



COMPARISON OF BIPLOAR VESSEL SEALING CLAMP WITH CONVENTIONAL CLAMPING & SUTURING TECHNIQUE IN NON-DESCENT VAGINAL HYSTERECTOMY

Dr Saurabh Vijay Bhangale*	Divisional Medical Officer, Department of Obstetrics & Gynaecology, Jagjivan Ram Hospital (Western Railway), Mumbai. *Corresponding Author
Dr Mamta Sharma	Medical Director, Department of Obstetrics & Gynaecology, Jagjivan Ram Hospital (Western Railway), Mumbai.
Dr Ashok Kumar	Senior Consultant, Department of Obstetrics & Gynaecology, Jagjivan Ram Hospital (Western Railway), Mumbai.
Dr Neha Dhok	Junior Resident, Department of Obstetrics & Gynaecology, Jagjivan Ram Hospital (Western Railway), Mumbai.

ABSTRACT **Background:** Hysterectomy is second most common major surgical procedure in women in world. A vaginal approach is preferred due to fewer complications, less postoperative pain, shorter hospital stay and lower cost over abdominal route.

Aim: To compare Bipolar vessel sealing clamp system (Group 2) with Conventional clamping & suturing technique (Group 1) for securing pedicles in non-decent vaginal hysterectomy. **Method:** Total 26 women (13 in either group) underwent vaginal hysterectomy. Results: Duration of surgery, Operative blood loss, Postoperative pain and Hospital stay was significantly lower in group 2 compared to group 1. **Conclusion:** Bipolar Vessel Sealing Clamp is an innovative & convenient technique leading to less operative time, less blood loss, less postoperative pain and faster recovery compared to conventional clamping & suturing in vaginal hysterectomy.

KEYWORDS : Bipolar Vessel Sealing Clamp, Non-Decent Vaginal Hysterectomy, Conventional Clamp & Suture.

INTRODUCTION

Hysterectomy is second most common major surgical procedure in women in world, next to caesarean section [1]. In US, approximately 600,000 hysterectomies are performed each year [2].

Indications of hysterectomy vary from benign condition to malignancies of genital tract. Hysterectomy can be performed abdominally, vaginally, laparoscopically or robotic depending on surgeon's preference & skills, indication for surgery, nature of disease and patient characteristics.

A vaginal approach is preferred due to fewer complications, less postoperative pain, shorter hospital stay and lower cost over abdominal route [3]. Recent studies found less than one third of hysterectomies are performed vaginally mainly due limited vaginal space for surgical access to vascular pedicles and surgical skills [4].

[5-8]	Conventional Clamp & Suture Group1	Bipolar Vessel Sealing Clamp Group 2
Tissue Traction, Damage to Surrounding Structures (nerves, vessels), Complication	More	Less
Access through Small Vaginal Space, Hemostasis	Difficult	Easy
Instruments, Suture Material	Multiple, More Sutures	Single, Less Suture
Convenient	Less	More

Newly developed vessel sealing devices build upon bipolar diathermy, ultrasonic & tissue sensing technology provides more consistent faster hemostasis with increased efficiency.

Aim

To compare Bipolar vessel sealing clamp system with Conventional clamping & suturing technique for securing pedicles in non-decent vaginal hysterectomy.

Objectives

1. To compare operative time & operative blood loss
2. To compare intraoperative & postoperative pain & complications
3. To compare duration of hospital stay

Study Detail

Study Type: Prospective Randomized Comparative Study at Department of Obstetrics and Gynecology, Jagjivan Ram Railway Hospital, Mumbai (September 2020 to September 2021)

Sample Size

Although no national statistics for hysterectomy is available, according to NFHS-4 (2012-2013) prevalence of hysterectomy was 6% in India out of which 17.8% were performed vaginally [9].

Sample size can be calculated using the Cochran's formula – $n = z^2 \frac{pq}{d^2}$
Where n is sample size,
 $Z = 1.96$ at 95 % confidence interval $P = \text{prevalence} = 17.8 \%$
 $q = 100 - p = 98.93 \%$

$d = \text{precision} = 5 \%$. Therefore, $n = \text{sample size for this study is } 234$.

Modification of Cochran formula for sample size calculation in smaller population [10]: $n' = \frac{n}{1 + \frac{(n-1)}{N}}$

Where n' is new adjusted sample size, n = Cochran's sample size recommendation, N = population size. (average number of hysterectomies done in our hospital in 1 year)

Using the above formula the sample size of this study is 34.

