

Comparative Analysis of Peri-Operative Outcomes Following Total Laparoscopic Hysterectomy with Conventional Bipolar-Electrosurgery versus High-Pressure Pulsed LigaSure Use

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Abstract

Objectives: Quick and effective hemostasis is essential for a successful laparoscopic surgery. Hence, it is of utmost importance for laparoscopic surgeons to understand the various available and emerging energy sources to tailor their use according to their properties and surgical requirement. The aim of this study was to compare LigaSure, an advanced bipolar versus conventional bipolar in total laparoscopic hysterectomy, with respect to operating time, mean blood loss, mean reduction in hemoglobin, intraoperative, and postoperative complications, and duration of prospective hospital stay.

Materials and Methods: It was a randomized controlled study. One hundred and twenty patients scheduled for elective hysterectomy for any benign indication were randomly allocated to two groups namely, conventional bipolar group and LigaSure group. Patients with a history of ≥ 3 laparotomies, uterine size >20 weeks were excluded. Total laparoscopic hysterectomy with bilateral salpingectomy/salpingo oophorectomy was done in all the patients and endpoints were evaluated.

Results: All the recruited participants ($n = 120$) achieved study endpoints. There was statistically significant difference in the meantime to dissect adnexal ligaments, primary and total operating time (for adnexal ligaments: Conventional bipolar-9.44 min vs. LigaSure-7.05 min; $P = 0.000$) (Primary: Conventional bipolar-97.03 min vs. LigaSure 74.39 min; $P = 0.000$) (Total: 142.5 min vs. 136.37 min $P = 0.002$). Mean blood loss (145 ml vs. 141.67 ml; $P = 0.846$), mean reduction in hemoglobin (0.802 versus 0.752; $P = 0.484$) and duration of postoperative stay (2.54 days vs. 2.32 days; $P = 0.128$) were comparable ($P > 0.05$). None of the participants suffered from any major complication during the surgery or in the postoperative recovery period.

Conclusion: With an ability to effectively reduce operating time, LigaSure is a safe and efficient instrument for laparoscopic hysterectomy.

Keywords: Blood loss, conventional bipolar, electrosurgery, hemostasis, hysterectomy, laparoscopic gynecologic surgery, LigaSure, operating time

INTRODUCTION

Hysterectomy is the second most commonly performed surgery in women worldwide, next only to cesarean section.^[1] According to Cochrane Database Review^[2] published in 2015 by Johnson *et al.*, in benign indications, Laparoscopic Hysterectomy is considered favorable to abdominal

hysterectomy due to lesser morbidity, early recovery, reduced hospitalization, and costs and improved quality of life. However, it is associated with a longer learning curve, especially with endosuturing. Energy sources serve to expedite the advanced laparoscopic surgeries, ensure

Article History:

Submitted: 06-Jan-2020

Revised: 14-Jul-2021

Accepted: 19-Aug-2021

Published: 04-May-2022

Access this article online

Quick Response Code:



Website:
www.e-gmit.com

DOI:
10.4103/GMIT.GMIT_69_20

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How to cite this article: Batra S, Bhardwaj P, Dagar M. Comparative analysis of peri-operative outcomes following total laparoscopic hysterectomy with conventional bipolar-electrosurgery versus high-pressure pulsed LigaSure use. Gynecol Minim Invasive Ther 2022;11:105-9.

adequate hemostasis, are safer to use, and reduce the learning curve for those who are not well versed with endosuturing. In addition, they ensure adequate hemostasis in minimal access surgery which can otherwise be a challenging task, especially while operating in self-contained spaces (e.g., pelvis).

