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A Comparative Study of Bipolar Vessel Sealing System versus Conventional Clamp Suture in Vaginal Hysterectomy in the Department of Obstetrics and Gynaecology, Sawai Man Singh Medical College & Attached Hospitals, Jaipur

Dr. Anant Chopra[1], Dr. Suniti verma[2], Dr. R N Sehra[3], Dr. Neelam Bunkar[4], Dr. Jyoti Saini[5]

[1,4] Resident doctor, [2,3]Senior Professor, [5]Assistant Professor

Department of Obstetrics & Gynaecology, SMS Medical College & Attached Group of Hospitals, Jaipur, Rajasthan

Corresponding Author: Dr. Suniti Verma, Senior Professor, Department of Obstetrics & Gynaecology, SMS Medical College & Attached Group of Hospitals, Jaipur, Rajasthan

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Abstract

Background: Vaginal route is considered to be the method of choice for removal of uterus and, in the absence of gross pelvic disease, can be carried out in most patients. Recent studies have shown that less than one-third of hysterectomies are performed vaginally. This could be due to technical difficulties occurring while operating in the narrow surgical field. This study was taken up to find out the easier alternatives in securing pedicles by using Electrosurgical Bipolar Vessel Sealer in Vaginal Hysterectomy.

Methods: A prospective observational study was conducted in the Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur. A total of 60 patients posted for vaginal hysterectomy were enrolled after informed consent.

Results: The operative time was significantly higher in conventional clamp group (55.60±5.21 min.) as compared to bipolar vessel sealer group (48.07±5.08 min.). Intra-operative haemorrhage was more in 4(13.33%) cases in conventional clamp group and in 1(3.33%) case in bipolar vessel sealer group In conventional clamp group 5(16.66%) cases had fever, 2(6.67%) cases had UTI after surgery whereas in bipolar vessels sealer group 5(16.66%) cases had fever, 1(3.33%) case had pain abdomen, 1 (3.33%) case had UTI after surgery. The hospital stay was significantly higher in conventional clamp group (6.03±1.19 days) as compared to bipolar vessel sealer group (4.97±1.00 days) because in BVSS group postoperative pain and post- operative complications were less.

Conclusions- We concluded that Bipolar Vessel Sealer surgery is suitable to be used for vaginal hysterectomy without serious complications.

Keywords: Blood loss, Conventional sutures, Electrosurgical bipolar vessel sealer, Vaginal hysterectomy

Introduction

Hysterectomy is one of the most commonly performed gynaecological procedure. The common indications for hysterectomy are fibroid, UV prolapse, AUB, chronic PID, PMB, endometrial hyperplasia. The main goal of removal of uterus is to improve quality of life.[1]

A typical Electrothermal Bipolar Vessel Sealing system consists of an electric current generator and an instrument for grasping blood vessels. During surgery,

a surgeon first grasps a blood vessel to be sealed with the instrument that is usually designed as a clamp. A surgeon then initiates a sealing cycle controlled by the generator. The generator produces an electric current across the blood vessel wall. Electromagnetic wave surrounding the current energizes the electrons within the blood vessel. These electrons release their energy as heat. As the blood vessel is heated, the collagen and elastin found in the blood vessel wall denature. The generator precisely controls the amount of energy delivered to the tissue through a computer algorithm that varies depending on the manufacturer. The majority of the generator systems monitor the impedance in the circuit and as it begins to rise automatically break the current. This prevents charring and burning of the vessel wall. The sealing cycle is complete with a period of cool-down during which the elastin and collagen form a seal. Some of the EBVS instruments are also able to cut the formed seal either with a blade incorporated into jaws of the instrument or with a harmonic scalpel technology. [2-3]

Material & Methods

Place of Study : Study was conducted in department of obstetrics and Gynaecology, SMS Medical College & Attached Hospitals, Jaipur

Duration of Study: MAY 2018 to august 2019.

Study Type: Interventional (Randomised Comparative Study)

Study Design : Prospective Study

Sample Size : Sample size was calculated at 80% study power and Error of 0.05 assuming SD Of 25 minute in operating time as founding in seed article.

For minimum detectable mean difference of 20 minute in operating time, 25 cases in each group required sample size which was increased to 30 cases in each group expecting 20 % dropouts/attrition as final sample size.

Purpose of Study

To provide a safe technique for securing the pedicles in vaginal hysterectomy for reducing complications and hospital burden .

Selection criteria

Inclusion criteria

- Uterovaginal prolapse.
- Fibroid less than 14 weeks
- Abnormal Uterine bleeding.
- Women giving consent.

Exclusion Criteria

- Women withdrawing consent.
- Women not co-operative and not able to understand.
- Known endometriosis, pelvic inflammatory disease.
- Uterine, cervical, ovarian malignancy.

