Harmonic Shears Versus Conventional Suture in Abdominal Hysterectomy

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Abstract

Objective: The aim of this study was to compare the blood loss and operative time of abdominal hysterectomy using Harmonic Shears (HS) versus using conventional sutures.

Methods: We randomized 60 patients scheduled for abdominal hysterectomy into two equal groups, 30 patients each. Ultrasonic vessel sealer (The Ultracision System: UltraCision® harmonic scalpel, Smithfield, RI) was used as the method of hemostasis in one group, while conventional sutures was the hemostasis technique in the other group. Procedure time was defined as time from initial skin incision to closure of the skin wound. Blood loss was estimated by the anesthesia service. Statistical methodology included the Student t and Mann-Whitney’s U tests, and all comparisons were two tailed, with p<0.05 considered significant.

Results: The mean procedure time in the Ultracision vessel sealer group was 40.3 minutes (range 30–95) versus 55.6 minutes (range 40–160) for the suture group (p=0.003). Mean estimated blood loss was also statistically less with Ultracision vessel sealer group: 74.9mL (range 30–250) versus 139.4ml (range 50–650) for the suture group (p=0.005). There was no significant difference in complication in both techniques.

Conclusion: Ultrasonic vessel sealer seems to provide significant reduction in reduced operation time and blood loss. It could be an effective alternative to conventional sutures in abdominal hysterectomy. Further studies on larger number of patients are needed for a more solid evidence.

Key Words: Abdominal hysterectomy – Ultracision – Harmonic shears.

Introduction

HYSTERECTOMY is one of the most frequently performed operations in Gynecology [1,2]. trials to find cost- effective method for achieving safe and fast technique have never stopped [3].

Technological advances in hemostatic methodology have provided the surgeons with a number of alternative methods for achieving hemostasis. Surgical clips, staples, and sutures are among some of the mechanical means of vessel ligation, whereas high frequency electrosurgery, harmonic shears, and lasers represent the bulk of energy-based technologies at the surgeon’s disposal. Each modality has its strengths and weaknesses. All of the mechanical methods introduce foreign bodies into the patient and, perhaps with the exception of sutures, carry an increased cost [3-6].

High-frequency electrosurgery has traditionally been the workhorse in the operating room, and recent development of an electrosurgical bipolar vessel sealer (The LigaSure System; Valleylab, Boulder, CO) offers the vaginal surgeon a safe and effective alternative hemostatic method [6].

Ultrasonic technology [Harmonic shears (Ultracision)] has the ability to achieve hemostasis with limited collateral thermal damage or lateral spread, minimizing undesired injuries to adjacent sensitive structure e.g. ureters; however, it was only labeled for vessels up to 2mm in diameter, thereby restricting its application in many procedures. Modern ultrasonic shears were developed to deal with larger vessels up to 4mm diameter with safe hemostasis [7,8].

The objective of this trial was to compare procedure time and blood loss with the use of the Ultrasonic (Ultracision–Harmonic Shears) sealer versus conventional sutures during abdominal hysterectomy in a randomized, controlled fashion.

Patients and Methods

This study was a randomized clinical trial conducted in the Obstetrics and Gynecology Department, between March 2010 and January 2012. Seventy two patients were enrolled as potential candidates for the study. They suffered gynecolog-
ical symptoms that, in the opinion of the gynecologist, justified total abdominal hysterectomy. They all had previous failed conservative and/or medical treatment, and had completed their families. Nine patients refused to go for TAH despite failure of medical treatment, and three patients were found to have pelvic adhesions and/or endometriosis at time of surgery that was not diagnosed before operation. Only 60 patients fulfilled the preset criteria for inclusion in the study.

All patients didn’t have any history of previous pelvic operations or infections, and no history or clinical findings suggestive of extra-uterine disease (e.g. endometriosis, adnexal mass).

Candidates for total abdominal hysterectomy (TAH) were randomly divided into two groups. Group (I) one were assigned for TAH using the harmonic shears (HS), and Group (II) were assigned for TAH using the conventional suture technique for hemostasis. Each one of the two techniques used in the study was written in a card and was put in an envelope, the sixty envelopes were all identical. Serially numbered sealed envelopes were held securely by trained nurse. The circulating nurse was asked to pull any card just before preparation for surgery. The patients were aware of the treatment methods and possible operative techniques for surgery, and signed an informed consent, and they had equal chances of entering any of the trial groups.

All candidate patients were subjected to the following:
- Careful history taking.
- Physical examination.
- Abdominal examination.
- Vaginal examination
- Cervical Pap smear.
- Ultrasound examination.
- Investigations: Complete blood count, blood group, Coagulation profile, liver function tests, and renal function tests.

Procedure

Abdominal hysterectomy was performed in a standard fashion for both study groups by the same surgeon. The procedure was performed under general anesthesia, with the patient in supine position. A self retaining Foley’s catheter was fixed, and the abdominal field as well as vagina was cleaned. A transverse suprapubic incision was made and the underlying fascia and fat were cut transversely till the sheath was reached; the latter was cut transversely to expose the recti muscles, which were split apart bluntly exposing the parietal layer of the peritoneum. This was opened, and an initial tour by inspection and palpation of the pelvis was done. Wound was slit open to expose surgical field using retractors, bowel were packed up and away from pelvic organs and uterus.

