

Electrosurgical Unipolar Vessel Sealing Versus Purohit Technique in Vaginal Hysterectomy (A Pilot Randomized Clinical Trial)

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ABSTRACT

Background: Vaginal hysterectomy should be performed in preference to abdominal hysterectomy, where possible as it has benefits; quicker return to normal activities, fewer complications, shorter operative time, less blood loss, and a shorter stay in hospital. Also, it is preferred to laparoscopic-assisted vaginal hysterectomy because of fewer bladder or ureteric damage as well as a shorter operating time and learning curve. **Aim of the Work:** To compare the between using unipolar electrocautery versus Purohit technique in vaginal hysterectomy as regards operative time. **Patients and Methods:** This pilot prospective randomized clinical trial was conducted at Ain Shams University Maternity and Women's Hospital during the period from June 2016 to February 2018. This study included patients presenting to the outpatient gynecologic clinic of Ain Shams University Maternity and Women's Hospital and planned to have vaginal hysterectomy for benign cause. **Results:** both total operative time and pedicle securing time were significantly longer in the Purohit technique group compared to the unipolar electrocautery group ($P < 0.001$). **Conclusion:** using unipolar electrocautery significantly reduces total operative time than using bipolar electrocautery without increasing rate of complications nor does it cause specific type of complications provided that special precautions are taken to avoid thermal effect on nearby structures. **Recommendations:** using unipolar electrocautery is recommended by well trained hands in suitable patient and should be offered for training by other surgeons of different levels to judge learning curve. Further studies with inclusion of patients having larger sizes of uteri using the same technique. Further settings with higher cautery up to 50W were found to be safe for further analysis.

Key words: Unipolar electrocautery, Purohit technique, vaginal hysterectomy

INTRODUCTION

Hysterectomy is the most frequently performed major gynecological operation in the world. For benign situations, hysterectomy is most usually done using either the abdominal or vaginal method. Nevertheless, a small proportion of women with benign conditions undergo laparoscopic hysterectomy, which was introduced in the 1980s in the United States⁽¹⁾.

The American College of Obstetrics and Gynecology recommended the vaginal route in case of uteri weighing 280gm or less which is about 12 weeks size⁽²⁾.

The experience of the surgeon and the knowledge of using surgical techniques as morcellation, bisection and myomectomy can overcome difficulties in dealing with large uteri vaginally⁽³⁾.

Vaginal hysterectomy is the method of choice for gynecologists who carry out hysterectomies. Undertaking this procedure regularly will enhance the gynecologist's level of skill and enable conditions such as ovarian cysts, broad ligament fibroids and other adnexal pathology to be dealt with vaginally during hysterectomy surgery without abdominal invasion⁽⁴⁾.

Vaginal hysterectomy should be performed in preference to abdominal hysterectomy, where possible. Vaginal hysterectomy means quicker return to normal

activities, fewer complications, shorter operative time, less blood loss, and a shorter stay in hospital compared to abdominal hysterectomy^(5,6,7). This is endorsed in the National Institute of Clinical Excellence (NICE) guidelines on heavy menstrual bleeding and in a meta-analysis review of the Cochrane database. Also, vaginal hysterectomy was preferred to laparoscopic-assisted vaginal hysterectomy because of fewer bladder or ureteric damage as well as a shorter operating time and learning curve⁽⁸⁾.

The American Association of Gynecologic Laparoscopists (AAGL)⁽⁹⁾ highlight that hysterectomy for benign uterine disease should be performed either vaginally or laparoscopically. This affirms the American College of Obstetricians and Gynaecologists' (ACOG) statement that the vaginal approach should be primary whenever feasible due to better patient outcomes and fewer complications than laparoscopic or abdominal surgery.

The overall incidence of major complications in vaginal hysterectomy is 4%, improvements can be done to reduce the complication rate in vaginal hysterectomy specially by carrying out careful patient selection, proper and thorough pre-operative assessment, expert surgical techniques and vigilant post-operative care⁽¹⁾.

