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Clinical utility of a novel ultrasonic vessel sealing device in transecting and sealing large vessels during laparoscopic hysterectomy using advanced hemostasis mode



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ARTICLE INFO

Article history:

Received 19 November 2015

Received in revised form 16 March 2016

Accepted 23 March 2016

Keywords:

Laparoscopic hysterectomy

Harmonic

Harmonic Ace +7

Ultrasonic energy

Harmonic energy

ABSTRACT

Objective(s): The ultrasonic advanced energy study device (AH device) is the first surgical device indicated to seal vessels up to and including 7 mm using ultrasonic technology alone. This study assesses clinical experience during total laparoscopic hysterectomy (TLH) using advanced hemostasis mode (AHM).

Study design: This was a prospective, non-randomized, single arm, multicenter, observational study which did not modify or influence current surgeon technique for elective TLH for benign disease.

Each surgeon assessed hemostasis, defined as the hemostatic transection of the uterine vasculature (left/right) with at least one use of the AH device in AHM without the use of additional hemostatic measures other than the AH device. Patients were followed for 4–6 weeks after surgery.

Vessel sealing performance was quantitatively assessed for transection and sealing of the uterine artery (UA), the uterine pedicle (UP; defined as cases where the UA could not be 'isolated') and the ovarian pedicle (OP) (when indicated). Adverse events (AEs) related to the AH device or procedures were collected.

Results: Forty patients underwent the procedure. Mean age was 49 years and mean body mass index was 28 kg/m². Mean surgical duration was 88 min. None required conversion to open procedure. Using only the AH device, hemostasis was achieved and maintained in 119 (94.4%) transections (both left and right sides of the UA/UP and OP). Additional hemostasis was achieved in 5 patients using conventional bipolar (4) or monopolar (1) energy. No patient required a blood transfusion postoperatively. Only one adverse event of pain was considered to be related to the use of the ultrasonic AH device during this study.

Conclusion: These results support that the AH device with its AHM has clinical utility in sealing named vessels in TLH. The new algorithm to deliver energy in the AHM has the potential to reduce the need for additional hemostatic devices or products as well as the potential to reduce the need for multiple instrument changes during surgery.

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Introduction

Hysterectomy is the second most frequently performed major surgical procedure after cesarean delivery among reproductive-age women with over 500,000 performed annually in the US [1].

Approximately one in ten (10.4%) women 40–44 years of age in 2011–2013 report having had a hysterectomy [2]. Minimally invasive surgical techniques lead to decreased post-operative pain, decreased morbidity, and faster recovery times when compared to open abdominal procedures [3]. According to committee opinions from The American Congress of Obstetricians and Gynecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL), the preferred route for hysterectomy is a minimally invasive approach via the vaginal route or laparoscopically if not feasible

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vaginally [4]. In order to circumvent the challenging nature of laparoscopic suture ligation, laparoscopic energy sources have been introduced for dissection and hemostasis [5,6]. These energy sources include monopolar, bipolar, ultrasonic and advanced bipolar technology. Ultrasonic energy was introduced to surgery in 1991. The energy is purely mechanical; avoiding electric current traveling within the patient [7]. Coagulation is achieved via denaturation of proteins as hydrogen bonds break due to vibrational energy transferred to the tissue. The first laparoscopic hysterectomy using ultrasonic energy was performed and published by Robbins and Ferland in 1995 [8]. This mode of action provides the lowest thermal spread, least amount of smoke production and tissue damage and the best subjective visibility score when compared to various advanced bipolar instruments [9,10]. Due to the limited number of studies in the literature, there is insufficient evidence to recommend one energy source over another [12].

Historically only advanced bipolar vessel sealing technologies were indicated to seal vessels up to 7 mm diameter. In 2013, Ethicon Endo-Surgery, Inc. developed the Advanced Hemostasis (AH) device which utilizes the Harmonic ACE Shears combined with an Adaptive Tissue Technology (ATT) algorithm to monitor the instrument and respond intelligently to tissue conditions. ATT provides more precise energy delivery leading to less thermal damage, fewer adhesions, faster transection, less visual obstruction and higher burst pressures as demonstrated in preclinical trials [7]. The AH device has further optimized this algorithm; the AHM is designed for larger vessels up to 7 mm in size. In this mode cutting speed is further reduced and hemostasis is maximized.

