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Comparison Of Efficiency And Safety Of Ligasure Vessel Sealing System For Securing Pedicles During Abdominal Hysterectomy With Conventional Method.

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Abstract
Background*: Abdominal hysterectomy (AH) is one of the most common gynaecological surgical procedures performed worldwide in the treatment of benign gynaecological diseases. During the past few years, a variety of energy based techniques for vessel ligation have been developed. LigaSure has the potential to replace the use of conventional suture ligature within a broad range of surgical procedures, also including removal of the uterus*
Aim*: To compare the efficiency and safety of LigaSure vessel sealing system for securing pedicles during abdominal hysterectomy with conventional method of securing the pedicles by suture ligation.*
Methods*: This was a comparative study done in women undergoing abdominal hysterectomy in Department of Obstetrics and Gynaecology, SMS Medical College and attached groups of hospitals, Jaipur from November 2022 to April 2023.*
Results*: The operative time was significantly higher in conventional clamp group (46.60 min) as compared to LigaSure group (38.60 min). The mean blood loss was significantly less in LigaSure group (50.15 ml) as compared to conventional clamp group (95.50 ml). Excessive intraoperative haemorrhage was seen in 4 (10%) cases in LigaSure group and in 2(5%) cases in conventional clamp group. The mean number of sutures used in LigaSure group was 3.32 ± 0.63 and in conventional group was 5.24. In LigaSure group 2 cases had fever, 1 case had UTI after surgery and in conventional clamp group 3 cases had fever, 2 cases had UTI after surgery. The pain score wise difference in both the groups was found to be statistically significant (p-value=0.001). Mean pain score was 7.14 at 12 hrs, 6.48 at 24 hrs, 5.66 at 36 hrs, 4.55 hrs at 48 hrs in LigaSure group whereas it was 8.18 at 12 hrs, 7.48 at 48 hrs, 6.68 at 36 hrs, 5.36 at 48 hrs in conventional clamp group. The mean change in haemoglobin in LigaSure group was significantly lower (0.70gm) than in conventional clamp group (1.34gm). The mean number of days of hospitalization in LigaSure group was 6.00 days and in conventional group was 6.62 days.*
Conclusion*: LigaSure is more efficient and safer method of vessel ligation than conventional suture ligation method in doing abdominal hysterectomy as it has lesser operative time, lesser intraoperative bleeding, lesser requirement of sutures, lesser postoperative pain and lesser postoperative hospital stay.*
Keywords: *Abdominal hysterectomy (AH), conventional, LigaSure*

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I.Introduction

Abdominal hysterectomy (AH) is one of the most common gynaecological surgical procedures performed worldwide in the treatment of benign gynaecological diseases. However, AH as the most invasive procedure, is associated with some limitations such as abdominal trauma, intraoperative and postoperative complications, and slow postoperative recovery.[1]

Surgical haemostasis can be secured by a variety of methods, including mechanical means (sutures, clips or Staples) or by vessel coagulation (high frequency electrocautery, ultrasound or laser). Electro-coagulation diathermy is unreliable for vessels larger than 2 mm in diameter. Therefore, suture ligation is preferred for securing larger vascular pedicles. However, it can be time consuming as the pedicles need to be clamped, cut and ligated[2].

LigaSure is a new haemostatic system that is able to seal vessels up to7 mm in diameter and is based on the combination of pressure and bipolar electrical. This device causes permanent fusion of the vascular layers and obliteration of the lumen as it delivers a controlled high power current at low voltage to melt the collagen and elastin within the tissue. The collagen and elastin within the tissue reform to make a 'seal zone' which appears as a translucent area and has plastic resistance to deformation[2].

The purpose of this study is to find an efficient and safe surgical technique of ligating stumps in abdominal hysterectomy and to compare the efficiency and safety of LigaSure vessel sealing system for securing pedicles during abdominal hysterectomy with conventional method.

II.Material and Methods

This comparative prospective study was carried out on 80 women undergoing abdominal hysterectomy under Department of obstetrics and gynaecology Sms medical College and attached hospitals. A total 80 women undergoing abdominal hysterectomy were selected on basis of inclusion and exclusion criteria. Written and informed consent of the patient was taken prior to study. Institute review board and ethical committee approval was taken.