There have been constant attempts to devise newer, more efficient energy sources and techniques, with a desire to come up with the most perfect device which can incorporate multiple functions into one, to reduce surgical time and instrument traffic without compromising on the quality of surgery and overall patient well-being. A range of review articles has been published comparing the various electrosurgical devices in our armamentarium, particularly monopolar, bipolar, and various advanced bipolar instruments.^[3,4]

The concept of electrocautery was first used by a French physicist, Becquerel in early 19th century. Direct current was used to generate heat in a wire which comes in direct contact with the tissue to cause hemostasis. Electrosurgery, which uses alternating current, came to the front due to efforts of Arsonoval in 1881.^[5,6] Electrosurgical systems use very high frequencies (>100 KHz) as compared to the standard electrical current that alternates at 60-Hertz. This is because the usual frequency of 60 cycles per sec would cause excessive neuromuscular stimulation in the body. Hence, a generator is used which converts the 60-Hertz current to over 200-KiloHertz, and at this frequency neuromuscular stimulation ceases, causing minimum risk of electrocution.^[5,6] Electrosurgical generators can produce different electrical waveforms. As the waveform changes, the corresponding tissue effects also change. Typically, electrosurgical waveforms can be of three different types: Pure cut waveform, pure coagulation and a blend, with different proportions and characteristics.

After the first use of high-frequency electric current for treatment in 1893, Bovie^[7,8] in 1928, organized a production of electrosurgical equipment and described three different effects of this energy type: Desiccation, dissection, and coagulation, which led to the establishment of fundamentals in modern electrosurgery and helped to advance diagnostic laparoscopy into operative.

Conventional bipolar isolates the tissue between the two electrodes, limiting stray current and injuries as seen with monopolar instruments. However, thermal spread does occur beyond its confines, ranging from 2 to 22 mm depending on the duration of application of current. LigaSure is an advanced bipolar instrument^[5] with a feedback – controlled response system which suspends the energy delivery when the seal cycle is completed.^[9,10] It seals vessels up to 7 mm in diameter and has less thermal spread. Maximum temperature during activation is below 100°C, thus reduces thermal spread to 1 mm with LS Precise and to 1.5 mm with LS V.^[11,12]

There have been many comparative clinical studies and three meta-analyses of the performance of laparoscopic energy sources in colectomy,^[13] cholecystectomy,^[14] and thyroidectomy. Several comparative trials of energy sources in gynecologic surgery^[8] have been done so far.^[15-20] However, only one literature could be found on the comparison of perioperative outcomes using LigaSure and conventional bipolar in total laparoscopic hysterectomy.^[21]

In our study, we intend to compare two of these energy sources, LigaSure and Conventional bipolar, with respect to intraoperative and postoperative outcomes in total laparoscopic hysterectomy.

MATERIALS AND METHODS

This randomized controlled study was conducted on consenting inpatients ($n = 120$) in a tertiary care hospital in South Asia. The participants underwent total laparoscopic hysterectomy under general anesthesia from January 2014 to December 2015. The sample size was calculated based on primary operating time, defined as time from initial skin incision to the separation of the uterus. With references from previous studies,^[21] the primary mean operating time was estimated around 120-min. We considered a difference of 20% operating time between LigaSure and conventional bipolar, which comes out to be 25-min, and assumed to be clinically relevant. Taking the mean of standard deviation time mentioned in various literatures, it is assumed to be 48-min. To achieve a power of 80% at 5% significance level, required sample size of 120 was taken.

An approval from the Institutional Review Board was taken for collection and scientific publication of personal data obtained from the patient (approval number: EC/03/14/646).

