ORIGINAL ARTICLE

Efficacy and Safety of Electrothermal Bipolar Vessel Sealer vs ENSEAL in Total Laparoscopic Hysterectomy for Large Uterus: A Comparative Study in Mysuru, South India

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Abstract

Context: Hysterectomy is the most commonly performed gynecological procedure around the world. Hemostasis is of major concern in an enlarged uterus as chances of hemorrhage are more. New laparoscopic vessel sealing devices have been developed for laparoscopic tissue dissection and vessel sealing. In this study, an ALAN vessel sealer, an indigenous electrothermal bipolar vessel sealing device, is compared with ENSEAL device with respect to safety, efficacy, and perioperative outcomes in laparoscopic hysterectomy for a large uterus.

Aims and objectives: This study aimed to determine the efficacy and safety of electrothermal bipolar vessel sealer (ALAN vessel sealer) vs ENSEAL in total laparoscopic hysterectomy (TLH) for a large uterus.

Materials and methods: This prospective randomized case–control study included 100 women who underwent TLH for a large fibroid uterus. Of them, 50 women underwent TLH using ALAN vessel sealer, and the remaining 50 using ENSEAL. Efficacy, safety, and perioperative outcomes of both the groups were compared.

Statistical analysis: Statistical analysis was done using SPSS version 16.0 software. For evaluating continuous variables and discrete variables, independent T-tests, and Chi-square tests, respectively, were used.

Results: Duration of surgery in ALAN vessel sealer group was 56.90 ± 12.45 minutes and in ENSEAL group was 57.25 ± 13.54 minutes ($p = 0.9$) and mean blood loss in group A and group B was 111.40 ± 22.32 and 107.84 ± 20.33 mL, respectively ($p = 0.4$), both of the data were not statistically significant. No significant differences were noticed in the demographic characteristics, intraoperative, and postoperative complications between the two groups.

Conclusions: The ALAN vessel sealer is safe and as efficient as ENSEAL in decreasing blood loss and operative time when laparoscopic hysterectomy is performed for an enlarged uterus. It is cost-effective and a promising instrument for TLH in developing countries.

Keywords: Electrothermal vessel sealers, ENSEAL, Laparoscopic hysterectomy, Large uterus.

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Introduction

The study aimed to determine the efficacy and safety of electrothermal bipolar vessel sealer (ALAN vessel sealer) vs ENSEAL in total laparoscopic hysterectomy for large uterus.

Hysterectomy is the most commonly performed gynecological procedure around the world. Laparoscopic hysterectomy is a safe and efficient alternative to abdominal hysterectomy in managing benign gynecological conditions as it offers less blood loss, minimal postoperative discomfort, shorter duration of stay, faster convalescence, and fewer wound complications.[1]

Large uteri are always a technical challenge for laparoscopic surgery. Regardless of the surgical approach used, removal of an extremely large uterus is a challenge to surgeons. Most of the studies set the uterine weight of more than 500 gm as a large uterus. Giant myomas obstruct the pelvis and make the uterus extremely difficult to mobilize and manipulate. They also reduce the visibility of surrounding anatomy and impair the surgeon's ability to correctly develop spaces. Various studies have demonstrated increased intraoperative bleeding and postoperative complications when TLH is performed for a large uterus of more than 500 gm though few studies have also concluded that it is safe and feasible than laparotomy.[1,2]

Hemostasis is of major concern, especially in the enlarged uterus as chances of hemorrhage are more due to limited access to uterine vascular pedicles. In laparoscopic surgery, conventional mechanical hemostatic techniques like sutures or clips have almost completely been replaced by coagulation techniques using monopolar coagulation, bipolar coagulation, and ultrasonic instruments. These new electrosurgical devices have inbuilt tissue response generators, which provide computer-controlled feedback that senses tissue impedance, thereby allowing a consistently

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Fig. 1: ENSEAL generator

Fig. 3: ALAN generator

Fig. 2: ALAN vessel sealer hand instrument

defined bipolar sealing followed by dissection, thus giving better hemostasis even in a large uterus. They also have cost-saving properties as a result of decreased operative time, decreased use of postoperative analgesics, and shorter duration of stay. These devices have one major drawback that their instruments are disposable and are of economic concern.[3,4]

The ENSEAL device (NSEAL 535RE, Ethicon Endo-Surgery (Europe) GmbH) is used for laparoscopic tissue dissection and vessel sealing. It uses nanometer-sized particles embedded in a bipolar temperature coefficient matrix. The current flow is active only when the device jaws are closed. The nanoparticles embedded in them locally interrupt current flow to tissue when the temperature exceeds 100 °C, enabling sealing and transection to occur in a single step and also minimizing the thermal spread and tissue damage.

