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Original article

The Value of Knife Add-on to Vessel Sealing Devices: A Retrospective Comparison of Covidien Ligasure Impact and ERBE Biclamp 200 in Non-descent Vaginal Hysterectomy

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Abstract:

Background: non-descent vaginal hysterectomy (NDVH)is the differentiating procedure of gynecologic surgeons, introducing a new technique is crucial. **Aim:** To contrast perioperative consequences of employing Covidien LigaSure Impact™ with built-in add-on knife (Curved Large Jaw Open Sealer / Divider) and ERBE BiClamp®200C (Curved Sealer) standalone forceps with use of separate scissors for executing NDVH. **Patients and methods:** A retrospective analysis included 164 NDVH executed between January 2015 and April 2023 in Benha University Hospital. The LigaSure Impact™ group included 86 NDVH. The BiClamp® group included 78 NDVH. **Results:** Both groups showed no significant dissimilarity regarding their age, BMI, parity, preoperative mean hemoglobin levels, associated comorbidities, numbers of prior Cesarean section (CS), the indications for hysterectomy, the preoperative HBA1c or the preoperative hospital administration(P>0.05). Also, there was no difference between both groups in operative time, blood loss, removed uterine weight, intra-operative complications, need for blood transfusion, rates of incidental cystotomy, need for additional general anesthesia intraoperatively, shorter postoperative hospital stay, wound complications, less consumption of analgesic and lower amount as well as the need for postoperative venous thromboembolic prophylaxis (VTE), earlier ambulation, earlier return to daily activity, earlier resumption of coital activity, need to reoperate for wound-related complication (P>0.05). **Conclusion:** NDVH could be safely and efficiently achieved either Covidien LigaSure Impact™ or by ERBE BiClamp®200C. The gynecologist should follow the recommendations of gynecologic societies at least for feasible mobile non-scared uteri with uterine size up to 12 weeks needed to be extirpated to be accomplished vaginally.

Keywords: Non-descent vaginal hysterectomy, vaginal hysterectomy, BiClamp®, hysterectomy, LigaSure Impact™.

Introduction

Hysterectomy is the most common major procedure in gynecologic surgery. In the USA, 600,000 hysterectomies are operated yearly, compared with 100,000 in the UK and 75,000 in France [1,2]. Hysterectomy is a unique operation with multiple routes of access and multiple operative techniques. Its routes include the abdominal (TAH), laparoscopic (TLH), robotic (TRH), and vaginal (TVH). The American College of Obstetricians and Gynecologists (ACOG) [3], Society Obstetrics and Gynecology of Canada (SOGC) [4], International Society of Gynecologic Endoscopy (ISGE) [5], Society of gynecologic surgery (SGS) [6] and American Association of Gynecologic Laparoscopists (AAGL) [7] approved Total Vaginal Hysterectomy (TVH) to be the primary choice procedure whenever possible to accomplish Hysterectomy. At the same time, The French National College of Obstetricians and Gynecologists (FNCOG) suggested employing either Total laparoscopic Hysterectomy (TLH) or TVH to achieve Hysterectomy for benign conditions [8].

The 2015 Cochrane meta-analysis deduced that TVH is superior to TLH or total abdominal hysterectomy (TAH) because of lower postoperative pain, quicker recovery, and shorter hospital stay [9]. Despite these deductions, the rate of TVH remains low: less than 20% in the USA, 10% to 30% in the UK, 8% in Belgium, and 3%Norway [10,11] and rates have decreased in the Netherlands, from 36% to 25%, between 2007 and 2012 [12]. The mentioned claims for choosing TAH, TLH, or total robotic hysterectomy (TRH)over TVH by the gynecologic surgeon (GS) include insufficient training for both residents and surgeons already in practice, nulliparity, morbid obesity, prior pelvic surgery, extensive extrauterine pathologies, large-sized uteri and incentives of GS executing the Hysterectomy which is more for non-vaginal Hysterectomy as well as industrial pressures encouraging shifting toward TLH and TRH [10,13].In Egypt, TVH is reserved only for small sized, non-scared, prolapsed uteri by those who alleged themselves to be skilled gynecologists, even though most of such uteri are operated upon either abdominally by poorly skilled gynecologic practitioners, while those who claim themselves as key opinion leaders (KOL) of gynecologic surgery executed such cases laparoscopically with applying different Colpo-suspension techniques. The conditions necessitating Hysterectomy other than prolapse are usually operated abdominally and occasionally laparoscopically by GS, general surgeon, or even urologist and rarely, if ever, vaginally.

