

# A prospective randomized comparative study of non descent vaginal hysterectomy with sutures and with bipolar clamp or vessel sealing device (by bipolar energy source)

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## Abstract

**Objective:** The present study is a prospective randomized comparative study of Non- Decent vaginal hysterectomy with sutures and with bipolar clamp or Vessel Sealing device (by Bipolar Energy Source) to compare its effect on postoperative pain, blood loss, time taken for surgery, intraoperative and postoperative complications and hospital stay. **Materials and Methods:** 50 patients were selected for each group (total 100) over a period of 40 months. Inclusion criteria was no adnexal mass, no severe endometriosis, uterine size less than 12 weeks and descent should not be more than 1st degree. The primary outcome measure were operative time, blood loss and postoperative pain while secondary outcome measures were the intraoperative and postoperative complications and hospital stay. **Result and conclusion:** The most common indication was AUB. Patients in bipolar vessel sealer group had significantly reduced operating time, blood loss; pain status and hospital stay as compared to suture group. To conclude the use of bipolar vessel sealer reduces operative time. It allows safe and effective hemostasis compared with conventional suture ligation. It also reduces the operative blood loss, pain status and hospital stay.

**Key Word:** Non descent vaginal hysterectomy, Electrosurgical bipolar vessel sealing

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## INTRODUCTION

Hysterectomy is the most commonly performed gynecological procedures. The common indications for hysterectomy include abnormal uterine bleeding, fibroids and adenomyosis. The main goal of hysterectomy is to improve quality of life. Vaginal hysterectomy is considered to be method of choice for removal of uterus.

It has been shown to be associated with significantly fewer complications, shorter hospital stay and faster recovery than abdominal hysterectomy. In vaginal hysterectomy point of particular concern is ability to access, visualize and ligate structure while maintaining adequate hemostasis. Surgical hemostasis can be secured by a variety of methods including mechanical means by sutures or vessel sealing by bipolar energy source. The aim of present study is study of Non-Decent vaginal hysterectomy with sutures and with bipolar or vessel sealing by bipolar energy source to compare its effect on postoperative pain, blood loss, time taken for surgery, intraoperative and postoperative complications and hospital stay. Electrosurgical bipolar vessel sealing shortens the operation duration as result of limited steps and also reduces postoperative pain because of need of less traction and limiting innervational damage.

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### AIMS AND OBJECTIVES

The aims and objectives of present study is study of Non Decent vaginal hysterectomy with sutures and with bipolar / vessel sealing by bipolar energy source to compare its effect on postoperative pain, blood loss, time taken for surgery, intraoperative and postoperative complications and hospital stay. The hysterectomies were performed by Dr Ammbalal Gurram and Dr Annjalii Gurram, at ONP Hospital Pune, Lokmanya hospital Pune, Ashwinii Nursing Home Pune and Pawana hospital Talegaon during August 2014 to December 2017 (40 Months).

### MATERIALS AND METHODS

This prospective study was conducted during August 2014 to December 2017 (40 Months) at ONP Hospital Pune, Lokmanya hospital Pune, Ashwinii Nursing Home Pune and Pawana hospital Talegaon.

Patient satisfying following criteria were included in thid study-

1. Non malignant conditions
2. No adnexal mass
3. No severe endometriosis
4. Descent not more than 1<sup>st</sup> degree
5. Uterine size < 12 weeks.

Patients who participated in the study were randomized. Sample size was 50 patients in each group. Vaginal hysterectomy was performed according to the standard protocol. The amount of blood loss was the sum of volume collected by suction device during the procedure and the estimated volume of total number of gauzes used during procedure. Primary outcome was postoperative painafter surgery, measured by Visual analogue Scale VAS. Secondary outcomes were duration of surgery, amount of blood loss, complications during surgery and hospital stay.

### RESULTS AND OBSERVATIONS

100 Patients were included in the study. NDVH by bipolar or vessel sealer by bipolar was done in 50 patients and NDVH conventional sutures was done in 50 patients. The two groups were similar in respect to age, parity, body mass index, previous LSCS and indication of surgery. The Mean preoperative hemoglobin in both groups were 11g/dl and hematocrit were 34.2%. Indications for hysterectomy include abnormal uterine bleeding, fibroids and adenomyosis.