Despite this, there is reluctance towards vaginal hysterectomy (VH) due to the challenging surgical technique with limited access to deep vascular pedicles making haemostasis and suture ligation potentially problematic⁽¹⁰⁾.

Bipolar vessel sealing systems (BVSS) are proven to be safe, easy and efficacious with possible advantages over conventional methods, namely less post-operative pain, reduced blood loss, shorter operative time and hospital stay. Where previously, it was difficult to suture a pedicle deep within the pelvis or in circumstances where the introitus was narrowed or where there was no uterine descent, the bipolar coagulation forceps negated this and allowed a general gynaecologist to perform vaginal hysterectomy with greater ease and safety^(11,12).

Electrosurgical bipolar vessel sealing systems have been developed to seal large tissue bundles and blood vessels up to 7 mm in diameter. By using this technique, only one clamp has to be inserted through the vagina to secure the vessels and cut the tissue, instead of one clamp and one scissors. This might shorten the operation duration as the result of a limitation in surgical steps⁽¹¹⁾.

The main obstacles in using electrosurgical bipolar vessel sealing system (EBVS) are the relatively high cost and unavailability in many centers. A much easier alternative, more feasible and less costly approach has been described by Purohit⁽¹³⁾. In his technique, a right-angle long forceps with bipolar electro-coagulation was used in order to have the advantage of avoiding inaccessibility of the parauterine space with minimal use of large clamps.

In 2003, Purohit⁽¹³⁾ performed a prospective study on 214 women with benign disease of the uterus without prolapse, including cases with relative contraindications for vaginal hysterectomy as cases with endometriosis and uteri above 20 weeks size, the technique was found to be easy, safe and effective. Vaginal hysterectomy was successfully completed in 213 (99.53%) cases, with one failure (0.46%) which needed laparoscopic assistance. Vaginal salpingo-oophorectomy was completed in all indicated cases. So many abdominal and laparoscopic hysterectomies could be avoided by this technique.

Following the work of Purohit, another multicenter, two-arm, single-blind, randomized controlled trials to compare Biclamp vessel sealing (BVS) forceps against conventional suture ligation

for hemostasis in vaginal hysterectomy was carried out in Germany by Zubke *et al.*⁽¹⁴⁾. Postoperative pain was the primary outcome measure. Based on the type and potency of analgesic medication and the daily dose taken, lower analgesic requirements in the BVS group was found, particularly on postoperative day one. Also, intraoperative blood loss as assessed by the operating surgeons was markedly lower in the BVS group than in the controls.

Postoperative pain is found to be less using bipolar vessel sealing systems. Control of postoperative pain is determined by coagulation and destruction of nervous structures. It is also associated with reduction of inflammation because the absence of necrotic tissue and foreign bodies like suture is associated to reduction of resorption process and phagocytosis. Also the tradition suture of pedicles with tension and strain can increase pain for patients which is absent when using electrocautery^(15,16).

AIM OF THE WORK

To compare between using unipolar electrocautery versus Purohit technique in vaginal hysterectomy as regards operative time.

PATIENTS AND METHODS

Study Design: Pilot prospective randomized clinical trial.

Study setting: The study was conducted at Ain Shams University Maternity and Women's Hospital.

Study duration: The study was carried out during the period from June 2016 to February 2018.

Study population: The patients were recruited from women presenting to the outpatient gynecologic clinic of Ain Shams University Maternity and Women's Hospital and planned to have vaginal hysterectomy for benign cause.

Inclusion criteria: Age: 40 - 70 years. Uterine size <12 weeks. Body mass index < 40 Kg/m². Benign gynecological disease as an indication for hysterectomy e.g. fibroid uterus, abnormal uterine bleeding failed to respond to hormonal treatment or complex endometrial hyperplasia without atypia. Absence of significant scarring in the pelvis from previous surgeries.