The objective of this study is to assess the initial clinical experience with the AH device by quantitatively and qualitatively evaluating vessel sealing of the uterine and ovarian vasculature during TLH.

Materials and methods

Study design

Sponsored by the manufacturer of the AH device (Ethicon Endo-Surgery, Inc. Cincinnati, OH), this was a prospective, non-randomized, single arm, multicenter, observational study conducted at 4 centers, with 5 surgeons (Radboud University Nijmegen Medical Centre, Netherlands; The Royal Surrey County Hospital, Guildford, UK; The Advanced Gynecological Surgery Institute, USA; Florida Hospital Celebration Health, USA). The study was reviewed by each Institutional Review Board or Ethics Committee prior to initiation and was performed in compliance with the Health Insurance Portability and Accountability Act and Good Clinical Practices. (Clinicaltrials.gov identifier: NCT02278640).

The study utilized a new ultrasonic advanced energy device, Harmonic ACE[®] +7 Shears, to transect and seal the uterine and ovarian vasculature (Fig. 1).

The AH device was used throughout the procedures and AHM was used specifically to seal and transect the uterine artery/uterine pedicle (UA/UP) and ovarian pedicle (OP); hemostasis was assessed by each surgeon. The use of any energy device or hemostatic product to either establish initial hemostasis or maintain final hemostasis across each vessel and the number of touchup applications of the AH device that were required to achieve or maintain final hemostasis were recorded. Each patient had 4–6 weeks follow-up care. AEs were collected and assessed for relationship of the event to the procedure or AH device.

Patient selection

Patients from the United States and the European Union who were eligible to participate in the study included those indicated



Harmonic Ace +7 device transecting dissected left uterine artery

Fig. 1. Caption: Harmonic Ace +7 device transecting dissected left uterine artery.

for elective TLH for benign conditions, older than 40, with no future desire for fertility.

Preoperative exclusions included uncontrolled bleeding disorders, unwillingness or unlikely to comply with the protocol requirements, suspected malignancy, and positive pregnancy test. Patients were also excluded when intra-operative findings precluded the conduct of the study procedure.

Study procedure and post-operative follow up

TLH is defined as having the uterus and cervix removed and may be entirely performed laparoscopically. However, some surgeons prefer to suture the vaginal cuff using a vaginal approach.

TLHs were included in the study, with no influence on participating surgeons' techniques. Investigators performed TLHs using the AH device in compliance with their own standard surgical approach and product labeling. The study allowed only the Principal Investigator to apply the AH device.

Each patient was followed per the surgeon's standard of care. Study data was recorded onto medical charts and source worksheets and subsequently entered into an electronic Case Report Form. A laparoscopic video recording was made of the procedure and documented the sealing of each vessel.

Vessel transection assessments for the UA/UP and/or OP documented during the study procedure included: vessel name, location, application time, transection time, tissue sticking [via a 4-point Likert scale], additional harmonic touch-ups and use of any other device or product to achieve hemostasis.

Surgeon's workload to dissect and transect using the AH device throughout the TLH was subjectively evaluated utilizing the NASA Task Load Index (NASA-TLX), a validated fixed-format, self-administered, multidimensional tool to assess the following subscales: mental, physical, and temporal demands, self-performance, effort, and frustration.

Subscales were rated for transection and dissection with the AH device during the hysterectomy procedure, with a 100-point range utilizing 5-point steps. These ratings were combined to provide the task load index.

Approximately 4–6 weeks following surgery, adverse events, concomitant medications, and reoperation data were reviewed and changes recorded. An inspection of the vaginal cuff was completed and patients were exited from the study following this visit.

The primary endpoint for analysis was incidence of hemostasis at the named vessel/pedicle (UA or UP). Secondary endpoints included incidence of hemostasis at the OP on the left/right side, incidence of requirement for additional measures to obtain hemostasis and incidence of complications associated with vaginal cuff healing.

Statistical analysis

Descriptive statistics including confidence intervals were provided for all study endpoints. Summary statistics included counts and percentages for categorical variables and the number of patients, number of named vessels/pedicles, mean, standard deviation (SD), median, minimum, and maximum for continuous variables. All enrolled patients were included for the analysis of primary, secondary and safety endpoints. No imputation of missing data was performed. All statistical analyses were performed using SAS, version 9.3.

