

Bipolar Vessel Sealer versus Harmonic Scalpel in Laparoscopic Supracervical Hysterectomy

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Abstract

Aim: The aim of this study was to compare the use of Electrothermal Bipolar Vessel Sealer (EBVS) with Harmonic Scalpel (HS) during laparoscopic supracervical hysterectomy (LSH) with respect to operation time, estimated blood loss and related complications.

Methods: A randomized clinical study was conducted in the OB/GYN Department, Maternity Hospital, Kuwait, from March 2009 till January 2011. Forty candidates for Laparoscopic Supracervical Hysterectomy were enrolled and divided randomly into two equal groups of 20 patients each. Twenty hysterectomies (LSH) were performed using the Harmonic Shears (HS) (group I) and the other twenty patients (group II) had LSH operation using Electro-Thermal Blood Vessel Sealer (EBVS) technology. All the operations were performed by the same surgeon. Data about the characteristics of the patients, operation time, estimated blood loss, related complications and length of hospital stay were registered and compared.

Results: Mean operation time, Hemoglobin (Hb) and Hematocrite value (Ht) drop, and hospital stay were significantly less in the bipolar vessel sealer group. There was significant reduction in operation time using the EBVS technique (64.15 ± 12.02) minutes as compared to HS technique (138.25 ± 23.41) minutes. Blood loss during operation was significantly lower in group (II) patients compared to group (I) demonstrated by significant greater drop in hemoglobin and hematocrite in the latter compared to the former group. The mean Hemoglobin drop in group (I) patients was (3.15 ± 0.82) while hematocrite drop was (3.72 ± 0.74). The mean hemoglobin drop for group (II) patients was (0.43 ± 0.33), while hematocrite drop was (0.74 ± 0.41). The mean hospital stay time for group (I) patients was 2.0 ± 1.52 days. The mean hospital stay for group (II) was 1.65 ± 0.58 days; the difference was not statistically significant.

Conclusion: The bipolar vessel sealer technique seems to be less time-consuming during operation and caused less bleeding when compared with harmonic shears. Further studies with larger number of patients are required for stronger evaluation of the technique.

Keywords: Harmonic shears; Vessel sealer; Laparoscopic supracervical hysterectomy

Introduction

Hysterectomy is one of the commonest gynecologic surgical procedures practiced in the United States [1]. Laparoscopic hysterectomy was first described by Reich et al. [2]. Laparoscopic Supracervical Hysterectomy (LSH) is a type of hysterectomy that allows the woman to retain her cervix while taking out the part of the uterus that causes the painful periods and heavy vaginal bleeding. There has been no published data to confirm that the cervix helps to maintain pelvic organ support. Many studies have shown the cervix as important for keeping normal sexual function following hysterectomy. Many other studies have also shown no difference in sexual function between groups of women undergoing hysterectomy with removal of their cervix compared to women without removal of the cervix [3].

Laparoscopic supracervical hysterectomy is a minimally invasive procedure that was developed during the 1990s as a treatment for abnormal uterine bleeding. The literature regarding this procedure, mainly case series and retrospective comparisons, suggests that laparoscopic supracervical hysterectomy results in reduced operating time and blood loss and a quicker return to normal activity, compared with laparoscopic-assisted vaginal hysterectomy. A randomized, controlled trial that compared laparoscopic supracervical hysterectomy with hysteroscopic endometrial resection found that laparoscopic supracervical hysterectomy resulted in significantly better patient satisfaction at 2 years for similar costs. Unfortunately, there are no randomized trials that have compared laparoscopic supracervical hysterectomy to vaginal or abdominal hysterectomy. Given the lack of appropriate randomized, controlled trials and the limitations of the

existing research, the laparoscopic supracervical hysterectomy's true value and appropriate clinical indications remain unknown [4].