Exclusion criteria: Suspected or known gynecological malignancy. Endometriosis (known by previous subjective medical or surgical history). Presence of adnexal mass. Cervix flushed with the vagina. ie: thinned out cervix. Presence of significant

scarring in the pelvic area from previous surgery (as exploratory laparotomy, intestinal surgery or myomectomy) for the higher risk of potential complications, adhesions and operative difficulty.

Ethical and Legal Aspects: The study was approved by the Ethical Research Committee of both the Obstetrics and Gynecology Department and the Faculty of Medicine, Ain Shams University. The purpose and procedures of the study were explained to all eligible women before participating in the study. All recruited women had to sign an informed written consent before the operation. Each candidate has the right to withdraw from the study at any time before surgery without consequences for further treatment. The study would have to be stopped at anytime if major complications occur and pose risk to the patient safety.

Randomization and Allocation: Eligible women were randomly allocated to one of the two groups: **Group 1:** included women who had VH using monopolar electrocautery. **Group 2:** includes women who had VH using Purohit's technique. All included cases were performed by the same surgical team. Randomization was performed using a computer-generated randomization system. Randomization forms were contained in sealed opaque envelopes that were opened just before starting the procedure. Patients were strictly allocated to the group to which they were originally randomized. Patients whose surgical procedure was cancelled after being allocated to certain group were considered as 'dropped-out', without impairment of the randomization sequence. The study was a single-blinded one; the patient was not aware of her allocated technique.

Methodology:

All eligible women were subjected to the following: Thorough history taking, with special attention to previous medical and surgical history especially previous laparotomies or previous pelvic surgeries. General examination included measurement of the body mass index for every patient, blood pressure and pulse, auscultation of the lungs and heart. Abdominal examination including inspection for scars of previous laparotomies, uterine size and mobility. Vaginal examination for vaginal capacity, cervical size and motility. Bimanual examination for assessment of uterine size, mobility and any gross adnexal pathology. Transvaginal

ultrasonography by 2D ultrasound was done to assess uterine dimensions, endometrial thickness, number, site and size of fibroid if present and any adnexal pathology. Routine preoperative laboratory investigations including complete blood picture, hematocrit, liver and kidney function tests and coagulation profile were reported for every patient. Preoperative endometrial biopsy was done for cases with abnormal bleeding to exclude malignancy. Preoperative senior anesthetist assessment. Availability of 2 units of cross matched packed RBCs was ensured for each patient before surgery.

Surgical Procedures:

Anesthesia: Either: Regional: spinal anesthesia or epidural anesthesia or combined spinal and epidural anesthesia. Standardized general anesthetic technique.

Peri-operative Assessment under Anesthesia: All candidates allocated to receive intervention were assessed by a consultant who is expert in vaginal surgeries & mastering the technique, and scored according to "the modified **Sheth** scoring system⁽¹⁷⁾ for procedural difficulty" (table-1). Women who had scores < 8 were expected to undergo "straightforward" VH. Women who had scores \geq 8 were expected to undergo "difficult" VH.

Table (1): Modified Sheth's Score for Preoperative Assessment of Procedural Difficulty in Vaginal Hysterectomy⁽¹⁷⁾:

	0	1	2
Uterine Size	\leq 8 weeks	9-10 weeks	> 10 weeks
Previous abdominal surgery	None	-	Present
Vagina width	>3 fingers	3 fingers	< 3 fingers
POP-Q Stage	2	1	0
Uterine mobility	Good	Fair	Poor
Subpubic angle	> 90°	90°	<90°
Fornices depth	> 1 finger	1 finger	< 1 finger
Surgeon experience	Senior consultant	Junior consultant	Trainee

Preparation for Vaginal hysterectomy:

Patient Positioning: Dorsal lithotomy position + 10-15 degree trendelenburg position. **Antisepsis:** using povidone-iodine solution, Betadine® Surgical Scrub contains 7.5% or 10% povidone-iodine, manufactured by ACDIMA pharmaceutical company. **Towelling and catheterization.** **Instruments:** those specific to and useful in performing vaginal hysterectomy were used e.g. Briesky-Navratil vaginal retractors. Vaginal walls are incised by monopolar current using the cutting mode.

