Comparison of the Electrosurgical Bipolar Vessel Sealing with the Standard Suture Technique in Patients with Diverse Benign Indications for Abdominal Hysterectomy: A Controlled Trial

Abdominal Histerektomi İçin Çeşitli Benign Endikasyonları Olan Hastalarda Standart Sütür Tekniği ile Elektrocerrahi Bipolar Damar Mühürlemenin Karşılaştırılması: Kontrollü Bir Çalışma

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ABSTRACT Objective: To compare the safety and efficacy of the bipolar plasmakinetic vessel sealing versus standard technique while performing total abdominal hysterectomy for benign disease. **Material and Methods:** The study is a prospective, controlled trial involving 173 women who underwent total abdominal hysterectomy. Eighty procedures were performed using bipolar plasmakinetics vessel sealing and the remaining 93 with the standard suture technique. Both groups were compared in terms of their operative time, blood loss, postoperative pain scores, postoperative complications and the length of hospital stay. At the end of the operations, patients were given intravenous tramadol hydrochloride 1-1.5 mg/kg, and intramuscular 75 mg IM, 2x1 diclofenac sodium for postoperative analgesia. Pain scores of the patients were recorded postoperatively at 0 and 24 h. A visual analogue scale (VAS) in the range of 0-10 was utilized for scoring the patients. The statistical analysis was performed with SPSS 16.0 (Statistical Package for Social Sciences) for Windows. $p<0.05$ was considered statistically significant. **Results:** There were no statistically significant differences between two groups in terms of preoperative and postoperative hemoglobin values, postoperative complications or hospital stay. There were statistically significant differences between groups in terms of reduction (%) in hemoglobin levels, operation time and VAS scores at 0 and 24 h. The median reduction (%) in hemoglobin levels in the study group was -0.08% (min: -0.27-max: 0.10) compared to -0.08% (min: -0.29-max: 0.00) in the control group (p=0.033). The median operation time with LigaSure was 105 min (range70-175) compared to 130 min (range 60-230) with standard suture technique (p=0.001). In the study and control groups, the VAS scores at 0 h were 5 (min: 1- max: 8) and 8 (min: 7- max: 9) respectively (p=0.020), while at 24h they were 3 (min: 1- max: 3) and 4 (min: 3- max: 7), respectively (p=0.011). **Conclusion:** LigaSure is an effective and reliable device that provides a significant reduction in quantity of bleeding, reduction in operation time (approximately 15 min) and postoperative VAS scores.

Key Words: Electrocoagulation; hysterectomy; genital diseases, female

ÖZET Amaç: Benign hastalıklar nedeniyle total abdominal histerektomi yaparken, standart tekniğe karşı bipolar plazmakinetik vasküler sealing'in etkinlik ve güvenliğini kıyaslamak. **Gereç ve Yöntemler:** Total abdominal histerektomi yapılan 173 kadını kapsayan prospektif kontrollü çalışma. Seksen işlem bipolar plazmakinetik vasküler sealing ile, kalan 93'ü standart sütür tekniği ile yapıldı. Her iki grup; operasyon süresi, kan kaybı, postoperatif ağrı skorları, postoperatif komplikasyonlar ve hastanede kalış süresi bakımından kıyaslandı. Operasyon sonunda, hastalara tramadol hidroklorid 1-1,5 mg/kg intravenöz uygulandı. Postoperatif analjezik olarak da, intramüsküler 75 mg, diklofenak sodyum 2x1 kullanıldı. Hastaların ağrı skorları, postoperatif dönemde 0. ve 24. saatte kayıt edildi. Hastaların skorlama sisteminde Vizüel Analog Skala (VAS), 0-10 arası değerlerde kullanıldı. İstatistiksel analiz SPSS 16.0 (Statistical Package for Social Sciences) for Windows ile yapıldı. $p<0.05$ değeri, istatistiksel anlamlı kabul edildi. **Bulgular:** Preoperatif ve postoperatif hemoglobin düzeyleri, hemoglobinde azalma, postoperatif komplikasyonlar ve hastanede kalış süresi açısından gruplar arasında istatistiksel anlamlı fark yoktu. Operasyon süresi ve 0. ve 24. saatteki VAS skorları açısından ise, iki grup arasındaki fark istatistiksel anlamlı idi. Hemoglobin düzeylerindeki median azalma, kontrol grubunda %-0,08'e (min: -0,29)- maks: 0,00) kıyasla, çalışma grubunda %-0,08 (min: -0,27)-maks: 0,10) idi (p=0,033). Standart sütür tekniği kullanılan grupta median operasyon süresi 130 dakika (60-230) iken, LigaSure grubunda, 105 dakika (70-175) idi (p=0,001). Çalışma ve kontrol grubunda VAS skoru, 0. saatte, sırasıyla 5 (min: 1- max: 8) ve 8 (min: 7-max: 9) (p=0,020), 24. saatte sırasıyla 3 (min: 1 - max: 3) ve 4 (min:3- max: 7) (p=0,011) idi. **Sonuç:** LigaSure, kanama miktarında, operasyon süresinde (yaklaşık olarak 15 dakika) ve postoperatif VAS skorlarında anlamlı bir azalma sağlayan etkili ve güvenilir bir araçtır.

