

“Vaginal Hysterectomy Using Electrosurgical Bipolar Vessel Sealing System Versus Conventional Clamping and Suturing Method: A Prospective Study”

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Abstract:

Background: Vaginal hysterectomy is a challenging surgical technique due to difficulties occurring while operating in the narrow surgical field particularly the ability to access and to ligate pedicles. Surgical hemostasis can be secured by mechanical or electrosurgical method. BiClamp method is hemostatic system based on the combination of pressure and bipolar electrical energy and seals vessels up to 7 mm in diameter. The aim of the study is to compare the operating time, perioperative blood loss, intraoperative and post-operative complications and duration of hospital stay in patients undergoing vaginal hysterectomy by BiClamp versus clamping and suturing technique.

Materials and Methods: This is a prospective observational study, conducted in the Department of Obstetrics and Gynecology, KVG Medical College, Karnataka over a period of 6 months. A total of 60 patients with benign uterine disease underwent vaginal hysterectomy, BiClamp (n=30) and conventional suture ligation (n=30 controls). Data was statistically analyzed using SPSS software.

Results: Mean procedure time in suture group was 71.37min whereas in sealer group it was 34.9 min. Mean blood loss in suture group (159.4ml) versus sealer group (82.97ml). Mean pain score on Visual Analogue Scale showed significant difference in POD 0,1,2 and thereafter, did not differ significantly. Mean length of stay was 7.13days (suture group) versus 5.13 days (sealer group). Complication rate did not differ significantly.

Conclusion: The BiClamp procedure is superior to conventional ligation in terms of intraoperative blood loss, operating time, hospital stay and postoperative pain and is a safer alternative for securing pedicles allowing the surgeon to perform VH with improved ease and safety.

Key Word: vaginal hysterectomy; BiClamp; conventional suture technique; bipolar energy; intraoperative blood loss; operating time; hospital stay; postoperative pain.

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I. Introduction

Hysterectomy, abdominal or vaginal, total or subtotal laparoscopic assisted vaginal hysterectomy is by far the most frequently performed elective major operation in gynaecology.¹ The American Association of Gynecologic Laparoscopists (AAGL) highlights that hysterectomy for benign uterine disease should be performed either vaginally or laparoscopically.² This affirms that vaginal approach should be primary whenever feasible.³ Despite this, there is a reluctance towards vaginal hysterectomy due to challenging surgical technique with limited access to deep vascular pedicles making hemostasis and suture ligation potentially problematic.⁴ Energy based vessel sealing devices allow for rapid sequential tissue and vessel sealing (vessels up to 7 mm diameter) coagulation and transection of the pedicles in one handheld tool.⁷

BiClamp is a new hemostatic system based on the combination of pressure and bipolar electric energy (Figure no 1). 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, produces significantly reduced thermal spread energy as it automatically switches off when tissue impedance reaches a critical level.^{8,9} (thermo-fusion)

The present study is to compare vaginal hysterectomy performed with conventional clamping and suture techniques versus the one performed by electrosurgical bipolar sealing system in terms of operating time, perioperative blood loss, intraoperative and post-operative complications, duration of hospital stay and pain score.

II. Material And Methods

This is a prospective observational study which was done after approval from the hospital ethical committee.

Study Design: Prospective observational study

Study Location: It is a hospital-based study done in Department of Obstetrics and Gynecology, at KVG Medical College and Hospital, Sullia, Dakshina Kannada, Karnataka, India.

Study Duration: September 2019 to February 2020.

Sample size: 60 patients.

Sample size calculation: Considering mean operating time of conventional (n=30) as 55.66 minutes and mean operating time of BiClamp (n=30) as 27.75 minutes and by using the above parameter, we assumed 95% confidence interval, 80% power. Cohen's D effect size was calculated to be 0.93, at this effect size, the sample size was estimated to be 30 in each group.

Subjects & selection method: The study population was drawn from women being admitted for vaginal hysterectomy who met inclusion criteria mentioned below. Patients were divided into two groups (each group had 30 patients) by random sampling method to avoid bias.