Purohit's technique: Vaginal walls are incised by monopolar current. A right angle forceps is

used throughout to elevate all the lateral attachments of uterus and vessels; tissues are desiccated by bipolar current and then divided by scissors. Conventional volume reduction maneuvers are used as associated procedures in cases of large uteri to create the parauterine space for bipolar forceps and scissors and to overcome possible adhesions in previous pelvic surgery.

Vaginal Hysterectomy Using Unipolar Electrocautery: Vaginal walls are incised by monopolar current. A curved bulldog clamp is applied just 0.5 cm lateral to uterine border along its attachments all through the pedicles. Then unipolar electrocautery is applied to the pedicles along the lateral border of the uterus medial to the artery with maximum thickness 1 cm. Conventional volume reduction maneuvers are used as associated procedures in cases of large uteri to create the parauterine space to approach the lateral attachments and to overcome possible adhesions in previous pelvic surgery.

Postoperative Care: An indwelling Foley’s urinary catheter was routinely kept for 12 hours postoperatively. Follow up vital data (Pulse, Blood pressure & temperature) hourly for 6 hrs then every 4 hrs. Follow up of urinary output & intraperitoneal drain every 2 hrs. Oral clear fluid intake was started 6 hours postoperatively. Patients received postoperative analgesia in the form of NSAIDs 75 mg at least once and then on demand. Postoperative haemoglobin and hematocrit were measured for all participants after 24 hrs from the procedure. Urine analysis was done for all patients after removal of the catheter. Uncomplicated cases were discharged 24 hours postoperatively. All patients were called up for return follow up visit at 1 week & 6 weeks postoperatively to ask patient about any urinary or gastrointestinal symptoms to assess late complications.

Outcome: Operative time (both total and pedicle securing time).

Measurement of Operative time: Total operative time in minutes (time from mucosal incision till closure of the vaginal vault with good hemostasis). Pedicle securing time (starts with clamping the first pedicle and ends with securing the last one). Time of concomitant or added surgical procedures was calculated separately e.g. classical repair or sacrospinous fixation.

RESULTS

The current study was conducted in Ain Shams University Maternity and Women’s Hospital

during the period between June 2016 and February 2018. It included a total number of 80 women recruited from outpatient gynecology clinic.

Statistical Analysis

Basic demographic and clinical characteristics of the study groups

No statistically significant differences between women of both groups regarding age, body mass index, menstrual status or presence of associated medical comorbidities.

Table (2): Comparison between study groups regarding basic demographic and clinical characteristics.

	Unipolar Electrocautery Group	Purohit Technique Group	P
Age (Yrs)			
Range	42.0 – 60.0	40.0 – 60.0	0.67 ^a
Mean ± SD	50.60 ± 5.33	51.70 ± 6.27	
BMI (Kg/m²)			
Range	30.0 – 38.0	30.0 – 38.0	0.44 ^a
Mean ± SD	33.60 ± 2.59	34.50 ± 2.52	
Menstrual status			
Perimenopausal	11 (44%)	11 (45.83%)	0.81 ^b
Postmenopausal	14 (56%)	13 (54.16%)	
Medical comorbidities			
Hypertension	7 (28%)	5 (21.73%)	0.21 ^b
Diabetes mellitus	5 (20%)	6 (26.08%)	
Chronic liver disease	2 (8%)	1 (4.34%)	
Ischemic heart disease	1 (4%)	0 (0%)	
Others	2 (8%)	1 (4.34%)	

^aAnalysis using unpaired t-test with Welch’s correction. ^bAnalysis using Fisher exact test.