Results

A total of 41 patients were consented and 40 were enrolled and operated on between November 2014 and May 2015. One patient was excluded due to intraoperative findings. Table 1 summarizes the preoperative characteristics of all enrolled patients. Mean age was 48.5 years (range 36–67), 39 (97.5%) patients were white, and mean body mass index was 28.2 kg/m² (range 17.7–47.4 kg/m²). Pregnancy history was available for 37 women, with 30 reporting at least one pregnancy and 29 reporting at least one delivery. Six patients reported a history of one or more caesarean sections.

In 7 (17.5%) patients a TLH was performed conserving the ovaries and salpinges. In 8 (20.0%), the salpinges were removed, but ovaries were conserved. In 25 (62.5%) women, one or both ovaries and salpinges were removed.

Complexity of the cases was graded by each surgeon on a subjective basis but was mainly influenced by uterine size, adhesions, and severity of endometriosis; medium or high complexity ratings were assigned in 36 (90.0%) of the cases.

Mean duration of the procedure was 88.4 min (range 33–209). The average uterine size was 200 grams (range 46–564). A laparoscopic colpotomy approach was utilized in 20 (50.0%) patients and a vaginal approach was utilized in 20 (50.0%) patients. In two patients the specimens required morcellation with the Lina Morcellator to extract due to uterine size (484 and 348 g). No patients were converted to open procedures or required blood transfusions.

Using only the AH device, hemostasis was achieved and maintained in 119 (94.4%) transections (both left and right sides

Table 1
Baseline characteristics of patients entering the study.

	n = 40	SD
Age, yrs	48.5 (36.0, 67.0)	6.9
Race		
White	39 (97.5%)	
Black or African American	1 (2.5%)	
BMI	28.2 (17.7, 47.4)	5.6
Parous women (having 1 or more deliveries)	29 (72.5%)	
Patients previous cesarean sections:	6 (15.0%)	
Indication for hysterectomy		
Abnormal bleeding	13 (32.5%)	
Endometriosis	6 (15.0%)	
Dysmenorrhea	6 (15.0%)	
Fibroids	5 (12.5%)	
Atypical or hyperplastic endometrium	4 (10.0%)	
Prolapse	2 (5.0%)	
Adenomyosis/ovarian cyst	2 (5.0%)	
PAP smear abnormalities	1 (2.5%)	
Pyometrium	1 (2.5%)	
Histological diagnosis		
Fibroids	21 (52.5%)	
Adenomyosis	14 (35.0%)	
Endometriosis	13 (32.5%)	
Endometrial abnormality	9 (22.5%)	

Data are presented as mean (range) or number (%). Abbreviations: BMI, body mass index; SD, standard deviation.

of the UA/UP and OP). The entire surgical procedure could be completed using only AH device for vascular division/control in 35 (87.5%) patients. In 5 patients, an additional energy device was needed to maintain hemostasis; bipolar was used for 4 patients and monopolar for the 5th patient. Details regarding the need for additional touch-ups to achieve final hemostasis are shown in Table 2.

Mean NASA-TLX was 19.2 (range 0–100), indicating that surgeons did not perceive the AH device to lead to an increased workload. Surgeons felt the study device was the same in 30.0% of cases and better in 62.5% of cases for transecting the UA/UP compared to past experience using other advanced energy devices or dissection modalities. Similarly, sealing of the UA/UP was deemed the same or better in 92.5% of cases compared to past experience using advanced energy devices or other hemostatic modalities.

Table 2
Endpoints and surgery details.