Being a minimal invasive surgical procedure, the goal of operative laparoscopy is to reduce tissue damage and postoperative adhesion and to speed up recovery; therefore, the scalpel used in operative laparoscopy should not only reduce tissue injury, but also decrease postoperative adhesion and inflammation. Studies have shown that postoperative adhesion is closely connected with temperature at the incision site [5]. Concerning tissue dissection and coagulation, electro surgery displayed some complications and limits related to minimally invasive technique [6,7]. The search for a safer energy source has resulted in the use of high frequency ultrasound energy for surgical use [8]. This source has also been adapted successfully for laparoscopic use [9]. Electrothermal bipolar vessel sealer is a newly developed technology that allows precise thermal sealing of blood vessel's wall, with high efficacy, precision, and minimal lateral spread, which adds a privilege to laparoscopy as a minimal invasive procedure [10].

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The aim of this study was to compare the use of electrothermal bipolar vessel sealer (EBVS) with Harmonic Scalpel (HS) during Laparoscopic Supracervical Hysterectomy (LSH) with respect to operation time, estimated blood loss and related complications.

Patients and Methods

This study was a randomized clinical trial conducted in the Obstetrics and Gynecology Department, Maternity Hospital, Kuwait, from March 2009 till January 2011. The study protocol was approved by the scientific committee of the department. Forty candidates for Laparoscopic Supracervical Hysterectomy (LSH) were randomly divided into two groups. Group (I) was assigned for LSH using the Harmonic Shears (HS), and Group (II) was assigned for LSH using the Electrothermal Bipolar Vessel Sealer (EBVS). Each one of the two techniques used in the study was written in a card and was put in an envelope, the forty envelopes were all identical. Serially numbered sealed envelopes were held securely by trained nurse. The circulating nurse was asked to pull any card just before preparation for surgery. The patients were aware of the treatment methods and signed an informed consent, and they had equal chances of entering any of the trial groups.

An informed consent was taken from all patients; all women were subjected to the following:

- Careful history taking.
- Physical examination.
- Abdominal examination.
- Vaginal examination
- Cervical Pap smear.
- Ultrasound examination.

Inclusion criteria

All included patients:

- Suffered gynecological symptoms that, in the opinion of the gynecologist, justified hysterectomy.
- Had previous failed medical or conservative treatment.
- With negative cervical Pap smear.
- Signed written informed consent for the procedure.

Exclusion criteria

- Confirmed or suspected malignant disease of any part of the genitourinary system.
- Uterine size greater than the size of 12-weeks pregnancy.
- Any medical disorders that contraindicate laparoscopic surgery.
- Patient refusing the consent for the operation.

All operations were done by the same surgeon and surgical team. We used at least 3 and possibly 4 laparoscopic ports: a 10-mm umbilical port, one 5-mm and one 10- to 12-mm lateral port. The fourth port, if used, is usually placed in a suprapubic location. After entry and successful insufflation, the pelvis and abdomen are inspected in a thorough anatomical tour, with special focus on the anatomy of the ureter, the presence or absence of adhesions or pelvic pathology, any injury caused by the needle or the trochars, and the feasibility of the procedure. The utero-ovarian ligament, or the infundibulo-pelvic ligament if ovarian removal is desired, is divided with the use of the energy source selected. We used Harmonic Shears (HS) (UltraCision[®] harmonic scalpel, Smithfield, RI) for group (I), and Electrothermal Bipolar Vessel Sealer (EBVS) for group (II) patients (Valleylab, Boulder, Colo), the manufacturer of the electrosurgical bipolar vessel sealer is (LigaSure). The round ligament and remainder of the broad

ligament are divided. The vesico-uterine peritoneum is dissected off the anterior portion of the uterus, and the uterine arteries are skeletonized. At this point, the ascending branch of the uterine artery is identified, cauterized (or sealed), and divided. The cervix is amputated from the corpus using monopolar hawk at a point just below the internal cervical os and superior to the uterosacral ligaments. The excised uterine corpus is removed using the morcellator (Johnson & Johnson). Hemostasis was secured and peritoneal wash using isotonic saline solution was done. Peritoneum was then deflated and incisions at sites of entry were sutured and closed. Self retaining Foley's catheter was fixed till 6 am next morning, and removed.