Anahtar Kelimeler: Elektrokoagülasyon; histerektomi; genital hastalıklar, kadın

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The electrothermal bipolar vessel sealing system (EBVS, LigaSure, Covidien Energy-based Devices, Boulder, Colo) has been shown to achieve hemostasis in small, medium, and large arteries in several animal studies.[1-3] LigaSure, a controlled high-power current at low voltage, melts the collagen and elastin in tissue, leads to permanent fusion of the vascular layers and obliterates the lumen. The device fuses vessels up to 2-7 mm in diameter.[4]

The application of LigaSure as an alternative for conventional suture technique for hemostasis during surgery first began in nongynecologic procedures including hemorrhoidectomies, prostatectomies and hepatectomies.[5-8] It then used in gynecologic surgery, in hysterectomies including robotic radical parametrectomies.[9-19] Studies comparing abdominal or vaginal hysterectomies with LigaSure and conventional methods have indicated that there are differing results in the operative time, blood loss, postoperative pain scores, complications and length of hospital stay associated with these procedures.

The objective of this study was to compare outcomes of LigaSure versus conventional suturing methods during abdominal hysterectomy in patients with different benign gynecologic pathologies. In particular, we evaluated the impact of LigaSure on operative time, blood loss, length of hospital stay, complications, and postoperative pain scores in comparison to conventional clamping methods with suture ligation.

MATERIAL AND METHODS

STUDY DESIGN

This prospective, controlled study was conducted between December 2010 and November 2012. The local ethical committee approval and patient consents have been obtained. The cases with uterine myomas more than 14 weeks in size, uterine, cervical, ovarian malignancies and contraindications for general anesthesia were excluded from the study. Two experienced consultant gynecologists performed the operations. The patients participating in the study were divided into two groups: group A, in which the LigaSure (Valleylab, Boulder, Colo., USA) method was applied, included 80 patients; and group B, in which conventional sutures were used, included 93 patients. Randomization was performed using a list of computer-generated random numbers. The LigaSure instrument was used in a resterilized manner (6 times each).

All patients included in the study underwent extrafascial total abdominal hysterectomy (type 1) under general anesthesia. In each case, patients were given a perioperative prophylactic, intravenous (IV) first-generation cephalosporin antibiotic (cefazolin sodium 1 g). The clamping and cutting of the tissues were followed by tying with polyglactin suture materials in conventional abdominal hysterectomies, while in the LigaSure method, the clamping was followed by sealing and cutting.

At the end of the operation, patients were given tramadol hydrochloride 1-1.5 mg /kg IV, and 75 mg intramuscular diclofenac sodium 2x1 for postoperative analgesia. Pain scores of the patients were recorded postoperatively at 0 and 24 h. When the patient's responsiveness of time, place, person and event was normal, she was questioned in terms of VAS scoring and this score was taken as VAS score at 0 hour. A visual analogue scale (VAS) in the range of 0-10 was utilized in the scoring system of the patients (0=absence of pain; 10=worst possible pain). The qualification of the VAS score was carried out by emergency medicine physician who did not take the role in the diagnosis and operation of the patients. Both groups were compared in terms of their operative time, blood loss, postoperative pain scores (VAS scores), postoperative complications and length of hospital stay. The operation period was reported as the time elapsing from anesthesia induction to wakening, bleeding amount was defined as a reduction between preoperative and postoperative hemoglobin levels.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS 16.0 (Statistical Package for Social Sciences) for Windows. Continuous data homogeneity was evaluated by histogram, stem and leaf and box plots. The data

was normally distributed. Categorical variables were described using frequency distribution and compared with Pearson Chi-square and Fisher Freeman Halton tests. As a result of Kolmogorov-Smirnov test, to compare continuous variables between groups, Independent Sample T-test was used for normally distributed variables and Mann-Whitney U test was used for normal undistorted variables. Preoperative and postoperative changes were analyzed with Paired sample t test in the normally distributed data, with Wilcoxon Signed Ranks test in normally undistorted data. In case of application of non-parametric tests, descriptive statistics were calculated and reported as median (min-max). $P<0.05$ was accepted as the level of significance.