Study Design : Prospective Comparative Study

Sample Size: 80 patients

Subjects and Selection method: The study population was drawn from women who presented to the OPD with benign gynecological diseases and were planned for total abdominal hysterectomy from November 2022 to April 2023. Total of 80 patients were studied and were distributed randomly as 40 in each group: in Group-A hysterectomy was done by using LigaSure and Group-B hysterectomy was done by conventional method.

Inclusion Criteria

1. Women between age group 45-55 years.
2. BMI: 18.5-29.99 kg/m2.
3. Uterus size <10 weeks with no prior abdominal surgery.
4. Planned for Abdominal hysterectomy under spinal anaesthesia.
5. Patient willing to give consent & participate in study.

Exclusion Criteria

1. Medical co-morbidities
2. Patients unfit for Spinal anaesthesia
3. Immunocompromised states eg HIV

Procedure and methodology

After obtaining written informed consent Patients admitted for total abdominal hysterectomy were evaluated and randomly allocated group A or group B .Injection hyperbaric bupivacaine 10mg was used for spinal anaesthesia in all the patients. After painting and draping, abdomen was opened using pfannenstiel incision deep till general peritoneal cavity. Uterus and bilateral adenexa were identified.

In group A we used LigaSure vessel sealing system for securing pedicles whereas in group B stumps were secured by conventional method using Polyglactin 910 no. 1 suture. Vault was then closed by continuous interlocking Polyglactin 910 no. 1 suture in both the groups.

In both the groups parietal peritoneum was closed by using Polyglactin 910 no.2-0 sutures, muscle was closed by interrupted sutures with Polyglactin 910 no. 2-0, rectus sheath by continuous suture with Polyglactin 910 no.1-0 and skin was closed by subcutaneous suture with Polyglactin 910 no. 1-0. Intraoperative parameters and postoperative condition of women were assessed and recorded as per Proforma. To control inter-observer variability same surgeon, same anaesthetist and same drugs during and after surgery were prescribed.

Intraoperative parameters

• Time from skin incision to closure was noted.
• Vital parameters like pulse, blood pressure and temperature were noted and recorded.
• Blood loss was assessed by weighing the dry and soaked mops preoperatively and postoperatively respectively and adding the blood in suction jar.
• Preoperative and postoperative (after 48 hrs) haemoglobin was done of all women and difference in haemoglobin was noted.
• Any complications during surgery were noted.

Post-operative condition

Post-operative condition was noted. Post-operative antibiotics used in all women were Injection Ceftriaxone (Ig IV AST 12 hourly), Injection Amikacin 500 mg IV 12 hourly and Injection Metronidazole 500 mg in 100 cc solution IV 8 hourly. Injection Diclofenac sodium 75 gm was administered IM 8 hourly for first 48 hours. Post-operative subjective pain scoring was done with visual analogue scale which consists of numerical

pain rating scale using a 10 cm line with the numbers ranging from 0-10 Numeric intensity scale. Patient was made to understand the significance of number and asked to point out number that corresponds to the level of pain severity which they were experiencing. Pain score was assessed 12 hourly for first 48 hours. Presence of fever, nausea, vomiting, pain, haemorrhage, vault hematoma, abscess, urinary problems were noted in each group.

Statistical Analysis

Continuous variables were summarized as mean and were analyzed by using unpaired t test. Nominal / categorical variables were summarized as proportions and were analyzed by using chi-square/ Fischer exact test. P-value <0.05 was taken as significant.

III.Result

As observed in Table 1, the mean age of LigaSure group was 48.24 ± 1.92 yrs and in conventional clamp group was 47.72 ± 1.83 yrs. The age wise difference between both groups found statistically insignificant (p value = 1.72) The mean BMI in LigaSure group was 22.78 ± 1.88 kg/m2 and in conventional group was 22.86 ± 1.87 kg/m2. The BMI wise difference between both groups was found to be statistically insignificant (p-value=0.835).