Group A (N=30 patients) (Sealer Group) → Women undergoing VH by BiClamp method.

Group B (N=30 patients) (Suture Group) → Women undergoing VH by Conventional suture method.

Inclusion criteria:

Benign gynecological problems (Myoma, Uterovaginal descent, Abnormal uterine bleeding, Adenomyosis)

Exclusion criteria:

1. Uterine size greater than 14 weeks, tubo-ovarian abscess.
2. Suspected uterine cervical or ovarian malignancy.
3. Severe endometriosis and previous three caesarean sections.

Procedure methodology:

After written informed consent was obtained, detailed history, preoperative examination and investigations were recorded on predesigned proforma. Patients underwent preanesthetic checkup and fit patients were taken up for vaginal hysterectomy. The patients were allotted to either using BiClamp or conventional suturing method by random sampling method by computer generated random number. The same surgeon operated all surgeries to avoid bias. Vaginal hysterectomy was performed using standard protocol for both the study groups.

A circular incision was made around the cervix, the pouch of Douglas was opened posteriorly and the bladder was separated from the uterus anteriorly. In conventional suturing technique group, pedicles were clamped, cut and then transfixed (uterine artery pedicle was ligated) using vicryl 1-0 suture. For those patients who were operated by electrosurgical bipolar vessel sealer, vessel sealer (BiClamp) was used on all of the pedicles on both the sides (cardinal ligament, broad ligament including the uterine arteries, and the round and utero-ovarian ligaments) *Figure no 2, 3*. The pedicles were clamped and sealed. The clamp was released after the two-beep sound from the system (indicating adequate coagulation) and coagulated pedicle was cut. Closure of vaginal cuff was identical in both study groups.



Figure no 1: BiClamp instrument



Figure no2: Uterosacral ligament (left) coagulated using BiClamp

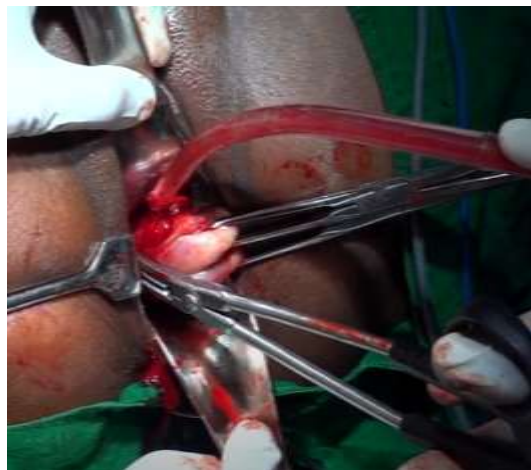


Figure no3: Uterosacral ligament (right) coagulated using BiClamp

The procedure time for all cases was calculated from initial incision on the vaginal mucosa to complete removal of uterus. Time taken for pelvic repair and other concomitant procedures was not included.

Blood loss was estimated by weighing the mops on weighing scale (taking initial weight of dry mop and final weight of wet mop and taking the difference of two), multiplying by 1.0 (as mean density of blood) and volume obtained in suction container was added, if any, to obtain blood loss in ml.

Intra-operative complications like injury to bladder and bowel, labial burns, additional haemostatic sutures, ureteric injury while vault closure, laparotomy conversion was recorded. Post-operative complications like urinary retention, pelvic hematoma, constipation, ileus, persistent pelvic pain, urinary tract infection, need for transfusion was documented.

All patients received Ceftriaxone 1gram and Metrogyl preoperatively and second dose after surgery. Analgesia in the form of pethidine and nonsteroidal was given.

All patients were asked to score their pain post-operatively on the picture depicting the Visual Analogue Scale (VAS) on a scale of 0 to 10 visual scale (0=no pain; 10=unbearable pain), as shown in *table no1*. Patients were re-evaluated post-operatively on the same evening and then daily during their stay in hospital.