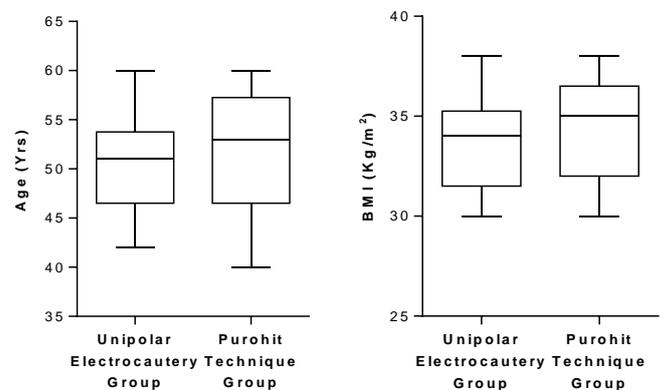


Figure (1): Box Plots of age and BMI of the study groups.

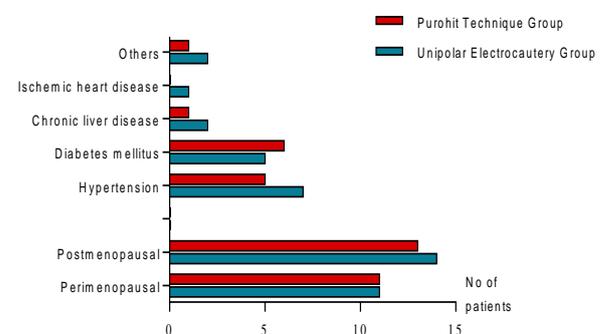


Figure (2): Bar graph summarizing menstrual status and medical comorbidities of the study groups.

Preoperative assessment parameters of the study groups

No significant differences were found between patients of the two groups regarding indication for vaginal hysterectomy, preoperative Sheth score or estimated uterine size.

Table (3): Comparison between study groups regarding preoperative assessment parameters.

	Unipolar Electrocautery Group	Purohit Technique Group	P
Indication for VH			
Dysfunctional uterine bleeding	8 (32%)	7 (29.16%)	0.85 ^a
Uterine fibroid(s)	6 (24%)	4 (16.66%)	
Uterine prolapse	6 (24%)	6 (25.0%)	
Endometrial hyperplasia	5 (20%)	7 (29.16%)	
Sheth score			
Range	5.0 – 11.0	6.0 – 12.0	0.64 ^b
Mean ± SD	7.80 ± 2.34	8.30 ± 2.35	
Uterine size (wks)			
Range	8.0 – 12.0	8.0 – 12.0	0.88 ^c
Median (IQR)	9 (8 – 10)	10 (8 – 10)	

^aAnalysis using chi-square test. ^bAnalysis using unpaired t-test. ^cAnalysis using Mann Whitney test.

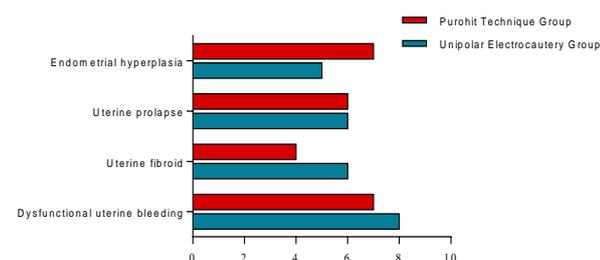


Figure (3): Bar graph summarizing indications for vaginal hysterectomy the two subgroups.

Analysis of Operative time in both study groups

Both total operative time and pedicle securing time were statistically significantly longer in the Purohit technique group compared to the unipolar electrocautery group. Unipolar electrocautery reduces pedicle securing time by 26 minutes.

Table (4): Comparison between study groups regarding operative time.

	Unipolar Electrocautery Group	Purohit Technique Group	P
Total operative time (min)			
Range	75.0 – 120.0	105.0 – 180.0	<0.001 ^a
Mean ± SD	102.31 ± 17.02	138.70 ± 22.13	
Pedicle securing time (min)			
Range	54.0 – 107.0	86.0 – 162.0	<0.001 ^a
Mean ± SD	81.80 ± 13.34	107.30 ± 32.35	

^aAnalysis using unpaired t-test.

DISCUSSION

Hysterectomy is the most frequently performed major gynecological operation in the world ⁽¹⁾.