To render TVH a safer and easy-to-execute operation, industries have recently introduced a faster, easier, convenient, and more efficient hemostatic method rather than conventional knot tying for vessel ligation. The potential advantages of using electrosurgical bipolar vessel sealing (EBVS) for vaginal hysterectomies have been demonstrated in randomized controlled trials (RCTS) [14-21], large retrospective cohorts [22-24], and systematic reviews & meta-analysis [25-27]. Bipolar vessel sealing system (BVSS) *Covidien LigaSure Impact*™ (Curved Large Jaw Open Sealer / Divider) (Autosuture, Valleylab, Boulder, CO, USA) is a hemostatic system based on the simultaneous delivery of pressure and

bipolar electrical energy that seals vessels up 2–7 mm in diameter by denaturing collagen and elastin within the vessel wall and in the surrounding connective tissue with built-in add on a knife, so sealing and pedicles division could be done with single system application [(28)]. Electrosurgical bipolar vessel sealing (EBVS) *ERBE BiClamp®200C*(Erbe, T€ubingen, Germany)) is a thermo-fusion clamp in which the delivery of pressure is manual by GS at that time bipolar electrical energy seals the clamped vessels up 2–7 mm in diameter by denaturing collagen and elastin within the vessel wall and in the surrounding connective tissue, the *ERBE BiClamp®200C* is a standalone sealing clamp without built-in add on a knife, the GS should utilize a separate scissor to divide the sealed pedicle [(22,23)]. To the date of writing this manuscript, there are no prospective or retrospective published studies comparing these two devices in TVH or in Non-Descent Vaginal Hysterectomy (NDVH).

The present retrospective analysis aimed to compare EBVS without add on the knife the *ERBE BiClamp®200C* forceps as just only sealer against BVSS with adding on the knife the *Covidien LigaSure Impact*™ as a combined sealer divider in patients who underwent TVH for non-prolapse indications, namely NDVH. We also aimed to describe the technical "tips and tricks" gained from practicing NDVH with these newly introduced surgical devices.

Patients and Methods:

This is a retrospective observational cohort study in which, the available medical records either paper or electronic of women who underwent electrosurgical bipolar energy-based vessel sealing NDVH between January 2015 and April 2023 at the obstetrics and gynecology department of Benha university hospital, Benha, Egypt as well as private centers. We scrutinized the records to extract and arrange the relevant data. We obtained ethical approval from the Benha Faculty of Medicine ethical committee (NO: RC.9.7.2023). Written consent from participants was deemed unneeded, as this is our institutional review board (IRB) policy concerning retrospective studies.

Women were involved if meet all the following criteria : (1) BMI ≥ 18.5 kg/m^2,(2) the achieving of hysterectomy through the vaginal route, (3) the achieving of hysterectomy by either EBVS *ERBE BiClamp®200C* forceps or BVSS *Covidien LigaSure Impact*™, (4) execution of general or spinal anesthesia to underwent NDVH (5) age ≥18 years old; (6) clinical follow-up until completely cured or at least 30 days postoperatively (7) non-prolapse uteri which isn't more than the first-degree uterine descent even under anesthesia (8) benign uterine diseases.

Women were omitted if they had any of the following criteria :(1) women with suspected malignancy, (2) women found to be second-degree uterine decent or more after achieving the anesthesia, (3) women in whom other surgical intervention other than hysterectomy was performed, (4) cases with incomplete medical records or who failed to be followed for 30 days postoperatively. All NDVH cases were executed by senior gynecologic surgeons highly interested in vaginal route for Hysterectomy where they were challenging nearly all alleged claimed contraindications for TVH and NDVH.

The extracted preoperative parameters included age, height, weight, BMI, parity, indications for hysterectomy, comorbid

conditions such as diabetes mellitus, hypertensive disorders, liver diseases, renal disorders, orthopedics problems, and airway obstructive disorders, previous abdominal or vaginal surgery, hemoglobin concentration (CBC), length of preoperative hospital administration to control the comorbid status as uncontrolled diabetes mellitus (LOPA), percentage of glycated hemoglobin A1C (PHBA1C) and American Society of Anesthesiologists (ASA) physical status classification as ASA 1 (regular healthy patient), ASA 2 (patient with mild systemic disease), ASA 3(patient with severe systemic disease), ASA 4 (patient with severe systemic disease that is a constant threat to life).