In our study duration of surgery was <60 min in 40 (100%) patients in LigaSure group whereas it was <60 min in 38 patients and ≥60 min in 2 patients in conventional clamp group. Findings in table 2 shows that the mean operative time was significantly higher in conventional clamp group (46.60 ± 6.58) minutes as compared to LigaSure group (38.60 min ±4.59) minutes.

In our study total number of sutures used in LigaSure group was 3 in 22 (55%) patients, ≥4 in 15 (37.5%) patients and 2 in 3(7.5%) patients whereas in conventional clamp group it was ≥4 in 40 (100%) of patients.The mean number of sutures used in LigaSure group was 3.32 ± 0.63 and in conventional group was 5.24 ±0.69. The number of suture wise difference in both the group was found to be statistically significant (p-value=0.001).

In our study 29 (72.5%) women had 51-100 ml blood loss & 11 (27.5%) women had 30-50 ml blood loss in LigaSure group whereas 40 (100%) women had 51-100 ml blood loss in conventional clamp group. The mean blood loss in LigaSure group was 50.15 ± 11.30 ml & in conventional clamp group was 95.50 ± 10.86 ml. The blood loss wise difference in both the groups was statistically significant (p-value=0.001).

As observed in Table 3 in LigaSure group 2 cases had fever, 1 case had UTI after surgery and in conventional clamp group 3 cases had fever, 2 cases had UTI after surgery.

The pain score wise difference in both the groups was found to be statistically significant (p-value=0.001). Mean pain score was 7.14 ± 0.73 at 12 hrs, 6.48 ± 0.52 at 24 hrs, 5.66 ± 0.64 at 36 Hrs, 4.55 ± 0.58 hrs at 48 hrs in LigaSure group whereas it was 8.18 ± 0.80 at 12 hrs, 7.48 ± 0.54 at 48 hrs, 6.68 ± 0.47 at 36 hrs, 5.36 ± 0.56 at 48 hrs in conventional clamp group. The mean change in Hb in LigaSure group was 0.70 ± 0.39 gm% and in conventional clamp group was 1.34 ± 0.41 gm%. The difference in both the group was statistically significant (p-value=0.001).

In our study 35 (87.5%) patients were hospitalized for <7 days and 5 (12.5%) were hospitalized for ≥7 days in LigaSure group whereas 26(65%) patients were hospitalized for <7 days & 14 (35%) were hospitalized for ≥7 days in conventional clamp group. Table 4 shows that the mean number of days of hospitalization in LigaSure group was 6.00 ± 0.64 days and in conventional group was 6.62 ± 0.64 days which was statistically insignificant (p-value=0.124).

Table 1: Distribution of Cases According To Demographic Features.

	Group A	Group B	t-value	p-value
Age (in yrs) Mean ± SD	48.24 ± 1.92 yrs	47.72 ± 1.83 yrs.	1.37	1.72
BMI (in kg/m2) Mean ± SD	22.78 ± 1.88 kg/m2	22.86 ± 1.87 kg/m2	0.208	0.835

Table 2: Comparison Of Intraoperative Parameter

	Group A	Group B	t-value	p-value
Duration of Surgery (in minutes) Mean ± SD	38.60 ± 4.59	46.60 ± 6.58)	6.81	0.001
Number of Suture Used Mean ± SD	3.32 ± 0.63	5.24 ± 0.69	14.51	0.001
Blood Loss (in ml) Mean ± SD	50.15 ± 11.30	95.50 ± 10.86	17.07	0.001

Table 3: Distribution of Cases According to Postoperative Parameter

	Group A		Group B	
Postoperative Complications				
	No.	%	No.	%
Fever	2	5	3	7.5
UTI	1	2.5	2	5
None	37	92.5	35	87.5
Total	40	100	40	100
Pain score	Group A	Group B	t-value	p-value
At 12 hrs	8.18 ± 0.80	7.14 ± 0.73	6.79	0.001
At 24 hrs	7.48 ± 0.54	6.48 ± 0.52	9.01	0.001
At 36 hrs	6.68 ± 0.47	5.66 ± 0.64	11.04	0.001
At 48 hrs	5.36 ± 0.56	4.55 ± 0.58	7.76	0.001
Mean drop in Hb (in gm%)	0.70 ± 0.39	1.34 ± 0.41	5.74	0.001

