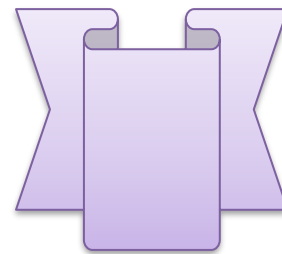
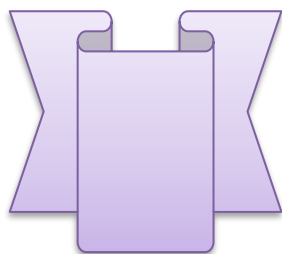
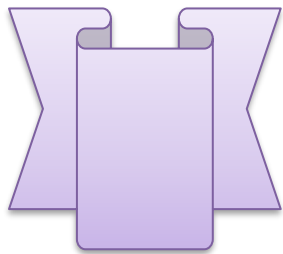
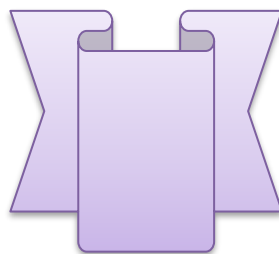
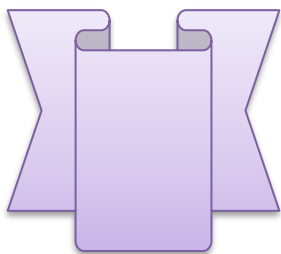
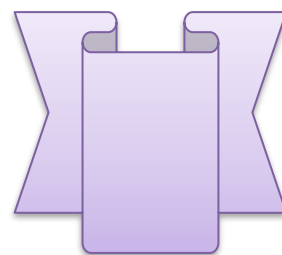
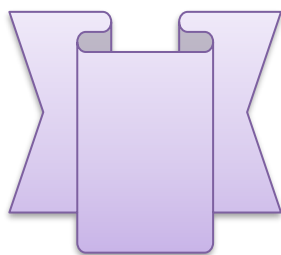
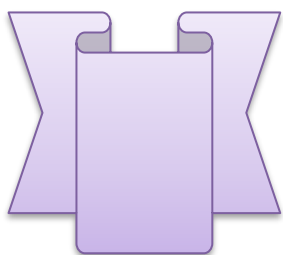


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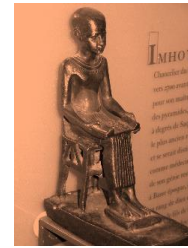
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## Original Article

# Comparative Study of Bipolar Vessel Sealing Clamp versus Traditional Method for Vaginal Hysterectomy

Esraa Salah Ahmed \*, Mahmoud Farouk Midan, Walaa Mohamed Elbassioune

Department of Obstetrics and Gynecology, Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt

## ABSTRACT

### Article information

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\*Corresponding author

**Email:** [esraasalah8993@gmail.com](mailto:esraasalah8993@gmail.com)

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**Background:** Hysterectomy is a gynecological surgical procedure that has been linked to raised women morbidity and mortality. The two most common problems related to hysterectomy are bleeding and pain. Hemostatic measures are constantly evolving, and LigaSure could be one of the significant milestones in this field.

**Aim of the work:** To compare impacts of electrical bipolar vessel sealing clamp and conventional suturing method in woman undergoing vaginal hysterectomy.

**Patients and Methods:** This was a prospective comparative randomized controlled trial, included 40 women diagnosed with benign lesions in uterus and scheduled for vaginal hysterectomy. Patients were separated into two groups; group [A]: Electrical bipolar clamp sealing method [20 patients], and group [B]: Traditional suturing ligation method [20 patient]. Groups were compared regarding operative duration, intra operative blood loss, post-operative pain and short-term complications from operation until postoperative day fourteen.

**Results:** The LigaSure group had significant short operative duration [ $53.95 \pm 6.94$  min. vs.  $62.90 \pm 7.28$  min.;  $P = < 0.001$ ] and less blood loss [ $P = 0.002$ ] compared to conventional method. Postoperative analgesia requirement at evening after surgery, day-1 and day-2 was significantly lower among vessel sealing than among conventional. Postoperative analgesia requirement at week-6 was not required in both groups.