The extracted intra-operative parameters were type of surgical procedures either EBVS *ERBE BiClamp®200C* forceps with scissors or the integrated system BVSS *Covidien LigaSure Impact*™, as well as additional procedures as bilateral salpingo-oophorectomy(BSO), bilateral salpingectomy(BS), the utilized morcellation techniques including cervical amputation, uterine bisection, wedge resection, uterine coring, myomectomies, vaginal wound closure techniques either transverse or anteroposterior (vertical), operative time (from time of colpotomy to surgery termination), type of anesthesia either general or spinal(in this study if anesthesia executed spinally but during procedure due to lack of exposure or failed spinal and women needed general anesthesia , she were classified as general anesthesia) , estimated blood loss (EBL)(based on gauze weight ,visual blood volume estimation), Intra-operative complications included significant blood vessel or organ injury (including bowel, bladder and ureter) and need for blood transfusion. The extirpated uteri were weighed immediately once completely removed and classified into Small (≤100 g), Standard (101–300 g), Large (301–600 g), and very large (>600 g) following the classification of Henri Clave' [(22)].

The extracted postoperative parameters were hemoglobin concentration(CBC), return to operative room (OR), length of postoperative hospital stay (LOS), hospital readmission within 30 days, pelvic or vault hematoma, vault cellulitis, vault dehiscence, vault abscess, abdominal wound status in women who converted to TAH including cellulitis, seroma collection, wound dehiscence, length of wound care, need to reoperate on wound sequels, pelvic Infection, urinary tract infection, thromboembolic disease as well as other medical status deterioration. The extracted parameters of all participating women in this study were unnamed and summarized.

The main extracted issues were: 1) Operative time(OT),2) Operative blood loss (EBL), 3) Decline in hemoglobin(HB) value (the difference between preoperative and postoperative HB)(Δ HB),4) Operative consequences as blood transfusion, conversion to TAH and the cause of conversion, bowel or visceral injuries, incidental cystotomy 5) Early postoperative follow up including (a) Postoperative pain classified as either no pain, mild pain, moderate pain, severe pain and very severe pain, (b) Need for analgesia, (c)length hospital stay(LOS) (d) Febrile morbidity (body temperatures > 38C° in two consecutive measurements > 4 hour apart), (f) Time to get out of bed activity (hours),(e) Time to pass stool or gas from end of the procedures. 7) Remote postoperative follow-up includes time to resume the prior daily life activities and time of sexual life resumption in sexually

active women and postoperative vaginal length.

We executed statistical analysis by Medcalc easy-to-use statistical software for Windows desktop (www. medcalc.org) 2016 (Medcalc, software, bvba). We presented continuous variables as mean ± 2 standard deviations and range. At the same time, we used independent samples (unpaired) student's t-test to compare continuous variables between the two groups. We presented categorical variables as numbers and percentages, while we assisted it using either Fisher's exact test or Pearson's Chi-square test as analysis methods to identify differences between the EBVS ERBE BiClamp®200C forceps with scissors (BiClamp®) or the integrated system BVSS Covidien LigaSure Impact™ (LigaSure Impact™) groups. We considered a two-sided p <0.05 as statistical significance.

Results:

One hundred sixty-four women with non-prolapsed uteri who required hysterectomy were involved in this retrospective observational analysis, 86 women underwent NDVH by BVSS with add-on knife the Covidien LigaSure Impact™ (*LigaSure Impact*™ group), while 78 women underwent NDVH by EBVS without add on knife the ERBE BiClamp®200C forceps (*BiClamp*® group) in between January 2015 and April 2023 in Benha university hospitals and private centers.

The clinical and demographic criteria of participators subjected to NDVH achieved by either *LigaSure Impact*™ or *BiClamp*® were exhibited in Table (1). Participators in both *LigaSure Impact*™ and *BiClamp*® groups were similar. They showed no significant differences with respect to age, BMI, parity, Clinical uterine size (weeks), Ultrasound uterine volume Cm^3, absent of prior vaginal birth, preoperative hemoglobin (gm/dl), the associated preoperative medical comorbidities, the indication for hysterectomy as well as participators percentage with uncontrolled diabetes mellitus (DM), the Length of Preoperative Administration (LOPA) to control the medical comorbidities, the preoperative Glycated Hemoglobin A 1C (PHBA1C) and participators percentage of American Society of Anesthesiologists (ASA) physical status classes (p>0.05).

Table (1): Demographic and clinical characteristics of women who underwent NDVH by either BiClamp® or LigaSure Impact™.