Hemostasis results	Left	Right
Uterine artery or pedicle	n = 40	n = 40
Vessel skeletonized	26 (65.0%)	25 (62.5%)
Hemostasis achieved	39 (97.5%)	37 (92.5%)
Single application of AH device	26 (65.0%)	24 (60.0%)
Hemostasis maintained	37 (92.5%)	31 (79.5%)
1. Additional touch up required	6 (15.0%)	8 (20.0%)
2. Additional touch ups required	6 (15.0%)	6 (15.0%)
3. Additional touch ups required	2 (5.0%)	2 (5.0%)
Additional hemostatic products	0 (0.0%)	0 (0.0%)
required		
Additional energy devices required	3 (7.5%)	4 (10.0%)
No tissue sticking	39 (97.5%)	40 (100.0%)
Ovarian pedicle	n = 23	n = 23
Hemostasis achieved	23 (100.0%)	23 (100.0%)
Single application of AH device	16 (69.6%)	18 (78.3%)
Hemostasis maintained	21 (91.3%)	22 (95.7%)
1. Additional touch up required	1 (4.3%)	4 (17.4%)
2. Additional touch ups required	4 (17.4%)	0 (0.0%)
3. Additional touch ups required	1 (4.3%)	1 (4.3%)
4. Additional touch ups required	0 (0.0%)	0 (0.0%)
5. Additional touch ups required	1 (4.3%)	0 (0.0%)
Additional hemostatic products required	0 (0.0%)	0 (0.0%)
Additional energy devices required	0 (0.0%)	0 (0.0%)
No tissue sticking	23 (100.0%)	23 (100.0%)
Surgery details	n = 40	
Length of stay, days	1.4 (0.0, 5.0)	
Surgery Time, min	88.4 (33.0, 209.0)	
	SD 45.1	
No. of blood transfusions	0 (0.0%)	
No. of cases converted to open	0 (0.0%)	
Uterine weight, g	200.1 (46.0, 564.0)	
Colpotomy approach		
Laparoscopic	20 (50.0%)	
Vaginal	20 (50.0%)	
Colpotomy method		
Monopolar energy	3 (7.5%)	
Ultrasonic energy	17 (42.5%)	
Cold knife	20 (50.0%)	
Patients requiring no additional hemostatic products or additional energy devices to achieve hemostasis	35 (87.5%)	
40 patients had applications on the Left and the Right UA/UP for a total of 80 applications on the UA/UP		
25 patients had applications to the Left and/or Right OP		

Data are presented as mean (range) or number (%). Abbreviations: UA/UP, uterine artery/uterine pedicle; OP, ovarian pedicle; SD, standard deviation.

Hemostasis was initially achieved on UA/UP in 37 of 40 (92.5%) patients using only the AH device. A single activation of the AH device on both uterine arteries achieved hemostasis in 17 (42.5%) patients. In 4 (10.0%) patients, one additional activation (totaling 3 activations over both uterine arteries) was necessary to achieve hemostasis. Four activations of the AH device were required in 13 (32.5%) patients, and 6 (15.0%) patients required 5 or 6 activations over the two uterine vessels. The majority (8 of 9) of cases where hemostasis was not maintained occurred on the right side. Slight tissue sticking was reported in one patient on the left UP.

Oophorectomy data is presented in [Table 2](#). Oophorectomies were performed in 25 patients (46 individual oophorectomies) with hemostasis achieved in 100.0% of patients. Hemostasis was initially achieved on the OP in 25 of 25 (100.0%) patients using only the AH device. A total of 16 of 25 (64.0%) patients required a single application of the AH device to obtain initial hemostasis. Hemostasis of the OP was maintained in 22 of 25 (80.0%) patients and additional applications of the AH device were required to maintain hemostasis in the remaining 3 (12.0%) patients. Tissue sticking was not reported on any of the OP transections. The AH device was the only energy or hemostatic product required to transect the ovarian pedicles in 25 of 25 (100.0%) patients.

The surgeons began the UA/UP cuts on the right side in 21 (52.5%) patients. There was no apparent association between the side of first transection and the lack of hemostasis on initial application of the AH device or the failure to maintain hemostasis.

One patient reported pain that was considered possibly related to the study device. No other AEs were considered to be related to the AH device. Three serious adverse events were reported – an infected haematoma, urinary retention, and vaginal haemorrhage. All patients completed the study and events were resolved with no further complications.

No patients required post-operative transfusions or reoperations. All colpotomies healed with no complications during the 6 weeks follow-up.

Discussion

The study demonstrated that using the AH device alone, hemostasis could be achieved and maintained in 119 (94.4%) transections (both left and right sides of the UA/UP and OP). Hemostasis was achieved on the UA/UP in 37 of 40 (92.5%) patients using only the AH device. The entire TLH could be completed using only AH device in 35 (87.5%) of patients. In 5 patients, an additional energy device was needed to maintain hemostasis; bipolar was used for 4 of those patients and monopolar for the 5th patient.