Methodology

- Women undergoing vaginal hysterectomy on the basis of inclusion and exclusion criteria were selected.
- Informed consent of the women was taken prior to study.
- Institute review board and ethical committee approval was taken.
- Randomization was done to allocate women in each group using computer generated random numbers.
- Spinal anesthesia was given to all .
- A circumferential vaginal incision was made around the anterior portion of the cervix between the transverse cervical ligaments and extended postero-medially 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 bipolar vessel sealing system or conventional 'clamp, cut and suture' technique was used for securing the

hysterectomy pedicles. The bipolar device consists of a bipolar radio-frequency generator, the generator delivers a low voltage high power current.

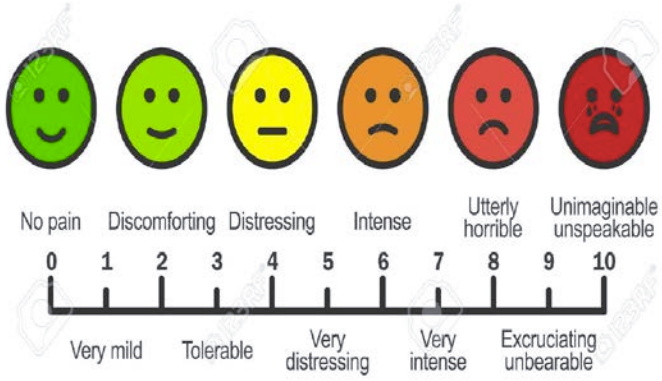
- When the suturing technique was used, the pedicles were clamped, cut, transfixed and doubly ligated using Vicryl No.1 sutures.
- The vault was closed similarly in both groups by continous interlocking suture.
- Intraoperative parameters and postoperative condition of women till follow up period of 45 days was assessed and recorded as per Performa.
- To control inter-observer variability same surgeon, same anesthetist and same drugs during and after surgery were prescribed.

Intra Operative Parameters

- Time from circumferential incision (on anterior portion of cervix) to vault closure by continuous interlocking sutures.
- Blood loss was assessed by weighing the dry and soaked mops preoperatively and postoperatively respectively and adding the blood in suction jar.
- Preoperative and postoperative (after 24 hours) haemoglobin was done of all women and difference in haemoglobin was noted.
- Any complication during surgery was noted.

Post Operative Condition

- Post-operative condition was noted.
- Post-operative antibiotics to be used in all women was injection ceftriaxone (1g iv AST 12 hourly), injection Amikacin 500mg iv 12 hourly and injection metronidazole 500mg in 100cc solution i.v. 8 hourly.
- Injection diclofenac sodium 75mg was administered I.M. 8 hourly for first 48 hours. Postoperative pain was assessed, first after 2 hours post operatively, then 8 hourly for 48hours. Subjective pain scoring was done with visual analogue scale.



Presence of fever, nausea, vomiting, pain, hemorrhage, vault hematoma, abscess, urinary problems were noted in each group.

Statistical Analysis

Linear variables were described as mean and SD and were compared by using unpaired 't' test.

Catagorical variables were described as percentages and was compared by using X2 test/fisher exact test.P-value <0.05 will be taken as significant.

Results

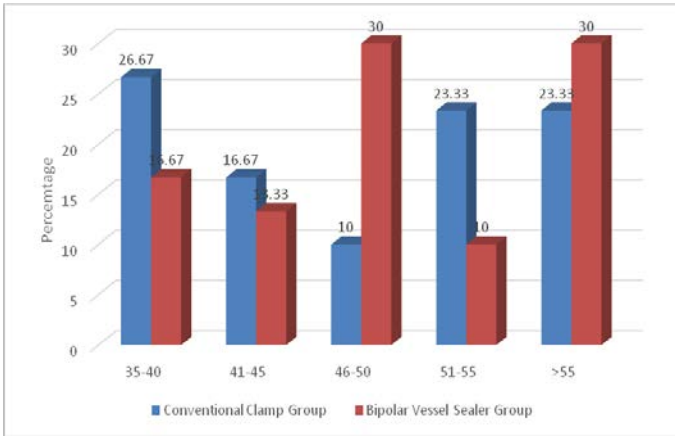


Fig.1: Age wise distribution

In our study 8(26.67%) women were 35-40 Yrs age group, 7(23.33%) women were 51-55 Yrs & >55 Yrs age group, 5(16.67%) women were 41-45 Yrs age group, 3(10.00%) women were 46-50 Yrs age group in conventional clamp group whereas 9(30.00%) women

were >55 Yrs & 46-50 Yrs age group, 5(16.67%) women were 35-40 Yrs age group, 4(13.33%) women were 41-45 Yrs age group, 3(10.00%) women were 51-55 Yrs age group in Bipolar Vessel Sealer Group. The mean age of conventional clamp group was 49.43±9.14 Yrs and in Bipolar Vessel Sealer Group was 51.30±9.60 Yrs. The age wise difference between both groups found statistically Insignificant. (p-value=0.443)

