

A Retrospective Study of Complications Following Pelvic and Para-Aortic Lymphadenectomy in Gynecologic Oncology

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Abstract

Background: Lymphadenectomy plays an essential role in the staging protocols for gynecologic cancers, as recommended by International Federation of Gynecology and Obstetrics (FIGO). While its benefits vary, complications may arise during intra-operative, acute post-operative, or long-term periods. Notably, lymphadenectomy-associated systemic morbidity and specific complications such as lymphocele and lymphedema have been reported.

Methods: This retrospective study involved 399 patients with cervical, endometrial, and ovarian cancers who underwent pelvic and para-aortic lymphadenectomy. The follow-up period was at least 3 months. Intra-operative complications encompassed adjacent organ injury and significant blood loss, while acute post-operative complications occurred within 29 days. Post-30-day complications included lymphocele and lymphedema. Logistic regression analysis identified predictors for complications.

Results: The overall complication rate was 42.4%, with intra-operative, acute post-operative, and long-term rates of 26.1%, 11.0%, and 14.0%, respectively. Predictors for overall complications included laparotomy, positive lymph nodes, and operative time > 240 min. For intra-operative complications, age > 60 years, laparotomy, positive lymph nodes, and operative time > 240 min were significant predictors. Symptomatic lymphocele and lymphedema occurred in 6.0% and 2.0% of patients, respectively, mainly in the long-term period.

Conclusion: Although the overall complication rate after gynecologic surgery was found to be almost half of all cases, the rate of severe complications was low. Additionally, the rates of symptomatic lymphocele and lymphedema were low. Lymphadenectomy in gynecologic cancer surgery can be performed safely.

Keywords: Gynecologic cancers; Lymphadenectomy; Complication; Lymphocele; Lymphedema

Introduction

Lymphadenectomy is a crucial component of the staging procedures for gynecologic cancers, as proposed by the International Federation of Gynecology and Obstetrics (FIGO) [1-3]. Pelvic lymphadenectomy is recommended for the treatment of early-stage cervical cancer [2]. Sentinel lymph node (SLN) assessment is an alternative option for the patients with low-risk stage IA2 [2]. Lymphadenectomy is required for accurate staging for patients with endometrial cancer and SLN mapping is preferred [1, 4]. While systematic pelvic and para-aortic lymphadenectomy of non-enlarged nodes may not enhance overall survival in ovarian cancer patients, the removal of bulky nodes proves beneficial in improving progression-free survival [5].

The complications of lymphadenectomy can occur during an intra-operative, acute post-operative or long-term periods. A systematic review and meta-analysis of lymphadenectomy for the management of endometrial cancer reported a significant higher risk of surgical-related systemic morbidity (e.g., chest infection, thrombo-embolic events, cardiac events, cerebrovascular accident) and lymphedema/lymphocyst formation in patients who underwent lymphadenectomy compared with those who did not undergo lymphadenectomy [6]. Non-specific intra-operative and acute post-operative complications include bleeding, injury to adjacent organs, post-operative infection, wound complications, etc. [6, 7]. Lymphocyst formation and lower-limb lymphedema are post-operative complications associated with lymphadenectomy. The overall incidence of lymphocyst and lymphedema was reported as 17.3-20.2% [8, 9] and 11.4-36.9% [7, 8], respectively.

According to the FIGO staging revision in 2018, SLN mapping has been utilized for surgical staging of endometrial cancer of low-risk endometrial cancer, but its role in high-risk patients remains controversial. For cases with high-risk features, complete lymphadenectomy is recommended [1]. As well as cervical cancer, FIGO recommended that the complete lymphadenectomy continues to be a part of surgical staging procedures [2]. However, many recent studies supported SLN mapping in high-risk endometrial cancer and cervical cancer,

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National Comprehensive Cancer Network (NCCN) recommended SLN mapping for endometrial and cervical cancer [4, 10]. In some developing countries or low-resource areas, SLN mapping is limited, highlighting the important role of lymphadenectomy in these situations.

