
VAGINAL HYSTERECTOMY USING VESSEL SEALING CLAMP VERSUS CONVENTIONAL SURGERY; A RANDOMISED TRIAL

HAMDY MOHAMED TALKHAN,
MD OBS & GYN, faculty of
medicine, Al Azhar University
, Assistant Consultant at Al
Sahil Teaching Hospital, General
Organization of Teaching
Hospitals and Institutes. EGYPT

HANAN NABIL
MD OB GYN, ASSISTANT
.PROFESSOR OBS & GYN, Faculty
of Medicine, MANSOURA
UNIVERSITY

MOHAMMED IBRAHIM
MD OBS & GYN, LECTURER
OB GYN, Faculty of Medicine,
MANSOURA UNIVERSITY

Abstract

Objective: To compare the effects of electrical bipolar vessel sealing clamp and conventional suturing on postoperative pain, operative time, blood loss, and costs, in women undergoing vaginal hysterectomy.

Patients and Methods: 20 women scheduled to undergo vaginal hysterectomy for prolapsed and non prolapsed uterus with benign indication of hysterectomy. Women were randomized randomly into two groups; Conventional vaginal surgery Group and a Group using vessel sealing Erbe machine. Ten patient in each group. Operative time, intraoperative assessment of blood loss, postoperative pain, and estimated cost were evaluated and compared between both groups.

Results: Pain was evaluated few hours post-operative. Patients in the vessel-sealing clamp group showed statistically significant less pain (5.7 versus 4.5 on a scale of 0–10, $P=0.03$), but this followed by comparable pain in both groups later. Operative time was shorter in vessel sealing clamp group (39 versus 61 minutes = $P<0.05$). Amount of Blood lost was also less vessel sealing clamp group. However, regarding the estimated cost, no significant difference between both groups (2903 versus 3102, $P=0.26$).

Conclusion: Using electrical bipolar vessel sealing clamp during vaginal hysterectomy showed less pain on the first few hours after surgery but not in the following days, shorter operative time, less operative blood loss, with no statistically significant differences in cost were found between the two groups. **(Pictures and videos available)**.

Introduction

Hysterectomy is the commonest gynecological operation done for many indications including benign conditions as abnormal uterine bleeding. *FLORY ET AL, (2005) AND VANDEN ET AL (1998)*. Hysterectomy done to treat such conditions aims to improve patient's life and of course, this involve avoidance of possible side effects of the operation. Vaginal hysterectomy is the preferred route with many advantages including fewer complications, shorter hospital stay and lower costs. *VAN DEN ET AL (1998) AND JOHNSON ET AL (2006)*. Vaginal hysterectomy carries the difficulty of gaining access to the vascular pedicles, *HEFNI ET AL (2015)*. To overcome such difficulty more traction on the pedicles is needed which may cause nerve injury, urinary bladder dysfunction and increase post-operative pain. *LAKEMAN ET AL (2010) AND (2011)*. Electrosurgical bipolar vessel sealing clamps used to obliterate tissue bundles and blood vessels up to 7mm in diameter. The clamp allow occluding blood vessels and cutting the tissues at the time which shorten the operative

Corresponding Author:

Hanan Nabil
MD OBS & GYN, ASSISTANT
PROFESSOR OBS & GYN, MANSOURA
UNIVERSITY
Email hanannobil00@yahoo.com
Email hanannobil75@gmail.com
Tel: 01000571004

time and may reduce the post-operative pain by applying less traction on the pedicles of the uterus. In addition, using electro-surgical bipolar vessel sealing clamp enable surgeons to cut tissues close to the uterus preserving the nerves extensively located in the supporting uterine ligaments.

The advantages of vessel sealing clamp were evaluated by few randomized studies, which reported safety, efficacy, short operative time and less post-operative pain *Hefni et al 2015, Elhao et al 2009 and Silva et al 2009*. The effect on postoperative recovery and on the costs of the operation was not evaluated before. Although Vaginal Hysterectomy (VH) has many advantages, it represents a surgical challenge for surgeons where a narrow space to perform a major surgery and difficult hemostasis.

This study is carried out to compare electrical bipolar vessel sealing clamping and conventional suturing regarding pain after surgery, operative time, blood loss, and costs, in vaginal hysterectomy.

Patients and Methods

This randomized controlled trial was performed in a private hospital Alkhobar, Saudi Arabia to compare electrical bipolar vessel clamp sealing with conventional suturing in vaginal hysterectomy.