The target population in our study comprised female patients aged 35–65 years. The subjects were selected based on inclusion and exclusion criteria. The uterine size was limited corresponding to around 20 weeks. Patients with suspected malignancies, previous 3 or more surgeries, conversion to laparotomy, and those with concomitant surgeries were excluded from the study. The total duration of subject participation was 6 weeks, including a period of follow-up. The subjects were divided randomly into two equal groups of 60 each, using a computer based random number generator. Women who had given an informed written consent were allocated into the two groups. After admission and allocation, detailed history taking, and clinical examination was done. The baseline characteristics of selected patients were then recorded with regards to their demographic factors such as age and BMI along with the indication of surgery, general examination, and local examination findings. Predefined pro forma was filled for all the patients. After baseline investigations and preanesthetic assessment, patients were

taken up for the surgery. Ovarian conservation or removal was done, complying with the patient's wishes. Prophylactic bilateral salpingectomy was however, done in both the groups, keeping in mind the recent theories regarding tubal origin of primary serous ovarian/peritoneal cancers.^[22] All laparoscopic hysterectomies were performed by a single well trained and experienced specialist in minimally invasive gynecology, in a well-equipped operation theatre. In one group, LigaSure was used for dissection and hemostasis, whereas a conventional bipolar instrument was used in the other group. The steps for hysterectomy were standardized. The outcomes of interest included time to dissect adnexal ligaments, primary and total operating time, mean blood loss, intraoperative and postoperative complications and duration of postoperative stay.

Primary operating time was taken as the time from the first incision till complete detachment of the uterus to reduce the variation in time caused by morcellation. Total operating time was calculated from initial skin incision to final skin closure. For the assessment of intraoperative blood loss, amount of irrigation fluid left in the bottle after surgery was subtracted from the initial volume, and the volume of fluid used for irrigation was calculated. This number was subtracted from the volume of fluid collected in the suction bottle. Any accidental injury to bowel, bladder or ureter due to the choice of instrument was noted down. The presence of fever, drain output, duration of return of bowel activity, or status of bladder activity was noted down, on the day of discharge. Length of postoperative hospital stay was recorded from the day of operation to the day of discharge.

RESULTS

Both the groups were found comparable in terms of demographic statistics such as age, body mass index, presenting complaints, indication, history of medical treatment, uterine size, and use of morcellation, as enlisted in Table 1.

The main outcome measures in both the groups are tabulated in Table 2.

DISCUSSION

Safe and effective hemostasis is essential for a successful laparoscopic surgery. Excessive bleeding not only hampers the view but has also been found to be associated with an increased risk of urinary tract injuries and conversion to laparotomy.^[23] There have been rapid advancements in the field of electrosurgery to ensure safer, faster, and meticulous surgery. It is, hence, of utmost importance for laparoscopic surgeons to understand the various available and emerging

Table 1: The baseline characteristics in each of the groups

| Parameter | Conventional bipolar (n=60) | LigaSure (n=60) | P |
|--------------------------------------|-----------------------------|-----------------|-------|
| Mean age (years) | 49.33±6.144 | 48.80±6.449 | 0.993 |
| Common indications (%) | | | |
| Fibroid | 53.3 | 48.3 | |
| Adenomyosis | 23.3 | 20 | |
| BMI | 28.823±4.23 | 30.485±5.27 | 0.06 |
| Uterine size (weeks) | 12.867±2.815 | 13.067±3.85 | 0.914 |
| Number of previous laparotomy, n (%) | 21 (35) | 24 (40) | 0.774 |
| H/O medical treatment, n (%) | 32 (53.3) | 31 (51.7) | 0.855 |
| Morcellation done, n (%) | 18 (25) | 25 (41.7) | 0.813 |

BMI: Body mass index

Table 2: Results obtained in our study in the two groups

| Outcome measure | Conventional bipolar (n=60) | LigaSure (n=60) | P |
|--|-----------------------------|-----------------|-------|
| Mean time to dissect adnexal ligaments (min) | 9.4486±2.155 | 7.05±1.466 | 0.000 |
| Primary operating time (min) | 97.0319±13.425 | 74.388±11.84 | 0.000 |
| Total operating time (min) | 142.50 | 136.37±14.35 | 0.002 |
| Mean blood loss (ml) | 145±84.7 | 141.67±101.75 | 0.846 |
| Mean difference in hemoglobin | 0.802±0.41 | 0.752±0.35 | 0.484 |
| Duration of postoperative stay (days) | 2.54±0.988 | 2.32±0.560 | 0.128 |

energy sources to tailor their use according to their properties and surgical requirement.