In Thailand, SLN mapping is available in some tertiary hospitals, especially in Bangkok. Most gynecologic oncologists in rural tertiary hospitals typically perform lymphadenectomy. In a 2020 survey on the practice of retroperitoneal lymph node surgical evaluation for endometrial cancer among Thai gynecologic oncologists, it was revealed that 67.6% conducted systemic dissection, and 85.3% resected both pelvic and para-aortic nodes [11]. Concerned about the complications of lymphadenectomy, the authors conducted this study to determine the incidence of complications in patients with gynecologic cancers who underwent pelvic and para-aortic lymphadenectomy, including intra-operative, acute post-operative, and long-term complications.

Materials and Methods

After obtaining approval from the ethical committee of Navamindradhiraj University, we conducted a retrospective review of the medical records of patients with cervical cancer, endometrial cancer, and ovarian cancer from January 2015 to March 2020. After all patients had informed and signed consent form, they underwent staging surgery, including pelvic and para-aortic lymphadenectomy, at the Faculty of Medicine, Vajira Hospital, Navamindradhiraj University. The operations were performed by experienced surgeons in gynecologic oncology or by fellowship trainees under supervision. The follow-up period for post-operative complications was at least 3 months after surgery. We excluded patients with incomplete medical records and a follow-up period of less than 3 months or loss of follow-up.

Intra-operative complications are defined as those occurring during surgery which are adjacent organs, blood vessels, or nerve injury and blood loss exceeding 1,000 mL. Acute post-operative complications are defined as those occurring in the immediate post-operative period up to 29 days after surgery [12]. These complications include cellulitis, cystitis, wound infection, sepsis, bleeding, relaparotomy for hemostasis, venous thromboembolism (VTE), and others. Post-operative complications are defined as those occurring after 30 days of surgery and include lymphocele, lymphedema, relaparotomy for bowel obstruction, VTE, incisional hernia, and others. Major complications are defined as grade 3-5 according to Common Terminology Criteria for Adverse Events (CTCAE) v5.0 [13].

The data were analyzed using Stata Statistical Software (Release 15, 2017, StataCorp LLC, College Station, TX). Continuous variables were presented as mean \pm standard deviation (SD), while categorical variables were reported as percentages. Continuous variables were compared using Student's *t*-test or Mann-Whitney U test, and categorical variables were compared using Chi-square or Fisher's exact test. Logistic regression analysis was employed to investigate the relationship between factors and the occurrence of complications. Kaplan-

Table 1. Clinical Characteristics of 399 Patients Who Underwent Pelvic and/or Para-Aortic Lymphadenectomy

Characteristics	Mean \pm SD or N (%)
Age (years)	53.7 \pm 12.4
BMI (kg/m ²)	25.8 \pm 5.8
25 - 29.9	118 (29.6)
30 - 39.9	65 (16.3)
\geq 40	11 (2.8)
Underlying disease	
No	160 (40.1)
Yes	239 (59.9)
Diabetes mellitus	85 (21.3)
Hypertension	143 (35.8)
Dyslipidemia	94 (23.6)
Cerebrovascular accident	7 (1.8)
Cardiovascular disease	5 (1.3)
Venous thromboembolism	13 (3.3)
Hyperthyroidism	8 (2.0)
Hypothyroidism	7 (1.8)
HIV infection	7 (1.8)
Obstructive sleep apnea	5 (1.3)
Gynecologic cancers	
Cervical cancer	81 (20.3)
Endometrial cancer	174 (43.6)
Ovarian cancer	140 (35.1)
Synchronous cancer	4 (1.0)

BMI: body mass index; SD: standard deviation.

Meier method was used for survival analysis. The predictive factors were quantified using odds ratios (ORs) with corresponding 95% confidence intervals (95% CIs). A significance level of $P < 0.05$ was applied to all analyses.

Results

A total of 416 patients met the inclusion criteria. Among these, 17 patients were excluded due to incomplete medical records ($N = 1$) and a post-operative follow-up period of less than 3 months ($N = 16$). The analysis involved 399 patients. The median follow-up time was 26 months (range: 3 - 75 months). Clinical characteristics and operations are presented in Tables 1 and 2. The mean age was 53.7 ± 12.4 years, and the mean body mass index (BMI) was 25.8 ± 5.8 kg/m². Sixty percent of all patients had at least one underlying disease. A total of 174 cases (43.6%) were diagnosed with endometrial cancer, 140 (35.1%) with ovarian cancer, 81 (20.3%) with cervical cancer and four (1%) with synchronous endometrial and ovarian cancer. Among 174 patients with endometrial cancer, 129 cases (74.1%) were in stage I-II and 45 cases (25.9%) were in stage

