Clinical Study

Application of a New Integrated Bipolar and Ultrasonic Energy Device in Laparoscopic Hysterectomies

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Objective. A retrospective study to evaluate the Thunderbeat, a new vessel sealing device in a small group of patients undergoing laparoscopic hysterectomy to test the safety and effectiveness in achieving hemostasis. **Method.** The Thunderbeat was used in 12 cases of total laparoscopic hysterectomy. Operative performance involving hemostasis, sealing/coagulation, cutting, dissection, and tissue manipulation was evaluated. **Results.** No complications were encountered intraoperatively and postoperatively. Intraoperative experience involving hemostasis, sealing/coagulation, and cutting was optimal. Tissue handling was acceptable except for fine dissection. **Conclusion.** The Thunderbeat is an efficient and safe alternative to standard bipolar in laparoscopic hysterectomy. Larger studies are required to evaluate the cost-effectiveness and significant reduction in operating times as compared to conventional bipolar energy.

1. Introduction

Hysterectomy is one of the most commonly performed gynaecological surgeries in the world [1]. Although a Cochrane review favours the transvaginal route because of earlier return to normal activities, fewer febrile episodes, and shorter hospital stay [2], about two-thirds of hysterectomies are still performed abdominally due to uterine size and the technical challenge of access. The last two decades have seen an advent in laparoscopic surgeries primarily due to improved capabilities in optics, energy technology, and increasing surgical expertise. This has allowed minimally invasive surgery to confer the same advantages of the vaginal hysterectomy even for the more challenging cases. Similar to vaginal hysterectomy, laparoscopic hysterectomy has less operative bleeding, less postoperative pain, shorter hospital stay, and shorter convalescence time compared to abdominal hysterectomy [3, 4].

Haemostasis is fundamental in all surgical procedures, and even more so in minimally invasive surgery. Traditional methods of staples and clips have gradually been abandoned due to cost, difficulty with repeated applications, and problems of displacement [4]. Suturing is difficult to master, technically challenging, and time-consuming. Standard

energy devices—monopolar and bipolar coagulation—are currently widely used due to their inexpensive nature and reusability. However, this involves high instrument traffic, thermal spread, and sticking and charring of tissues. New products in the market include advanced bipolar coagulation (LigASURE, Bicision, and EnSeal) and ultrasonic energy (Harmonic Ace). Advanced bipolar devices possess active feedback control over the power output. Heat production is kept below 100°C [5]. However, there is no simultaneous tissue division and is required a cutting blade for division, thus increasing operating time. Ultrasonic devices combine both the sealing and cutting steps into a single process, thus increasing dissection speed. However, the literature had reported the ultrasonic devices creating temperatures of up to 200°C. This can potentially put adjacent tissue at risk to lateral damage [6].

2. Thunderbeat Vessel Sealing Device

The Thunderbeat (Olympus, Japan) has been developed as the first device to integrate both ultrasonically generated frictional heat energy and advanced bipolar energy in one instrument. This multifunctional device can interchangeably

deliver the energies, thus allowing the gynaecological endoscopist to simultaneously seal and cut vessels up to 7 mm in size with minimal thermal spread. The jaw is designed to provide precise, controlled dissection and continuous bipolar support with grasping capability.

The literature search revealed only two publications involving animal model using this new device. There has been no publication of the use of this device in clinical practice at the time of this writing. Milsom et al. [7] compared the Thunderbeat with other commercially available energy devices in the market, namely, Harmonic Ace (Ethicon Endo-Surgery, USA), LigaSure (Covidien, USA), and EnSeal (Ethicon Endo-Surgery, USA) in the porcine model. Comparing with the other 3 devices, the Thunderbeat showed faster dissection speed, similar bursting pressure, and similarly acceptable thermal spread. The device was proven to be safe in cutting, coagulating, and tissue dissection. In another experiment led by Seehofer et al. [8], the Thunderbeat was compared to the Harmonic Ace and LigaSure in a pig model. Temperature profile, seal failures, maximum burst pressure, and cutting speed were measured, and the Thunderbeat was this time faster than Harmonic Ace in terms of dissection while equalled the sealing efficacy of the LigaSure. Heat production was similar. Armed with the results based on animal models and the approval of the use of the device by the U.S. Food and Drug Administration (FDA) in endoscopic surgery, we evaluated the Thunderbeat device in a small series of patients undergoing total laparoscopic hysterectomy (TLH). We aim to assess its safety, effectiveness, and the ease of use of this new energy platform in actual surgical context, especially in achieving haemostasis.