Table 1: Duration of surgery (minutes)

	Conventional Clamp Group		Bipolar Vessel Sealer Group		P value
	Mean	SD	Mean	SD	
Operative time	55.60	5.21	48.07	5.08	P<0.001
Range	49-70 min		35-58 min		

The operative time was significantly higher in conventional clamp group (55.60±5.21 mint.) as compared to bipolar vessel sealer group (48.07±5.08 mint.).

Table 2: Blood Loss (ml)

	Conventional Clamp Group		Bipolar Vessel Sealer Group		P value
	Mean	SD	Mean	SD	
Blood Loss	92.90	10.09	81.77	8.61	P<0.001
Range	80-118 ml		60-105 ml		

The blood loss was significantly higher in conventional clamp group (92.90±10.09 ml) as compared to bipolar vessel sealer group (81.77±8.61 ml).

Table 3: Intra Op. Complications

	Conventional Clamp Group		Bipolar Vessel Sealer Group	
	Number of cases	%	Number of cases	%
Haemorrhage	4	13.33	1	3.33
None	26	86.66	29	96.67
Total	30	100.00	30.00	100.00
P value	0.350 (NS)			

Haemorrhage was seen in 4(13.33%) cases in conventional clamp group and in 1(3.33%) case in bipolar vessel sealer group. (p-value 0.350)

Table 4: Post Op. Complications

	Conventional Clamp Group		Bipolar Vessel Sealer Group	
	Number of cases	%	Number of cases	%
Fever	5	16.66	5	16.67
Pain Abdomen	0	0	1	3.33
UTI	2	6.67	1	3.33
None	23	76.67	23	76.67
Total	30	100.00	30	100.00
P value	0.986 (NS)			

In conventional clamp group 5(16.66%) cases had fever, 2(6.67%) cases had UTI after surgery and in bipolar vessels sealer group 5(16.66%) cases had fever, 1(3.33%) case had pain abdomen, 1(3.33%) cases had UTI after surgery.

The post operative complication wise difference in both groups was found to be statically Insignificant. (p-value=0.968)

Table 5: Hospital Stay (Days)

	Conventional Clamp Group		Bipolar Vessel Sealer Group	
	Mean	SD	Mean	SD
Hospital Stay	6.03	1.19	4.97	1.00
Range	5-10		4-7	
P value	0.0003 (S)			

The hospital stay was significantly higher in conventional clamp group (6.03±1.19 days) as compared to bipolar vessel sealer group (4.97±1.00 days).

Table 6:Pain Score

	Conventional Clamp Group		Bipolar Vessel Sealer Group	
	Number of cases	%	Number of cases	%
Score 1	1	3.33	0	0
Score 2	3	10.00	5	16.67
Score 3	5	16.67	12	40.00
Score 4	7	23.33	7	23.33
Score 5	7	23.33	4	13.33
Score 6	5	16.67	2	6.67
Score 7	2	6.67	0	0.00
Total	30	100.00	30	100.00
P value	0.031 (S)			

Seven (23.33%) patients had score 4 & score 5 level pain, 5 (16.67%) patients had score 6 & score 3 level pain, 3(10.00%) patients had score 2 & score 7 level pain, 1 (3.33%) patient with score 1 level pain after surgery in conventional clamp group whereas 12 (40.00%) patients had score 3 level pain, 7 (23.33%) patients had score 4 level pain, 5(16.67%) patients with score 2 level pain, 2 (6.67%) patients had score 6 level pain after surgery in bipolar vessels sealer group.

The pain score wise difference in both group was found stastically significant (p-value=0.031)

Discussion

The operative time was significantly higher in conventional clamp group (55.60±5.21 min.) as compared to bipolar vessel sealer group (48.07±5.08 min.) in our study. In concordance with our findings, previous studies comparing vessel sealing with conventional clamping, all reported reduced operation time.[4-5] The most plausible explanation for this finding is that energy-based vessel-sealing devices allow for rapid vessel sealing, coagulation and transection of the pedicle in one handheld tool.[6-7] The clinical relevance of 7.52-minute difference in operating time is a point of discussion, especially as this 15% shortening of operation duration did not seem to induce a quicker recovery or shorter hospital admission. However every minute shorter the operation lasts, does reduce the costs of the procedure.