Variable	*BiClamp*® (n=78)	*LigaSure Impact*™ (n= 86)	Δ(95% CI)	P value
- Age (year) (mean ±SD) (range)	44.6 ±6.3 (38– 65)	45.7 ± 5.8 (401– 63)	1(-0.76 to 2.9)	**0.2**
- Parity (mean ±SD) (range)	2.4± 1.5 (0 - 7)	2.5± 1.6(0 – 6)	0.1(-0.37 to 0.57)	**0.6**
- BMI (kg/m2)(mean ±SD) (range)	30.6 ± 5.6 (20.5 – 40.5)	31.3 ± 6.8 (21.5 – 42.6)	0.7(-1.2 to 2.6)	**0.4**
- Clinical uterine size (weeks) (mean ±SD) (range)	11.3 ± 4.1 (6 – 24)	11.6 ± 3.8 (6 – 24)	0.3(-0.91 to 1.51)	**0.6**
- Ultrasound uterine volume Cm^3 (mean ±SD) (range)	150 ± 76 (65 – 1100)	165 ± 77 (70 – 1200)	15(-8.62 to 38.62)	**0.2**
- Nulliparity	16(20%)	15(17%)	3% (-8.87% to 15.07%)	**0.6**
-Absent of previous vaginal birth	30(38%)	34(39%)	1% (-13.68% to 15.52%)	**0.8**
-preoperative HB (g/dl) (mean ±SD) (range)	10.1±1.1(9.5-13.5)	10.7±.9(9.8-12.9)	0.6(-1.42 to 2.62)	**0.5**
- Previous pelvic surgery:				
- Cesarean section	35 (44%)	40(46%)	2% (-12.98% to 16.81%)	**0.7**
- other	7(8%)	8(9%)	1% (-8.28% to 9.98%)	**0.8**
-virgin lower abdomen	36(46%)	38(44%)	2% (-12.94% to 1686%)	**0.7**
- Comorbidity:				
- HTN	42(53%)	39(45%)	8% (-7.17% to 22.67%)	**0.3**
- DM	19(24%)	17(19%)	5% (-7.52% to 17.60%)	**0.4**
- uncontrolled DM	16(20%)	14(16%)	4% (-7.76% to 15,96%)	**0.5**
-PHBA1C (%)	8.3±3.5(5.1%-17.4%)	7.3±4.6(4.9%-18.8%)	-1(-2.27 to 0.27)	**0.1**
-LOPA (days)	2.9± 1.3(2-10)	3.5± 1.2(2-11)	0.6(0.21 to 0.98)	**0.002**
-ASA score :				
- ASA 1	56(71%)	54(62%)	9% (-5.45% to 22.80%)	**0.2**
-ASA 2	13(16%)	17(19%)	3% (-8.89% to 14.55%)	**0.6**
-ASA 3	8(10%)	14(16%)	6% (-4.67% to 16.39%)	**0.2**
-ASA 4	1(1.2%)	1(1.1%)	0.1% (-5.09% to 5.75%)	**0.9**
- Indication for hysterectomy:				
- PMB	63(80%)	67(77%)	3% (-9.72% to 15.36%)	**0.6**
- EH	23(29%)	27(31%)	2% (-11.9% to 15.6%)	**0.7**
-CIN	10(12%)	13(12%)	3% (-7.87% to 13.56%)	**0.5**
- Adenomyosis	26(33%)	30(38%)	5% (-9.57% to 19.15%)	**0.5**
- Fibroid	32(41%)	29(33%)	8% (-6.65% to 22.29%)	**0.2**

Abbreviations: NDVH: Non-Descent Vaginal Hysterectomy, BiClamp®: the EBVS ERBE BiClamp®200C forceps, LigaSure Impact™: the integrated system BVSS Covidien LigaSure Impact™, BVSS: Bipolar vessel sealing system, EBVS: electrosurgical bipolar vessel sealing, BMI: Body Mass Index, HTN: Hypertension, DM: Diabetes Mellitus, PMB: Perimenopausal Bleeding, EH: Endometrial Hyperplasia, CIN: Cervical Intraepithelial Neoplasia. PHBA1C: Preoperative Glycated Hemoglobin A 1C, LOPA: Length of Preoperative Administration, ASA: American Society of Anesthesiologists

- Values were given as mean ± standard deviation (range) or number (percent).