3. Material and Methods

In this pilot series, the Thunderbeat was evaluated in 12 cases of total laparoscopic hysterectomy (TLH). Our centre performed various types of TLH, namely, conventional TLH, minilaparoscopic TLH and single-incision laparoscopic surgery (SILS) TLH. We started collecting our data after the ethics approval of the study was cleared from the national Domain Specific Review Board (DSRB). Hysterectomy was performed in the following technique.

Primary energy source was the 5 mm Thunderbeat sealing device (Figure 1) used together with the Olympus ESG-400 electrosurgical generator. In addition, we used the RUMI system of Uterine Manipulators, the Advincula Arch, the Koh Cup vaginal delineator, and the Colpo-Pneumo Occluder. Pneumoperitoneum was created via open Hasson's technique. The round ligament was first dissected followed by the dissection of the anterior and posterior leaf of the broad ligaments. This was followed by dessication and division of the infundibulopelvic ligament or ovarian ligament (based on ovarian conservation) and the fallopian tubes. From the anterior broad ligament, the uterovesical fold was pushed down the bladder using the Thunderbeat. The uterine pedicle was fashioned before the uterine arteries were dissected. These were performed with the Thunderbeat as the main instrument for coagulation, cutting, hemostasis dissection and tissue manipulation. Backup instruments including the

FIGURE 1

TABLE 1

Followup period	101.9 days (58 to 160 days)
Operation team	3 endoscopic surgeons, 2 residents
Median operating time	2 hr 58 min (2 hr, 10 min to 4 hr, 38 min)
Median clinical size of uterus	14.2 weeks (6 weeks to 20 weeks)
Mean weight of uterus	359 g (87 g to 1250 g)
Average hospital stay	2.1 days

conventional bipolar grasper and scissors were on standby. The vault was cut using monopolar hook. Uterus was morcellated (if necessary) and removed per vagina. Vaginal vault was subsequently sutured either with V-Loc suture or Vicryl 1-0 sutures. In all cases, the TLHs are performed by the hospital endoscopic team.

4. Results

The types of hysterectomy done included 4 cases of total laparoscopic hysterectomies (TLHs) only, 6 TLHs with bilateral salpingo-oophorectomy and 2 TLHs with cystectomy. The method of hysterectomy included 8 cases via conventional laparoscopy, 3 via minilaparoscopy, and 1 via single-incision surgery. Operation findings included 2 patients with endometriosis only, 6 with fibroids only, and 4 with endometriosis and fibroids.

In all the 12 hysterectomy procedures (Table 2), no complications were encountered intraoperatively or postoperatively. The follow up period was 101.9 days (18 to 120 days). No conversions were required for the single-incision and minilaparoscopic surgery. The Thunderbeat successfully sealed all major vessels without the need for additional energy sources in all the cases. Hemostasis was good, and no incidents of postoperative bleeding or hematoma were reported. Sealing/coagulation was effective with complete seal as noted at the end of each application of the "cut" mode. Cutting was quick with complete tissue transection at each application.

The operation was mainly performed by 3 main surgeons and 2 residents. The data was analysed with SPSS programme and was represented by a skewed distribution. Median