A new bipolar vessel sealing device (ALAN vessel sealer, Alan Electronic Systems Pvt. Ltd., Thane, Maharashtra, India), which is cost-effective as it is a reusable instrument, has been developed. This study aimed to compare the efficacy, safety, and perioperative outcomes of ALAN vessel sealer vs ENSEAL in laparoscopic hysterectomy for a large uterus of more than 12-week size (Figs 1 to 3).

Materials and Methods

This is a prospective randomized case–control study done at JSS Hospital, Mysuru, Karnataka including 100 women. Patients with fibroid uteri of size between 12 weeks and 28 weeks were included in the study. Patients with other indications for TLH were excluded.

Patients included in the study were subjected to detailed medical history check-ups and examination including abdominal, vaginal, and bimanual examination. Institutional Ethics Committee approval was obtained and after obtaining the informed consent from the participating patients, the data collected were included for statistical analysis.

All procedures were performed by a single surgeon. Out of 100 women, 50 women who underwent TLH using ALAN vessel sealer were considered in group A and the remaining 50 who underwent TLH using ENSEAL were considered in group B. Protocols for anesthesia, preoperative, and postoperative management were the same among all the patients. Patients were followed up once 2-, 4-, and 6-week after the surgery to look for any subsequent complications.

The ENSEAL device is designed for laparoscopic vessel sealing and tissue transection. The first electrode is integrated into the static lower jaw of the device and the second one in the movable upper jaw. The impedance of the nano-based material of the upper electrode depends on the temperature and is based on the tissue temperature; it regulates the energy output, thus not allowing the temperature to exceed 100°C. While moving the blade to the front position, the double T-shaped cutting blade located longitudinally in the instrument axis closes the jaws. The coagulation and cutting processes occur almost simultaneously, and the clamping force depends on the blade position in which the two jaws are substantially parallel in a closed position.

The ALAN vessel sealer uses a special type of bipolar current for tissue dissection. Lower tissue impedance is sensed by the machine following which it delivers a specially designed bipolar current for the dissection instrument, plasma bisector. The jaws of the plasma bisector are designed circularly, when the jaws are closed a very narrow portion of the plasma bisector comes in contact with the tissues. This enables the maximum concentration of current and rapid dissection of the tissues. The microplasma which is generated following the passage of dissection current rapidly vaporizes the tissue held between the jaws of the plasma bisector. Due to the

unique design and construction of the plasma bisector, the tissues close to the dissection area also get a small concentration of current, which helps provide better hemostasis and cut the tissues without causing any bleeding. Vessel sealing can be done with the same instrument by varying the pressure and applying a bipolar sealing current. But this sealing needs some expertise from the surgeon as this instrument is essentially designed for dissection.

As per the manufacturer's instructions, standard settings were maintained. Instruments were used for both vessel sealing and tissue transection.

All the subjects were administered required perioperative antibiotics and the standard approach for TLH was adopted. The patients were put in a lithotomy position. Foley's catheterization was done and then a uterine manipulator was inserted. Using one 10-mm and three 5-mm trocars and cannulas, abdominal access was obtained. The 10-mm port was introduced supraumbilical or 5 cm above the upper border of the uterus, whichever was higher. After creating pneumoperitoneum, both the pelvis and abdomen were inspected for any abnormalities interfering with the surgical approach. The site, size, and the number of myomas were assessed at the start of the procedure. Manipulation of a large uterus may be very difficult so a myoma screw was inserted through one of the 5-mm ports for uterus manipulation, wherever necessary.

Sequential bipolar sealing and transection of the round ligaments, bipolar sealing, and transection of the infundibulopelvic ligament in patients with risk-reducing salpingo-oophorectomy (RRSO) or utero-ovarian ligament and fallopian tube in patients without salpingo-oophorectomy, opening of the ureterovesical fold and mobilizing the bladder downwards, sealing and transection of bilateral uterine vessels were done using Alan vessel sealer in group A and ENSEAL in group B. Colpotomy was done using Alan vessel sealer in group A and monopolar hook in group B. Removal of the uterus was done by vaginal morcellation. Vaginal cuff closure was done by vaginal route. At the end of vault closure, the laparoscope was reintroduced to ensure adequate hemostasis.

Results

The patients with fibroid uterus of 12–28-week sizes were randomly allocated to undergo laparoscopic hysterectomy with either Alan vessel sealer or ENSEAL. All the procedures were done successfully by laparoscopy and no patient was converted to laparotomy in our study. The baseline patient characteristics including age, parity, BMI, and history of previous surgeries were found similar in both the groups and showed no statistical significance as depicted in Table 1.

The weight of the uterus was measured after the specimen retrieval following the surgery. The mean weight of the uterus in group A was 451.60 ± 150.39, and 447.80 + 154.87 g in group B, which was comparable between groups ($p = 0.9$) (Table 2).

