

Usefulness of Vascular Clips in Surgery for Gynecologic Cancer

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Research Article

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Abstract

In gynecological surgery for cervical cancer and endometrial cancer with lymphadenectomy, many lymph vessels are ligated to prevent postoperative lymph leakage and lymphocele, and many blood vessels leading to the pelvic floor are ligated. Therefore, the labors required for ligation are very large. However, no studies have examined ligation methods in gynecologic cancer surgery. Therefore, we retrospectively examined gynecologic cancer patients who had been treated at our hospital by dividing them into a group using absorbent threads and a group using titanium clips. In addition, the surgical procedure was classified into three groups: a group with only pelvic lymphadenectomy, a group with pelvic and para-aortic lymphadenectomy, and a group with radical hysterectomy with pelvic lymphadenectomy. As a result, analysis of all cases clearly showed less complications and less time for surgery in the clip group. Furthermore, the analysis of RH + PLN group showed that surgery time was clearly shorter and less complications tended to occur in the clip group. In conclusion, by using this easily usable device, surgery for gynecologic malignancies will be more comfortable and safer.

1. Introduction

In recent years, minimally invasive surgery such as laparoscopic surgery and robotic surgery has become the main trend in research on surgery for endometrial cancer and cervical cancer¹. But it is still difficult for developing countries or hospitals without top facilities, and therefore it is necessary to improve the level of surgical technique by laparotomy^{2,3,4,5}. Furthermore, because of the denial of the laparoscopic approach compared to the laparotomy for cervical cancer in the LACC trial reaffirmed the importance of radical hysterectomy with the laparotomy approach⁶.

In the surgical operation of lymphadenectomy performed as a part of radical surgery for endometrial cancer and cervical cancer, ligation of lymphatic vessels has long been performed using absorbent thread in our hospital to prevent postoperative lymphatic leakage and lymphocele. However, the burden of labor and time were non-negligible amount for the surgeon due to frequent ligation⁷. In addition, especially in deep pelvic procedures such as deep uterine vein ligation, ligation must be performed in a narrow space, which often makes it difficult to control unexpected bleeding^{8,9}.

On the other hand, the vascular ligation clip device can send titanium or absorbent clips to the surgical field to ligate thin blood vessels or lymphatic vessels with a short action¹⁰. Although this vascular clip is widely used in various surgical fields^{11,12,13,14,15}, there are few research reports on gynecological surgery.

We searched for articles with the query "((clip) OR (metallic clip) OR (titanium clip)) AND (gynecology)" in Pubmed, and we found only one manuscript on clips related to gynecological surgery: Comparison of Absorbent Clips and Titanium Clips¹⁶.

Therefore, in order to verify the effectiveness of using clips in gynecologic surgery, we retrospectively examined information on gynecologic cancer patients treated at our hospital.

2. Material & Method

2.1 Ethical approval

Written informed consent was obtained from all patients. In addition, approval was obtained from the Ethics Committee of the Nippon Medical School Chiba Hokusoh Hospital (approval number: 893).

2.2 Patient history

From April 2019 to December 2020, 48 patients who underwent surgery including lymphadenectomy for the diagnosis of cervical cancer or endometrial cancer were retrospectively examined. The classification of the cases was cervical cancer in 24 cases and endometrial cancer in 24 cases. 12 patients underwent only pelvic lymphadenectomy, 12 patients underwent pelvic lymphadenectomy and para-aortic lymphadenectomy, and 24 patients underwent radical hysterectomy and pelvic lymphadenectomy.