Post operative care included

- CBC on the first and second day of the procedure.
- Monitoring of oxygen saturation and vital signs including temperature, blood pressure, pulse, and respiratory rate was performed hourly for the first 6 hours, and 6 hourly thereafter.
- The estimated blood loss was estimated by drop of HB% concentration from the preoperative value.
- Hospital stay was calculated from transfer from room of the theater till discharge from the hospital.

Data about the patients' characteristics, operation time, estimated blood loss, related complications and length of hospital stay were registered and compared.

Statistical methodology

Prior calculations indicated that a sample size of 20 subjects in each treatment arm would provide enough power and confidence to detect difference between both techniques. When one side had 5% significance and a test power of 90%, the required total sample size was 40 cases in both groups. Data were collected and coded then entered into an IBM compatible computer, using the SPSS version 12 for Windows. Qualitative variables were expressed as number and percentage while quantitative variables were expressed as mean (OLE Object) and standard deviation (S). Independent samples *t*-test was used as a parametric test of significance for comparison between two sample means, after performing the Levene's test for equality of variances. The Fisher's exact test was used as a non-parametric test of significance for comparison between the distributions of two qualitative variables whenever the χ^2 -test was not appropriate. It gives a *p*-value directly. A 5% level is chosen as a level of significance in all statistical significance tests used.

Results

This study comprised 40 patients divided into 2 equal groups. Group (I) underwent LSH operation using the Harmonic Shears (HS). Group (II) patients had the LSH operation using the electro-thermal bipolar vessel sealer technique. Table 1 demonstrates the study groups to have no significant difference in their demographic data and criteria.

	Group I N = 20	Group II N = 20	p value
Age (years)	44.17 (5.34)	45.67 (4.15)	0.067*
Parity (mean)	5	6	0.073*
Body mass index (kg/m ²)	28.8 (6.4)	30.6 (3.50)	0.064*
Preoperative HB%	11.6 (1.2)	12.1 (0.9)	0.066*
Preoperative Ht%	35.4 (2.23)	36.0 (3.5)	0.073*

*Non significant difference. Values are expressed as means \pm SD
Values are expressed as mean \pm SD

Table 1: Characters of study groups.

Table 2 reveals the significant reduction of operation time using the EBVS technique (64.15 ± 12.02) min as compared to HS (138.25 ± 23.41) min. Blood loss during operation was significantly lower in group (II) patients compared to group (I) demonstrated by significant greater drop in hemoglobin and hematocrite in the latter compared to the former group. The mean Hemoglobin drop in group (I) patients was (3.15 ± 0.82) while hematocrite drop was (3.72 ± 0.74). The mean hemoglobin drop for group (II) patients was (0.43 ± 0.33), while hematocrite drop was (0.74 ± 0.41). The mean hospital stay time for group (I) patients was 2.0 ± 1.52 days. The mean hospital stay for group (II) was 1.65 ± 0.58 days; the difference was not statistically significant.

There was higher rate of complications among group (I) patients (25%) as compared to group (II) patients (10%); however the difference was not statistically significant (Table 3). Complications recorded were all in the form of intra-operative bleeding from larger vascular stumps or uterine vessels. Two patients from group (I) were converted into laparotomy due to failure to control bleeding from stumps.

