Original Research Paper

Volume-8 | Issue-11 | November-2018 | PRINT ISSN No 2249-555X

Gynecology

ELECTROSURGICAL BIPOLAR VESSEL SEALING(EBVS) VS. CONVENTIONAL CLAMPING AND SUTURING FOR VAGINAL HYSTERECTOMY:A RANDOMISED CONTROLLED TRIAL.

Dr. Shafika Mansuri Resident Doctor,Department of Obstetrics and Gynecology, B. J. Medical College, Civil Hospital, Ahmedabad

Dr. Prerak Modi* Assistant Professor,Department of Obstetrics and Gynecology, B. J. Medical College, Civil Hospital, Ahmedabad *Corresponding Author

ABSTRACT

Objective: To compare the efficiency of electrosurgical bipolar vessel-sealing system with conventional sutures ligation method in vaginal hysterectomy.

Methods: A Prospective observational study was conducted over a period of 1 and half year between March 2017 to Aug, 2018 in Dept of OB-GY, Civil Hospital, Ahmedabad. A total of 86 patients were operated for Vaginal Hysterectomy for benign conditions who were randomised for vessel sealing or conventional surgery. The patients were re-evaluated after 1-3 months.

Results: The operating time (min) was significantly shorter in electrosurgical bipolar group than the conventional suture group. Operative blood loss (ml) and the reduction in hemoglobin level (gm/dL) were significantly lower in electrosurgical bipolar group in comparison to the conventional suture group. The hospitalization (days) of electrosurgical bipolar group was also significantly lower than the conventional suture group. No significant difference was found between the two groups in major intra-operative and immediate postoperative complications, whereas, the pain score was significantly higher in the conventional suture group compared with electrosurgical bipolar group.

Conclusion: Electrosurgical bipolar vessel sealing system is a preferred and a safe alternative method when compared with the conventional suture ligation method in vaginal hysterectomy. It has the advantages of shorter operating time, reduced blood loss, less reduction level of hemoglobin, shorter time of hospitalization, and lower pain score.

KEYWORDS : Conventional sutures, Blood loss, Electrosurgical bipolar vessel sealing system, Vaginal hysterectomy.

INTRODUCTION:

Hysterectomy is one of the most commonly performed gynecological procedure. Commonest indications of hysterectomy are all benign conditions such as abnormal uterine bleeding, dysmenorrhoea, abdominal pain or mechanical obstruction caused by large uterus. The main goal of removal of uterus is to improve quality of life. Therefore, possible side effects of hysterectomy which negatively influence the quality of life have to be carefully evaluated and if possible, limited. 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. The advantages of vaginal hysterectomy include less perioperative morbidity, shorter hospitalization, and early return to normal activity.[7] Despite these advantages of vaginal hysterectomy, only one third of hysterectomies are done vaginally because of the limited surgical planes for securing the pedicles. Of particular concern for vaginal surgeons is the ability to assess, visualize and ligate structures while maintaining adequate haemostasis during the vaginal approach through a small opening. To create adequate visualisation, traction is applied to the tissue. This might cause not only increased postoperative pain, but also nerve damage, possibly explaining the increased rate of postoperative micturition symptoms found after vaginal hysterectomy.

Vascular pedicles during hysterectomy can be secured using usual mechanical ways (sutures, clips or staples), or by vessel coagulation (high frequency electrocautery, ultrasound or laser). To replace the usual methods of haemostasis, the electrosurgical bipolar vessel sealing apparatus was launched by Valleylab (Boulder, CO, USA).

The present study was planned to evaluate the use of electrosurgical bipolar vessel sealer as it is expected that bipolar vessel sealer reduces the blood loss and procedure time when compared to conventional suturing. Its use is also expected to lower the major intra-operative and post-operative complications.

METHODS:

A prospective observational study was conducted between March, 2017 to August, 2018 in Department of Obstetrics and Gynaecology, Civil Hospital, Ahmedabad. A total of 86 patients participated in this study. Detailed history, preoperative examination and investigations were recorded on predesigned proforma. Patients were subjected to preanesthetic check-up and fit patients were taken up for vaginal hysterectomy. Medical ethics committee approved this study.

After woman has signed the informed consent they were allocated to one of the treatment groups based solely on the operating surgeon's choice. However, both woman and medical team responsible for postoperative care were blinded to allocated intervention. Consealment of allocation was assured by not providing the information to the woman during the first postoperative year about which surgical technique was used. Also, the nurses and physicians in the ward and postoperative care were not informed about treatment allocation.