Operative time was recorded from the transection of the first pedicle until the completion of colpotomy. It was noted that the duration of surgery in the ALAN vessel sealer group was 56.90 ± 12.45 minutes and in the ENSEAL group was 57.25 ± 13.54 minutes. Hence, there was an insignificant difference in the total time taken for surgery in both groups.

Blood loss in the intraoperative period was assessed by measuring the amount of blood in the suction apparatus minus the irrigation fluid. In group A, the mean blood loss was 111.40 ± 22.32 mL and in group B it was 107.84 ± 20.33 mL. There was no statistically significant blood loss between the groups ($p = 0.4$).

Table 1: Baseline and demographic characteristics

	Group-A (N = 50)	*Group-B (N = 50)*	*p-value*
Age, years (mean ± SD)	43.68 ± 5.35	45.06 ± 5.79	0.21
BMI* (mean ± SD)	25.37 ± 2.47	25.52 ± 2.25	0.21
Parity, *n*			
Nulli	3	3	0.7
Primi	5	3	
Multi	42	44	
History of previous surgeries, *n*			
None	43	45	0.73
Yes	7	5	

Group-A, ALAN vessel sealer; Group-B, ENSEAL; *BMI: body mass index

Table 2: Weight of the uterus in different groups

	Group-A	*Group-B*	*p-value*
Weight of uterus, *g* (mean ± SD)	451.60 ± 150.39	447.80 ± 154.87	0.9

Table 3: Intraoperative findings

	Group-A	*Group-B*	*p-value*
Blood loss, mL (mean ± SD)	111.40 ± 22.32	107.84 ± 20.33	0.4
Operative time, min (mean ± SD)	56.90 ± 12.45	57.25 ± 13.54	0.9
Complications			
Bowel injury	0	0	NA
Bladder injury	0	0	

Table 4: Postoperative findings

	Group-A	*Group-B*	*p-value*
Complications (*n*)			
Secondary hemorrhage	2	1	0.68
Leukorrhea/vault granulation	4	3	0.78
Vault dehiscence	0	0	NA
Bladder complications	1	1	NA
Bowel complications	0	0	NA

Intraoperative complications involving bladder or bowel were also noted in both groups (Table 3).

During the postoperative period, all the subjects were followed up with general, abdominal and vault examinations at 2-, 4-, and 6-week to look for complications. Two cases of secondary hemorrhage in the ALAN vessel sealer group and one case in ENSEAL group were noted. Leukorrhea or vault granulation was seen totally in seven cases, with 4 cases in group A, and 3 cases in group B. Bladder complications were one case in each group and were followed by an examination that reported them as vesicovaginal fistula. All the complications were similar in both the groups and were statistically insignificant as are depicted in Table 4.

Discussion

Laparoscopic hysterectomy has been the subject of controversy when it comes to the large uterus. Many studies have concluded

that TLH is a feasible and safe technique even in an enlarged uterus with various benefits and fewer intraoperative complications when compared to the open method. A seven-year-long study by Sinha et al. done in Mumbai, India concluded that TLH could be performed even in an enlarged uterus with no increase in complication rates and short-term recovery. Garry et al. did EVALUATE hysterectomy study in 2004, which noted that LH had a significantly higher risk of major complications and longer operative time but less postoperative pain, faster recovery when compared to open hysterectomy.[1,5]

Maintaining hemostasis is fundamental in all surgical procedures more so in minimally invasive surgery. The risk of hemorrhage is more especially in the enlarged uterus due to lack of exposure and distorted pelvic anatomy. Traditional methods of staples and clips have gradually been abandoned due to cost and technical difficulties. The evolution of laparoscopic hysterectomy is closely linked to continuous technological advancements in the visual and electrosurgical units. Various energy-based vessel sealing technologies have been introduced as these devices allow rapid sequential tissue and vessel sealing, coagulation and transection. These advanced bipolar vessel sealing devices have been widely used as they are easy to use, less time-consuming, and provide better hemostasis even in a large uterus where the risk of hemorrhage is greater.

The purpose of this randomized case–control study was to compare one such indigenous electrothermal bipolar vessel sealing device, ALAN vessel sealer with ENSEAL with respect to safety, efficacy, and perioperative outcomes in the enlarged uterus.

Before morcellation of an enlarged uterus, the blood supply to the uterus should preferably be controlled. Measures like pre-treatment with a gonadotropin-releasing hormone (GnRH) agonist may be necessary to induce uterine tissue shrinkage and decrease vascularity. Injection of dilute vasopressin solution around the largest myoma may also help control capillary bleeding. But none of these methods was used in our study.