Table no 1: Visual Analog Pain Scale

VISUAL ANALOG PAIN SCALE	
10	Agonizing (unbearable distress)
8	Horrible
6	Dreadful
4	Uncomfortable
2	Annoying
0	No distress

Patients were discharged on the advice of the consultant, after patient’s vitals were stabilized, they resumed bladder and bowel function and pain relieved consistently. And hospital stay duration was recorded including the day of discharge.

Statistical analysis:

For descriptive statistics, the data was entered in Microsoft excel 2007. 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.

III. Result

Sixty patients were included in the study, thirty cases each were operated using vessel sealer and conventional suturing. The two groups were similar with respect to age, parity, BMI and indications for surgery as shown in *table no 2,3*. Mean age for suture group was 44.97 years, whereas, mean age for BiClamp group was 48.13 years. Age-wise distribution of patients of both groups shows that the two groups are comparable. Associated co-morbidities and previous history of surgeries were noted.

Table no 2: Baseline characteristics

CHARACTERISTICS	BiClamp	Suture	Total
Number of women (percentage)	30 (50%)	30 (50%)	60 (100%)
Age (years)	48.13 (14.48)	44.97 (13.12)	46.55 (13.79)
Parity (median)	2 (1 - 8)	2 (0 - 5)	2 (0 - 8)
Nullipara	0	1	1
Para 1	6	4	10
Para 2	14	14	28
Para 3	6	9	15
Para 4	3	1	4
Para 5	0	1	1
Para 8	1	0	1
Height (centimetres)	163.63 (5.57)	163.83 (6.56)	163.73 (6.03)
Weight (kg)	65.27 (5.63)	66.33 (6.70)	65.8 (6.16)
BMI (kg/m2)	24.53 (2.59)	24.77 (2.57)	24.65 (2.56)
Previous Abdominal Surgery	8 (34.78%)	15 (65.22%)	23 (38.33%)
LSCS	4	8	12
Appendectomy	1	2	3
Cholecystectomy	1	1	2
Cystectomy	1	2	3
Myomectomy	1	2	3
Nil	22	15	37
Co-morbidities			
Asthma	1	2	3
Chronic Kidney Disease	1	0	1

Diabetes Mellitus	5	4	9
Hypertension	6	2	8
Diabetes mellitus + hypertension	2	0	2
Hypothyroidism	3	5	8
PCOD	1	2	3
COPD	0	3	3
Nil	11	12	23

Table no 3: Indication for vaginal hysterectomy

INDICATION FOR HYSTERECTOMY	BiClamp (n=30)	Suture (n=30)	Total (n=60)
UV Prolapse	15	8	23
PID	6	6	12
AUB	2	5	7
DUB	0	1	1
Adenomyosis	2	0	2
Cervical Elongation	0	4	4
Fibroids	2	5	7
Others	3	1	4

Patients in BiClamp group had a significantly shorter mean operating time of 34.9 (SD=8.17) minutes compared to control group 71.37 (SD=17.86) minutes. In the sealer group, mean blood loss was 82.97ml while in suture group mean blood loss was 159.37ml. Mean length of hospital stay in sealer group is 5.13 days, whereas, in suture group it was 7.13 days. Average length of hospital stay is significantly less in sealer group as compared to suture group. (table no 4)

Table no 4: Outcome of surgery

OUTCOME	BiClamp	Suture
Duration of surgery (minutes)	34.9 (8.17)	71.37 (17.86)
Blood loss (ml)	82.97 (22.87)	159.37 (26.30)
Duration of Hospital stay (days)	5.13 (1.14)	7.13 (1.94)

Mean pain score on VAS on evening of surgery (POD 0) was 8.2 for suture but in sealer group it was 5.47. On applying unpaired t-test p value obtained was less than .0001. Mean VAS score on POD 1 in sealer group was 3.8 and in suture group it found to be 6.13 On POD 2, it was 1.73 in sealer group and 3.73 in suture group. Mean pain score on Visual Analogue Scale showed significant difference in POD 0,1,2 and thereafter, did not differ significantly as shown in table no 5, figure no 4.