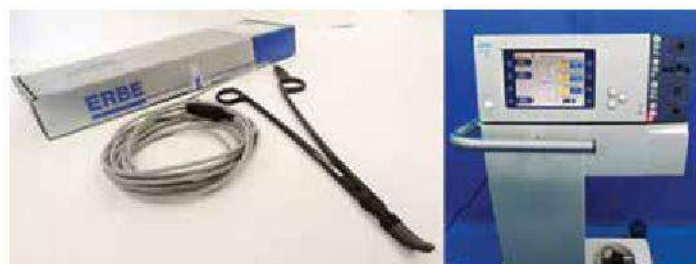
The study was preceded by a pilot study done upon 10 women at a private hospital in Mansoura Egypt using the same inclusion criteria assessing the value of vessel sealing clamping in vaginal hysterectomy on postoperative pain, operative blood loss and duration of surgery.

Cases diagnosed with benign lesions in the uterus and scheduled for hysterectomy vaginally were collected between April 2017 and March 2018. All cases were included after general, abdominal and local examination as well as pelvic ultrasound. The uterine size ranged from normal size to 10 wks. Exclusion criteria were suspected adnexal pathology or pelvic adhesions. The study was approved by the medical ethical committee. After signing the informed consent, women were randomized to one of the treatment groups by computerized randomization. Conventional vaginal surgery Group and a Group using vessel sealing Erbe machine. Ten patients in each group.

The ERBE BiClamp BVSS are insulated forceps with an automatic coagulation completion. The

technique has similar anatomical principles to conventional technique of vaginal hysterectomy. It uses only two instruments with easy access and lower risk of trauma. We investigated the use of ERBE BiClamp BVSS in VH with possible advantages over conventional suture ligation, namely less post-operative pain, reduced blood loss, shorter operative time and cost of surgery.

Surgical procedure:



Vaginal hysterectomy was done following steps of the standardized technique. Vaginal wall was incised circumferentially anteriorly below the bladder base. The Douglas pouch was incised posteriorly and a retractor was used to retract vaginal wall. The urinary bladder was then dissected from the vagina wall. The uterosacral ligaments were clamped, cut and ligated by Vicryl No. 1 sutures that kept long to be fixed to the vault later. In cases of conventional surgery, the rest of pedicles were clamped, cut and ligated by Vicryl No. 1 sutures. In cases of the vessel sealing clamp group the pedicles were clamped, transected and sealed using the Erbe bipolar vessel-sealing device. Vault closure was done in the same manner in both groups by Vicryl No. 1 sutures.

The amount of lost blood was calculated by the amount collected by a suction machine during the surgery and the total number of gauzes used during the procedure. This amount was estimated by the operation assistant and nurse.

Pain management:

Analgesics included morphine and nonsteroidal anti-inflammatory drugs as indicated combined with paracetamol for 3 days postoperatively were given according to a standard protocol.

Outcome measurements:

We used the visual analogue scale (VAS) to measure postoperative pain as a primary outcome during the first week after surgery. Operative time, amount of blood loss and estimated total cost were the Secondary outcomes.

Results

TABLE 1: Basline Characteristics Of Women According To Surgical Approach.

PARAMETER	CONVENTIONAL SURGERY GROUP	VESSEL SEALING GROUP
NUMBER OF WOMEN	10	10
AGE	49.1	50.0
PARITY(MEDIAN,RANGE)	2.0(1-5)	2.0(0-6)
BODY MASSINDEX KG/M2	27.6	26.9
PREVIOUS ABDOMINAL SURGERY INCLUDING CS	3	2
MEDICAL DISORDERS		
DIABETES	3	1
HYPERTENTION	4	2

MAIN INDICATION FOR VH		
ABNORMAL UTERINE BLEEDING	2	2
POSTMENUPOSAL BLEEDING	1	2
PELVIC PAIN	3	1
UTERINEPROLAPSE	4	5
THYROID DISORDERS	1	2

TABLE 2:Duraion And Average Intraoperative Blood Loss:

OUTCOMES	CONVENTIONAL SURGERY GROUP	VESSEL SEALING GROUP	P VALUE
DURATION OF SURGERY/ MINUTRS	61.3	39.6	< 0.05 S.SIG.
BLOOD LOSS/ML	427.7	231.0	< 0.05 S.SIG.