Surgical Procedure:

Vaginal hysterectomy was performed in a standard protocol in both the study groups. A circumferential vaginal incision was made around anterior portion of cervix below the line of bladder. The Pouch of Douglas was opened posteriorly and retractor was positioned. The bladder was then dissected from the vagina anteriorly. Pedicles were clamped, cut and then transfixed (uterine artery pedicle was ligated) using vicryl (polyglactin 910) 1-0 suture by conventional suturing technique in the suture group. For those patients operated by electrosurgical bipolar vessel sealer, vessel sealer 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). The pedicles were clamped and sealed. The clamp was released after the beep from the system (indicating adequate coagulation) and coagulated pedicle was then cut. The vault was closed similarly in both the groups using Vicryl No.1 suture. The procedure time for all cases was measured from initial incision on the vaginal mucosa to complete removal of uterus. Time taken for pelvic repair and other concomitant procedures was not included. The amount of blood loss was the sum of the volume collected by a suction device during the procedure and the estimated volume of the total number of gauzes used during the procedure. This amount was estimated by the operation assistants. All patients were given routine analgesics (NSAIDS±Paracetamol) until 3 days after surgery as per departmental protocols and they 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) during the stay and in the first week after surgery. Patients were re-evaluated post-operatively on the same evening and then daily during their stay in hospital. Patients were discharged on the advice of the consultants after patient's vitals were stabilised, they resumed bladder and bowel function and pain relieved consistently.

Outcome measurements

Primary outcome was postoperative pain, measured by the visual analogue scale (VAS) during the first week after surgery. Secondary

outcomes were duration of surgery, amount of blood loss, or complications during surgery, late complications related to surgery, time to resume normal daily activity, quality of life and costs.

RESULTS:

Vaginal hysterectomy was performed in total 86 patients out of which conventional suture method was used in patients and electrosurgical bipolar method was used in patients. The mean followup period was 3 months. Basic characteristics of patients of both the study groups were similar, i.e. age, parity, height, weight and BMI.

Out of total 86 patients, randomised 42 cases(48.83%) were done using Vessel Sealer method and randomised 44 cases (51.16%) were done using conventional suturing method.

As shown in Table 1(distribution of patients undergoing VH as per indication), 18.6% patients underwent hysterectomy for indication of dysmenorrhoea, 60.46% patients for fibroid and 20.9% patients for indication of adenomyosis.

TABLE 1 Indications of Vaginal Hysterectomy

Indication for VH	Suture	Percentage	Vessel Sealer	Percentage
DUB	10	11.62	6	6.97
Fibroid	28	32.55	24	27.91
Adenomyosis	6	6.97	12	13.95

Table 2(Operative time in each method) shows that there is significant statistical difference in the time taken by both the methods.

TABLE 2 Operative Time for Both Groups

Operative Time Interval	Suture	Percentage	Vessel Sealer	Percentage
30-45 min	14	16.27	38	44.18
>45 min	30	34.88	4	4.65
Mean Time	53 minutes		40 minutes	

Table 3(Post-operative pain score on VAS) shows comparison of mean pain scores on Visual Analogue Scale on evening of Surgery(POD1), on 3rd Postoperative day (POD3) and on 5th Postoperative day (POD5). Mean pain score was also taken between 1-3 months of discharging the patients. There was significant difference in pain scores of both the groups.

TABLE 3 Postoperative Pain Score on VAS

Average VAS pain score on	Suture	Sealer
Day1	7.1	6.05
Day3	3.20	2.5
Day5	2.42	1.3
Further follow up(1-3 months)	1	0.5

Table 4 depicts blood loss in two groups. In the conventional group, mean blood loss was 180 ml and in the electrosurgical bipolar group, mean blood loss was 111 ml. This difference was significant.

TABLE 4 Blood Loss Volume in Both Groups

Blood Loss Volume(ml)	Suture	Percent	Sealer	Percent
<100 ml	13	15.11	35	40.69
100-300 ml	25	29.06	6	6.97
>300 ml	6	6.97	1	1.16
Mean blood loss	180 ml		111 ml	

Table 5 shows Major Intraoperative and post-operative complications, which include blood loss >300 ml, labial burn and injury to bowel, bladder.

TABLE 5 Major Intraoperative Complications

Complications	Suture	Percent	Sealer	Percent
Blood loss >300 ml	6	6.97	1	1.16
Bowel and bladder Injury	3	3.48	0	0
Labial Burn/Vaginal Burn	0	0.00	4	4.65

DISCUSSION:

Hysterectomy is a major gynaecological procedure, which is indicated in cases of abnormal uterine bleeding, uterine fibroid or genital prolapse. Vaginal hysterectomy is preferred over abdominal hysterectomy because of less perioperative morbidity and quicker recovery and return to normal activities. Also, nowadays combining oophorectomy with vaginal hysterectomy by experienced surgeons makes it a good alternative surgical procedure with lower risk of morbidity especially in the absence of uterine prolapse. Electrosurgical bipolar sealing system makes the surgical field more accessible which may be reflected on increasing the indications of vaginal hysterectomy.

Gynecologists are looking for less invasive and more effective operative techniques using the vaginal route. Electrosurgical bipolar vessel sealing system has the advantage of reducing the blood loss and achieving safe method of vessel sealing with lower rate of morbidity compared to conventional sutures in vaginal hysterectomy. It is also important to have shorter operation time and to reduce the use of conventional sutures as these will lower the morbidity and the cost of the operation.