This study utilized the expertise of high volume surgeons to assess the efficacy of the AH device during a TLH. The majority of cases were reported as medium or high complexity, with only 4 cases (10%) being low complexity. This is likely due to the recruitment of high case-volume surgeons who routinely perform more difficult surgeries. Fifty three percent were for uterine fibroids implying that the majority of cases had enlarged uteri with the largest uterine size being 564 g. Among the 21 subjects who were identified as having a histological diagnosis of fibroids, this variability was also observed as the uterine weights ranged from 57 to 564 g, with a mean weight of 256.2 g and a median weight of 235.5 g. Uterine size did not appear to be associated with the need for additional touchups. [Table 2](#) indicates two subjects on the left and two subjects on the right who required 3 additional touch ups. The uterine weights for these 4 subjects were 68, 128, 183, and 490 g. These larger uteri physiologically have larger uterine pedicles to maintain blood flow to the uterus. The AH device was effective despite reported uterine size and case difficulty.

The recommended vessel diameter for previous versions of the harmonic shears was up to 5 mm. In one study, a failure rate of 22%

was reported for sealing a 4–5 mm vessel with a harmonic scalpel alone [11]. Often, surgeons will utilize ultrasonic energy for cutting and dissection due to its proven benefits, yet still will rely on a second energy source for coagulation and vessel sealing of larger vessels. Using two energy sources for one procedure is not only cumbersome, but increases both the operating time and the cost of the surgery. Data presented here suggest that the new advanced hemostasis technology is able to reduce the need for alternate energy sources during hysterectomy. In the majority of cases (65%) the surgeons reported that the use of the AH device had led to fewer instrument exchanges. It must be noted that the uterine artery is one of the more difficult vessels to effectively ligate or seal in abdominal surgery. The uterine artery's point of entry into the end organ is located in dense fibrous tissue making it more difficult to clearly isolate the main branch. It also lies in close proximity to the ureter, leading to the common technique of increased traction on the uterus to increase the distance between vessel and ureter to avoid collateral damage. The result is that while using advanced energy devices to seal and cut, the vessel may be transected before a full seal has been achieved.

Surgeons' preference during surgery may have influenced the findings in the study. In particular, the utilization of the instrument in different trocars may affect the hemostasis obtained. One surgeon utilized the AH device in a center trocar; the others utilized side trocars. Some surgeons kept the instrument in the same trocar irrespective of the side of the pedicle being transected while others changed trocar sites. Not optimizing the angle of approach by changing trocar sites may theoretically affect the number of touch ups needed for the 'opposite' pedicle as the view is invariably obscured. Another potential cause of increased touch ups is back bleeding from the initial pedicle transected. In this study, however, there was no apparent association between the side of first transection and the lack of hemostasis on initial application of the AH device or the failure to maintain hemostasis. Interestingly, the majority of the touch ups were on the right side (8 out of 9). Potentially the surgeons' position at the operating table, could explain a more difficult angulation to approach the vessel and a subsequent inferior seal/transection technique.

Of interest in this study is that, in half of the cases (by a single surgeon [AK]), the colpotomy was systematically performed vaginally as opposed to laparoscopically. The technique utilizes a true intra-fascial approach around the cervix starting above the insertion of the cardinal ligaments leaving the peri-cervical ring and utero-sacral arch intact. This utilizes the excellent dissecting and cutting capabilities of the harmonic technology. The same approach is difficult to achieve with advanced bipolar devices. The remainder of the split thickness vagina is then easily incised vaginally (by means of a cold knife) and sutured vaginally. This approach may reduce the risk of vault dehiscence.

The safety profile of the TLH is confirmed in this study, specifically when using harmonic technology. There were no intra operative complications reported throughout the cases. No cases were converted to open cases, no collateral damage secondary to advanced energy use was reported, no blood transfusions were needed and no re-operations were required. The post-operative AEs were consistent with AEs reported in other studies describing this technique [13,14]. However, the most concerning post-operative AEs were one case of vaginal hemorrhage and one case of infected hematoma formation.

The fact that it involved multiple surgeons adhering to their own technique yields some external validity to the findings. The ability to use these larger vessels as the endpoint in this study successfully demonstrates the effectiveness of the instrument in a range of clinical settings. Limitations of this study are its small sample size and that there is no comparison group to further help the clinician make a choice of which advanced energy product to

use in the TLH procedure. Generalized ability of the study could be criticized as the study was performed by high volume surgeons who have experience utilizing laparoscopic energy during their surgeries, so this study does not reflect a potential learning curve inherent to all medical devices.