Discussion

Laparoscopic Supracervical Hysterectomy operation (LSH) has been the subject of prospective cohort studies, retrospective case-control studies, and numerous case series [11-16]. Most of the early reports compare LSH to LAVH in terms of operative time, complications, costs, and postoperative outcomes. All of these studies found that LSH resulted in reduction in estimated blood loss and hospital stay, when compared with LAVH. Most studies concluded that LSH had lower complication rates [17-22]. Campagnacci et al., have proven in their laparoscopic colorectal experience, EBVS Ligasure has proven safer and more effective in vessel sealing as compared to harmonic shears. Patients in whom EBVS device was used had less blood loss and slight advantages in operating time and postoperative hospital stay [23]. Demirturk et al. have published a study in 2007 comparing the use of electrothermal bipolar vessel sealer with harmonic scalpel in total laparoscopic hysterectomy [10]. Electrothermal bipolar vessel sealer was found to be less time-consuming and caused less bleeding when compared to harmonic shears. Mean procedure time and estimated blood loss were significantly less in the EBVS arm compared to the

harmonic shears arm (59.57 +/- 3.71 vs 90.95 +/- 5.73 min, $p < 0.005$; 87.76 +/- 25.48 vs 152.63 +/- 60.90 mL; $p < 0.005$, respectively). The changes in hemoglobin and hematocrite values were found to be more significant in the harmonic shears group.

Our study demonstrated similar results when compared to Campagnacci et al. [23], and Demirturk et al. work [10]. There was significant reduction in operation time using the EBVS technique (64.15 ± 12.02) min as compared to HS (138.25 ± 23.41) min. Variation in operation time from that of Demirturk et al. study [10] may be attributed to individual variations in surgical experiences of operating teams. Our work revealed that blood loss during operation was significantly lower in EBVS group compared to HS group demonstrated by significant greater drop in hemoglobin and hematocrite in the latter compared to the former group. This could be attributed to the limited ability of HS technique to deal with larger vascular stumps such as the infundibulo-pelvic and large uterine stumps. We also had more occasional bleeding in the HS group. Bleeding source was mainly from the uterine vessels due to inadequate sealing by the harmonic shears in some patients, which caused more blood loss, and time consumption in trials to control bleeding. We had to convert two of these cases into laparotomy due to excessive uncontrolled bleeding. We also had the feeling that Harmonic shears seems to take more time in completing the coagulation-cut cycle in each pedicle as compared to EBVS technique, but we did not record the time difference. Bleeding stumps were manifested intraoperatively in 5 out of 20 (25%) patients in the HS group, compared to 2 out of 20 (10%) in the EBVS group the difference was not statistically significant, however, it is a considerable variation. Bleeding from uterine stump in the EBVS group was among the first few cases when experience with the technique was still new, however this disappeared when the surgeon got familiar with the instrument. Harmonic shears group had longer hospital stay time as compared to the electrothermal vessel sealer group; however the difference was not statistically significant. This is attributed to the higher frequency of bleeding from stumps and conversion to laparotomy in 2 cases in the former group. These results are similar to those of Demirturk et al. [10].

Conclusion

Electrothermal bipolar vessel sealer technique seems to provide better control of stump sealing with consequent less blood loss, and showed less operative time consumption during LSH operation as compared to harmonic shears technique. This study is underpowered to reach a strong solid conclusion, and further studies on larger number of patients are still needed.

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Details	Groups	N	Mean	SD	t test	p value
Operative Time	Group I	20	138.25	23.41	12.59	< 0.005**
	Group II	20	64.15	12.02		
Hemoglobin drop %	Group I	20	3.15	0.82	13.73	< 0.005**
	Group II	20	0.43	0.33		
Hematocrite drop %	Group I	20	3.72	0.74	15.67	< 0.005**
	Group II	20	0.74	0.41		
Hospital Stay (days)	Group I	20	2.00	1.52	2.076	0.354*
	Group II	20	1.65	0.58		

*=non significant difference
**= significant difference

Table 2: Operative and post operative details of the studied cases.

Complications	Group I		Group II	
	No.	%	No.	%
No	15	75.0	18	90.0
Yes	5	25.0	2	10.0
	20	100.0	20	100.0
Significance	FET = 0.407 *			

* = Non significant
FET = Fisher Exact Test

Table 3: Complication rate among study groups.

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