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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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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/m^2. 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.

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

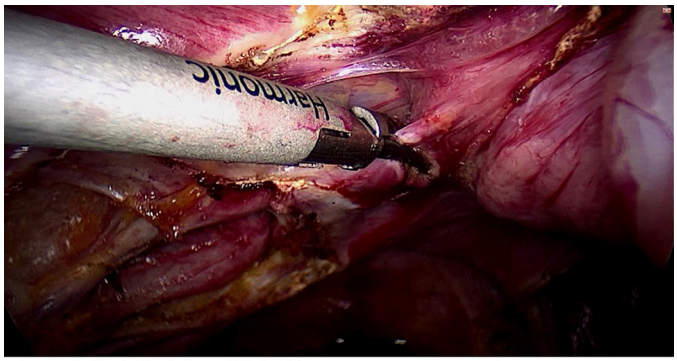
Sponsored by the manufacturer of the AH device (Ethicon Endo-Surgery, Inc. Cincinnati, OH), this was a prospective, non-randomized, single arm, multicenter, observational study conducted at 4 centers, with 5 surgeons (Radboud University Nijmegen Medical Centre, Netherlands; The Royal Surrey County Hospital, 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 for elective TLH for benign conditions, older than 40, with no future desire for fertility.



Harmonic Ace +7 device transecting dissected left uterine artery

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

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.