Procedure reviews by a third party to assess the primary and secondary endpoints would have provided another level of objectivity. Finally, it must be noted that the study was funded by the manufacturer of the ultrasonic technology.

Taken together, the data presented in this study indicate that the AH devices have clinical utility for TLH. Moreover, this work adds to the body of evidence supporting the positive benefit-risk analysis of the minimally invasive approach to hysterectomy [3]. The new algorithm to deliver energy in the AHM has shown the potential to reduce the need for additional hemostatic devices or products as well as the potential to reduce the need for multiple instrument changes during surgery.

A brief video of one of the surgical procedures from this study is included to show the AH Device being used during the Laparoscopic Hysterectomy of a 49 year old woman with prolonged heavy periods who opted for definitive management in the form of a laparoscopic intrafascial hysterectomy and bilateral salpingo-oophorectomy. The video demonstrates the AH Device is an appropriate instrument for performing a Laparoscopic Hysterectomy intrafascial (LHi). Utilising the LHi technique with the AH device results in simultaneous vessel coagulation and cutting allowing for virtually no instrument changes and seamless operating.

Acknowledgements

Ethicon Endo-Surgery, Inc. for providing the funding for this study. Aileen Caceres, MD, Florida Hospital, for recruitment of subjects. Jennifer Kelch, Ethicon Endo-Surgery, Inc., for protocol development. Jonathan Batiller, Ethicon, Inc., for project oversight. Elizabeth Cowie, Ethicon, Inc., for monitoring support and project management. Jenny Mitchell, Ethicon, Inc., for project management.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.ejogrb.2016.03.035>.

References

- [1] Agency for Healthcare Research and Quality. www.ahrq.gov [accessed August 2015].
- [2] Center for Disease Control and Prevention. www.cdc.gov [accessed August 2015].
- [3] Aarts JWM, Nieboer TE, Johnson N, et al. Surgical approach to hysterectomy for benign gynaecological disease (review). *Cochrane Libr* 2015;(8).
- [4] American College of Obstetrics and Gynecology. Choosing the Route of Hysterectomy for Benign Disease. ACOG Committee Opinion Number 444, November 2009.
- [5] Demirturk F, Aytan H, Caliskan AC. Comparison of the use of electrothermal bipolar vessel sealer with harmonic scalpel in total laparoscopic hysterectomy. *J Obstet Gynaecol Res* 2007;33(3):341–5.
- [6] Gyr T, Ghezzi F, Arslanagic S, et al. Minimal invasive laparoscopic hysterectomy with ultrasonic scalpel. *Am J Surg* 2001;181(6):516–9.
- [7] Broughton D, Welling AL, Monroe EH, et al. Tissue effects in vessel sealing and transaction from an ultrasonic device with more intelligent control of energy delivery. *Med Devices* 2013;6(1):151–4.
- [8] Kauko M. New techniques using the ultrasonic scalpel in laparoscopic hysterectomy. *Curr Opin Obstet Gynaecol* 1998;10(4):303–5.
- [9] Lamberton GR, Hsi RS, Jin DH, et al. Prospective comparison of four laparoscopic vessel ligation devices. *J Endourol* 2008;22(10):2307–12.
- [10] Gruber DD, Warner WB, Lombardini ED. Laparoscopic hysterectomy using various energy sources in swine: a histopathologic assessment. *Am J Obstet Gynecol* 2011;205(5):494. e.1–e.6.
- [11] Newcomb WL, Hope WW, Schmelzer TM, et al. Comparison of blood vessel sealing among new electrosurgical and ultrasonic devices. *Surg Endosc Other Interv Tech* 2009;23(1):90–6.
- [12] Law KSK, Lyons SD. Comparative studies of energy sources in gynecologic laparoscopy. *J Minim Invasive Gynecol* 2013;20(3):308–18.
- [13] Donnez O, Jadoul P, Squifflet J, et al. A series of 3190 laparoscopic hysterectomies for benign disease from 1990 to 2006: evaluation of complications compared with vaginal and abdominal procedures. *BJOG* 2009;166(4 (March)):492–500.
- [14] Clarke-Pearson DL, Geller EJ. Complications of hysterectomy. *Obstet Gynecol* 2013;121(3 (March)):654–73.