Table no 5: Comparison of mean pain scores on Visual analogue scale

PAIN SCORE	BiClamp	Suture
Day 0	5.47 (0.89)	8.2 (0.61)
Day 1	3.8 (0.61)	6.13 (0.50)
Day 2	1.73 (0.69)	3.73 (0.87)
Day 3	0.33 (0.76)	1.13 (1.01)

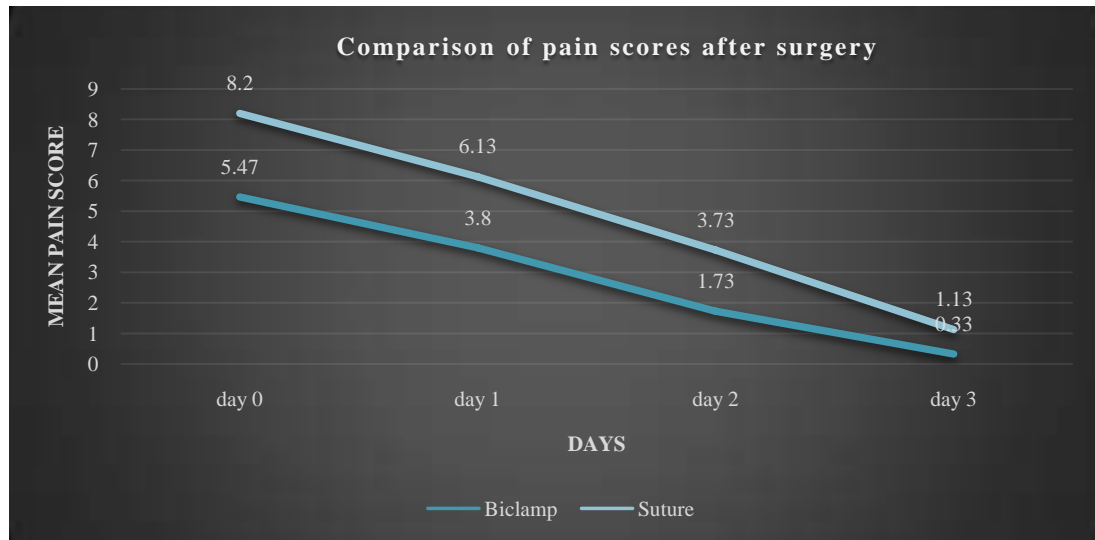


Figure no 4: Mean pain score

In the BiClamp group, three patients sustained unilateral labial burn when the hand-piece came in contact with the labia inadvertently which was immediately detected and managed conservatively. The healing occurred without scarring. One patient had injury to bladder in suture group. Pelvic hematoma was noticed in one patient in suture group. Both the groups had similar ratio in regards to UTI. Urinary retention was noticed in 1 patient in BiClamp group and 2 patients in suture group. Complication rate did not differ significantly. *Table no 6 and Figure no 5* shows intra-operative and post-operative complications encountered in both study groups.

Table no 6: Intraoperative and post-operative complications

COMPLICATIONS	BiClamp (n=30)	Suture (n=30)
Injury to bowel and bladder	0	1
Labial burns	3	0
Additional Hemostatic Sutures	2	2
Urinary Retention	1	2
Pelvic Hematoma	0	1
Urinary Tract Infection	2	2
Need of transfusion	0	1
Total	8	9