2.3 Study design

We retrospectively examined 48 patients with cervical cancer and endometrial cancer who were treated at the Nippon Medical School Chiba Hokusoh Hospital from April 2019 to December 2020. Patients were divided into two groups: those who used absorbent threads for intraoperative lymphatic and vascular ligation (thread group) and those who used clips (clip group). Table 1 summarizes the age, BMI, surgery time and blood loss of all patients. Regarding the occurrence of lymphedema, only those in the early postoperative period (1 month after the operation) were analyzed. Lymphedemas were diagnosed by the nurse or the doctor who received special education on lymphedema. Below, the group of patients with endometrial cancer who underwent total hysterectomy + bilateral salpingo-oophorectomy + pelvic lymphadenectomy is defined as the PLN group. The group of patients who underwent total hysterectomy + bilateral salpingo-oophorectomy + pelvic lymphadenectomy + para-aortic lymphadenectomy is referred to as the PLN + PAN group, and the group of patients who underwent radical hysterectomy + pelvic lymphadenectomy for cervical cancer is referred to as the RH + PLN group.

2.4 Statistical analysis

Continuous variables are shown as means and standard deviations; these data were compared using Student t test or the Mann-Whitney U test. The Fisher's exact test was used to analyze the occurrence of postoperative recurrence and intraoperative complications associated with the clips.

All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of the R commander, which is designed to add statistical functions that are frequently used in biostatistics¹⁷. All tests were 2-tailed, and the threshold for significance was $P < .05$.

2.5 Surgical procedure

The extent of lymphadenectomy in endometrial cancer cases was determined using the method of Imai et al¹⁸. That is, patients with score 0 are not administered lymphadenectomy, patients with score 1-2 are administered only pelvic lymphadenectomy, and patients with score 3-4 is pelvic lymphadenectomy and para-aortic lymphadenectomy. All patients with cervical cancer underwent nerve-conserving radical hysterectomy with pelvic lymphadenectomy (type C1 radical hysterectomy)¹⁹. Pelvic and para-aortic lymph nodes were removed as en bloc as possible. The cranial and foot ends of the lymph vessels were ligated with absorbent threads or clips to prevent postoperative complications of lymphatic leakage and lymphocele.

2.6 Surgical instruments

In the thread group, 2-0 COATED VICRYL PLUS VIOLET 12X18 "TIE (Ethicon, Inc. Somerville, New Jersey, USA) was used for ligation. In the clip group, LIGACLIP® EXTRA Ligating Clips (Ethicon, Inc. Somerville, New Jersey, USA) was used in 15 cases, and Premium Surgiclip™ II Clip Applier (Covidien, Dublin, Ireland) was used in 9 cases. For intraoperative vascular and lymphatic vessel amputations, the vascular sealing system LigaSure™ Maryland 23 NC (Medtronic plc, Dublin, Ireland) was used.

3. Results

3.1 All cases

There were 24 cases in clip group and 24 cases in thread group. There was no difference in age, BMI, frequency of lymphedema, blood loss, or recurrence rate, statistically (Table 1). Totally eight intraoperative or postoperative complications occurred. The breakdown was lymphocele in 1 case, left obturator nerve injury in 1 case, ureteral injury in 2 cases, femoral nerve palsy in 2 cases, bladder injury in 1 case, and cellulitis in 1 case. 7 complications were occurred in the thread group, and one in the clip group.

There were significantly fewer complications and shorter surgery time in the clip group. The amount of blood loss and the surgery time were correlated (Spearman's rank correlation coefficient 0.507 P value = 0.000233).

3.2 PLN

There were 6 cases in clip group and 6 cases in thread group. There were no significant differences in BMI, age, surgery time, blood loss, recurrence and incidence of lymphocele. Blood loss and surgery time were correlated (Spearman's rank correlation coefficient = 0.61, 95% confidence interval 0.0563-0.877, P value = 0.035).

3.3 PLN+PAN

There were 8 cases in clip group and 4 cases in thread group. There were no significant differences in BMI, age, surgery time, blood loss, recurrence, and lymphocele incidence. Blood loss and surgery time

were not correlated (Spearman's rank correlation coefficient 0.531 P-value = 0.0793).