In 1998, a multicenter randomized trial was done to compare LH vs TAH. Myoma being the most common indication in the trial, it was observed that blood loss was significantly less in the LH group compared to the TAH group.[6] The present study noted that mean blood loss in ALAN vessel sealer group and ENSEAL group was 111.40 ± 22.32 and 107.84 ± 20.33 mL, respectively. Both ENSEAL and ALAN vessel sealer devices have an inbuilt feedback system that determines the quantity of tissue being sealed and adjusts the strength of the current accordingly to provide a better hemostatic effect. Also in the ALAN vessel sealer group, tissues were held along the full length of the jaws during coagulation and only at the tip covering one-third of the jaw length while cutting, thereby ensuring precise cutting and minimizing blood loss.

A German study by Rothmund et al. compared ENSEAL with standard bipolar coagulation. It was noted that blood loss between both groups was not statistically significant. Another randomized prospective study by Aytan et al. compared LigaSure vs HALO PKS cutting forceps vs ENSEAL and noted more blood loss in the ENSEAL group compared to other groups.[3,7] Bicer et al. compared LigaSure vessel sealer both in small and large uterus subjects who underwent LH and noted that blood loss was more in the large uterus group but was not statistically significant.[8] In our study, the amount of blood loss was similar in both groups and was statistically insignificant ($p = 0.4$).

Mean operative time in group A was 56.90 ± 12.45 minutes and in group, B was 57.25 ± 13.54 minutes. Hence, there was no significant difference ($p = 0.9$) noted in the duration of surgery between the groups. A study by Aytan et al. also noted that operative time was the same in all three groups that used LigaSure, HALO PKS cutting forceps, and ENSEAL, respectively. Another prospective trial was done on 132 patients in Turkey by Yüksel et al. who compared the efficacy of LigaSure vs. ENSEAL and found that operative time was significantly more in ENSEAL group; however, no such differences were noted in the current study.[7,9]

The size of the uterus is an important factor in the occurrence of intraoperative hemorrhage and postoperative complications during a laparoscopic hysterectomy, especially with uterus weight >500 gm. Subjects with a history of prior gynecologic surgeries have an increased risk of complications due to adhesions. Kondu et al. did a retrospective evaluation of 38 patients with uterine weight >1000 g who underwent hysterectomies and reported no significant difference in both intra-op and post-op complications in the laparoscopic group compared to the open method group.[10]

Glaser et al. reported that the incidence of bowel and urinary tract injury during laparoscopic hysterectomy were 0.39 and 0.73–1.8%, respectively. Both the groups had no intraoperative complications in this study.[11] During the postoperative period, no cases were reported with bowel complications in our study but one case in each group reported developed bladder complications. Both the cases had a history of previous C-sections and were reported to have vesicovaginal fistulas, which were further managed by a urologist.

Secondary hemorrhage is a rare but life-threatening complication following TLH. Secondary hemorrhage was reported to occur more following TLH than other hysterectomy approaches in a retrospective observational study done at Paul's hospital, Kochi. Another study at the same center reported that cumulative incidence of secondary hemorrhage following TLH was 1.3%.[12,13] Large uterus size, excessive use of energy source, vaginal vault hematoma, or infection could be the possible factors. A total of three cases of secondary hemorrhage were detected in our study and were managed conservatively by vaginal packing and tranexamic acid.

Leukorrhea was seen in four cases in the Alan vessel sealer group and three cases in ENSEAL group as secondary to vault granulation, vaginal vault inflammation, or excessive tissue charring. All the cases were treated conservatively with a course of oral and local antibiotics. Vault dehiscence following TLH is an infrequent but devastating complication. Excessive use of thermal energy leading to tissue necrosis and devascularization was attributed to being a possible cause. Hur et al. reported that vault dehiscence was more following TLH and suggested the use of laparoscopic scissors over thermal energy.[14] No case was reported to have vault dehiscence in this study.

Postoperative complications were similar in both the groups and no statistical difference was observed in our study. Katherine et al. also observed no significant difference in the complication rate in subjects who underwent laparoscopic hysterectomy regardless of uterine weight.[15] The study by Bicer et al. who compared LigaSure in both small and large uteri also reported no significant difference in the minor and major complications between the groups and their finding was on par with the current study.[8]

The capital investment and running cost of these vessel sealer devices are of economic concern as they have disposable hand instruments but ALAN vessel sealer is less expensive due to its

reusable hand instruments. With adequate training and proper technique, these devices can also be used in TLH even in an enlarged uterus. Thus patients could benefit from all the advantages of minimally invasive surgery.

Conclusion

Laparoscopic hysterectomy is a safer alternative to open hysterectomy even in a large uterus. The ALAN vessel sealer is comparably safe and as efficient as ENSEAL. It is more cost-effective with its reusable hand instruments; hence, could be a promising instrument for patients undergoing laparoscopic hysterectomy in developing countries like India.

Ethical Approval

Institutional ethics committee approval has been taken.

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