P<0.05: Statistically significances

The intraoperative criteria of participators subjected to NDVH achieved by either *LigaSure Impact*™ or *BiClamp*® were exhibited in Table (2). There were no statistically Significant differences between groups regarding total operative time (min), operative blood loss (ml), Intraoperative complications, including visceral injuries, blood transfusion, and postoperative uterine weight (gram). There were 3 cases of conversion to laparotomy in both groups; all were due to trailing

considerable uterine size with a single intracavitary myoma. All participators subjected to NDVH achieved by either *LigaSure Impact*™ or *BiClamp*® morcellations techniques were almost always employed. Also, there were no statistically Significant differences between group participators subjected to bilateral salpingectomy (BS) and bilateral salpingo-oophorectomy (BSO) (p>o. o5); this could be attributed to operator gynecologists' attitude toward such issues. Regarding vesical injuries, there were no differences in rates between both groups; there were 3/164(1.8%), all were repaired by the primary operator, and all women who had an incidental cystotomy and primary repair showed sound postoperative consequences regarding these complications.

Table (2): Comparison of intra-operative outcome measures of women who underwent NDVH by either BiClamp® or LigaSure Impact™.

Outcome	*BiClamp*® (n =78)	*LigaSure Impact*™ (n =86)	Δ(95% CI)	P value
Total operative time (min) (mean ±SD) (range)	90±20 (30– 210)	85±25 (40-220)	-5(-12.02 .to. 2.02)	**0.16**
Operative blood loss (ml) (mean ±SD) (range)	475 ± 140(100-1150)	525 ± 120(150 -1250)	50(9.89 .to. 90.10)	**0.01**
General anesthesia	15(19%)	21(25%)	6% (-5.93% to 19.42%)	**0.28**
Spinal anesthesia	63(80%)	65(75%)	5% (-7.92% to 17.49%)	**0.44**
Morcellations techniques	78(100%)	86(100%)	0% (-4.27% to 4.69%)	**1**
Intraoperative complications*				
- visceral injuries	2 (vesical) (2.5%)	(vesical) (1.1%)	1.1% (-4.0 % to 7.7%)	**0.4**
- blood transfusion	5(6.4%)	6(6.9%)	0.5% (-8.07% to 8.74%)	**0.89**
-Conversion to laparotomy	2(2.5%)	1(1.1%)	1.4% (-4.01% to 7.74%)	**0.49**
Concomitant procedures				
-BS	42(53%)	48(55%)	2% (-12.97 %to	**0.79**
- BSO	36(46%)	38 (44%)	16.88%)	**0.79**
- others	2(2.5%)	5(5.8%)	2% (-12.94% to 16.86%) 3.3% (-3.79 %to 10.61%)	**0.29**
-P. O uterine weight(g) (mean ±SD) (range)	210 ± 75 (60 – 1150)	220 ± 85 (65 – 1250)	10(-14.82 to 34.82)	**0.42**
-Uterus weight (category)				
-Small (≤100 g)	12(15%)	10(11%)	4% (-6.43% to 14.78%)	**0.44**
-Standard (101–300 g)	44(56%)	54(62%)	6% (-8.87% to 20.58%)	**0.43**
-Large (301–600 g)	16(20%)	14(16%)	4% (-7.76% to 15.96%)	**0.50**
-Very large (>600 g)	6(7.6%)	8(9.3%)	1.7% (-7.54% to 10.67%)	**0.69**

Abbreviations: NDVH: Non-Descent Vaginal Hysterectomy, BiClamp®: the EBVS ERBE BiClamp®200C forceps, LigaSure Impact™: the integrated system BVSS Covidien LigaSure Impact™, BVSS: Bipolar vessel sealing system, EBVS: electrosurgical bipolar vessel sealing, Δ(95% CI): Point estimate difference with 95% confidence interval, BS: Bilateral salpingectomy, BSO: Bilateral Salpingo-Oophorectomy, P.O: postoperative.- Values were given as mean ± standard deviation(range) or number (percent). P<0.05: Statistically significances

Table (3) displayed the early and late postoperative consequences in this retrospective review. Participators subjected to NDVH achieved by either *LigaSure Impact*™ or *BiClamp*® showed no statistically Significant differences between groups in relation to the percentage of severe pain status at six h

and 24 h postoperative and lower consumption of analgesia both narcotic and non-steroidal anti-inflammatory drugs (NSAID) (P >0.05) as well as regards the decline in 24-hour hemoglobin, the Febrile morbidity, pelvic cellulitis, cystitis (p>0.05). There were also no differences regards the time to get out of bed, time to pass flatus, length of postoperative hospital stay (LOS), return to usual activity time (day), wound complications, reoperation for wound, need for venous thromboembolism (VTE) prophylaxis (days) and duration of VTE prophylaxis(days), time to resume coital activity and postoperative vaginal length(cm)(p>0.05), all these items supporting superiority of TVH. It was noticed that vaginal spotting was significantly lower in this study despite this being deemed clinically insignificant in the postoperative course.