Table 2. Surgical Characteristics and Complications of 399 Patients Distinguished by Types of Cancer

	Total (N = 399)	Types of cancer		
		Cervix (N = 81)	Endometrium (N = 174)	Ovary (N = 140)
Surgical approach (%)				
Laparotomy	354 (88.7)	73 (90.1)	139 (79.9)	138 (98.6)
Laparoscopy	45 (11.3)	8 (9.9)	35 (20.1)	2 (1.4)
Lymphadenectomy (%)				
Pelvic lymphadenectomy	103 (25.8)	66 (81.5)	22 (12.6)	15 (10.7)
Para-aortic lymphadenectomy	5 (1.3)	4 (4.9)	1 (0.6)	0 (0.0)
Pelvic and para-aortic lymphadenectomy	291 (72.9)	11 (13.6)	151 (86.8)	125 (89.3)
Operations (%)				
Hysterectomy (± BSO ± omentectomy)	372 (93.2)	72 (88.9) ^b	171 (98.3)	125 (89.3)
USO/BSO (± omentectomy)	13 (3.3)	0 (0.0)	1 (0.6)	12 (8.6)
Other operations	8 (2.0)	4 (4.9)	1 (0.6)	3 (2.1)
Lymphadenectomy alone	6 (1.5)	5 (6.2)	1 (0.6)	0 (0.0)
Operative time (min) (mean ± SD)	273.9 ± 88.2	275.0 ± 81.3	259.6 ± 79.3	293.2 ± 98.5
Total blood loss (mL) (mean ± SD)	689.7 ± 757.3	559.3 ± 416.5	432.4 ± 428.5	1,077.1 ± 1,033.0
Total number of LN (mean ± SD)	20.4 ± 10.3	19.7 ± 10.6	21.1 ± 10.7	19.7 ± 9.5
LN status (%)				
Negative	318 (79.7)	69 (85.2)	143 (82.2)	102 (72.9)
Positive	81 (20.3)	12 (14.8)	31 (17.8)	38 (27.1)
Overall complication (%)	169 (42.4)	32 (39.5)	52 (29.9)	83 (59.3)
Intra-operative complication (%)				
Vessel injury	104 (26.1)	16 (19.8)	22 (12.6)	65 (46.4)
Bowel injury	13 (3.3)	0 (0.0)	6 (3.4)	7 (5.0)
Bladder injury	13 (3.3)	1 (1.2)	3 (1.7)	9 (6.4)
Ureteric injury	5 (1.3)	0 (0.0)	1 (0.6)	4 (2.9)
Blood loss ≥ 1,000 mL	3 (0.8)	1 (1.2)	0 (0.0)	2 (1.4)
Acute post-operative complication (%)	83 (20.3)	15 (18.5)	15 (8.6)	52 (37.1)
Surgical site infection	44 (11.0)	8 (9.9)	17 (9.8)	19 (13.6)
Urinary retention	16 (4.0)	1 (1.2)	10 (5.7)	5 (3.6)
Bowel obstruction	3 (0.8)	3 (3.7)	0 (0.0)	0 (0.0)
Bowel ileus	3 (0.8)	0 (0.0)	0 (0.0)	3 (2.1)
Cystitis	8 (2.0)	1 (1.2)	3 (1.7)	4 (2.9)
Lymphocele	6 (1.5)	1 (1.2)	3 (1.7)	2 (1.4)
Venous thromboembolism	4 (1.0)	0 (0.0)	0 (0.0)	4 (2.9)
Hospital acquired pneumonia	3 (0.8)	2 (2.5)	0 (0.0)	1 (0.7)
Long-term complication (%)	2 (0.5)	0 (0.0)	1 (0.6)	0 (0.0)
Lymphedema	56 (14.0)	13 (16.0)	21 (12.1)	21 (15.0)
Lymphocele	8 (2.0)	2 (2.5)	4 (2.3)	2 (1.4)
Venous thromboembolism	24 (6.0)	3 (3.7)	7 (4.0)	14 (10.0)
Urinary retention	12 (3.0)	3 (3.7)	8 (4.6)	1 (0.7)
Others (bowel obstruction, vaginal stump evisceration, cystocele)	3 (0.8)	3 (3.7)	0 (0.0)	0 (0.0)
	11 (2.8)	2 (2.5)	4 (2.3)	4 (2.9)

^aSynchronous cancer: ovarian cancer with endometrium cancer in four cases. ^bType 2 or 3 hysterectomy. BSO: bilateral salpingo-oophorectomy; LN: lymph node; SD: standard deviation; USO: unilateral salpingo-oophorectomy.