Operative duration was shorter for vessel sealing group (39.6 versus 61.3 = $P < 0.05$) **statistical-ly significant**. Blood loss was less in vessel sealing group (231.0 versus 427.7 = $p < 0.05$) **statistically significant**.

Women in the vessel-sealing group showed significantly less pain few hours after surgery (5.7 versus 4.5 on a scale of 0–10, $P = 0.03$) which was **significant**, but after that pain scores were similar in both groups

TABLE 3: Estimaatedcost Of Surgery (SR) *:

COST PARAMETER	CONVENTIONAL SURGERY GROUP MEAN COST	VESSEL SEALING GROUP MEAN COST	P VALUE
INPATIENT HOSPITAL CARE	2903(2651-3225)	3102(2958-3250)	0.26 NS
OUTPATIENT HOSPITAL CARE	57(37-79)	115(71-167)	0.037
TOTAL	2943(2692-3264)	3188(3040-3341)	0.18 NS

*SR : SAUDI RIYALS

Outpatient hospital costs (i.e. care by medical staff the GP, physiotherapist and company physician) of the vessel-sealing group were significantly higher compared with conventional surgery. Four cases needed multiple outpatient clinic visits because of different complaints: constipation, pain and urinary tract infection. All of them were in the vessel-sealing group, which increased the cost. However, the total cost was similar in both groups

Discussion

This randomized controlled trial evaluated the effects of using electrical bipolar vessel sealing on postoperative pain, operative time, blood loss, and cost. Vessel sealing machine group showed less Postoperative pain few hours after surgery, but pain was similar in both groups after that. Operative time and blood loss was lower in electrical bipolar vessel sealing group. Total costs were similar in both groups with no statistically significant differences.

Both cases as well as the medical staff following them after surgeries remained blinded to the used technique. As a result, bias in the counseling on experienced pain, based on the cases' or the nurses' preferences was avoided. A validated questionnaire was used before and after surgery to evaluate pain and analgesia effects.

One of the most important outcomes was the postoperative pain. In accordance with two previous clinical trials showing that pain was less few hours after vaginal hysterectomy when using vessel-sealing clamp CRONJE ET AL (2005) AND SILVA ET AL (2009). The current study found the decreased postoperative pain few hours after operation in the vessel-sealing group, which became similar in both groups after the first day of surgery. The overall low pain scores found in both studied groups after the first postoperative day probably explain this.

Comparing the results of our study with previous studies included women scheduled for abdominal hysterectomy LAKEMAN ET AL (2008), the overall pain scores were significantly high following abdominal hysterectomy owing to pain of the abdominal incision JONSON ET AL (2006).

The mean hospital stay was slightly long in this study in contrast to previous studies CRONJE ET AL (2005), SILVA ET AL (2009) AND DING ET

AL (2005). However, when compared with hospital stay in other studies for cases of vaginal hysterectomy, it was within average range JONSON ET AL (2006). The large difference in hospital stay duration could be explained by local cultural factors, and by surgeon, as well as participant expectations matched with a meta-analysis done by KROFT ET AL (2011). Hospital stay in our study was shorter, but not statistically significant among women in the vessel-sealing group.

Our study results regarding the operative time were similar to previous studies comparing vessel sealing with conventional method. All reported reduced operation time HEFNI ET AL (2015), ELHAW ET AL (2009), LEVY ET AL (2003), SILVA ET AL (2009) AND DING ET AL (2005). This could be explained by the ability of the vessel-sealing clamp to rapidly seal, coagulate and cut the pedicles in one hand held tool LAMBERTON ET AL (2008).

Reduction of the operative time is a matter of discussion. Although the reduction was as high as 40%, it does not mean a quicker recovery or shorter hospital stay. However, reduction in the operative time reduced the cost of the operation.

Decrease in blood loss using vessel sealing was found by many studies LEVY ET AL (2003), SILVA ET AL (2009) AND DING ET AL (2005). Results of the current study are in agreement with these studies. However, studies on larger scale did not find significant difference in estimated blood loss ELHAW ET AL (2009).

Vessel-sealing technique cost was expected to be higher than the conventional method owing to the cost of the device. The cost was slightly higher in the vessel-sealing cases (2903 versus 3102 SR $P=0.26$), which is explained by the added cost of the ERBE BICLAMP device. However, this is compensated by shorter operative time (conventional surgery 688SR versus vessel sealing 616SR), and shorter hospital stay after vessel sealing (conventional surgery 1852SR versus vessel sealing 1713SR).