3.4 RH+PLN

There were 10 cases in clip group and 14 cases in thread group. As shown in Table 4, the surgery time was significantly shorter in the clip group. There were no significant differences in BMI, age, blood loss or incidence of lymphocele. The thread group tended to have more complications. Blood loss and surgery time were not correlated (Spearman's rank correlation coefficient 0.338 P-value = 0.107).

4. Discussion

We got two important clinical implications in this study.

First, in the analysis of all cases, the clip group represented less complications and shorter surgery time. Second, the analysis of the RH + PLN group showed that the clip group tended to have fewer complications and the surgery time was significantly shorter.

First, in the analysis of all cases, there were significantly few complications in the clip group, the surgery time was significantly short (Table 1). The surgery time was shorter by 36.7 minutes in clip group. In the surgical procedures, we often use one set of clips (30 shots) in PLN alone, and two sets of clips (60 shots) in PLN + PAN and RH + PLN. This corresponds to 30 and 60 suture ligations (absorption sutures and cuts) in the thread group, respectively. The time difference required for one action accumulated, which probably led to a reduction in the total surgery time. There was no difference in recurrence rates, so there should be no need to worry about different surgical procedures affecting prognosis. The incidence of complications, the most important outcome for patients, were significantly lower in the clip group, so clips should be actively used for gynecological surgery with lymphadenectomy.

Second, in the examination of individual groups based on lymphadenectomy and differences in surgical procedures, analysis of the RH + PLN group showed that the clip group had significantly shorter surgery time of approximately 1 hour, and tended to have fewer complications (Table 2).

The most important difference of surgical procedure between PLN group / PLN + PAN group and RH + PLN is the amount of vascular ligation to the deep uterine veins and other blood vessels. The results of the PLN group and the PLN + PAN group did not demonstrate the benefits of clips during surgical procedures for lymphadenectomy alone. Therefore, clips may be the most effective in ligating blood vessels around the uterus in RH + PLN surgery. As the amount of bleeding and the surgery time are not related, this group is considered to be the most beneficial procedure to use the clip.

So far, no studies have examined the usefulness of titanium clips in gynecological surgery involving lymphadenectomy. Regarding the occurrence of complications, only 2 patients in the thread group had postoperative pelvic lymphocele in the PLN group, but there was no significant difference from the clip group. Therefore, there is no need to worry about the incidence of lymphocele and lymphedema due to different ligation methods.

5. Conclusion

Gynecological surgery, including lymphadenectomy, especially RH + PLN, can be performed quickly and safely using clips. By using this easily usable device, surgery for gynecologic malignancies will be more comfortable and safer. The proof of this study may need to be implemented by future prospective clinical studies.

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7. Tables

Table 1
All cases

	With clip	Without clip	p
No.	24	24	
BMI	22.5 ± 4.4	24.1 ± 4.9	0.215
Age	55.6 ± 14.0	53.2 ± 10.9	0.5074
Surgery time	239.4 ± 49.0	276.1 ± 67.6	0.0366
Blood loss	709.5 ± 590.7	875.2 ± 563.2	0.3252
Complication -	23	17	0.0479
Complication +	1	7	
No lymphedema	20	22	
Level 1 lymphedema	3	1	0.419
Level 2 lymphedema	1	1	
No recurrence	23	21	
Recurrent	1	3	0.6085

Table 2
RH + PLN

RH	With clip	Without clip	p
No.	10	14	
BMI	20.4 ± 2.8	22.2 ± 2.9	0.145
Age	53.6 ± 13.8	50.8 ± 11.1	0.586
Surgery time	239.6 ± 43.4	296.8 ± 67.5	0.02829
Blood loss	974.9 ± 737.7	1062.5 ± 634.1	0.7581
Complication -	10	9	0.053
Complication +	0	5	
No recurrence	10	11	0.239
Recurrent	0	3	
Lymphocele -	10	14	1
Lymphocele +	0	0	