**Conclusion:** The use of LigaSure device can decrease operative time. When compared to traditional suture ligatures, it allows for faster, safer and more useful hemostasis while decreasing operative blood loss, pain status and hospital stay.

**Keywords:** Vaginal hysterectomy; Bipolar vessel sealing system; Ligasure.



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## INTRODUCTION

Globally, hysterectomy is a common elective surgical procedure. Seventy percent of these surgeries are conducted for benign diseases like uterine fibroids, adenomyosis, menstrual irregularities and genital prolapse [1].

In modern gynecological surgery, vaginal, abdominal, laparoscopic, robotic and combined approaches are used to perform hysterectomy. Vaginal hysterectomy is considered as a minimally invasive surgery [2].

The vaginal route is a recommended method for surgical excision of uterus, and in lack of gross pelvic disease, it can be carried out in many cases. The vaginal hysterectomy is a natural orifice surgical process that provides all benefits of fast-tracking surgery. Benefits of vaginal hysterectomy contain less blood loss, shorter hospitalization, and early return to normal activity [3].

The bipolar clamp BVSS are insulated forceps with automatic coagulation completion. This method has similar principles of anatomy as the usual techniques, decreasing learning curve. It needs two tools, making it easier to use and lowers the risk of trauma [4].

Previous researches about vaginal hysterectomy using bipolar clamp suggest that it is associated with less post-operative pain and shorter operative time and coagulation impacts on innervation of surgical field. These impacts prevent back-bleeding, ensuring better hemostasis and decreasing surgical field visual impairment [5].

Liga sure, low-voltage controlled high-power current is used to melt collagen and elastin in tissue, resulting in permanent

fusion of vascular layers and obliteration of lumen. Device fuses vessels with diameters ranging from two to seven mm [6]. In order to evaluate the hemostatic effect and other surgical outcomes, the present study was conducted to compare between electrical bipolar vessel sealing clamp and conventional suturing method in patients scheduled for vaginal hysterectomy.

## PATIENTS AND METHODS

This was a comparative prospective randomized controlled clinical trial. The research was conducted at the Obstetrics and Gynecology Department, Al-Azhar University Hospital [New Damietta]. It was conducted between November 2020 and November 2022.

Sample size was calculated to prevent type II error. To be of clinical significance, we would need to study 40 patients 20 subjects in each group with a ratio of [1:1]. Group A] [electrical bipolar clamp sealing] [20] patient. Group B] [traditional suturing ligation method] [20] patient.

**Inclusion criteria:** Women who will undergo vaginal hysterectomy for benign indications, age 40-55 y, uterine size <16 wk. and BMI < 35 kg/m<sup>2</sup>

**Exclusion criteria:** Endometriosis [suspect of pelvic adhesion] and chronic medical disorders [uncontrolled diabetes, liver and renal diseases].

**Method of randomization:** Randomization was done using single and paired numbers: **Group A** [single numbers 1, 3, 5....so on] who was hysterectomized vaginally by using LigaSure [figure 1], **Group B** [paired numbers 2, 4, 6.....so on] who was hysterectomized vaginally by conventional suturing method.



Figure [1]: Ligasure device [Valley Lab]

**Ethical Consideration:** This study protocol was approved prior to conduction by the research ethics committee, Al-Azhar Faculty of medicine [New Damietta]. A written consent will be obtained from every case.

## Methodology

**Preoperative care:** Prophylactic antibiotics [cefazolin, 2 g IV] within one hour before incision. Prophylaxis for venous thromboembolism [low molecular weight heparin; enoxaparin forty mg] beginning 2 hours before incision].

**Anesthesia:** General or regional anesthesia according to surgeon and patients' preference.

**Procedure:** Cases are placed in dorsal lithotomy position. After studied cases is positioned, weighted speculum is inserted into posterior vagina, and right-angle retractor is inserted anterior to cervix, whereas anterior and posterior cervix lips are grasped with single- or double-toothed tenaculum.

**Vaginal incision and opening of posterior peritoneum:** First vaginal incision is made circumferentially, beginning at level of vaginal rugae and continuing thru entire thickness of vagina, just beneath bladder reflection.

**Division and ligation of uterosacral ligaments:** Uterosacral ligaments are identified and clamped, with clamp tip incorporating lower cardinal ligaments. Clamp is positioned perpendicular to uterine axis, and pedicle is cut so that 0.5 cm of tissue is distal to clamp.