REASONS: High frequency electrocautery used in vessel sealing system has been the workhorse of operating rooms and recent development of an electrosurgical bipolar vessel sealer offers vaginal surgeons a safe and effective alternative haemostatic method. The device delivers a controlled high-power current at low voltage to melt the collagen and elastin in the tissue leading to permanent fusion of the vascular layers and obliteration of the lumen. The collagen and elastin within the tissue reform 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 with existing bipolar instruments, as energy is automatically switched 'off' when tissue impedance reaches a critical level. The current delivered to achieve haemostasis takes between 2 and 7 seconds, and hence, can be relatively faster compared with suture ligation. Electrocoagulation diathermy is unreliable for vessels larger than 2 mm in diameter. Electrosurgical bipolar vessel sealer consists of a specialised electrosurgical generator and handset which can effectively seal vessels and vascular bundles upto 7mm in diameter. It has been found that operating time and operative blood loss are significantly lower when operating with electrosurgical vessel. Placing sutures high in the pelvis, under and around a narrow pubic arch is difficult. Vessel sealer seems uniquely suited for vaginal surgeries.

It is well known that bleeding is one of the important drawbacks of hysterectomy. Using electrosurgical bipolar will give the surgeon a better and easier surgical field which will be reflected on the outcome including the bleeding, duration of surgery, and thrombotic complications.

The strength of vessel seal obtained by electrosurgical bipolar is comparable to conventional methods and better than other energy dependent modes. Some studies did not show any statistical significance in reducing blood loss using electrosurgical bipolar method. The results of this study are in agreement with several previous studiesthat showed a significantly lower blood loss in ligature group compared with conventional group. Improving the accessibility of the surgical plane in a limited space using the electrosurgical bipolar is reflected on shorter operative time and no need for space for the use of needles, in addition to reducing the risk of stings. The intra-operative procedure time was noted beginning from initial incision on vaginal mucosa till complete removal of uterus. This end point was deliberately chosen to exclude the procedure time for cystocoele, enterocoele, rectocoele repair and other concomitant procedures that were done according to the needs of patients.

The results of this study also showed a significant shorter operating time for vaginal hysterectomy of the electrosurgical bipolar group compared with conventional sutures group. This result is comparable to other studies that showed similar finding.

Several studies showed that the complication rate of using electrosurgical bipolar varies from 8.0% to 16.0%. None of the cases operated in our theatre had major hemorrhagic complications as requiring conversion to abdominal route, or a bowel perforation, slippage or retraction of stump or a readmission for bleeding. There was no significant complication regarding intra-operative and immediate post- operative period with regard to major blood vessels injury, ureteric injury, and bladder injury. There was also no soft tissue hematoma, or a need for laparotomy for significant bleeding or vulvar burn. These results were found previously in the literature.

Labial burn is purely a complication of sealer group, 2 patients out of 42 i.e. 4.76 % patients had labial burn. Both were superficial, <1cm

burns, were managed conservatively with daily dressing and healed well without scarring. The burn was superficial and was managed conservatively. Vaginal burn was also seen in 2 patients(4.76%). This mainly included obese patients who had more soft tissue obstruction and less perineal space.

The post-operative pain is reduced after using electrosurgical bipolar because there is no foreign body in the form of ligature as electrosurgical bipolar system is giving certain current of energy which is confined to 1.5mm from the sealed vessel, this will cause less inflammation and less chance of fibrosis in the pelvis. Moreover, reducing the pain score enhances the possibility of early hospital discharge and reduce the operation cost. Furthermore, electrosurgical bipolar will cause less tissue pressure compared with the conventional methods. Significant lower post-operative pain score was found previously in the ligature group than the conventional group. This finding matches the result of this study about pain score in ligature group compared with conventional group.

We conducted present study on a mixed group of patients with various indications, with different surgical difficulties in different groups. Inferences of each indication could not be drawn. Other limitations were small sample size and lack of randomisation, as done in other studies. In order to give more valuable results, further research is needed with larger sample size.

CONCLUSION:

Bipolar vessel sealer is an effective alternative to conventional suturing in vaginal hysterectomy. Significant reduction in intra-operative blood loss, procedure time, immediate post-operative pain, and significant difference in VAS on POD 1,2,3 was seen. Major intra-operative blood loss>300ml which was found in significant number of cases in suture group. However, we found no significant difference in major intra-operative complications in terms of bladder or bowel perforation. None of the patients in our study needed conversion to laparotomy or readmission for any major bleeding. Labial/Vaginal burn occurred in 4 patients which was superficial burn <1cm and healed well with conservative management. As students need training in vaginal hysterectomy because of technical skills needed which are difficult to acquire, especially with a narrow surgical field, vessel sealer appears safer and more effective in the hands of trainees and relatively less experienced surgeons as much as more experienced ones. No such study has been conducted in this part of India. Present study was conducted to find easier alternatives to minimize the technical difficulties in vaginal hysterectomy.

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