Conclusion

It seems that ERBE BiClamp BVSS is a safe, effective technique for vaginal hysterectomy compared to conventional method. The technique resulted

in less pain, shorter operative times, less blood loss, shorter hospital stay and lower total cost. The reduced post-operative pain observed allowed rapid mobilization and recovery.

Recommendations

Further studies with more number of patients is recommend, as well as studies concerning the effects of the two different methods for vaginal hysterectomy on the urinary bladder function and pelvic floor function.

References

1. Flory N, Bissonnette F, Binik YM. Psychosocial effects of hysterectomy: literature review. *J Psychosom Res* 2005; 59:117–29.
2. Van den Eeden SK, Glasser M, Mathias SD, Colwell HH, Pasta DJ, Kunz K. Quality of life, health care utilization, and costs among women undergoing hysterectomy in a managed-care setting. *Am J ObstetGynecol* 1998; 178:91–100.
3. Johnson N, Barlow D, Lethaby A, Tavender E, Curr E, Garry R. Surgical approach to hysterectomy for benign gynecological disease. *Cochrane Database Syst Rev* 2006; 2:CD003677
4. 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: randomized controlled trial. *BJOG* 2001 5;112:329–33.
5. Lakeman MM, van der Vaart CH, Roovers JP. Hysterectomy and lower urinary tract symptoms: a nonrandomized comparison of vaginal and abdominal hysterectomy. *GynecolObstet Invest*2010;70:100–6.
6. Lakeman MM, van der Vaart CH, Roovers JP. A long-term prospective study to compare the effects of vaginal and abdominal hysterectomy on micturition and defecation. *BJOG* 2011; 118:1511–7.
7. Elhao M, Abdallah K, Serag I, El-Laithy M, Agur W. Efficacy of using electro-surgical bipolar vessel sealing during vaginal hysterectomy in patients with different degrees of operative difficulty: a randomised controlled trial. *Eur J ObstetGynecolReprodBiol* 2009;147:86–90.
8. Cronje HS, de Coning EC. Electro-surgical bipolar vessel sealing during vaginal hysterectomy. *Int J GynaecolObstet* 2005;91:243–5.
9. Levy B, Emery L. Randomized trial of suture versus electro-surgical bipolar vessel sealing in vaginal hysterectomy. *ObstetGynecol* 2003; 102:147–51.
10. Silva-Filho AL, Rodrigues AM, Vale de Castro MM, da Rosa DG, Pereira e Silva YM, Werneck RA, et al. Randomized study of bipolar vessel sealing system versus conventional suture ligation for vaginal hysterectomy. *Eur J ObstetGynecolReprodBiol* 2009; 146:200–3.
11. Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program for Women Research Group. *NeurourolUrodyn* 1995;14:131–9.
12. van der Vaart CH, de Leeuw JR, Roovers JP, Heintz AP. [The influence of urinary incontinence on quality of life of community-dwelling, 45–70 year old Dutch women]. *Ned Tijdschr Geneesk*2000; 144:894–7.
13. Van Brummen HJ, Bruinse HW, Van De PG, Heintz AP, van der Vaart CH. Defecatory symptoms during and after the first pregnancy: prevalences and associated factors. *IntUrogynecol J Pelvic Floor Dysfunct* 2006; 17:224–30.
14. Ware JE Jr. SF-36 health survey update. *Spine (Phila Pa 1976)* 2000;25:3130–9.
15. Hakkaart-van Roijen L, Tan SS, Bouwmans CAM. Manual for Costing: Methods and standard costs for economic evaluations in health care. [In Dutch]. Amstelveen: Dutch Health Insurance Executive Board, 2010.
16. Lakeman M, Kruitwagen RF, Vos MC, Roovers JP. Electro-surgical bipolar vessel sealing versus conventional clamping and suturing for total abdominal hysterectomy: a randomized trial. *J Minim Invasive Gynecol* 2008; 15:547–53.
17. Barber JA, Thompson SG. Analysis of cost data in randomized trials: an application of the non-parametric bootstrap. *Stat Med* 2000;19:3219–36.
18. Ding Z, Wable M, Rane A. Use of Ligasure bipolar diathermy system in vaginal hysterectomy. *J ObstetGynaecol* 2005; 25:49–51.
19. Kroft J, Selk A. Energy-based vessel sealing in vaginal hysterectomy: a systematic review and meta-analysis. *ObstetGynecol* 2011;118:1127–36.