**Opening of anterior peritoneum:** Anterior peritoneum is then opened with great care. Tissue forceps are used to grasp peritoneal reflection, which is then tented and opened with scissors with their tips pointing toward uterus.

**Division and ligation of cardinal ligaments:** Following that, cardinal ligaments are recognized, clamped, cut, and suture-ligated in same manner as uterosacral ligaments.

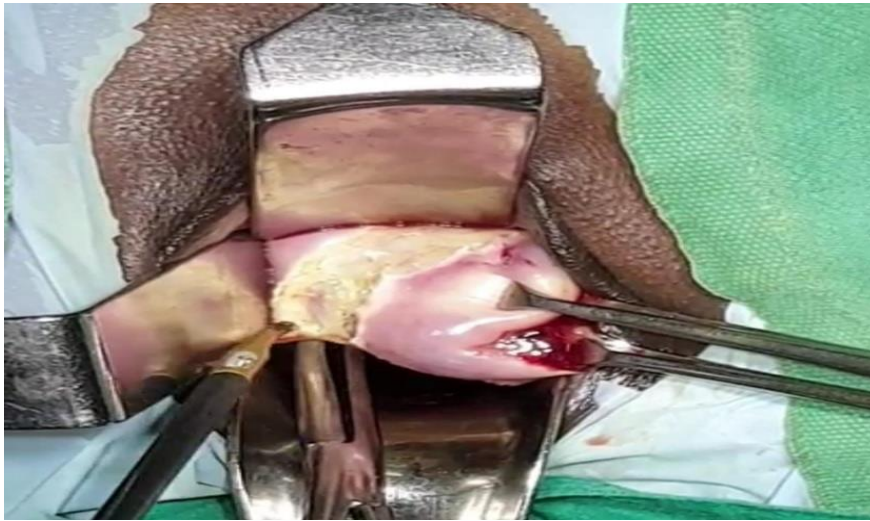
**Completion and closure:** Sponge-stick or laparotomy pad is inserted into peritoneal cavity to enable surgeon to visualize every pedicle and ensure adequate hemostasis. If any bleeding points are found, suture is used to ligate bleeding vessel while patient is under direct vision.

**Group A:** The Uterosacral and cardinal ligaments were divided and separated from the uterus using the Ligasure. The uterine vessels were transected using the Ligasure. The adnexa and round ligaments were divided and separated from the uterus using the Ligasure. The peritoneum was closed using continuous sutures, and the vaginal cuff was closed with interrupted sutures [figure 2 and 3].

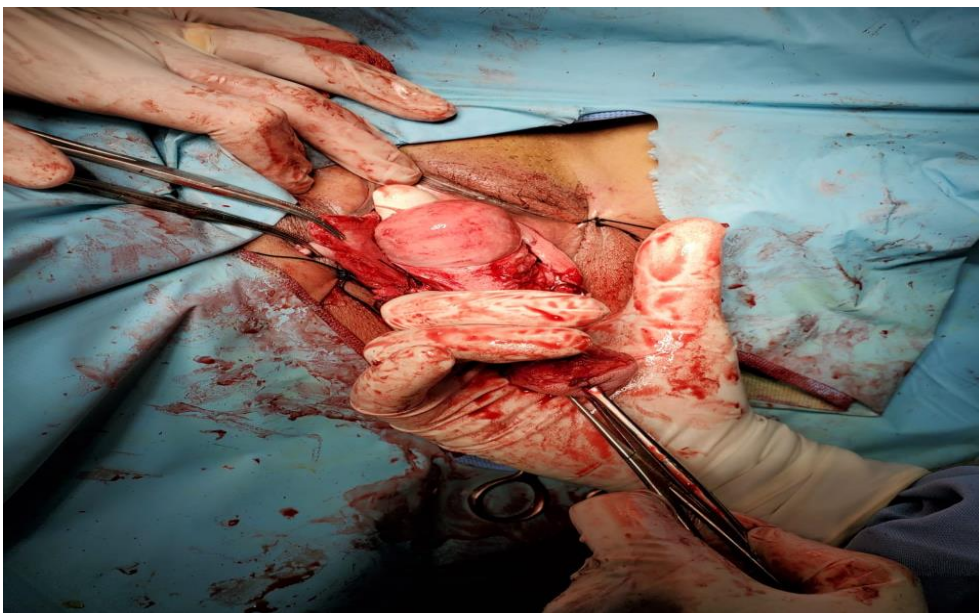
**Group B:** Uterine vessels were transected using standard hemostasis technique. Adnexa and round ligaments were split and separated from uterus using standard hemostasis technique. Continuous sutures were used to close peritoneum, and interrupted sutures were used to close vaginal cuff [figure 4 and 5].