The mean duration to dissect adnexal ligaments was 9.4486 min in bipolar group and 7.05 min in LigaSure group. The difference was found to be highly statistically significant ($P = 0.000$). Janssen *et al.*^[21] reported this parameter as the only statistically significant outcome measure in their study. In bipolar group, the mean primary operating time was 97.0319 min, whereas in LigaSure group was 74.388 min. This difference was also found to be highly statistically significant ($P = 0.000$) in our study. However, the primary operating time in study conducted by Janssen *et al.* was not statistically significant ($P = 0.39$) in their study. The rest of the studies calculated the mean operating time.

The average total operating time in bipolar group was 142.50 min whereas in LigaSure group, it was 136.37 min, and the difference was statistically significant ($P = 0.002$). Janssen *et al.*^[21] reported no significant difference in the total operating time in the study conducted by them ($P = 0.46$). Aytan *et al.*^[24] also did not find any statistically significant

difference in the three groups of Ligasure, Enseal and Halo PKS, with a *P* value of 0.73. However, their sample size was less, with 15 subjects in each of the three groups. The difference in mean operating time in the study conducted by Cho *et al.*^[25] comparing between Conventional and pulsed bipolar was statistically significant (*P* < 0.001). Lee *et al.*^[26] also found statistically significant reduction in total operating time with pulsed bipolar system when compared to conventional bipolar (*P* < 0.001). We found highly statistically significant difference in all three operating time recorded in the study. This could be due to highly efficient coagulation with cutting done by LigaSure, compared from conventional bipolar. Bipolar also requires instrument change, which adds on to the operating time. It sticks to the tissues, requires frequent cleaning, causes charring, and forms excess smoke plume. Due to lack of impedance matching, it requires repeated attempts and longer time to coagulate tissues effectively. All this could have contributed to the increase in operating time.

The mean blood loss in bipolar group was 145 ml and in LigaSure group was 141.67 ml. The difference was not found to be statistically significant (*P* = 0.846) in our study. This could be ascertained to the fact that we ligated uterine arteries bilaterally in all the patients. Suture ligation stands as a confounding factor in comparing the mean blood loss between the two groups in our study. The mean difference in hemoglobin was also not found to be statistically significant. (*P* = 0.06). This could be a reflection of the fact that we did not find statistically significant difference in blood loss between the two groups.

We had no intraoperative complications in any of the groups. One patient in LigaSure presented to us with abdominal distension on day 5 of surgery, which was managed conservatively. There was one episode of fever on day 7, which was diagnosed as dengue fever on investigations. There was no incidence of vault prolapse, fistula, or conversion to laparotomy. The difference was not found to be statistically significant (*P* > 0.05). The duration of postoperative stay was also statistically similar in the two groups (2.54 ± 0.988 days in BP vs. 2.32 ± 0.560 days in LS; *P* = 0.128). None of the aforementioned studies found any statistically significant difference in the duration of hospital stay.

CONCLUSION

Electrosurgical devices are being modified to perform laparoscopy for all types of surgeries, in a more efficient and safe manner. These instruments reduce tissue damage, have less lateral thermal spread, are less time consuming and may also serve to decrease postoperative adhesions and inflammation due to relatively less charring. The new

vessel sealing technologies have been so successful that they have largely made the need for laparoscopic suturing of vascular pedicles redundant. However, this also comes with high instrument cost.^[27] The ideal instrument of choice still remains to be the one that the surgeon is most comfortable with. Since the use of laparoscopy in gynecological surgeries is no more restricted to tertiary care centers, considering the cost factor associated with advanced electrosurgery, it is highly imperative to understand the physics and basics of electrosurgery, to be able to use the instruments logically, prevent complications as well as deal with them appropriately.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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