Most common indication was abnormal uterine bleeding AUB.details of indications are shown in table 1.

Table 1: Indications

Diagnosis	NDVH (Bipolar)	NDVH (Sutures)
AUB	22 (44%)	28 (56%)
Fibroids	19 (38%)	19 (38%)
Adenomyosis	8 (16%)	3 (6%)
Others	1 (2%)	0
Total	50	50

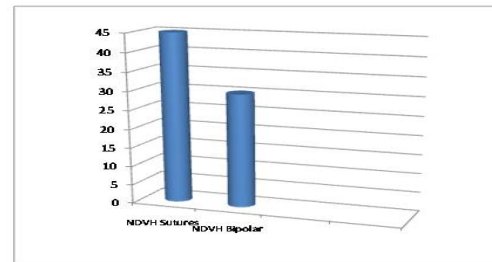


Figure 1: Operative Time in minutes NDVH (sutures) Vs NDVH (Bipolar)

Average operative time in NDVH (sutures) is 45 minutes and in NDVH (Bipolar) is 30 minutes. Patients in the NDVH Bipolar group had significantly shorter mean operating time compared to NDVH Sutures (P<0.001).

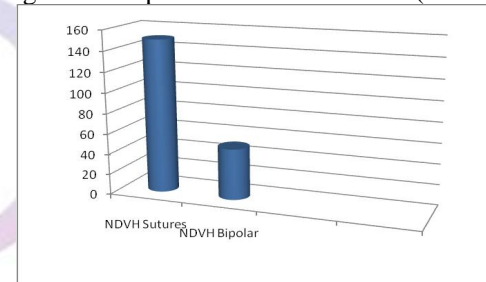
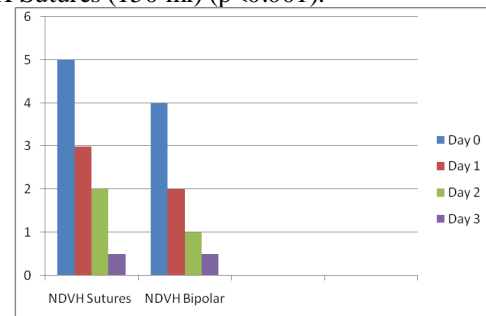
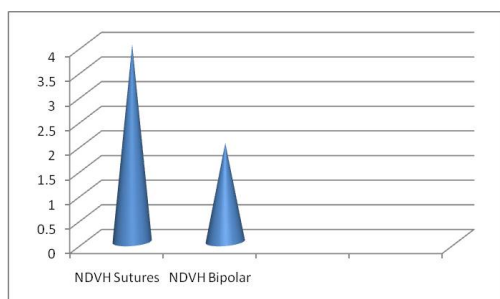


Figure 2: Blood Loss In ml Ndvh (Sutures) Vs Ndvh (Bipolar)

The mean operative blood loss was significantly decreased in NDVH Bipolar (50 ml) as compared to NDVH Sutures (150 ml) (p<0.001).



Pain Score on VAS scale. Postoperative pain on VAS scale was more in NDVH Sutures Group on all postoperative days.



Total hospital Stay in NDVH Sutures group was 4 days in NDVH Bipolar was 2 days. Intraoperative complications – Only one patient undergoing surgery with history of previous 2 LSCS had bladder injury which was managed successfully. No other major complications were encountered in the study.