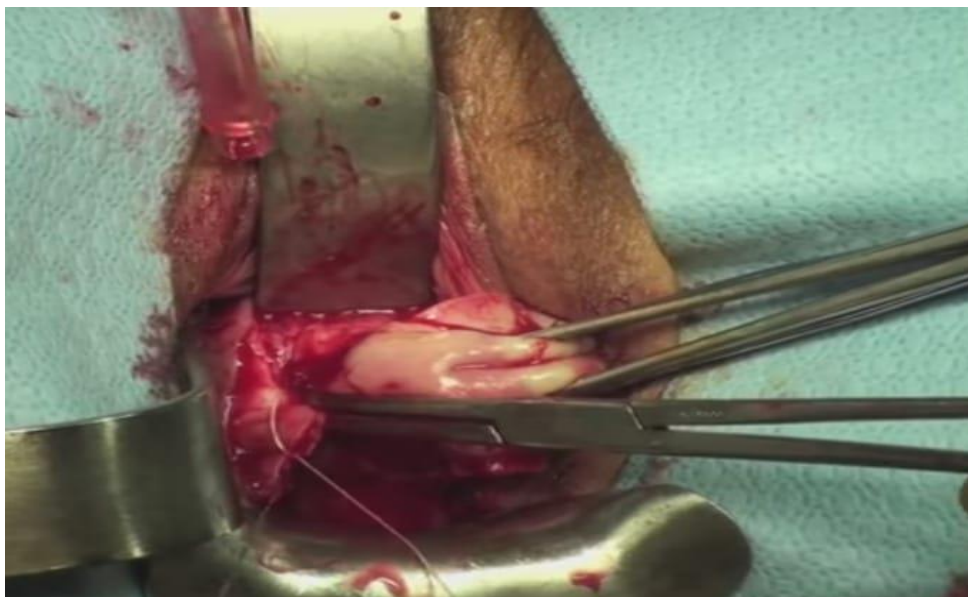
**Fig [2]:** field during surgery by Ligasure



**Fig [3]:** Field during surgery by ligasure



**Fig [4]:** Field during surgery by conventional method



**Fig [5]:** Field during surgery by conventional method

## Outcomes

**Operative duration:** described as duration among start of incision into anterior vaginal fornix and final closure of vaginal cuff.

**Intraoperative blood loss:** Intraoperative blood loss was calculated using following 2 parameters: surgeon classified blood loss immediately after surgery into 3 groups: "one hundred mL", "one hundred-three hundred mL", and "> three hundred mL" based on suction device content and towel weight. Variation among preoperative Hb levels measured one or two days before surgery and those on postoperative day one was used to calculate decline in hemoglobin levels [Hb g/dL].

**Post-operative pain:** Postoperative pain assessment using the visual analogue scale, and need for analgesics. VAS consists of 10 cm line on which 0 cm is no pain and 10 cm is pain as bad as it could be. Numeric scales [e.g., 1 to 10 cm] and pain descriptive rating scales e.g., no pain, mild, moderate, severe are also used. Postoperative pain was assessed by recording postoperative consumption of analgesics throughout first 3 postoperative days.

**Short term complications:** From operation till day fourteen was recorded as postoperative hematoma, fever and thromboembolism.

**Statistical analysis:** Data was fed into computer and analyzed with IBM SPSS software package version 20.0. Numbers and percentages were used to define qualitative data. Kolmogorov-Smirnov test was used to confirm distribution's normality. Range [minimum and maximum], mean, standard deviation, median, and interquartile range were used to define quantitative data. Student t test and Mann-

Whitney tests were used to analyze two continuous variables. Chi square and Fisher's Exact tests were used to analyze two categorical variables. significance of data was determined at five percent level.

