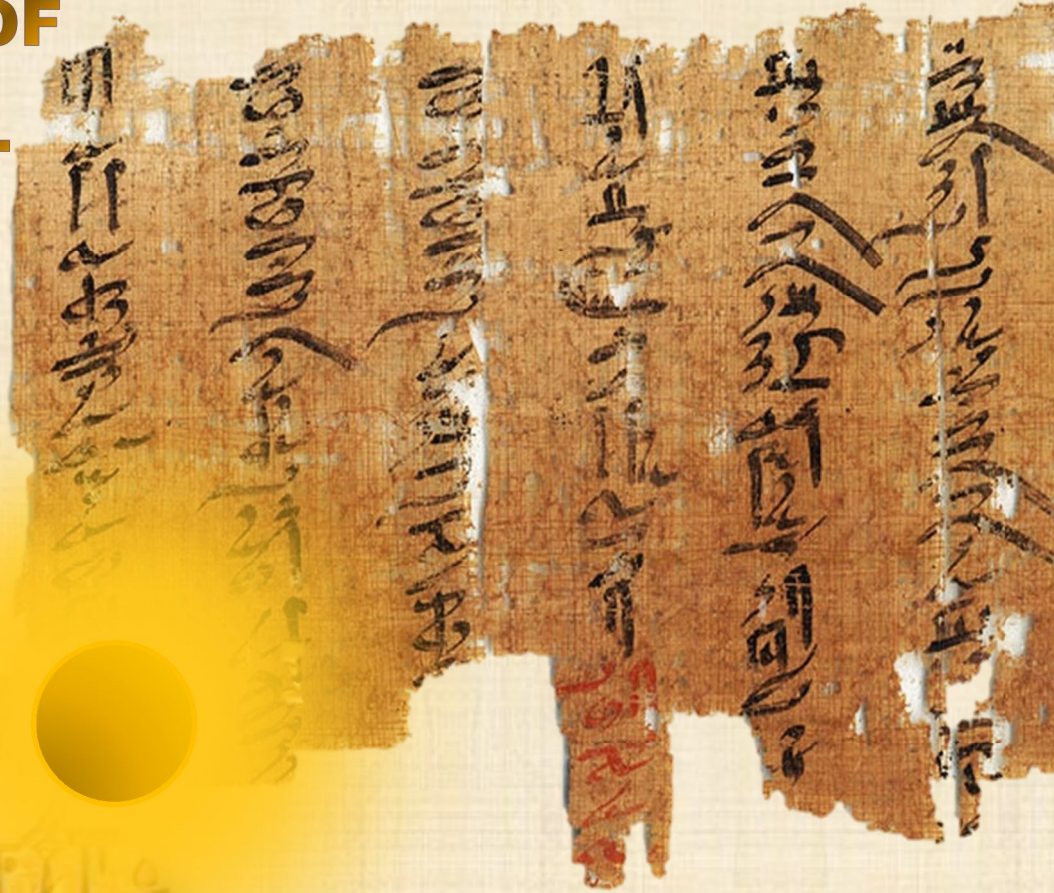


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Original article

Comparative Study of Electrosurgical Bipolar Vessel Sealing Using Ligasure versus Conventional Suturing for Total Abdominal Hysterectomy

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ABSTRACT

Background: Hysterectomy is a common gynecological surgical intervention, which could be associated with increased female morbidity and mortality. Bleeding and pain represent two main complications associated with hysterectomy. Hemostatic measures are in a continuous development, and LigaSure could represent one of the most important milestones in this field.

Aim of the work: To compare LigaSure use versus conventional suturing in total abdominal hysterectomy.

Patients and Methods: Seventy patients who were scheduled for elective hysterectomy were included. They were assigned to equal groups [Ligasure [A] and Conventional suturing [B]]. All were screened preoperatively, prepared and both intra-and post-operative outcome were registered and compared between both groups [mainly blood loss and postoperative pain].

Results: Both groups were comparable as regard to patient age, body mass index, parity, and indications for hysterectomy. Operative time was significantly reduced among vessel sealing when compared to conventional group [54.9±6.7 vs 63.1±6.6 minutes respectively]. In addition, vessels sealing group was associated with significantly low blood loss [142.7±23.1 vs 285.7±28.4 ml], high postoperative hemoglobin [11.3±1.0 vs 11.0±0.9], low hemoglobin reduction, and significant reduction of postoperative pain at evening, first and second postoperative days and low need for analgesia.