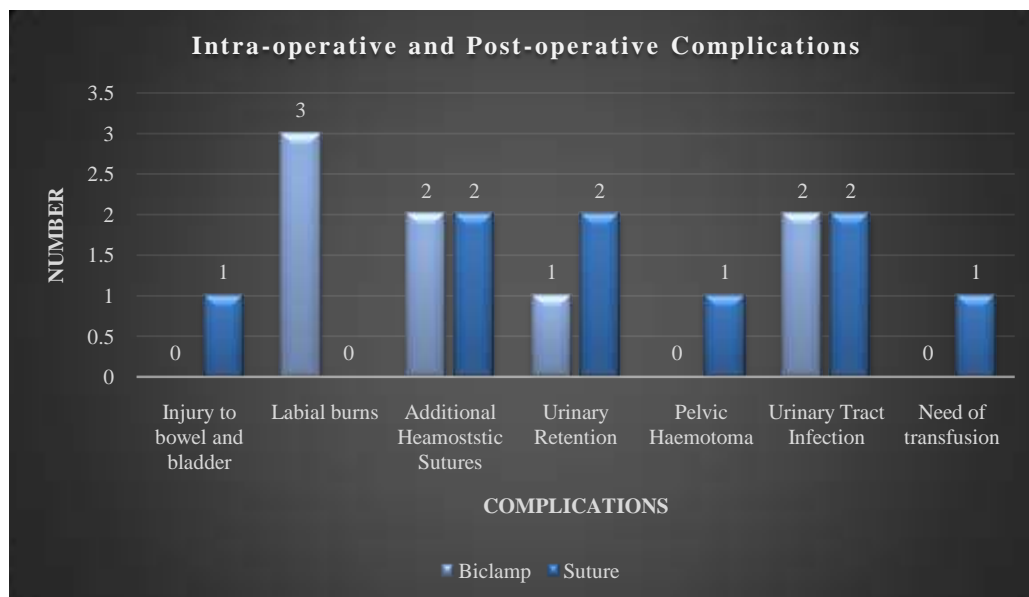


Figure no 5: Intra-operative and post-operative complications

Table no 7: Comparison of outcomes

CHARACTERISTICS	BiClamp	Suture	p value	t test value	Significance
Duration of surgery	34.9	71.37	< 0.00001	-10.16736	significant
Blood loss	82.97	159.37	< 0.00001	-12.00562	significant
Duration of hospital stay	5.13	7.13	< 0.00001	-4.86664	significant
Complications	8	9	0.092065	1.37569	not significant
Pain Score					
Day 0	5.47	8.2	< 0.00001	-13.77261	significant
Day 1	3.8	6.13	< 0.00001	-16.103	significant
Day 2	1.73	3.73	< 0.00001	-9.86854	significant
Day 3	0.73	1.13	0.052512	-1.64672	not significant

IV. Discussion

It has been emphasized that vaginal hysterectomy should be the primary method of uterine removal. It is every surgeon's goal to adopt the least invasive, fastest, least complicated and most effective operative techniques necessary for the shortest hospital stay at the lowest cost. Despite clearly meeting this goal, the vaginal approach is used in only 20% to 25% of the women who undergo hysterectomy due to lack of training and difficulty in approach.⁸ 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.

Mean age for suture group was comparable to that of sealer group was 44.97 years versus 48.13 years which was comparable with studies done by Ibrahim et al, Lewy et al, and Hefni et al.^{9,10,11} The common indication for vaginal hysterectomy was utero-vaginal prolapse (23 out of 60) followed by chronic pelvic inflammatory disease (12/60), abnormal uterine bleeding (7/60) and myoma (7/60). Myomas up to 14 weeks size were included in our study. Most studies had similar indications for vaginal hysterectomies, though some include post-menopausal bleeding, fibroid with adenomyosis, dysmenorrhea and cervical pathologies.¹²

The operative procedure time in our study showed significant reduction in sealer group. Mean procedure time in sealer group was 34.9 min, whereas, in the suture group it was 71.37 min, the difference being significant statistically. Studies which depicted shorter intra-operative time are Ibrahim et al (40±8min versus 65±10minutes) and Lewy et al (39 min vs 53.6 min).^{9,10} However, few studies did not show significant reduction in intra-operative time like those of Hefni et al (57 versus 66 minutes), Lakeman et al. (71.3 min versus 59.7 min); and Cronje and de Coning (32 min versus 40 min).^{11,12,13} The time required for thermal hemostasis may appear to be rather long. It requires positioning the BiClamp, removing the BiClamp after the generator has switched off automatically, and making a cut with scissors—that is, a total of three steps. However, achieving a classical hemostasis with sutures requires positioning the hemostasis clamp, cutting the pedicle with scissors, positioning the suture with a needle holder, knotting the sutures, removing the clamp, and cutting the suture with scissors—that is total six steps with several changes of instruments. In addition, thermal hemostasis also has a hemostatic effect on the two edges of the pedicle, preventing a backflow of blood and

obviating the necessity of aspirating the blood or frequent swabbing with compresses. The visibility of the operative site is also improved, which in turn affects the length of the operation.¹⁴