Table (3): Comparison of early and late postoperative outcome measures between women who underwent NDVH by either BiClamp® or LigaSure Impact™.

Outcome	*BiClamp*® (n= 78)	*LigaSure Impact*™ (n= 86)	Δ(95% CI)	P value
Postoperative pain				
- severe at 6h	24(30%)	25(29%)	1% (-12.7% to 14.8%)	**0.8**
- severe at 24 h	6(7.6%)	8(9.3%)	1.7% (-7.5% to 10.6%)	**0.6**
Analgesic requirements over 24h (mean ±SD) (range)				
-Total narcotic (mg)	17.8 ± 7.2(10-40)	18.2 ± 9.8(10-50)	0.4(-2.27 to 3.07)	**0.7**
-Total parental NSAID (mg)	140.5 ± 45.5(100-300)	130.5 ± 40.6(100-350)	-10(-23.27 to 3.27)	**0.1**
Time to get out of bed (h) (mean ±SD) (range)	4.9 ± 1.2(2-12)	5.3 ± 1.6(2-14)	0.4(-0.03 to 0.83)	**0.07**
Time to flatus(h) (mean ±SD) (range)	6.8 ± 2.2(3-24)	7.1 ± 1.8(10-50)	0.3(-0.31 to 0.91)	**0.3**
decline in hemoglobin at (24h) (mean ±SD) (range)	1.1 ± 0.6(0.5-1.7)	1.1± 0.3(0.7-1.9)	0(-0.14 to 0.14)	**1**
LOS (days) (mean ±SD) (range)	1.1 ±0.5(0.5-10)	1.2± 8.9(0.5-8)	0.1(-1.89 to 2.09)	**0.9**
Return to usual activity time (day) (mean ±SD) (range)	9.6 ± 4.6(3-15)	8.9 ± 5.9(4-16)	-0.7(-2.34 to 0.94)	**0.4**
Resumption of coitus(days) (mean ±SD) (range)	14.6 ±6.4(4-50)	15.5±5.8(5-60)	0.9(-0.98 to 2.78)	**0.3**
Febrile morbidity	6 (7.6%)	9 (10.4%)	2.8% (-6.6% to 11.9%)	**0.5**
Vaginal spotting	5 (6.4%)	7(8.1%)	1.7% (-7.0% to 10.2%)	**0.6**
Pelvic cellulitis	4 (5.1%)	4(4.6%)	0.5% (-6.8% to 8.3%)	**0.8**
Cystitis	8 (10%)	10(11.6%)	1.6% (-8.4% to 11.3%)	**0.7**
Wound complications	1(1.2%)	1(1.1%)	0.1% (-5.0% to 5.7%)	**0.9**
Reoperation for wound	1(1.2%)	1(1.1%)	0.1% (-5.0% to 5.7%)	**0.9**
Need for VTE prophylaxis(days)	5(6.4%)	6(6.9%)	0.5% (-8.0% to 8.7%)	**0.8**
Duration of VTE prophylaxis(days) (mean ±SD) (range)	0.9±0.4 (0.5-3)	0.8±0.5 (0.5-5)	-0.1(-0.2 to 0.04)	**0.1**
postoperative vaginal length(cm) (mean ±SD) (range)	7.5±1.5(5-10)	7.3±1.8(5-10)	-0.2(-0.71 to 0.31)	**0.4**

Abbreviations: NDVH: Non-descent vaginal hysterectomy, BiClamp®: the EBVS ERBE BiClamp®200C forceps, LigaSure Impact™: the integrated system BVSS Covidien LigaSure Impact™, BVSS: Bipolar vessel sealing system, EBVS: electrosurgical bipolar vessel sealing, Δ(95% CI): Point estimate difference with 95% confidence interval, NSAID: Non-steroidal anti-inflammatory drugs, VTE: venous thromboembolism, LOS: length of postoperative stay in hospital Values were given as mean ± standard deviation or number percent. P<0.05: Statistical significance.

