet Gynecol* 2001;97:712-6.
4. Doucette RC, Sharp HT, Alder SC. Challenging generally accepted contraindications to vaginal hysterectomy. *Am J Obstet Gynecol* 2001;184:1386-91.
5. Kovac SR. Clinical opinion: guidelines for hysterectomy. *Am J Obstet Gynecol* 2004;191:635-40.
6. Kennedy JS, Stranahan PL, Taylor KD, Chandler JG. High burst strength, feedback controlled bipolar vessel sealing. *Surg Endosc*

- 1998;12:876-8.
7. Lamberton GR, His RS, Jin DH, Lindler TU, Jellson FC, Baidwin DD. Prospective comparison of four laparoscopic vessel ligations devices. *J Endourol* 2008;22:2307-12.
 8. Fleshman J. Advanced technology in the management of haemorrhoids; stapling, laser, harmonic scalpel and Ligasure. *J Gastrointest Surg* 2002;6:299-301.
 9. Maresh MJ, Metcalfe MA, McPherson K, Overton C, Hall V, Hargreaves J, et al. The VALUE national hysterectomy study: description of the patients and their surgery. *BJOG* 2002;109:302-12.
 10. Kovac SR. Vaginal hysterectomy. *Baillieres Clin Obstet Gynaecol* 1997;11:95-110.
 11. Davies A, Vizza E, Bournas N, O'Connor H, Magos A. How to increase the proportion of hysterectomies performed vaginally? *Am J Obstet Gynecol* 1998;179:1008-12.
 12. Palazzo FF, Francis DL, Clifton MA. Randomized clinical trial of Ligasure versus open haemorrhoidectomy. *Br J Surg* 2002;89:154-7.
 13. Thorbeck CV, Montes MF. Haemorrhoidectomy: randomized controlled trial of Ligasure compared with Milligan-Morgan operation. *Eur J Surg* 2002;168:482-4.
 14. Segupta S, Webb DR. Use of a computer controlled bipolar diathermy system in radical prostatectomies and other open urological surgeries. *ANZ J Surg* 2001;71:538-40.
 15. Zubke W, Hornung R, Wasserer S, Hucke J, Fullers U, Werner C, et al. Bipolar coagulation with the Biclamp forceps versus conventional suture ligation, a multicenter randomized controlled trial in 175 vaginal hysterectomy patients. *Arch Gynecol Obstet* 2009;280:753-60.
 16. Cronje HS, de Coning EC. Electrosurgical bipolar vessel sealing during vaginal hysterectomy. *Int J Gynaecol Obstet* 2005;91:243-5.
 17. Elhao M, Abdallah K, Serag I, El-Laithy M, Agur W. Efficacy of using electrosurgical bipolar vessel sealing during vaginal hysterectomy in patients with different degrees of operative difficulty; a randomized controlled trial. *Eur J Obstet Gynaecol Reprod Biol* 2009;147:86-90.
 18. Hefni MA, Bhaumik J, El-Toukhy T, Kho P, Wong I, Abdel-Razik T, et al. Safety and efficacy of using the Ligasure vessel sealing system for securing the pedicles in vaginal hysterectomy ;a randomized controlled trial. *BJOG* 2005;112:329-33.
 19. Levy B, Emery L. Randomised trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. *Obstet Gynaecol* 2003;102:147 -51.
 20. Silva-Filho AL, Rodrigues AM, Vale de Castro Monteiro M, da Rosa DG, Pereira e Silva YM, Werneck RA, et al. Randomized study of bipolar vessel sealing system versus conventional suture Ligasure for vaginal hysterectomy. *Eur J Obstet Gynecol Reprod Biol* 2009;146:200-3.

Cite this article as: Agrawal VB, Agrawal A, Agrawal SB. Comparison of efficacy of bipolar electrosurgical vessel sealing with conventional suturing in securing vascular pedicles during vaginal hysterectomy. *Int J Med Sci Public Health* 2014;3:1325-1328.

Source of Support: Nil

Conflict of interest: None declared

IJMSPH