There was significant reduction in intra-operative blood loss. Mean blood loss in the sealer group was 82.97 ml and in the suture group it was 159.37 ml. Our observations were comparable with studies conducted by Lewy et al. (68.9 ml sealer group versus 126.7 ml in suture group), Elhao et al (230ml vs 360ml), Vinita B Agrawal et al (135.0 ml vs 191.23 ml).^{10,15,16} Most of the studies concluded that there was significant difference in blood loss between two study group, whereas Cronje and de Coning and Hefni et al did not find any significant difference in blood loss between the two study group.^{11,13}

Post-operative pain was evaluated using visual Analogue Scale on a score of 1-10. Mean pain score on the evening after surgery was 8.2 for suture group and 5.47 for sealer group, up to POD 1,2 there was significant difference. Thereafter, the pain scores did not differ much between the two groups. In the present study, the sealer group presented lower pain status. Ibrahim et al, Cronje and Coneney and Zubke et al, also evaluated postoperative pain status and got similar result.^{9,11,17} But Lakeman et al, found that the post-operative pain was significantly different only on the evening after surgery and thereafter pain score was similar in both groups.¹² BiClamp 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.¹⁸ In addition, the side effects like nausea, vomiting, drowsiness associated with the usual administration of postoperative analgesics did not occur, which meant that sealer group's postoperative experiences were completely different. In fact, the majority of patients in sealer group were able to get out of bed only a few hours after the operation to go to evacuate the bladder and save themselves unpleasant and sometimes futile efforts with bedpans.¹⁴

Intra-operative and post-operative complications which were noted are bladder perforation, labial burn, pelvic hematoma, urinary retention, UTI. No other major complications like bowel perforation, conversion to abdominal route, uncontrolled bleeding was noted. Bladder perforation was noted one case in suture group. Ibrahim et al. and Lewy et al had no significant complications during intraoperative and post-operative period.^{9,10} We encountered with labial burn in 3 patients in sealer group, Hefni et al and Zubke et al, each had one case in sealer group.^{11,17} The burn was superficial and was managed conservatively.

Mean length of stay at hospital was less in the vessel sealer group (5.13 days) as compared to suture group (7.71 days). A significant reduction in hospital stay was also seen by Lewy et al (1 vs 3 days), Clave et al (6 days vs 1 day) and Zubke et al (6.6 vs 7.4 days).^{10,14,17} Cronje and de Coning did not find a significant difference.¹¹

Other applications of the bipolar coagulation forceps:

Open surgery, abdominal hysterectomy and for other operations, e.g., vulvectomy and inguinal lymphadenectomy, major abdominal cancer surgery and exenteration. BiClamp is a very useful instrument for the above types of surgery, and this has been confirmed by reports from other groups.¹⁸

Limitations of the study:

The main limitation of the study was small sample size. In order to give more valuable results, further research is needed with larger sample size. Our study was a single center approach, multicentric trial must conducted for better outcome.

V. Conclusion

Bipolar coagulation with the BiClamp combined with current modulation driven by specially developed software is a reliable surgical instrument. It leads to less blood loss, less postoperative pain, and more rapid convalescence. It also offers economic advantages over conventional methods: less use of analgesics, shorter hospital stays, and possibly also a shorter duration of surgery. The present study demonstrates that the bipolar vessel sealing with the BiClamp forceps is an effective and efficient alternative to suture ligation in vaginal hysterectomy and its use must be encouraged.

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