Conclusion: Electrosurgical bipolar vessel sealing is an effective alternative to sutures in abdominal hysterectomy. It is associated with significant operative time shortening, low blood loss and low postoperative pain.

Keywords: Hysterectomy; Bleeding; LigaSure; Sutures; Complications.

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* Main subject and any subcategories have been classified according to research topic.

INTRODUCTION

Hysterectomy is a commonly performed gynecological surgical procedure. As reported in current literature around 10-30% of females - of the industrialized countries- had been submitted to hysterectomy before the age of 65 and about 20% of females in the developing world had been subjected to hysterectomy by the age of 55^[1]. In Egypt, annual incidence rate for hysterectomy was 165,107^[2]

Abdominal hysterectomy refers to surgical removal of the uterus through a laparotomy. When both uterus and cervix were excised, it is the total hysterectomy, while subtotal [supracervical] hysterectomy refers to removal of the uterus without cervix may be performed. Clinical situation, surgeons expertise and patient preferences are the factors that govern the choice of surgical approach^[3]. Including duration between 1998 and 2010, the distribution of the hysterectomy technique was: abdominal [65%], vaginal [20%], conventional laparoscopic [13%], robotic [0.9%], and radical [1.2%]^[4]. Abdominal hysterectomy had the advantages of the following: 1] provides a good visibility, 2] easily access to pelvic structures and 3] enables removal of a very large uterus or large areas of endometriosis, adeno-myosis, or adhesions^[5].

In successful total abdominal hysterectomy, the quick, harmless, and complete vessels sealing remains a significant issue; as number of large vessels must be dissected. Therefore, many techniques have been performed for securing vascular pedicles in this operation; as mechanical ligation by conventional suture, and Electrothermal Bipolar Vessel Sealing [EBVS] systems [LigaSure]^[6]. Surgical suture ligation has been preferred for securing vascular pedicles; however, suturing includes clamping, cutting, and ligation, which consumes considerable time, resulting in long operative time and increased blood loss in hysterectomy^[7].

Electrothermal Bipolar Vessel Sealing [EBVS] devices have been introduced to seal large blood vessels [with diameter up to 7mm] for some models. The technology was pioneered by Valleylab in the 1990s, primarily for use in laparoscopy. Several manufacturers have produced similar systems that are available in the

United Kingdom [UK]^[8].

LigaSure, a controlled high-power current at low voltage, used to liquify the collagen and elastin in tissue, with subsequent permanent fusion of the vascular layers and obliteration of the lumen. The device fuses vessels up to 2–7 Mm in diameter^[9].

Feedback-control mechanism, with an automatic “off” switch when the impedance reaches a dangerous level, safeguards that tissues are not charred by over coagulation^[10].

Aiming to decrease blood loss in cesarean section, we proposed that, the use of LigaSure could be associated with reduction of blood loss than conventional suturing. In addition, we believe that, LigaSure if associated with reduction of blood loss, should be introduced as a standard tool in cesarean delivery at our institution.

AIM OF THE WORK

To compare LigaSure use versus conventional suturing in total abdominal hysterectomy as Time of operation, Blood loss during operation, Intra operative complications, Hemoglobin level 24 hours post-operative, Short term [two weeks] post-operative complications.

PATIENTS AND METHODS

It is a prospective randomized clinical trial. It had been conducted at the Obstetrics & Gynecology Department, Al-Azhar University Hospital [New Damietta], during the period from May 2018 to November 2019. The calculated sample size of the study revealed the need for 30 participants for each group at 5% level of significance and 80 % power. We had been decided to increase the sample for each group to 35 patients to compensate for the failures with incomplete data and to increase the study power. Thus, the present work included 70 patients, who had been admitted to Obstetrics and Gynecology Department and had been scheduled for elective hysterectomy. A full explanation of the study had been performed before an informed consent had been signed by each patient and her husband. The criteria to be included in the study were: 1] Benign uterine pathology, 2] Uterine size < 16 weeks, 3] Age: 40-55 years, 3] Body mass index [BMI] ≤35kg/m², and 5] No previous pelvic operations. Otherwise, patient had been excluded if she had, 1. malignant uterine pathology, endometriosis and

pelvic inflammatory disease [suspecting extensive pelvic adhesions], 2. uterine size > 16 weeks [suspecting extensive bleeding], 3. medical disorders as uncontrolled diabetes mellitus, immune-compromised, hepatorenal diseases, 4. Anti-coagulant drugs, 5. previous laparotomy, and 6. Anemia [hemoglobin < 10gm/dl].