A systematic review of 47 randomized controlled trials (RCTs) including 5,102 hysterectomies concluded that a vaginal approach is the safest and most cost effective route of hysterectomy ⁽⁷⁾.

One of the main limitations of the vaginal route is that it offers relatively limited space for surgical access to vascular pedicles ⁽¹⁸⁾. Sealing blood vessels using bipolar coagulation before cutting of the coagulated area with scissors requires less room and is easier than grasping, transecting and ligating vessel stubs ⁽¹³⁾.

The present study was a prospective, pilot randomized controlled trial to compare vaginal hysterectomy using unipolar versus bipolar electrocautery. Eligible patients were randomly allocated to one of two treatment arms in a single blind manner by computer generated system.

A total number of 102 patients were recruited and eligible to participate in the study. Only 49 patients actually received the intervention. They all had virginally sterectomies, being divided randomly into 2 groups. 25 patients underwent VH using unipolar electrocautery, while 24 patients underwent VH using bipolar electrocautery.

Only in one patient in the Purohit's ⁽¹³⁾ technique group, avulsion of the right uterine artery pedicle occurred with failure of control of bleeding by bipolar electrocautery alone. Conventional sutures where used to control bleeding and in the subsequent steps of vaginal hysterectomy without the need for blood transfusion. It should be noted that this patient was excluded from the subsequent statistical analysis.

In the current study, the characteristics of the patients are nearly similar in both arms of the study. This excludes possibility of presence of any confounding factors that might affect the study results and interpretation.

In the present study, both total operative time and pedicle securing time were significantly longer in the Purohit technique group compared to the unipolar electrocautery group (**P valueis <0.001**). Increased pedicle securing time when using bipolar electrosurgery compared to monopolar electrosurgery may be attributed to due

to charring and adherence to tissue with incidental tearing of adjacent blood vessels

Significant reduction in the operative time when using ligature was found in three RCTs by **Hefni et al.**⁽¹⁸⁾; **Elhao et al.**⁽¹⁹⁾; **Abdelzaher et al.**⁽²⁰⁾. Also, two RCTs by **Zubke et al.**⁽¹⁴⁾ and **Leo et al.**⁽²¹⁾ concluded that the operating time was lower for the BiClamp vessel sealing group compared with the control group. Variations in operative time reflect the variability in local procedures as well as surgeon and patients' factors.

In the present study, there were no statistically significant differences found between the patients of both groups regarding the incidence of surgical complications.

In our study, there was one case of rectal injury in the unipolar electrocautery group during dissection of dense adhesions in the Douglas pouch. It was diagnosed and repaired intraoperatively with no further complications. Similarly one case of rectal injury in the control group was reported by **Zubke et al.**⁽¹⁴⁾. However in the study carried out by **Purohit**⁽¹³⁾ were no cases of rectal injury.

In the current study, three patients of the unipolar electrocautery group sustained unintended burns early in the study in the form of superficial labial and vaginal burns due to unintended contact between the non-toothed forceps and labial/vaginal tissues during applying the electrocautery current. They were managed conservatively with topical ointments and healing occurred without scarring. There were also six cases of postoperative transient pyrexia (>38°C) in the first 24 postoperative hours (Two cases in the unipolar group versus four cases in the Purohit group). None of them needed further management. We interpreted the increased temperatures as a septic fever, resulting from the generous coagulation of ligaments during amputation of the uterus.

Similarly in the study conducted by **Zubke et al.**⁽¹⁴⁾, four clearly method-related cases of thermal injury to the vulva were recorded in the Bicalmp group in addition to four cases of transient fever (>38.5°C). The thermal lesions were successfully treated with ointment and the fevers resolved either without (two cases) or with antibiotics (two cases).

CONCLUSION

Further studies with inclusion of patients having larger sizes of uterine using the same technique and with using higher cautery up to 50W were recommended for further analysis.

RECOMMENDATIONS

Further studies with inclusion of patients having larger sizes of uteri using the same technique and with using higher cautery up to 50W were recommended for further analysis.

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