## RESULTS

There was no variation among 2 studied groups as regard basic data [age, body mass index, parity and indication for surgery]. The most frequent indication in both groups is second degree uterine prolapse [table 1].

Operation time was significantly lower among vessel sealing than among conventional [53.95 ± 6.94 min. vs. 62.90 ± 7.28 min.; P= < 0.001]. Blood loss was significantly lower among vessel sealing than among conventional. There was no variation among two tested groups regards intra-operation complications [table 2].

No variation among two tested groups regarding preoperative hemoglobin and hematocrit. Postoperative hemoglobin and hematocrit were greater among vessel sealing than among conventional [table 3].

No variation among both groups regarding postoperative complications [table 4].

Postoperative pain at evening after surgery, day-1 and day-2 was significantly lower among vessel sealing than among conventional. Postoperative pain at week-6 was non-significantly lowers among vessel sealing than among conventional. Postoperative analgesia requirement at evening after surgery, day-1 and day-2 was significantly lower among vessel sealing than among conventional, Postoperative analgesia requirement at week-6 was not required in both groups [table 5].

**Table [1]:** Basic data of studied group

History data		Bipolar vessel sealing [n =20]	Conventional [n =20]	Test	p
<b>Age [years]</b>	Mean ± SD	45.50 ± 3.89	44.50 ± 3.89	t=0.814	0.421
<b>Weight [kg]</b>	Mean ± SD	75.30 ± 6.33	75.88 ± 4.73	t= 0.326	0.747
<b>Height [cm]</b>	Mean ± SD	163.4 ± 5.40	165.3 ± 4.60	t=1.166	0.251
<b>BMI [kg/m<sup>2</sup>]</b>	Mean ± SD	28.14 ± 0.90	27.76 ± 0.82	t=1.401	0.169
<b>Parity</b>	Primary	5 [25.0%]	4 [20.0%]	$\chi^2=0.263$	1.000
	Multi	15 [75.0%]	16 [35.0%]		
<b>Uterine size</b>	Median [IQR]	11.0 [11.0 – 12.0]	12.0 [11.0 – 13.0]	U=133.50	0.072
<b>Indication of hysterectomy</b>					
	Uterine prolapse [complete procidentia]	5 [25.0%]	4 [20.0%]	$\chi^2=2.14$	0.34
	Uterine prolapse [Second degree]	12 [60.0%]	9 [45.0%]		
	Menorrhagia	3 [15.0%]	7 [35.0%]		

**Table [2]:** Comparing of two studied groups according to intra-operation data and intra-operative problems

Intraoperation data	Bipolar vessel sealing [n = 20]	Conventional [n = 20]	Test	p
<b>Operation time [min]</b>				
Min. – Max.	44.0 – 65.0	53.0 – 74.0	t= 3.979*	<b>&lt;0.001*</b>
Mean ± SD.	53.95 ± 6.94	62.90 ± 7.28		
Median [IQR]	54.0 [48.50 – 59.50]	62.0 [56.0 – 69.0]		
<b>Blood loss [mL]</b>				
Min. – Max.	100.0 – 600.0	100.0 – 1150.0	U= 90.0*	<b>0.002*</b>
Mean ± SD.	315.0 ± 191.3	592.5 ± 296.2		
Median [IQR]	325.0 [100.0 – 475.0]	550.0 [350.0 – 750.0]		
<b>Blood loss ≥ 1 L</b>				
No	20 [100.0%]	18 [90.0%]	3.243	0.231
Yes	0 [0.0%]	2 [10.0%]		
<b>Blood transfusion</b>				
No	20 [100.0%]	19 [95.0%]	2.105	0.487
Yes	0 [0.0%]	1 [5.0%]		
<b>Bowel and UT injury</b>				
No	20 [100.0%]	20 [100.0%]	–	–
Yes	0 [0.0%]	0 [0.0%]		