RESULTS

The patients (n=173) participating in the study were divided into two groups: group A, in which the LigaSure (Valleylab, Boulder, Colo., USA) method was applied, n=80 patients; and group B, in which conventional sutures were used, n=93 patients. The study and control groups were compared in terms of indications of abdominal hysterectomy, patients' baseline characteristic, operations and concomitant procedures and operative complications, and homogeneity of distributions were tested. Both groups were similar. Indications of abdominal hysterectomy in both groups are presented in Table 1. The data concerning age, parity, previous Cesarean section and abdominopelvic operations of 173 patients who underwent type 1 abdominal hysterectomy under general anesthesia are shown in Table 2. In the LigaSure group, the mean age of patients was 47.86±8.09 years (range, 32-78), and in the conventional suture group, it was 48.08±8.10 years (range, 33-71). There was no significant difference between the two groups regarding age, parity, history of previous pelvic surgery and previous cesarean section.

Retroperitoneal ureter dissection was necessary to avoid ureter injury in 2 cases in the LigaSure group and 3 cases in the conventional suture group.

Eighteen procedures were applied in group A and 18 additional procedures were performed in group B, as shown in Table 3. Moreover, 54 pa-

TABLE 1: Indications of abdominal hysterectomy.

	Study Group (n=80)		Control Group (n=93)		Total		
	n	%	n	%	n	%	p
Myoma Uteri	35	43.8	39	41.9	74	42.8	
Cervical Intraepitelial Neoplasia	6	7.5	5	5.4	11	6.4	
Pelvic Pain or Endometriosis	5	6.3	6	6.5	11	6.4	
Endometrial Hyperplasia	5	6.3	7	7.5	12	6.9	0.974
Abnormal Uterine Bleeding	8	10.0	9	9.7	17	9.8	
Adnexal Mass (Benign)	20	25.0	27	29.0	47	27.2	
Invasive Mole	1	1.3	0	0.0	1	0.6	
Total	**80**	**46,2**	**93**	**53,8**	**173**	**100,0**	

TABLE 2: Patients' baseline characteristic.

	Study Group (n=80)	Control Group (n=93)	p
Age, median(min-max)	47.0 (30-79)	46.0 (33-71)	0,824
Mean parity ±SD	2.9±0.5	2.7±0.8	
Previous abdominopelvic surgery (n/%)	41 (51.3)	44 (47.3)	0,605
Previous cesarean section (n/%)	9 (11.3)	11 (11.8)	0,906

TABLE 3: Operations and concomitant procedures.

Operations	Study Group (n=80)	Control Group (n=93)	Total	p
TAH-BSO/USO	54 (67.5)	63 (67.7)	117 (67.6)	0.973
TAH	26 (32.5)	30 (32.3)	56 (32.4)	
Total	80 (46.24)	93 (53,76)	173	
Concomitant procedures				
-Colporaphy or perineoplasty	4 (22.2)	6 (33.3)	10 (27.8)	0.821
-Burch	5 (27.8)	5 (27.8)	10 (27.8)	
-Repair of enterocel	7 (38.9)	4 (22.2)	11 (30.6)	
-Repair of Hernia	0 (0.0)	1 (5.6)	1 (2.8)	
-Adhesiolysis	2 (11.1)	2 (11.1)	4 (11.1)	
Total	18 (50.0)	18 (50.0)	36 (100.0)	

TABLE 4: Operative complications.

	Study Group (n=80)		Control Group (n=93)		
	Number	Percent	Number	Percent	p
Wound infection	1	1.2	1	1.1	1.000
Hemorrhage	0		3	3.2	0.250
Bladder injury	0		2	2.2	0.500
Total complication	1	1.2	6	6.5	0.125

tients in the LigaSure group and 63 patients in the conventional suture group underwent hysterectomy with removal of adnex or adnexa.

The operative complications are presented in Table 4. There was a marked infection in one of the patients in the LigaSure group and also one in the control group, two bladder injuries in the control group and three patients with a hemorrhage requiring blood transfusion.

Perioperative outcome parameters are shown in Table 5. There was no statistically significant differences between the parameters of two groups in terms of preoperative and postoperative hemoglobin levels and hospital stay. There were statistically significant differences between the groups in terms of reduction in hemoglobin, operation time and VAS scores at 0 and 24 h. The median value of reduction (%) in hemoglobin level was -0.08% (min: -0.27- max: 0.10) in the study group compared to -0.08% (min: -0.29-max: 0.00) in the control group (p=0.033). The median operation time using LigaSure was 105 min (range: 70-175) compared to 130 min (range: 60-230) using conventional suture (p=0.001). The VAS scores of both groups at 0 h and 24 h are shown in Table 5 (p=0.020 and p=0.011, respectively).