The study population had been randomly divided into two groups with closed envelope technique. Each group included 35 patients. **Group A:** This group for "total abdominal hysterectomy using bipolar vessel sealing by LigaSure". **Group B:** This group for "total abdominal hysterectomy using conventional sutures". The preoperative assessment consisted of detailed history, clinical evaluation and routine laboratory investigations to assure fitting for surgery. In addition, availability of blood had been ensured for each patient before surgery.

All hysterectomies had been completed under general anesthesia, in supine position, and vulva & perineum had been disinfected with povidone iodine solution and a Foley catheter had been inserted. The abdomen then had been prepped from the anterior thighs to the xiphoid process. The type of EBVS generator used in the current work was the LigaSure vessel sealing generator with instant response technology, produced by Valleylab, an Irish company founded in 1967 as a Medical Product distributor. LigaSure device [Valley Lab LS10]. Abdominal hysterectomy had been performed through Pfannenstiel incision in slight Trendelenberg position. After the abdomen had been explored, a retractor had been placed, and the bowel had been packed superiorly to afford good exposure of the pelvis, the bowel had been packed away and exposure to the pelvis was satisfactory, then uterine clamps had been applied. The broad ligament had been opened, with exposure of the retroperitoneal space by a blunt dissection; the peritoneal incision had been extended caudally to the bladder reflection, and clamps had been applied as the following using EBVS [Group A]: 1. Clamp, relax tissue traction, seal, and both round ligaments had been divided, window had been performed in broad ligament then. 2. Clamp, relax tissue traction, seal, and divide both utero-ovarians 3. Clamp, relax tissue traction, seal, and both uterine vessels had been divided. 4. Clamp, relax tissue traction, seal, and both cardinal ligaments had been, and 5. Clamp,

relax tissue traction, seal, and both utero sacral ligaments had been divided. *If uncontrollable bleeding was encountered, the conventional suturing technique was used and the cases was appointed as a failure.* 6. Incision of the vagina and excision of the uterus had been performed. 7. Closure of vault of the vagina. The vaginal mucosa had been re-approximated in a horizontal manner, using continuous sutures. The sutures had been placed through the entire thickness of the vaginal epithelium, closure of the anterior abdominal wall in layers with insertion drain after homeostasis had been ensured^[11]. In Group [B], the same steps had been carried out by the conventional clamping and suturing techniques using Kocher clamps and sterile synthetic absorbable sutures which are braided polyglactin 910 [vicryl 1], manufactured by ACE surgical supply company were done

Primary outcome measures: 1. **Operative time** [from clamping of round ligament or the use of LigaSure till closure of the vaginal vault and achieving good hemostasis], 2. Intra- and post-operative complications, 3. Postoperative pain assessment using the visual analogue scale [VAS] and need for analgesics, 4. Post-operative hospital stay, and 5. Cost effectiveness via reduction of suture materials, hospital stay, complications and blood transfusion. In addition, all patients followed up after 3 months for assessment of remote post-operative complications.

The study had been adhered to ethical principles of value, validity, avoidance or risk exposure, consent was informed, voluntary and can be withdrawn at any time. The privacy of participants is protected, and their wellbeing is monitored^[12].

Statistical analysis: Data had been analyzed using the Statistical Package of Social Science [SPSS] program for Windows [Standard version 21]. The normality of data had been first tested with one-sample Kolmogorov-Smirnov test. Categorical variables data had been presented as numbers and percent. Association between categorical variables had been tested by Chi-square test. Continuous variables had been presented as mean±SD [standard deviation] for parametric data and median for non-parametric data. The two groups were compared by Student *t* test for parametric data and Mann Whitney test for non-parametric. P value < 0.05 was set as the level of

significance.