Discussion:

Hysterectomy is the most executed gynecological procedure worldwide. It is a unique operation with multiple routes of access and multiple operative techniques. As the interest has shifted towards minimally invasive techniques as well as the most value-based procedures, total vaginal hysterectomy (TVH) should be ranked first because TVH represents an original natural orifice surgery and the highest value-based Hysterectomy when compared with intermediate invasive and intermediate value-based conventional TLH, and to maximally invasive TAH as well as least value-based TRH [(29)]. TVH offers the least invasive approach to hysterectomy, with the lowest associated risks and costs. Despite these documented benefits, TVH execution rates have shown a decline in the last two decades worldwide. The real underutilization of TVH is likely due to the decline of vaginal surgical skills among gynecologic surgeons due to a more recent focus on laparoscopic and robotic proficiency. Despite TVH not being risk-free and not the best route for all conditions, it should be given first-line preference when planning to achieve hysterectomy for a benign indication, favoring the gynecologist's determining route as recommended by pioneers of gynecologic surgery [(32-34)].

TVH has evolved dramatically in the last two decades by introducing electrosurgical energy-based bipolar vessel sealing devices with or without built-in add-on knives to divide the sealed vessels. Technical "tips and tricks" to safely and efficiently achieving electrosurgical bipolar vessel sealing (EBVS) includes avoiding traction upon non-descent uteri at the time of EBVS to allow perfect effective tissue thermo-fusion and consequently stable vessel sealing, Cervix amputation transformed a pear-shaped uterus into an apple-shaped uterus and thus facilitate the vaginal approach and rotation of the uterine body, so the pedicle to operate upon it came to the center of surgical field, applying either BiClamp® or LigaSure Impact™ once or more before cutting along the edge of the uterus. Differences between BiClamp® and LigaSure Impact™ include that the LigaSure Impact™ is disposable while BiClamp® is reusable, the jaws of LigaSure Impact™ are more prominent than those of BiClamp®, the add-on knife in LigaSure Impact™ making it a complete sealer/divider system through compression as well as tissues thermos-fusion. While operating with BiClamp®, the GS needs to compress a conventional-style clamp with curved Jaws at the time of electrosurgical unit activation and then divide the sealed tissue with scissors (Figure 1a, b, c, d).

This study confirms that NDVH could be safely and efficiently accomplished with EBVS devices as the incidental cystotomy is like that reported in the FINHYST study (3 out of 164 (1.8%) in our study vs. 0.64% in FINHYST vs. 1.1% (11/998) in French study $p > 0.05$) [(22,31)]. In addition, the incidental cystotomy that occurred was not related to EBVS device employment; all were identified and repaired intraoperatively, with no consequences, while the French large retrospective cohort involved 1000 TVH reported one vesicovaginal fistula [(22)]. Our results agree with the prior published studies of (30-34), and the 2015 Cochrane review [(9)] regarding both the percentage of and risk factors for urinary consequences, which

are a surgical sense and a clinical observation rather than an evidence-based medicine because of its low prevalence that makes challenging to establish an inference. In this study, three cases were converted to TAH due to very large intracavitary myoma, resulting in an inability to achieve anterior colpotomy. At the same time, we did not have bleeding consequences that needed reoperations like that reported in the French study [22]. As we do not consider the presence of a uterus of significant or substantial volume to be a contraindication for TVH, like pioneer gynecologic surgeon [32-34] so women with large and extra-large uterine size were trialed vaginally firstly, and conversational rates like that reported in literatures. The evaluation of costs differences between the utilizations of these two devices seems to be a neglected item in our retrospective analysis, however the main differences between the two devices is the permanent utilizations of *BiClamp*® after easy cheap autoclavable sterilization, but also multiple usage of *LigaSure Impact*™ is now available but the sterilization technique is somewhat costly and eventually the disposable hand will sooner damaged, however nowadays a commercial permanent usable hands like *LigaSure Impact*™ were available by different medical suppliers.