The suture arm consisted of suture ligation employing a polyglycolic suture number (0) to all pedicles. This was preceded by double clamping, cutting, and suture transfixion of round ligament, infundibulo-pelvic ligaments, uterine vessels, and supra-vaginal part of the cardinal ligaments pedicles respectively. Bladder flap was cut by sharp scissors and dissected away from the uterus and upper vagina immediately after cutting of the round ligaments. Ovaries were not removed in both treatment arms of the study. Colpotomy was done, and uterus and cervix were excised. Vaginal stump was sutured using polyglycolic (0) sutures in a continuous locked technique for better hemostasis. Vaginal canal was left open for drainage.

The Ultracision (Harmonic Shears) device consists of a standard-size Heany-type clamp (The Ultracision System: UltraCision® harmonic scalpel, Smithfield, RI) connected to a central unit for production of the ultrasonic energy. Control of the system is obtained through pedals, and varies from maximum intensity for cutting and minimum intensity for coagulation. We used the minimum intensity for coagulation of vessels within the pedicles, till complete coagulation is obtained. For better hemostasis, we used to coagulate the pedicles in 2 adjacent sites, and cut in between with the same shears using the high (max) intensity power.

The clamp was used in exactly the same fashion as standard hysterectomy clamps. Pedicles are clamped, coagulated, and then cut on the uterine side before the clamp is released and advanced to the next pedicle. Pedicles were severed in exactly the same order as in suture group. Harmonic shears was used to open the vesico-uterine peritoneal flap, dissection of the bladder, and for colpotomy. Vaginal stump edges were not stitched by any sutures, as HS were used for arrest of any oozing of blood and hemostasis. Vaginal canal was left open for drainage.

Procedure time for the abdominal hysterectomy of all cases was measured from initial skin incision to complete closure of the skin.

Blood loss was estimated by the anesthesia service by observing the suction drainage reservoir, to guard against potential surgeon bias.
Additional data collected include, uterine weight, and postoperative morbidity. Postoperative complications were assessed by two follow-up clinic visits at weeks 2&4 after the procedure.

**Statistical methodology:**

Prior calculations indicated that a sample size of 30 subjects in each treatment arm would provide enough power and confidence to detect difference between both techniques. Data were collected and coded then entered into an IBM compatible computer, using the SPSS version 12 for Windows. Entered data were checked for accuracy then for normality, using Kolmogorov-Smirnov & Shapiro-Wilk tests.

Quantitative variables were expressed as median, mean and standard deviation. Independent samples t-test was used as a parametric test of significance for comparison between two sample means, after performing the Levene’s test for equality of variances. Independent samples Mann-Whitney’s U-test (or Z-test) was used as a non-parametric test of significance for comparison between two sample medians. All comparisons were two tailed, with a p value less than 0.05.

**Results**

The two groups were comparable in terms of age, parity, body mass index (BMI), and uterine weight (Table 1).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Ultracision (n=30)</th>
<th>Suture (n=30)</th>
<th>Statistical significance (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>45.1±8.4</td>
<td>48.4±9.6</td>
<td>0.62</td>
</tr>
<tr>
<td></td>
<td>(43.3 (39–69.5)</td>
<td>46.4 (38.5–73)</td>
<td></td>
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<tr>
<td>Parity</td>
<td>1.6±1.2</td>
<td>1.8±1.1</td>
<td>0.81</td>
</tr>
<tr>
<td></td>
<td>(5.0 (2–8)</td>
<td>5.0 (1–9)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.8±7.8</td>
<td>29.1±8.5</td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>(26.0 (20.1404)</td>
<td>27.8 (20.4–42.0)</td>
<td></td>
</tr>
<tr>
<td>Uterine mass (g)</td>
<td>252.3±217.2</td>
<td>26.8±223.1</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>(215 (154–450)</td>
<td>225.0 (165–665.0)</td>
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*BMI = Body mass index.
Age data normally distributed and analyzed with the Student t-test.
All other data analyzed with the nonparametric Mann-Whitney’s U-test

Total time for abdominal hysterectomy procedure was assessed. Use of harmonic shears (HS) resulted in shorter procedure time (Fig. 1). The mean abdominal hysterectomy procedure time for the (HS) arm was 40.3±19.7 minutes, versus 55.6±22.4 minutes for the suture arm (p=.003). Mean estimated blood loss was also statistically less in the (HS) arm: 74.9±56.7ml versus 139.4±118.4ml for the suture arm (p=.005) (Table 2, Fig. 2).

<table>
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<td>Procedure time (min)</td>
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<td>0.003</td>
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<tr>
<td></td>
<td>(37 (30–95)</td>
<td>50 (40–160)</td>
<td></td>
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<tr>
<td>Estimated blood loss (MI)</td>
<td>74.9±56.7</td>
<td>139.4±118.4</td>
<td>0.005</td>
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<tr>
<td></td>
<td>(60.0 (30–250)</td>
<td>150 (50–650)</td>
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All data analyzed with the Mann-Whitney’s U-test.