Preoperative and postoperative changes in two groups are shown in Table 6.

DISCUSSION

In our study, we found that the operation time diminished in the LigaSure group compared to the conventional suture group (p=0.001). This result has already been shown in different studies.[4,10,11,14,15,17] In the conventional suture type operation, vascular structures and uterosacral-cardinal ligaments were clamped, cut and tied while these steps were carried out in only one application with LigaSure. Therefore, we assume that LigaSure application shortens the operation time.

TABLE 5: Perioperative outcome parameters.

Variables	Study Group (n=80)	Control Group (n=93)	P
Preop. hemoglobin, gr/dl (Mean±SS)	11.60±1.34	11.91±1.44	0.144
Hemoglobin reduction (%) (Median/Min.-Max)	-0.08 ((-0.27)-0.10)	-0.08 ((-0.29)-0.00)	0.033
Operation time, min (Median/Min.-Max)	105.0 (70-175)	130 (60-230)	0.001
Hospital stay, days (Median/Min.-Max)	5 (2-17)	5 (3-17)	0.150
VAS score at 0 h (Median/Min.-Max)	5 (1-8)	8 (7-9)	0.020
VAS score at 24 h (Median/Min.-Max)	3 (1-3)	4 (3-7)	0.011
Reduction in VAS scores(Median/Min.-Max)	2 (0-5)	4 (2-4)	0.439

TABLE 6: Preoperative and postoperative changes.

	Study Group (n=80)	p	Control Group (n=93)	p
Preop.hemoglobin, gr/dl (Mean±SS)	11.60±1.34	0.001	11.91±1.44	0.001
Postop.hemoglobin, gr/dl (Mean±SS)	10.70±1.36		10.69±1.44	
VAS score at 0 h (Median/Min.-Max)	5 (1-8)	0.066	8 (7-9)	0.024
VAS score at 24 h (Median/Min.-Max)	3 (1-3)		4 (3-7)	

LigaSure application is easy to learn and is not dependent on a surgeon's experience. In a meta-analysis comparing LigaSure for surgical hemostasis with other methods, a reduction in operative time was reported in 24 of 26 studies.[15]

In our study, when length of hospital stay was compared in between two groups and no statistically significant difference was seen. In a randomized controlled study comparing LigaSure with conventional suture method in abdominal hysterectomy, the mean hospital stay was longer following Liga-Sure operations (10 days with Liga-Sure vs. 6 days with conventional suture), probably due to a certain age imbalance between the study groups.[12] We observed no difference in terms of hospital stay between two groups [median 5 days (min: 2-max: 17) vs. 5 (min: 3- max:17)]. In contrast, some other studies reported a shorter hospital stay in vaginal hysterectomy when LigaSure was used.[14,17]

There was significant difference in terms of VAS pain scores of the patients when checked at 0 and 24 h in the postoperative period. It has been shown that the LigaSure sealing leads to less inflammatory reaction and pelvic fibrosis owing to the absence of suture material as a foreign body. In addition, the LigaSure sealing forms less strain on pedicles, so that they stay in their normal anatomical localization. Therefore, it is argued that it results in a reduction in postoperative pain and the amount of analgesia needed.[11,17]

In our study, the preoperative and postoperative hemoglobin values and the reduction in the hemoglobin levels were found to be insignificant in both groups. However, there was significant difference in terms of the reduction (%) in the hemoglobin levels between two groups (p=0.033). In addition, we have experienced that the application of LigaSure led to less bleeding resulting in clear vision of anatomical planes. This could have contribute to the shortening of duration of surgery. The literature on bipolar vessel sealing system regarding intraoperative blood loss is contradictory. Although there are some articles suggesting that bipolar vessel sealing system does not affect operative blood loss, there are other reports claiming reduction in operative blood loss.[10,11,13,14,16,17] We noticed no statistically significant difference in intraoperative blood loss between two groups.

CONCLUSION

LigaSure is an effective and reliable vessel sealing system that should be found in the surgical armament of the gynecologic surgeon. This device provides a significant reduction in blood loss, reduction in operation time (approximately 15 min) and postoperative VAS scores during abdominal hysterectomy and also decreases the final cost of the procedure LigaSure is reused. In addition, we think that it can reduce the need for analgesia.

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