RESULTS

Results of the present work revealed that, patient age ranged between 35 and 55 years, while BMI ranged between 25.1 and 29.8 kg/m². In addition, parity ranged between 0 and 8, while uterine size ranged between 9 and 16 cc; and there was no significant difference between both groups. In addition, no significant difference was observed between vessel sealing and conventional groups regarding indications of hysterectomy [it was menorrhagia, metrorrhagia, dysmenorrhea, adenomyosis and chronic abdominal pain among 5, 8, 3, 15, 4 successively in vessel sealing group, compared to 3, 4, 6, 14 and 8 with the same order among conventional group [Table 1]. In the present

work, operative time ranged between 38 and 81 minutes with significant reduction among vessel sealing when compared to conventional group [54.9±6.7 vs 63.1±6.6 minutes respectively]. However, no significant difference between groups was observed regarding duration of hospital stay, preoperative hemoglobin, IO complications, PO complications or PO pain at the week 6 postoperatively. Otherwise, vessels sealing group was associated with significantly low blood loss [142.7±23.1 vs 285.7±28.4 ml], significantly high postoperative hemoglobin [11.3±1.0 vs 11.0±0.9], significantly low hemoglobin reduction, and significant reduction of PO pain at evening, first and second postoperative days and significantly low number of patients need PO analgesia [Table 2].

Table [1]: Patient characteristic and indications for hysterectomy among studied groups

Variables		Vessels sealing	Conventional	Test of sig.	P value
Age		44.3±3.8; 35-55	44.8±3.3;38-54	0.87	0.38
BMI		27.4±0.9; 25.1-29.5	27.6±0.9; 25.4-29.8	1.49	0.13
Parity		1.9±1.5;0-8	1.9±1.4;0-6	0.113	0.91
Uterine size		11.7±1.3;9-16	11.3±1.2;9-15	1.017	0.31
Indications	Menorrhagia	5[14.3%]	3[8.6%]	4.20	0.37
	Metrorrhagia	8[22.9%]	4[11.4%]		
	Dysmenorrhea	3[8.6%]	6[17.1%]		
	Adenomyosis	15[42.9%]	14 [40.0%]		
	Chronic abdominal pain	4[11.4%]	8[22.9%]		

BMI: body mass index

Table [2]: Outcome among studied populations

Variables		Vessels sealing	Conventional	Test of sig.	P value
Operative time [min]		54.9±6.7; 38-67	63.1±6.6; 52-81	7.57	<0.001*
Hospital stay [day]		0.80±0.93; 0-2	1±1; 0-2	0.86	0.39
Blood loss		142.7±23.1; 100-200	285.7±28.4; 200-400	4.96	<0.001*
Hemoglobin	Preoperative	12.2±1.0; 10.1-14.2	12.3±0.8; 10.4-14.2	0.42	0.67
	Postoperative	11.3±1.0; 9.2-13.6	11.0±0.9; 8.7-12.8	2.09	0.030*
	Reduction	0.9±0.7; 0.1- 3.6	1.3±0.7; 0.1-3.4	3.36	<0.001*
IO complications	UT injury	2 [5.7%]	1[2.9%]	0.34	100
	Bowel injury	0	0	-	-
PO complications	Total	5 [14.3%]	8[22.9%]	0.83	0.54
	Hematoma	1[2.9%]	2 [5.7%]	0.34	100
	Dehiscence	1[2.9%]	3		
	Fever of UO	1[2.9%]	2 [5.7%]	0.34	100
	Paralytic ileus	2 [5.7%]	1[2.9%]	0.34	100
	Pneumonia	0	0	-	-
	thromboembolism	0	0	-	-
PO pain	Evening	54.3±4.8; 45-65	68.3±4.0; 56-77	19.32	<0.001*
	Day 1	46.1±4.7; 36-59	60.3±5.7; 38-74	16.65	<0.001*
	Day 2	34.1±5.7;21-45	43.0±5.0;31-54	10.21	<0.001*
	Week 6	10.6±2.1;6-14	11.1±1.8; 7-15	1.56	0.12
PO analgesia	Evening	2[5.7%]	21[60.0%]	23.37	<0.001*
	Day 1	1[2.9%]	20[57.1%]	24.55	<0.001*
	Day 2	1[2.9%]	18[51.4%]	20.87	<0.001*
	Week 6	0	0	-	-

*= Significant; IO: intraoperative; PO: postoperative

DISCUSSION

The current study was designed to compare the effectiveness of electrosurgical bipolar vessel sealing versus conventional clamping and suturing in securing the pedicles in total abdominal hysterectomy and also to assess the efficacy.