There were no cases of postoperative hemorrhage or return to the operating room in either arm of the trial. Three patients in the electrosurgical bipolar vessel sealer arm experienced cystitis treated with oral antibiotics. Two suture patient experienced vaginal infection treated with antibiotics according to culture and sensitivity test. A third patient in the suture arm was readmitted 11 days after surgery with a pelvic abscess. This was treated with antibiotics and percutaneous ultrasound guided drainage. Because of the small sample size, statistical significance of the difference in complications rates [three of 30 (10%) for Harmonic Sealer and three of 30 (10%) for the suture arm] cannot reliably be determined.
Discussion

Though there are multiple surgical approaches for hysterectomy for benign causes, abdominal hysterectomy is still the commonest technique used [1,2]. Abdominal hysterectomy has been associated with decreased costs as compared to laparoscopic hysterectomy [3], however, the latter provides shorter lengths of stay, and lower complication rates relative to abdominal hysterectomy [4]. Vaginal hysterectomy is another approach that provides safer option for hysterectomy, especially in obese patients, with less morbidity, cost, and hospital stay as compared to abdominal route [3-5]. Despite these positive reports, the abdominal approach continues to be performed in the vast majority of patients with proven pelvic pathology that preclude vaginal route [3,5].

Kovac devised a system of guidelines in 1995 to help in selection of the most appropriate route for hysterectomy. He and several others have demonstrated that the adoption of evidence-based practice guidelines offer the best route of hysterectomy to be chosen as each step of the algorithm requires an evidence demanding question that needs an appropriate answer before selecting the route of hysterectomy. This removes the possible inappropriate selection of a particular route of hysterectomy based upon a surgeon’s lack of expertise and preference [9].

Patients with morbid obesity and/or narrow deep pelvis continue to pose a surgical challenge. Placing sutures deep in the pelvis is difficult and often quite frustrating. Not only is it difficult to move the needle holder in these regions, but also accurately placing a stitch and retrieving the needle is problematic. These difficulties may lead to increased blood loss, and slipped ligatures as well as unnecessary rough manipulation of delicate pelvic structures [10,11]. Harmonic shears technology seems uniquely suited for surgery in such occasions. The surgical steps other than placement of suture are identical to those used during standard abdominal hysterectomy. Pedicles can be controlled rapidly and effectively with this device, virtually eliminating the need for sutures [12].

The most common energy technologies used in gynecologic surgeries are thermal energy devices, electro-coagulation, and the Harmonic ultrasonic energy devices. The advantages of the Harmonic devices compared with the other devices include less generation of heat and smoke, and the diminishing of some of the risks of electrical energy, such as arcing and coupling with minimal lateral spread of heat. This minimizes direct and indirect thermal insult to delicate vital pelvic structure e.g. ureters and bladder [12]. Both Ligasure and Ultracision (HS) are safe and effective for total laparoscopic hysterectomy. Ligasure is superior in the management of uterine vessels, while the Ultracision (HS) is more effective in opening the vesicle and separating the cardinal ligament [13].

Harmonic device seems to be more versatile than the other hemostatic devices. It’s not just a coagulator; it can also be used to cut, to grasp, and even to dissect structures. With the Harmonic device, surgeons can grasp tissue, seal it, and then it divides. With the HS, there’s an economy of motion because surgeons are not stopping to ask for an instrument to be passed back and forth because of the way the surgeon’s ability to grasp, to coagulate, and to cut with the HS coagulating Shears makes it a multipurpose instrument. Further, it allows surgeons to maintain their focus on the surgical field. The traditional method requires to use a needle, and it has to be the right size and placed in the needle holder, then apply the stitch, tie a square knot, and cut the suture at the correct length. This certainly adds time to the procedure [8,10,12].

These data explain the results obtained in this study. The mean operative time recorded for procedures done using HS, (45.1±8.4) minutes, was significantly shorter than that recorded for procedures done by conventional technique (48.4±9.6) minutes.

In the current study, use of Harmonic sealer resulted in a significant reduction in blood loss (p=0.05) when compared to conventional suture technique for hemostasis. The results were comparable to the similar study conducted by Barbara et al., comparing bipolar vessel sealer to conventional suture in TAH [8]. The principal and mechanics of Ligasure (electrothermal bipolar vessel sealer) instrument are not far from those used in HS technique. Single clamp, single hand approach as well as efficiency of the sealer to block and seal the vessels in stumps minimizes the risk of slipped ligature or bleeding stump. Our results are also comparable to reports of Carl Giesler and coworkers [12].

Conclusion:

This study concluded that the Harmonic Shears is a tool that seems to facilitate access, minimizes procedural time, and decreases blood loss relative
to conventional sutures technique for abdominal hysterectomy operations. This study is underpowered to reach a strong solid conclusion, and further studies on larger number of patients are still needed.

References