By adding 10% loss to follow up, sample size of the study was 38.

As our hospital was also catering COVID-19 patients, non-emergency services were curtailed in COVID-19 pandemic. Hence, study was done on 26 subjects, 13 in each group.

Inclusion Criteria

- Women giving Consent
- Fibroid < 14 weeks (clinical assessment)
- Abnormal Uterine Bleeding
- Benign Endometrial Hyperplasia
- Adenomyosis
- Multiparity with good vaginal access

Exclusion Criteria

- Women not giving Consent.
- Uterine size > 14 weeks (clinical assessment)
- Restricted mobility
- Uterine, Cervical, Ovarian Malignancy, Adnexal Mass
- Known Endometriosis, Pelvic Inflammatory Disease, Adhesion

Methodology

After obtaining Ethical & Scientific Committee approval, eligible women giving written informed valid consent were included in study.

After randomization using computer generated random numbers, patients underwent pre-anaesthetic fitness and received Spinal Anaesthesia for surgery. Procedure-- After taking a circumferential incision at Cervix-Vaginal junction, urinary bladder was then dissected off the vagina anteriorly and the pouch of Douglas was opened posteriorly. The hysterectomy pedicles were secured using either conventional 'clamp, cut and suture (Vicryl no 1) technique (Group 1) or the bipolar vessel sealing system technique (Group 2). The vaginal vault was closed by continuous interlocking suture using Vicryl no 1 in both groups. All patients received Injection MONOCEF 1gm IV BD, Injection METRONIDAZOLE 500mg IV TDS along with Injection DICLOFENAC SODIUM 75 mg IV TDS for 48 hours post-operatively. Women were followed up till 45 days.

Parameters

- Duration of Surgery-- From cervical circumferential incision to vault closure
- Operative Blood Loss Assessment-- Weighing Dry (pre) & Soaked (post-operative) mops + Blood in Suction Jar
- Pre & post-operative (> 24 hours) Haemoglobin Difference
- Any Operative/Post-operative Complication (fever, nausea, vomiting, haemorrhage, vault hematoma, abscess, urinary problems etc)
- Postoperative pain was assessed at 2 hours, then 8 hourly for 48hours using visual analogue scale (Subjective Pain Score) in either group.



Statistical Analysis

Linear variables were described as mean & SD and were compared by using unpaired 't' test. Categorical variables were described as percentages and was compared by using X2 test/Fisher exact test. P-value <0.05 was taken as significant.

RESULT & DISCUSSION:

Age Distribution (years)

The mean age of Group 1 was 50.23 ± 8.11 & Group 2 was 50.30 ± 9.86 and age wise difference was Statistically Insignificant. (p=0.983)

Chanchai Suprasongsin et al [11] also found that age was statistical insignificance during hysterectomy (Group 1-43.97 vs Group 2- 46 years).

Urban vs Rural Residence

Majority of women were residing in urban areas - 9 out of 13 (69.2%) in Group 1 & 10 out of 13 (76.9%) in Group 2 and residence wise difference was Statistically Insignificant. (p=0.745)

According to census 2011, majority 62.4 % live in urban region of Mumbai district [12].

Socio-Economic Scale

Majority belong to Middle socio-economic scale - 8 out of 13 (61.5%) in Group 1 & 9 out of 13 (69.2%) in Group 2 and least belong to High socio-economic scale- 1 out 13 (7.7%) in both groups.

Socio-economic scale wise difference was Statistically Insignificant. (p=0.591)

Parity

Majority of women had parity 3 in 4 out of 13 (30.8%) followed by parity 4 in 3 out of 13 women (23.1%) in both groups and Parity wise difference was Statistically Insignificant (p=0.7).

Prior Surgery

Majority women 6 out of 13 (46.2%) in Group 1 & 7 out of 13 (53.8%) had no previous surgery. In Group 1, 5 (38.4%) had Tubal Ligation & 2 (15.4%) and in Group 2, 3 (23.1%) had LSCS & 1 (7.7%) had Tubal Ligation. Prior surgery wise difference was Statistically Insignificant. (p=0.67)

Chanchai Suprasongsin et al [11] and Singh H et al [13] both found that

maximum patients in both the groups had tubal ligation as previous surgical procedure followed by Caesarean Section.