**Table [3]:** Comparison of hemoglobin and hematocrit among studied groups

		Vessel sealing [n = 20]	Conventional [n = 20]	p
<b>Hemoglobin [g/dl]</b>				
<b>Pre-operative</b>	Range	10.6 – 13.7	10.6 – 13.8	0.468
	Mean ± SD	12.13 ± 0.9	12.27 ± 0.94	
<b>Post-operative</b>	Range	9.9 – 13.5	8.6 – 11.4	<b>0.001*</b>
	Mean ± SD	11.42 ± 1.27	10 ± 1.4	
<b>P value*</b>		<b>0.005*</b>	<b>&lt;0.001*</b>	
<b>Hematocrit [%]</b>				
<b>Pre-operative</b>	Range	34.9 – 42.3	35.9 – 42	0.353
	Mean ± SD	36.85 ± 2.98	37.44 ± 3.13	
<b>Post-operative</b>	Range	33.4 – 41.3	27.7 – 39	<b>0.039*</b>
	Mean ± SD	35.35 ± 4.04	32.01 ± 6.54	
<b>P value*</b>		0.07	<b>&lt;0.001*</b>	

\*: comparison of pre and post-operative data

**Table [4]:** Comparing among 2 studied groups according to postoperative complications

Postoperative complications	Bipolar vessel sealing [n = 20]		Conventional [n = 20]		$\chi^2$	P value
	No.	%	No.	%		
<b>No</b>	18	90.0	15	75.0	1.445	1.000
<b>Hematoma</b>	1	5.0	2	10.0		
<b>Dehiscence</b>	1	5.0	2	10.0		
<b>Unknown fever</b>	0	0.0	1	5.0		

**Table [5]:** Comparison between the two studied groups according to VAS-system and postoperative analgesia requirement

		Bipolar vessel sealing [n = 20]	Conventional [n = 20]	p	
<b>VAS system</b>	Evening after surgery	Mean ± SD	54.50 ± 4.47	67.20 ± 3.55	<b>&lt;0.001*</b>
	Day-1	Mean ± SD	46.70 ± 5.68	59.95 ± 4.52	<b>&lt;0.001*</b>
	Day-2	Mean ± SD	35.50 ± 6.82	53.50 ± 5.08	<b>&lt;0.001*</b>
	Week-6	Mean ± SD	11.20 ± 2.12	10.10 ± 1.48	0.066
<b>Postoperative analgesia requirement</b>	Evening after surgery	Yes	8 [40%]	17 [85%]	<b>&lt;0.001*</b>
	Day-1	Yes	4 [20%]	11 [55%]	<b>0.001*</b>
	Day-2	Yes	2 [10%]	5 [25%]	0.505
	Week-6	Yes	0 [0%]	0 [0%]	-



## DISCUSSION

Aiming to decrease blood loss in vaginal hysterectomy, use of LigaSure could be related to decrease of blood loss than conventional suturing. In addition, LigaSure if related to decrease of blood loss must be introduced as standard tool in vaginal hysterectomy at institution [7].

The aim of research was to compare impacts of electrical bipolar vessel sealing clamp [LigaSure] and conventional suturing method in women undergoing vaginal hysterectomy as regards, operative duration, intra operative blood loss, post-operative pain and short-term complications from operation until post-operative day fourteen [was documented as Postoperative hematoma, fever, incontinence and thromboembolism].

There was no variation among two studied groups as regard demographic data. **Abd Elzaher et al.** [8] showed that eighty studied cases undergoing vaginal hysterectomy for benign conditions were assigned to 1 of 2 groups: LigaSure [n=forty] or Suture [n=forty]. 2 groups were comparable in terms of age [p = 0.257], parity [p = 0.445], body mass index [p = 0.277], previous caesarean section [p = 0.762] and surgical indications.

**Mohamed et al.** [7] showed that 70 studied cases scheduled for elective hysterectomy were contained in study. They were divided into two groups of equal size [Ligasure [A] and Conventional suturing [B]]. Results of their work revealed that, patient age ranged between 35 and 55 years, while BMI ranged between 25.1 and 29.8 kg/m<sup>2</sup>. In addition, parity ranged between 0 and 8, while uterine size ranged between 9 and 16 cc; and there was no variation among both groups.

This research found that there was high variation among two studied groups as regard operation time and significant difference as regard blood loss.