Our study demonstrated that with the equal experiences in both methods, Bipolar Vessel Sealer surgery was easier to use therefore it ended up with significantly less operative time than the conventional method. In terms of complications, Bipolar Vessel Sealer surgery group showed less blood loss than conventional suture group. This finding is contrary to the earlier studies Hagen B et al and Pandey D et al in which EBVS was just introduced and the experiences of users were still limited.[8,9] However during that time in the complicated cases such as in vaginal hysterectomy, Bipolar Vessel Sealer surgery still showed benefit as less blood loss than the conventional method.[10] However this finding did not show any difference in intraoperative and postoperative complications. One important parameter that indicated an indirect benefit of Bipolar Vessel Sealer surgery is less pain in this group. The possible mechanism is less healing reaction in Bipolar Vessel Sealer surgery group due to less injury to surrounding tissue during operating process performed by Bipolar Vessel Sealer surgery. An earlier study Kennedy JS et al demonstrated that heat production from Bipolar Vessel Sealer surgery effected nearby tissue surrounding sealing point within less than 1.5 millimeters from that point.[11] Whereas in conventional suturing method the injury that occurs may include

tissue and nerve compression from clamping and suturing during operative procedure. Patients who underwent EBVS sealing procedure require less recovery period than those in the conventional clampgroup.[12]

In conclusion, Bipolar Vessel Sealer surgery is an expensive but convenient surgical procedure. With more experiences, Bipolar Vessel Sealer surgery demonstrates more benefits than conventional clamping methods in many ways for abdominal hysterectomy. The method provides a convenient procedure for vessels sealing resulting in less operative time, less blood loss and less postoperative pain. Furthermore this procedure needs less suture materials that can overcome an expensive cost if used in hospitals with high volume of patients. Even expensive, but its convenience and other direct and indirect benefits can overcome its disadvantage on high price. Therefore Bipolar Vessel Sealer surgery is suitable to be used for abdominal hysterectomy without serious complications.

Conclusion

In conclusion, Bipolar Vessel Sealer surgery is an expensive but convenient surgical procedure. With more experiences, Bipolar Vessel Sealer surgery demonstrates more benefits than conventional clamping methods in many ways for vaginal hysterectomy. The method provides a convenient procedure for vessel sealing thereby resulting in less operative time, less blood loss and less postoperative pain. Furthermore this procedure needs less suture material that can overcome an expensive cost if used in hospitals with high volume of patients. Even though expensive, but its convenience and other direct and indirect benefits can overcome its disadvantage on high price. Therefore Bipolar Vessel Sealer surgery is suitable to be used for vaginal hysterectomy without serious complications.

References

1. Flory N, Bissonnette F, Binik YM. Psychosocial effects of hysterectomy: literature review. J Psychosom Res 2005, 59 117-29.
2. Massarweh, NN; Cosgriff, N; Slakey, DP (Mar 2006). "Electrosurgery: history, principles, and current and future uses". Journal of the American College of Surgeons. 202 (3): 520–30.
3. Milsom, J; Trencheva, K; Monette, S; Pavoor, R; Shukla, P; Ma, J; Sonoda, T (May 2012). "Evaluation of the safety, efficacy, and versatility of a new surgical energy device (THUNDERBEAT) in comparison with Harmonic ACE, LigaSure V, and EnSeal devices in a porcine model". Journal of laparoendoscopic & advanced surgical techniques. Part A. 22 (4): 378–86
4. Hurskainen R, Teperi J, Rissanen P, Aalto AM, Grenman S, Kivela¨ 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.
5. Hurskainen R, Teperi J, Rissanen P, Aalto AM, Grenman S, Kivela¨ 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.
6. 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.

7. Levy B, Emery L. Randomized trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. Obstet Gynecol 2003;102:147-51.
8. Hagen B, Eriksson N, Sundset M. Randomized controlled trial of LigaSure versus conventional suture ligature for abdominal hysterectomy. Br J Obstet Gynecol 2005;112:968-70.
9. Pandey D, Sehgal K, Saxena A, Hebbar S, Nambiar J, Bhat RG. An audit of indications, complications, and justification of hysterectomies at a teaching hospital in India. Int J Reprod Med. 2014;2014
10. Hagen B, Eriksson N, Sundset M. Randomized controlled trial of LigaSure versus conventional suture ligature for abdominal hysterectomy. Br J Obstet Gynecol 2005;112:968-70
11. Kennedy JS, Stranahan PL, Taylor KD, Chandler JG. High-burst-strength, feedback controlled bipolar vessel sealing. Surg Endosc 1998;12:876-8.
12. Jones HW III. Hysterectomy. In : Rock JA, Jones HW III, editors. Te Lindeûs operative gynecology. 9th ed. Philadelphia: Lippincott Williams & Wilkins; 2003. p. 779-824.