Operative time was significantly reduced with EBVS, which confirm previous work of **Kriplani et al.**^[13], who had found that operative time using EBVS was shorter than using sutures. This could be due to the fact that, suturing involves clamping, cutting, and ligation, which require considerable time, resulting in prolonged operative time^[7]. On the other side, **Lakeman et al.**^[14] and **Darwade et al.**^[15] reported no superiority of LigaSure, as there were no significant difference between both groups.

Results of the current work revealed non-significant difference regarding duration of postoperative hospital stay. These findings disagree with **Levy and Emery**^[16], who found that duration of hospital stays using LigaSure shorter than using suturing methods. However, **Macario et al.**^[17], **Lakeman et al.**^[14], **Darwade et al.**^[15], found that there was no significant difference between using EBVS and suturing groups regarding the duration of hospital stay [as in the current study].

In the current work, there were significant difference decrease of blood loss in the vessel sealing group. This could be explained by considerable time needed by suturing technique which increased blood loss in hysterectomy^[7]. These results are comparable to previous studies^[15-16, 18-19] which revealed less blood loss among the vessel sealing group, but disagree with the results shown in **Lakeman et al.**^[14], who didn't stratify any significant reduction of blood loss. In addition, no difference was found in two RCTs^[18,20]. This was attributed to surgeon experience with establishment of a good surgical technique using sutures.

In the current study we had found a significant reduction in postoperative pain at evening after surgery, day 1, day 2 among the vessel sealing group while at 6 weeks it wasn't significantly lower than the conventional group and these data was manifested by reduction of postoperative analgesics requirements and better outcome in the visual analogue scoring system. These results agree with the data mentioned in **Cronje and de Coning**^[18];

and Douay et al.^[21], which stated that pain was significantly reduced in the tested [vessel sealing group]. Reduced pain could be attributed to the effect of LigaSure device, which does not compress tissues and nerves are coagulated where they are cut^[18]. In addition, additional clarification is that during vessel sealing, the traction to the tissue and autonomic innervation around the uterus is evaded as the clamps rather push in the opposite direction as they pull during conventional surgery. As a result during electrical activity, the LigaSure clamp does not provide any force on the tissues surrounding the uterus. It was supposed that the rapid recovery to normal daily life in the vessel sealing group is actually the result of the decreased postoperative pain that allows the patient to recover more comfortably^[22]. The development of electrosurgery has been fast and continues to advance upon itself. The ability of today's electrosurgical instruments to reduce blood loss and reduce operative times has had a marked impact across all specialties. Critical to obtaining optimal clinical effects and decreasing probable complications is a thorough understanding of the proper use of each energy modality^[23].

About intra- and post-operative complications, we had found that there was no significant difference was observed between both groups, which agree with the data shown in **Darwade et al.**^[15], and **Lakeman et al.**^[14]. Overall, the complication rates from using EBVS were either the same or slightly reduced when compared with using sutures. However, most previous studies had small patient numbers and the data did not achieve statistical significance^[24]. Two trials described a diversity of minor problems, which appeared unrelated to the operative technique^[20,25].

For economic analysis, the duration of hospital stay was shorter in EBVS group, although the difference did not reach statistical significance. In addition, there was significant reduction of operative time with decreased amount of anesthetic medications. Furthermore, EBVS only require one suture for closing the vaginal vault, a saving of approximately 6 sutures per case^[18,19]. Also, reduced pain is commonly associated with EBVS and can result in reduced use of morphine and other analgesics^[25,26]. Finally, blood loss was significantly lower for EBVS patients. All of these variables lead to significant reduction of the financial burdens on

the country and medical centers. Furthermore, Singh *et al.*^[27] concluded that, LigaSure group had significantly shorter operative time, reduction of blood loss. However, LigaSure had been associated with more intra-and post-operative comorbidities. The cost had been reduced by Ligasure as a consequence of reduction of suture consumption.

In summary, electrosurgical bipolar vessel sealing is an effective alternative to sutures in abdominal hysterectomy, resulting in significantly reduction of operative time and blood loss, postoperative pain without increasing the rate of occurrence of complications.

Financial and Non-Financial Relationships and Activities of Interest

Authors declare that, there was no competing interest

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