**Abd Elzaher et al.** [8] showed that; when compared to control group, studied cases in LigaSure group had shorter mean operating duration [37.1 ± 8.9 min vs. 63.8 ± 10.9 min; p <0.001]. LigaSure group had lower mean blood loss [125.5 ± 33.2 ml vs. 264.6 ± 70.4 ml; p <0.001].

**Hefni et al.** [9] showed that there was no variation between 2 groups in terms of mean number [1.2 operations/studied case in both groups] or type of concomitant processes conducted. Studied cases in LigaSure group had shorter mean operating duration, fifty-seven [SD twenty] minutes, compared to sixty-six [SD twenty-five] minutes in control group, P < 0.04.

A RCT by **Zubke et al.** [10] concluded that operating duration was lower for BiClamp vessel sealing group compared with control group. Variations in operative time reflect changeability in local processes in addition to surgeon and patients' factors.

Vaginal Hysterectomy for prolapsed and non-prolapsed uterus are different procedures with different duration of surgery [11]. Due to non-significant difference between both groups regarding the indication for hysterectomy, this difference in surgical intervention would not make a meaningful effect

One of the issues associated with performing a hysterectomy on an outpatient basis is how to effectively address and control pain during the hours following the surgery. In the current study, BVS was associated with significant improvement of post-operative VAS. Similarly, **Giraudet et al.** [12] conducted a study comparing conventional suture ligation and electrosurgical bipolar vessel sealer [BVS] in 32 patients undergoing vaginal hysterectomy. They found that all patients in the BVS group were able to be discharged the day after surgery, compared to 87.5% of the CSL group. Additionally, the BVS group reported significantly lower pain levels at the 8th, 12th, and 24th postoperative hours, as measured by the visual analog scale. These findings suggest that the use of thermofusion techniques like BVS may be beneficial in reducing postoperative pain and potentially allowing for outpatient vaginal hysterectomy.

According to **Lakeman et al.** [13], women who underwent vessel-sealing during surgery experienced less pain in the evening after the procedure compared to those who did not [on a scale of 0-10, the pain score was 5.7 versus 4.5, with a significance level of P = 0.03]. However, pain scores were similar between the two groups after that initial period. The duration of the operation was shorter for the vessel-sealing group [60 minutes versus 71 minutes, with a

significance level of  $P = 0.05$ ]. There were no differences in blood loss or hospital stay between the two groups

There was no variation among 2 studied groups as regard intra-operation complications.

**Abd Elzaher et al.** [8] showed that; in all study groups, general complication rate was ten percent [eight/eighty]. Each group had one case with bladder injury. Both cases with bladder injuries had one previous caesarean section and significant bladder adhesions to anterior peritoneum; both bladder injuries were identified and fixed vaginally throughout primary surgery.

This study showed that there was variation between two studied groups as regard Post-operative Hb. There was variation among Hb per and post operation in both groups. There was statistically variation among two studied groups as regard Post-operative HCT. There was statistically variation among HCT per and post operation in both groups.

**Abd Elzaher et al.** [8] showed that the post-operative hemoglobin level in the LigaSure group was greater. The LigaSure group had greater post-operative hematocrit values.

There was no variation among 2 studied groups as regard postoperative complications. A trial by **Hefni et al.** [9] defined diversity of minor complications, which seemed unrelated to operative method. they were diagnosed and repaired intraoperatively with no further complications. Similarly, one case of rectal injury in the control group was reported by **Zubke et al.** [10] though in research carried out by **Purohit et al.** [14] were no cases of rectal injury.

For economic analysis, time of hospital stay was shorter in EBVS group, although difference did not reach statistical significance. In addition, there was significant decrease of operative duration with decreased number of anesthetic drugs. EBVS only require one suture for closing vaginal vault, saving of approximately 6 sutures per case. Also, reduced pain is commonly related to EBVS and can result in decreased use of morphine and other analgesics. Finally, blood loss was significantly lower for EBVS patients. All of these variables lead to decrease of financial burdens on country and medical centers.

Furthermore, **Singh et al.** [15] 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.

**Conclusion:** The use of LigaSure device can decrease operative duration. When compared to traditional suture ligatures, it enables faster, safer and more useful hemostasis while decreasing operative blood loss, pain status and hospital stay.

**Conflict of Interest and Financial Disclosure:** None.

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