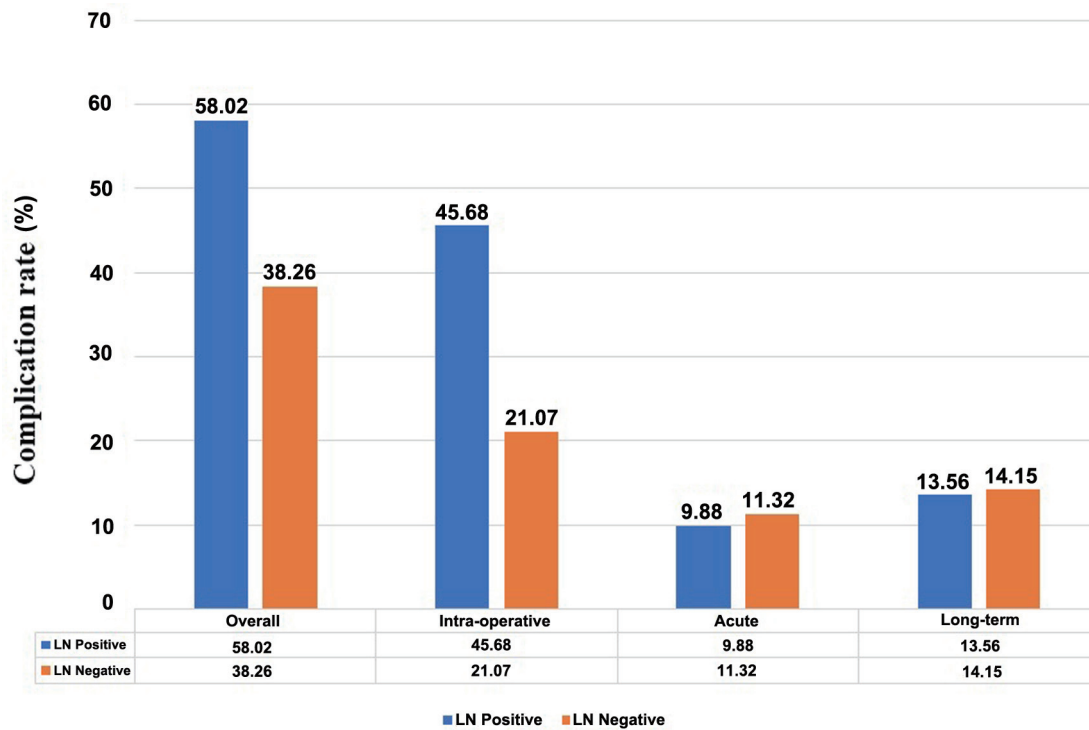


Figure 1. Complication rate of subgroup of patients with or without lymph node metastasis.

III-IV. Ovarian cancer tended to be in advanced stages, with 58 patients (41.4%) in stage III-IV and 82 (58.6%) in stage I-II. Of the 81 patients with cervical cancers, 67 cases were in the early stage, nine cases were initially diagnosed as early stage but had a final pathologic report indicating locally-advanced stage, and five cases with locally-advanced stage underwent bilateral pelvic lymphadenectomy \pm para-aortic lymphadenectomy with oophorectomy. Most cases (73%) underwent both pelvic and para-aortic lymphadenectomy. The mean (\pm SD) number of resected lymph node was 20.4 (\pm 10.3).