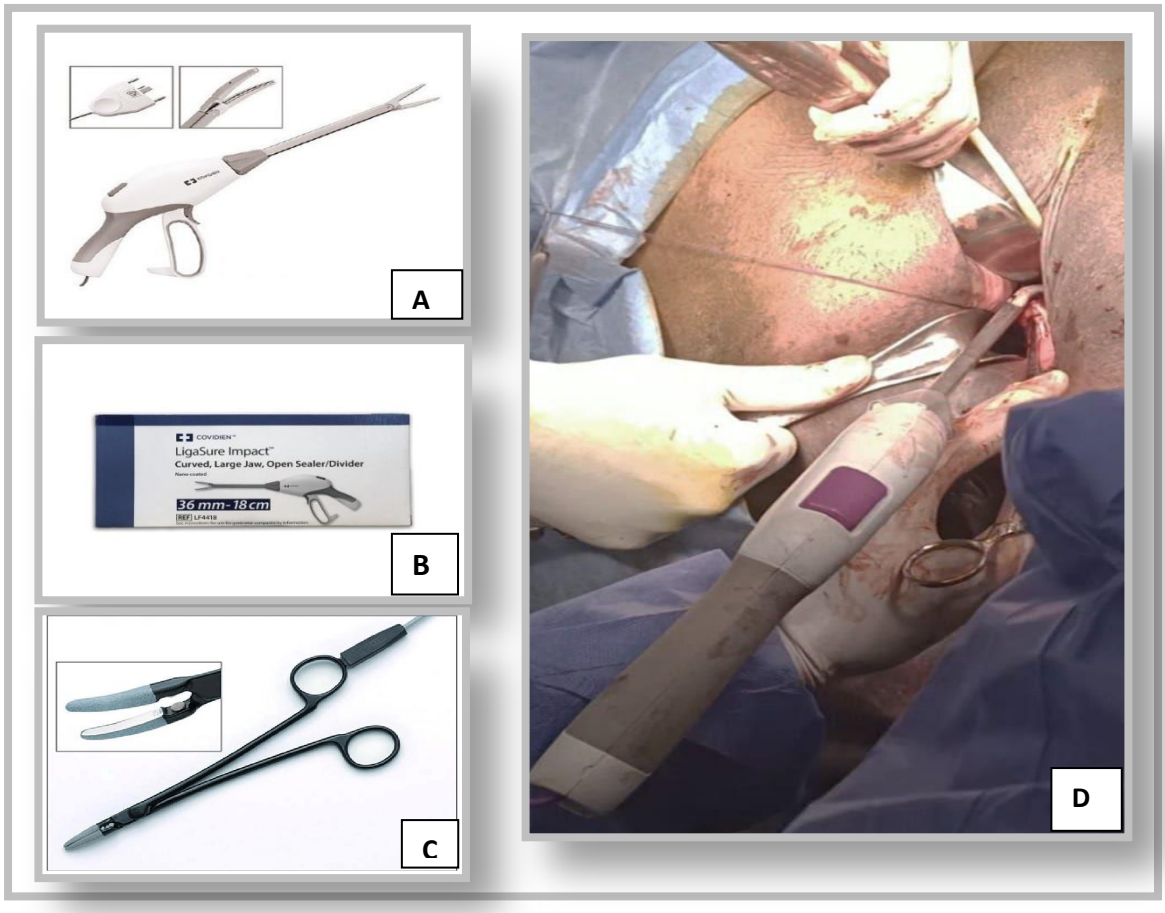

Figure 1: a) open LigaSure Impact™; the integrated system bipolar vessel sealing system, Covidien, b) in packaging LigaSure Impact™; the integrated system bipolar vessel sealing system, Covidien, c) the BiClamp® 200; the electrosurgical bipolar vessel sealing ERBE BiClamp®200C forceps, d) the LigaSure Impact™ on action at time of NDVH).

Our study Strengths includes its retrospective nature as being low cost and appraising actual work situations, including a relatively bigger sample size to get inferences as well as considering comparing the consequences of NDVH achieved by either *LigaSure Impact*™ or *BiClamp*® in women undergoing benign hysterectomy as well as being the first comparison exist in literatures till date between these two devises, also in this retrospective we challenged alleged contraindications to NDVH as nulliparity, morbid obesity, lack of uterine mobility, large and extra-large uterine size and we found that NDVH could be performed safely and effectively.

The weaknesses of this analysis were being retrospective, exposing it to selection biases, reporting biases, confounders such as the surgical experience of the gynecologists, as well as inability to generalize the outcomes as the skills of NDVH were limited and underutilized as all over the word. The low complication rate makes the utilization of complex logistic regression models difficult, so the analysis of risk factors more challenging.

Conclusions:

The principal deduction of this study is that non-descent vaginal hysterectomy (NDVH) achieved by either LigaSure Impact™ or BiClamp®200 in women undergoing benign hysterectomy is safe and is not associated with greater incidental cystotomy as well as other surgical consequences than reported in the literature. It is preferred to achieve NDVH by employing electrosurgical energy-based bipolar vessel sealing devices as well as gynecologic surgeons should consider themselves vaginalists rather than viewing themselves as laparotomists like general surgeons or laparoscopists and they should execute their benign hysterectomy though their unique naturally occurring vaginal opening.

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