Table 4 : Distribution of Cases According to Mean Number of Hospitalization Days in Postoperative Period

Number of Hospitalization Days in Postoperative Period	Group A	Group B	t-value	p-value
Mean ± SD	6.00 ± 0.64	6.62 ± 0.64	1.55	0.124

IV.Discussion

In our study mean operative time was significantly less in LigaSure group compared to conventional suture group. In a study conducted by Suprasongsin C et al[4], they found that the mean operative time in conventional suture group was 92.3, SD 26.54 minutes which was significantly higher than the electrosurgical bipolar vessel sealing (biclamp group) 70.03, SD 21.06 minutes ($p<0.001$). In another study conducted by Kyo S et al[5] they found that compared with the conventional suture group, the patients in the LigaSure group had a significantly shorter operation time (mean, LigaSure 242.8 ± 36.1 minutes vs conventional, 349.1 ± 82.6) minutes; $p < 0.001$). In a study conducted by Singh H et al it[6] was found that 66% of patients in LigaSure group had duration of surgery that was less than an hour in spite of associated comorbidities.

In a study conducted by Singh H et al[6] more no (76%) of patients in LigaSure group had significantly Less blood loss (<50 ml) as compared to 60% of patients in conventional clamp group and not a single patient required intraoperative or postoperative blood transfusion in LigaSure group. In a study conducted by Suprasongsin C et al[4] it was found that mean intraoperative blood loss in conventional suture group was 357, SD 245.34 ml versus 248.33, SD 154.52 ml for Biclamp group ($p =0.04$). In another study conducted by Kyo S et al [5] it was found that compared with the conventional suture group, the patients in the LigaSure group had lower blood loss (mean, 583.1 ± 287.6 mL vs 999.0 ± 524.2 mL; $p < 0.005$). Only 1 (0.06%) of the 18 patients in the LigaSure group was transfused, whereas 27 (40.2%) of the 67 patients in the conventional suture group were transfused. Because transfusion requirements may be affected by the surgeon's bias, they compared blood loss among untransfused patients and found that the LigaSure group still had significantly lower blood loss than the conventional suture group (mean, 550.9 ± 233.1 mL vs 745.49.0 ± 230.4 mL; $p < 0.01$). Haemoglobin level reduction after surgery in untransfused patients was significantly lower in the LigaSure group than in the conventional suture group (mean, 2.31 ± 2.22 mg/dL vs 3.22 ± 1.11 mg/dL; $p < 0.05$). Findings in our study were consistent with the above studies in terms of less mean intraoperative blood loss and less mean drop in haemoglobin in LigaSure group compared to conventional group. These findings indicate that the LigaSure vessel sealing system is useful to reduce blood loss and shorten operating time.

In our study the number of suture wise difference in both the group was found to be statistically significant (p-value=0.001). The mean number of sutures used in LigaSure group were significantly lower than in conventional group. In study conducted by Suprasongsin C et al[4] it was found that the requirement of surgical sutures was highly significantly lower in BiClamp group than in conventional suture group (mean 7.27 units versus 10.77 units, $p<0.001$). In another study conducted by Singh H et al[6] it was found that only one suture was used in 80% of patients in LigaSure group while in conventional clamp group all of the patients required more than one suture from stumps to vault, thereby reducing the cost of surgery in LigaSure group.

In our study the pain score wise difference in both the groups was found to be statistically significant (p-value=0.001). Mean pain score was significantly lower in LigaSure group in first 48hours compared to

theconventional clamp group. In a study conducted by Lakeman M et al[7] it was found that during the first 3 postoperative days, patients operated on using vessel sealing had statistically significantly lower pain scores. In yet another study conducted by Suprasongsin C et al[4] it was found that postoperative pain was no different between the two groups in the first 12 hours after surgery but highly significant lower in the BiClamp group than in the conventional suture group at 24 hours after surgery.

V. Conclusion

In this study we conclude that LigaSure is more efficient and safer than conventional suture ligation method in doing abdominal hysterectomy as it has several advantages in terms of less operative time, less intraoperative bleeding, less number of sutures, less postoperative pain and less postoperative hospital stay.

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