Indication of Hysterectomy

As our study mainly focused on non-decent vaginal hysterectomy, most common indication for hysterectomy was AUB-L 5 out of 13 (38.5%) followed by AUB-A- 4 out of 13 (30.8%) & PMB- 4 out of 13 (30.8%) in both groups and indication wise difference was Statistically Insignificant. (p=1.0)

Similarly, Singh H et al [13] & Pandey D et al [14] found most common indication was AUB, symptomatic fibroid.

Associated Co-morbidities

Associated comorbidity wise difference was Statistically Insignificant. (p=0.15)

	Group 1		Group 2	
	Number of cases	%	Number of cases	%
Anemia	1	7.7	1	7.7
DM	2	15.4	1	7.7
Heart Disease	1	7.7	0	0.0
Hypertension	3	23.1	3	23.1
Hypothyroidism	3	23.1	1	7.7
Obesity	2	15.4	0	0
None	1	7.7	7	53.8
Total	13	100	13	100
P value	0.15			

Duration of Surgery (minutes)

Operative time was Significantly higher (p=0.018) in Group 1 (55.07 ± 6.42) compared to Group 2 (49.76 ± 4.00).

Similarly, Hefni MA et al [7], Levy B et al [15] and MME Lakeman et al [16] found that operating time was significantly shorter in Liga Sure group vs control group (P < 0.04) & electrosurgical bipolar vessel sealer arm (39.1 vs 53.6 min, P=0.003) and shorter for vessel sealing (60 vs 71 mins, P=0.05).

In contrast, Hagen B et al [17] observed that mean operation duration was higher in Liga Sure (61.7 mins) than conventional suture ligature (54.5 mins).

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 [18,19]. The clinical relevance of 5.31 minutes 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 stay. However, every minute shorter the operation lasts, does reduce the costs of the procedure

Operative Blood Loss (ml)

Blood loss was Significantly higher (p=0.001) in Group 1 (133.92 ± 46.16) compared to Group 2 (83.15 ± 6.51).

Zubke W et al [20] observed that intraoperative blood loss & post op fall in hemoglobin was significantly lower in Electro bipolar sealer group (P < 0.001%) which was also observed by Vasileios Pergialiotis et al [21] in which Meta-analysis showed that Electro bipolar sealer system seem to produce less intraoperative blood loss without significantly lowering intraoperative time or complication rate. Similarly, Chanchai Suprasongsin et al [11] found more intraoperative blood in conventional suture group than Biclamp group (P=0.04).

Intra Operative Complications

Only 3 out of 13 (23.1%) in Group 1 had Hemorrhage & only 1 out of 13 (7.7%) in Group 2 had fever and the intra operative complication wise difference was Statistically Insignificant (p=0.124).

Change in Hemoglobin (gm/dl)

Change in hemoglobin level was higher in Group 1 (1.98 ± 0.48) compared to Group 2 (1.52 ± 0.31) but difference was found Statistically Insignificant (p=0.009).

Post Operative Complications

	Group 1		Group 2	
	Number of cases	%	Number of cases	%

Fever	2	15.4	1	7.7
Vault Collection	1	7.7	0	0
BPV	1	7.7	0	0
Pain Abdomen	0	0	1	7.7
UTI	1	7.7	1	7.7
None	8	61.5	10	76.9
Total	13	100	13	100
P value	0.615			

Post-operative complication wise difference was Statistically Insignificant ($p=0.615$).

Hefni MA et al [7] showed complication rate was statistically lower Group 2 as compared to conventional Group 1. (0% vs 6.8%, $P=0.057$)

Pain Score (Visual Analogue Scale)

Mean pain score was Significantly Lower ($p=0.001$) in Group 2 (4.00 ± 1.15) compared to Group 1 (5.61 ± 0.96) possibly due to less injury to surrounding tissue leading to less healing reaction. Lakeman M et al [5] found that vessel sealer group has statically significant lower pain scores during the first 3 postoperative days & resumed their normal daily activities on average 8 days earlier compared with the conventional group. Similarly, MM Lakeman et al [16] study in which the evening after surgery, women in the vessel-sealing group reported significantly less pain (5.7 vs 4.5, $P=0.03$). Chanchai Suprasongsin et al [11] study showed Postoperative pain was no different between the two groups in the first 12 hours after surgery but significantly lower in the Bi Clamp group than in the conventional suture group at 24 hours after surgery.

Hospital Stay (days)

Hospital stay was Significantly Higher ($p=0.001$) in Group 1 (7.00 ± 2.23) compared to Group 2 (4.07 ± 1.32).

Ding Z et al [22] also showed the hospital stay was shorter in the Ligasure hysterectomy group (1.2 vs 3 days, $P<0.05$).