20. Lamberton GR, Hsi RS, Jin DH, Lindler TU, Jellison FC, Baldwin DD. Prospective comparison of four laparoscopic vessel ligation devices. *J Endourol* 2008;22:2307–12.
21. Butler-Manuel SA, Buttery LD, A'Hern RP, Polak JM, Barton DP. Pelvic nerve plexus trauma at radical hysterectomy and simple hysterectomy: the nerve content of the uterine supporting ligaments. *Cancer* 2000;89:834–41.
22. Heliövaara-Peippo S, Halmesmaki K, Hurskainen R, Teperi J, Grenman S, Kivelä S, et al. The effect of hysterectomy or levonorgestrel-releasing intrauterine system on lower urinary tract symptoms: a 10-year follow-up study of a randomised trial. *BJOG* 2010;117:602–9.
23. Hurskainen R, Teperi J, Rissanen P, Aalto AM, Grenman S, Kivelä S, et al. Quality of life and cost-effectiveness of levonorgestrel-releasing intrauterine system versus hysterectomy for treatment of menorrhagia: a randomised trial. *Lancet* 2001;357:273–7.
24. Hurskainen R, Teperi J, Rissanen P, Aalto AM, Grenman S, Kivelä S, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. *JAMA* 2004;291:1456–63.
25. Bhattacharya S, Mollison J, Pinion S, Parkin DE, Abramovich DR, Terry P, et al. A comparison of bladder and ovarian function two years following hysterectomy or endometrial ablation. *Br J Obstet Gynaecol* 1996;103:898–903.
26. Neumann GA, Lauszus FF, Ljungstrom B, Rasmussen KL. Incidence and remission of urinary incontinence after hysterectomy—a 3-year follow-up studies. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;18:379–82.
27. Thakar R, Ayers S, Clarkson P, Stanton S, Manyonda I. Outcomes after total versus subtotal abdominal hysterectomy. *N Engl J Med* 2002;347:1318–25.
28. Thakar R, Sultan AH. Hysterectomy and pelvic organ dysfunction. *Best Pract Res Clin Obstet Gynaecol* 2005;19:403–18.
29. Altman D, Granath F, Chattingius S, Falconer C. Hysterectomy and risk of stress-urinary-incontinence surgery: nationwide cohort study. *Lancet* 2007;370:1494–9.
30. Brown JS, Sawaya G, Thom DH, Grady D. Hysterectomy and urinary incontinence: a systematic review. *Lancet* 2000;356:535–9.
31. van der Vaart CH, van der Bom JG, de Leeuw JR, Roovers JP, Heintz AP. The contribution of hysterectomy to the occurrence of urge and stress urinary incontinence symptoms. *BJOG* 2002;109:149–54.
32. Hysterectomy Statistics Uk 2011-2012. Yeovil, Somerset: The Hysterectomy Association; 2013. [[Last accessed December 2016]].
33. Aarts J, Nieboer TE, Tavender E, Garry R, Moi BJ. Surgical approach to hysterectomy for benign gynaecological disease. *Cochrane Database Systematic Reviews*. 2015 Issue 8.
34. NICE Clinical Guideline; 44 . Heavy menstrual bleeding. London: National Institute for Health and Care Excellence; 2007.
35. AAGL Position Statement: route of hysterectomy to treat benign uterine disease. *J Minim Invasive Gynecol*. 2011;18:1–3.
36. Choosing the route of hysterectomy for benign disease American College of Gynecology. Committee Opinion. 2009. [Last accessed December 2016]
37. AAGL Debits Online Master Course on vaginal hysterectomy. Cypress, California: American Association of Gynecologic Laparoscopists; 2015. [Last accessed December 2016].
38. Chen B, Ren DP, Li JX, Li CD. Comparison of vaginal and abdominal hysterectomy. A prospective non-randomized trial. *Pak J Med Sci*. 2014;30((4)):875–9.
39. Kovac SR. Clinical opinion: guidelines for hysterectomy. *Am J Obstet Gynecol*. 2004;191((2)):635–40.
40. 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: randomised controlled trial. *BJOG*. 2005;112((3)):329–33.
41. Elhao, 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 randomised controlled trial. *Eur J Obstet Gynecol Reprod Biol*. 2009;147((1)):86–90.