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Original Article

Single-Use Energy Sources and Operating Room Time for Laparoscopic Hysterectomy: A Randomized Controlled Trial

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ABSTRACT **Study Objectives:** To compare the intraoperative direct costs of a single-use energy device with reusable energy devices during laparoscopic hysterectomy.

Design: A randomized controlled trial (Canadian Task Force Classification I).

Setting: An academic hospital.

Patients: Forty-six women who underwent laparoscopic hysterectomy from March 2013 to September 2013.

Interventions: Each patient served as her own control. One side of the uterine attachments was desiccated and transected with the single-use device (Ligasure 5-mm Blunt Tip LF1537 with the Force Triad generator). The other side was desiccated and transected with reusable bipolar forceps (RoBi 5 mm), and transected with monopolar scissors using the same Covidien Force Triad generator. The instrument approach used was randomized to the attending physician who was always on the patient's left side. Resident physicians always operated on the patient's right side and used the converse instruments of the attending physician.

Measurements and Main Results: Start time was recorded at the utero-ovarian pedicle and end time was recorded after transection of the uterine artery on the same side. Costs included the single-use device; amortized costs of the generator, reusable instruments, and cords; cleaning and packaging of reusable instruments; and disposal of the single-use device. Operating room time was $94.14/min. We estimated that our single use-device cost $630.14 and had a total time savings of 6.7 min per case, or 3.35 min per side, which could justify the expense of the device. The single-use energy device had significant median time savings (-4.7 min per side, $p < .001$) and total intraoperative direct cost savings ($254.16 per case).

Conclusions: A single-use energy device that both desiccates and cuts significantly reduced operating room time to justify its own cost, and it also reduced total intraoperative direct costs during laparoscopic hysterectomy in our institution. Operating room cost per minute varies between institutions and must be considered before generalizing our results. Journal of Minimally Invasive Gynecology (2016) 23, 72–77 © 2016 AAGL. All rights reserved.

Keywords: Costs; Laparoscopic hysterectomy; Operating room time; Reusable energy devices; Single-use energy device

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Single-use bipolar radiofrequency hybrid devices are available that can both desiccate and cut vascular tissue during surgery with an integrated mechanical knife, but these devices add costs to the procedure. The Ligasure 5-mm Blunt Tip LF1537 (Covidien, Dublin, Ireland) desiccates tissue with impedance feedback using the Force Triad Generator (Covidien, Dublin, Ireland) and cuts using an integrated mechanical knife. With this device, an audible signal denotes when impedance rises to a level that suggests complete

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desiccation of the tissue between the 2 electrodes embedded in each jaw of the device; this creates a seal that can withstand 3 times the normal systolic blood pressure [1–3]. Several studies in the gastrointestinal literature that used a variety of Ligasure models have demonstrated a decrease in operating room time and/or blood loss compared with instruments that use ultrasonic or conventional radiofrequency energy [4–8]. A variety of Ligasure models have also been described for use in vaginal and laparoscopic hysterectomies [9–12]. Costs that should be considered when using a single-use radiofrequency device for a laparoscopic hysterectomy would be the purchase price of the single unit, the capital and amortized cost of the electrosurgical generator needed, and the cost of disposing of the instrument. Although some facilities "refurbish" these devices, this study focused on the cost as a single-use device.

Alternatively, at our hospital, if a reusable approach is chosen to perform a laparoscopic hysterectomy, a 5-mm Rotating Bipolar Forcep (RoBi; Karl Storz, Tuttlingen, Germany) is available that can desiccate vascular tissue, and a reusable 5-mm monopolar scissor (model 34425 mA, Karl Storz) that can transect tissue is also available. Costs that should be considered when using reusable instruments are the capital and amortized costs of the instruments, with cords, repairs, and cleaning, and processing during its theoretical 100-use lifetime, as well as the capital and amortized costs of the electrosurgical generator needed.

The purpose of this study was to determine if a single-use device that desiccates and cuts tissue during laparoscopic hysterectomy at an academic institution with resident physicians as first assistants could reduce operating room time and costs enough to justify its expense, when these and other intraoperative direct costs were compared between single-use and reusable devices.

Materials and Methods

This study was approved by the Institutional Review Board of both St. Louis University and St. Mary's Health Center. All women ages 18 years or older who presented for laparoscopic hysterectomy from March 2013 to September 2013 were asked to participate. They gave written consent to 1 of the 2 attending physicians (MBHS and PY) on the day of surgery. Both attending physicians have performed >500 laparoscopic hysterectomies. Exclusion criteria included age younger than 18 years, suspected malignancy, or if the first assistant was another attending physician, surgical assistant, or fellow. Inclusion criteria required a resident physician to be the first assistant.

We chose a unique study design in which each patient could serve as her own control, and the energy source used on each side of the uterus was randomized. We used the Ligasure 5-mm Blunt Tip LF1537, using the Force Triad Electrosurgical Generator (software version 3.5 on a 2-bar standard setting that was never adjusted) to desiccate and transect 1 "side" of the uterine attachments. For each pedicle, including the uterine artery that was secured at the level of the internal os, 2 applications using the Ligasure were applied before transecting with the mechanical blade. Two reusable devices were used to desiccate and transect the other side. The reusable RoBi 5-mm Forceps were used to desiccate tissue using the same Force Triad Electrosurgical Generator at a standard setting of 35 W for bipolar coagulation. The attending physician subjectively assessed if desiccation had been achieved by visual and tactile feedback. The reusable 5-mm monopolar scissors (model 34425 mA, Karl Storz), which is standard for any laparoscopic tray at our hospital, was used to transect tissues using the Force Triad Electrosurgical Generator, with a cutting current of 30 W. The uterine artery was always secured and transected at the level of the internal os. The attending physician always operated on the left side of the patient, and the resident operated on the right. The resident always completed their side first. We hoped that patients serving as their own controls would help control for other patient specific characteristics that could contribute to surgical difficulty (e.g., body mass index, uterine size, uterine shape, adhesions, and mobility).

Once consent was obtained before the start of the procedure, a blank, sealed, opaque envelope with paper inserts was randomly chosen after shuffling a container that held all of the envelopes. These sealed envelopes were kept in a locked office with the 30 inserts designated "reusable" and 30 inserts designated "disposable" (for the single-use device). If the insert with disposable was chosen, the attending physician used the single-use device. If the reusable insert was chosen, the attending physician used the reusable instrument approach.

At the start of the procedure, adhesiolysis was performed, and the anatomy was normalized when needed before the start of the hysterectomy and recording of the times of the procedure. A side was defined as desiccation and transection of all upper pedicles, starting with the utero-ovarian (start time), fallopian tube and round ligament, to the final transection of the uterine artery (stop time). Adnexa were removed after the hysterectomy when indicated; these were not included in our analysis. The anterior leaf of the broad ligament was reflected inferiorly on each side using the designated energy source only to skeletonize the uterine vessels and safely displace the bladder. The full development of the bladder flap was not recorded in either side time, because the stopwatch was stopped and restarted when this plane needed to be developed to protect the bladder. Time was recorded in seconds by a medical student or circulating nurse, and was not discussed with the surgeons during the procedure. Colpotomy time was not included in the analysis. Data were entered into a database by a resident physician (JM) and validated by the statistician (JG).

We considered the following costs of the single-use device (the Ligasure 5-mm Blunt Tip): the purchase price of the device ($630); the amortized cost of the Force Triad generator (software version 3.5); and the disposal fee of