Zubke W et al [20] found average, 7-8 sutures/operation were saved with bipolar coagulation ($P<0.0001$) and ease of use ratings were significantly higher for bipolar vessel sealer group.

CONCLUSION

In conclusion, Bipolar Vessel Sealing Clamp is an innovative, tried & tested and convenient surgical technique for vessel sealing thereby resulting in less operative time, less blood loss, less postoperative pain and faster recovery compared to conventional clamping & suturing methods in vaginal hysterectomy. In high volume centers, its high one-time cost can be overcome by requirement of less suture material & instruments as well as by using it in many other surgeries.

RECOMMENDATIONS

Further studies are recommended to validate the findings of this study on larger sample size.

REFERENCES

1. Flory N, Bissonnette F, Binik YM. Psychosocial effects of hysterectomy: literature review. *J Psychosom Res* 2005; 59:117-29.
2. Wu JM, Wechter ME, Geller EJ, Nguyen TV, Visco AG. Hysterectomy rates in the United States, 2003. *Obstet Gynecol*. 2007;110(5):1091-5.
3. Van den Eeden SK, Glasser M, Mathas SD, Colwell HH, Pasta Kunz K. Quality of life, health care utilization and costs among women undergoing hysterectomy in a managed-care setting. *Obstet Gynecol* 1998; 178: 91-100.
4. Farquhar CM, Steinberg CA. Hysterectomy rates in United States 1990-1997. *Obstet Gynaecol* 2002;99:229-234.
5. Lakeman MM, Van der Vaart CH, Roovers JP. Along-term prospective study to compare the effects of vaginal and abdominal hysterectomy on micturition and defecation. *BJOG* 2011;118:1511-7.
6. Kovac SR. Clinical opinion: guidelines for hysterectomy. *Am J Obstet Gynecol* 2004;191:635-40.
7. 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*. 2005; 112(3): 329-33.
8. Elhao M, Abdallah K, Serag I, El-Laithy M, Agur W. Efficacy of using electrosurgical bipolar vessel sealing during vaginal hysterectomy in patient with different degree of operative difficulty: a randomized control trial. *Eur J Obstet Gynecol Reprod Biol* 2009;147:86-90.
9. 31. www.statisticshowto.com/probability-and-statistics/find-sample-size/
10. <https://www.statisticshowto.com/probability-and-statistics/find-sample-size/>
11. Chanchai Suprasongsin, Montree Boonyakitanon. Comparison of Conventional Suture versus Electrosurgical Bipolar Vessel Sealing in Abdominal Hysterectomy: A Randomized Control Trial. *Journal of Health Science*, 2012; 21(3): 416-20.
12. <https://www.census2011.co.in/census/city/365-mumbai.html>
13. Singh H, Jindal M, Gupta M, Goraya SPS, Behal M, Tanjeet. Comparative evaluation of abdominal hysterectomy by ligasure and conventional method. *Int J Reprod Contracept Obstet Gynecol* 2017;6:5587-91.
14. 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

15. Levy B, Emery L. Randomized trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. *Obstet Gynecol*. 2003;102(1):147-51.
16. Lakeman M, The S, Schellart R, Dietz V, ter Haar J, Thürkow A, Scholten P, Dijkgraaf M, Roovers J. Electrosurgical bipolar vessel sealing versus conventional clamping and suturing for vaginal hysterectomy: a randomised controlled trial. *BJOG* 2012;119: 1473-1482.
17. Hagen B, Eriksson N, Sundset M. Randomised controlled trial of LigaSure versus conventional suture ligation for abdominal hysterectomy. *Int J Obstet Gynaecol*. 2005;112(7):968-70.
18. 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.
19. Levy B, Emery L. Randomized trial of suture versus electrosurgical bipolar vessel sealing in vaginal hysterectomy. *Obstet Gynecol* 2003;102:147-51.
20. Zubke W, Hornung R, Wässerer S, Hucke J, Füllers 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(5):753-60.
21. Vasileios Pergialiotis I, Dimitrios Vlachos, Alexandros Rodolakis, Dimitrios Haidopoulos, Dimitrios Christakis, Georgios Vlachos. Electrosurgical bipolar vessel sealing for vaginal hysterectomies. <https://pubmed.ncbi.nlm.nih.gov/24728146/>
22. Ding Z, Wable M, Rane A. Use of LigaSure™ bipolar diathermy system in vaginal hysterectomy. *J Obstet Gynaecol*. 2005;25(1):49-51.