TABLE 2

Patient	Age	Surgery	Uterus size (weeks)	Uterus weight (g)	Operative time (hr)	Blood loss (mLs)	Hospital stay (days)	Followup (days)
1	46	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy	14	454	2.0	20	3	168
2	44	Total laparoscopic hysterectomy	12	338	3.4	20	2	126
3	46	Total laparoscopic hysterectomy	20	1250	3.5	20	2	126
4	51	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy (minilap)	14	265	3.1	10	2	119
5	43	Total laparoscopic hysterectomy, right cystectomy	8	380	3.3	30	2	119
6	50	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy (minilap)	16	478	3.3	20	2	112
7	48	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy	6	87	1.6	20	2	107
8	48	Total laparoscopic hysterectomy, right cystectomy, and cholecystectomy	18	608	2.3	40	2	98
9	54	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy	12	306	2.3	20	2	98
10	43	Total laparoscopic hysterectomy	16	489	4.0	20	2	90
11	47	Total laparoscopic hysterectomy, bilateral salpingo-oophorectomy	14	331	2.9	20	2	90
12	47	Total laparoscopic hysterectomy (minilap)	8	172	2.2	15	2	66

operative time was 2 hr, 58 min with much time spent on morcellation. The median clinical size of the uterus was 14.2 weeks (6 weeks to 20 weeks), and the median weight of uterus removed was 359 g (87 g to 1250 g). The average hospital stay was 2.1 days (Table 1).

5. Discussion

This is the first pilot study evaluating the Thunderbeat vessel sealing device as the primary energy source in clinical use; the new device was able to perform its role in hemostasis, sealing/coagulation, cutting, dissection, and tissue manipulation. The Thunderbeat device comprises both a “coagulation/sealing mode” as well as a “cutting mode.” This allowed tissue to be coagulated and cut at one motion, thus avoiding the dual action of applying the blade after coagulation as in most advanced bipolar devices.

Laparoscopic hysterectomies involve taking large vessels that include the infundibulopelvic ligament, the ovarian ligament, and the uterine arteries. For such large pedicles, our initial technique was to activate the “seal mode” back and forth at least 3 times before activation of the “cut” mode. Although standard bipolar was also put on standby throughout the surgery, this was only utilized in the first case where the surgeon was still relatively unfamiliar with the instrument. All subsequent hysterectomies did not require any additional energy source for hemostasis, reflecting the efficacy of use and quick familiarization with the device.

Cutting was efficient. There was no longer a need to activate the blade or to switch to a scissors during dissection, thus reducing unnecessary operative movements. The availability of a “coagulation/sealing” mode also allows confident coagulation of the larger vessels till the feedback system gets activated. This is unlike the ultrasonic energy devices whereby difference between cutting and sealing depends very much on the surgeons’ pressure on the vessel during firing.

Scarring and charring were noted to be minimal. This could prove to be important as hysterectomy involves dissection near vital organs such as the ureters, bladders, and colon. The reduced thermal spread would lower the chances of lateral thermal spread and damage to adjacent tissue. Further histological studies would be required to confirm this aspect.

The instrument is of course not without flaws; it employs single-action jaws which made dissection trickier. Tissue manipulation was also acceptable for grasping but became more delicate when fine tissue handling was involved. This was due to the diameter difference between the two blades which made precise pickup difficult. The thinner active blade can also cause tissue trauma during grasping at times due to its narrow shape. During the initial few cases, this resulted in bleeding from the uterine venous beds which was easily stopped with the Thunderbeat itself.

Ease of use was demonstrated as the Thunderbeat was quickly picked up, and all 5 surgeons were able to deploy the “coagulation/sealing” and “cut” mode effectively within

the first use. The extended average time recorded for the 12 hysterectomies could be attributed to surgical teaching material for residents (50% of hysterectomies had residents recorded as first surgeon) in the surgery as well as use of newer techniques of hysterectomy such as the single-port device and minilaparoscopy.

Hysterectomy, being one of the commonest surgeries in the world, would benefit tremendously in terms of operating room usage and cost if operating time is reduced. The Thunderbeat allows both coagulation and cutting to be performed within one motion. This cuts down instrument exchange and thus speeds up the surgery.

6. Conclusion

The Thunderbeat has shown to be an efficient and safe alternative to the standard bipolar in laparoscopic hysterectomy. As we successfully complete the evaluation without encountering any complications, effective, larger studies are required to evaluate the cost-effectiveness and significant reduction in operating time compared to conventional bipolar instruments.

Conflict of Interests

The authors have no direct financial relation with the commercial identity mentioned in this paper that might lead to a conflict of interests.

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