## DISCUSSION

Vaginal hysterectomy is a least invasive, fastest; least complicated and most effective operative technique with short hospital stay. Despite clearly meeting this goal the vaginal approach is used in only 20-25% of women who undergo hysterectomy (Deval *et al* 2003). Uterine enlargement, previous pelvic surgery and absence of uterine descent should not be considered as contraindication to vaginal hysterectomy (Darai *et al* 2001). Therefore, it is important to investigate alternatives in surgical technique, which might make the procedure technically easier, and be associated with a lower risk of complications and ultimately encourage more surgeons to operate vaginally. Patients with morbid obesity, significantly enlarged uteri, narrow vaginal canals, and contracted pelvises continue to pose a surgical challenge. Placing sutures high in the pelvis, under and around a narrow pubic arch, is difficult and often quite frustrating. Not only it is difficult to see in these regions, but also accurately placing a stitch and retrieving the needle is problematic. *These difficulties may lead to increase blood loss, necessitating conversion to laparoscopic or abdominal approaches.* Electrosurgical bipolar clamp / vessel sealing technology seems uniquely suited for vaginal surgery. The surgical steps other than placement of suture are identical to those used during standard vaginal hysterectomy. Pedicles can be controlled rapidly and effectively during with NDVH Bipolar. (Davies *et al* 1998). In the present study the bipolar group presented a lower pain status which may be the cause of the reduced hospitalization. Cronje and Coning were the only other study that evaluated post-operative pain status in women submitted to VH using bipolar / ligasure and found similar results (Cronje *et al* 2005). This 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 tissues decreases the inflammatory response and the post-operative pain (Kennedy *et al* 1998). Experimental studies comparing electrosurgical bipolar vessel sealing system (EBVS), monopolar, bipolar and ultrasonic coagulation demonstrated histologically that EBVS had the mildest side thermal injury and the fastest healing process (Diamantis *et al* 2006). A porcine model showed that EBVS is associated with less thermal damage to the media of the vessels (Person *et al* 2008). The EBVS creates seals that are stronger than the seals obtained with other energy-based ligation methods, and similar in strength to those obtained with mechanical ligation techniques (Kennedy *et al* 1998). The overall complication rate in the present study (1%) while with the 8.0% to 16.1% complication rates after vaginal hysterectomy reported in larger series. Makinen *et al* 2001 and Garry *et al* 2004. Unlike the seal provided by conventional suturing which is subject to slippage and dislodgement, seals created by the bipolar / ligasure device resist dislodgement because they are intrinsic to the vessel wall structure (Segupta *et al* 2001). In present study, the bladder injury was occurred one in bipolar group, and occurred in a patient with a previous cesarean section and significant bladder adhesions. There is no association between the use of EBVS and higher complication rates (Levy *et al* 2003 and Person *et al* 2008). One RCT and one observational study reported no complications in either group (Levy *et al* 2003 and Person *et al* 2008), and two studies described a variety of minor problems which appeared unrelated to the operative technique (Hefni *et al* 2005 and Cronje *et al* 2005). Two studies reported minor skin burns in the bipolar / Ligasure group early in their experience (Cronje *et al* 2005 and Clave *et al* 2005). These findings are in argument with seven studies that evaluated the use of bipolar/Ligasure in VH. Four of those were RCTs (Hefni *et al* 2005, Cronje *et al* 2005, Levy *et al* 2003 and Elhao *et al* 2009), while the others were prospective case-control studies (Clave *et al* 2005, Zubke *et al* 2004 and Ding *et al* 2005). Using the bipolar / Ligasure technique significantly decreases the operative blood loss; a desirable effect in patients undergoing hysterectomy for menorrhagia as they often suffers from iron deficiency anemia. Lower blood loss in bipolar/ Ligasure procedures reached statistical significance in only three studies, (Hefni *et al* 2005, Ding *et al* 2005 and Elhao *et al* 2009), determined by changes in the hemoglobin level and the 'surgeons' estimate of the volume lost during the procedure. No difference was found in two studies, (Cronje *et al* 2005 and Levy *et al* 2003), where authors attributed that to having already established a good surgical technique with conventional Sutures. In the present study, the total operative time was significantly shorter in the Bipolar group compared to the

suture group. Significant reductions in procedure time when using EBVS were found in the four RCTs, (Hefni *et al* 2005, Cronje *et al* 2005, Levy *et al* 2003 and Elhao *et al* 2009). Variations in operating times reflect the variability in local procedures as well as surgeon and patient factors. Using the electrosurgical bipolar / vessel sealing technique (EBVS) significantly decreases operative blood loss and operating time without increasing the complication rate of Vaginal hysterectomy procedures. The beneficial effect of bipolar/Ligasure in reducing the operative blood loss seems to be more pronounced in patients who underwent a more difficult procedure.

## CONCLUSION

In conclusion, the use of bipolar/Ligasure device can reduce operative time. It allows faster, safe and effective hemostasis compared with the conventional suture ligature, also reducing operative blood loss, pain status and hospital stay. The technique is to learn and use.

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