The overall complication rate was 42.4%. The rates of intra-operative, acute post-operative and long-term complications were 26.1%, 11.0% and 14.0%, respectively (Table 2). In terms of intra-operative complications, blood loss exceeding 1,000 mL occurred in 83 patients (20.3%). Among these cases, 52 were diagnosed with ovarian cancer and 24 were in an advanced stage. VTE occurred in three cases (0.8%) during the acute post-operative period (all were pulmonary embolism), and in 12 cases (3%) during the long-term period (four pulmonary embolism and eight deep vein thrombosis). The major complication rate was 13.5% for all cohort and 8.4%, 8.8% and 21.9% for cervical cancer, endometrial cancer and ovarian cancer, respectively.

The factors related to overall and intra-operative complications were surgical approach, lymph node status, and mean operative time (Supplementary Material 1, www.wjon.org). The patient with a positive lymph node had a higher overall complication rate and intra-operative complication rate than those with a negative lymph node (Fig. 1). The univariate analysis demonstrated that age \geq 60 years, laparotomy, posi-

tive lymph node, and operative time \geq 240 min were significant predictors for overall and intra-operative complications (Supplementary Material 2, www.wjon.org). In terms of acute post-operative and long-term complications, there were no significant factors related to the occurrence of complications. The multivariate analysis revealed that laparotomy (OR: 5.62, 95% CI: 2.27 - 13.86, P-value < 0.001), positive lymph node (OR: 2.10, 95% CI: 1.26 - 3.51, P-value = 0.005) and operative time \geq 240 min (OR: 1.90, 95% CI: 1.21 - 2.99, P-value = 0.006) were independent predictors for overall complications. Additionally, age \geq 60 years, laparotomy, positive lymph node, and operative time \geq 240 min were independent predictors for intra-operative complications.

The patients with at least one complication had a significantly lower 5-year survival rate than those without complication (Table 3 and Fig. 2). In subgroup analysis by lymph node status, there was no significant difference in survival between the patients with or without complications (Table 3 and Fig. 3). Among the patients without metastatic lymph node, those with at least one complication had a significantly lower survival rate than those without complications.

The complications directly associated with lymphadenectomy appeared in the long-term period. Symptomatic lymphocele and lymphedema were found in 24 patients (6.0%) at 16 to 1,301 days and eight patients (2.0%) at 51 to 204 days after surgery, respectively. Most of the patients with symptomatic lymphocele experienced spontaneous regression. Among the four patients with ovarian cancer who developed a symptomatic lymphocele, two cases were treated with surgical drainage, while the others were treated with antibiotics.

Table 3. Five-Year Survival Rate of 399 Patients With or Without Positive LN

	5-year survival rate (%)											
	Overall complication			Intra-operative complication			Acute complication			Long-term complication		
	No	Yes	P-value	No	Yes	P-value	No	Yes	P-value	No	Yes	P-value
All patients	97.39	92.31	0.017	96.27	92.31	0.080	94.93	97.73	0.3892	95.92	91.07	0.077
Positive LN	100.00	97.87	0.221	100.00	97.30	0.089	98.63	100	0.719	98.57	100.00	0.719
Negative LN	96.94	90.16	0.030	95.62	89.55	0.163	93.97	97.22	0.424	92.49	88.89	0.058

LN: lymph node.

Regarding symptomatic lymphedema, all patients developed mild symptoms and were treated by self-bandaging their legs and undergoing physical therapy.

Discussion

In this study, 42.4% of the patients undergoing pelvic and/or para-aortic lymphadenectomy for gynecologic cancer experienced at least one complication during the intra-operative, acute post-operative, or long-term periods. Considering the time when adverse events occurred, the rates of intra-operative, acute post-operative and long-term complications were 26.1%, 11.0% and 14.0%, respectively. Ereksan et al studied

22,214 women undergoing gynecologic surgery between 2005 and 2009 [14]. Of these, 1,463 cases undergoing radical dissection, lymphadenectomy, or debulking had a prevalence of 9.8% for major postoperative complications (143/1,463) and 1.1% for postoperative mortality (16/1,463). The major complication rate was 13.5% in our study which is higher than previous studies (3.6-3.7%) [14, 15]. In our study, the laparotomy approach was used in 93.2% of all cases which affected the complication rate.

Reporting adverse events after gynecologic cancer surgery has varied across previous studies. The results of LAAC trial revealed that 53% of the open surgery arm had any adverse event, compared to 59% in the minimally-invasive surgery arm [16]. Franchi et al reported a post-operative complica-

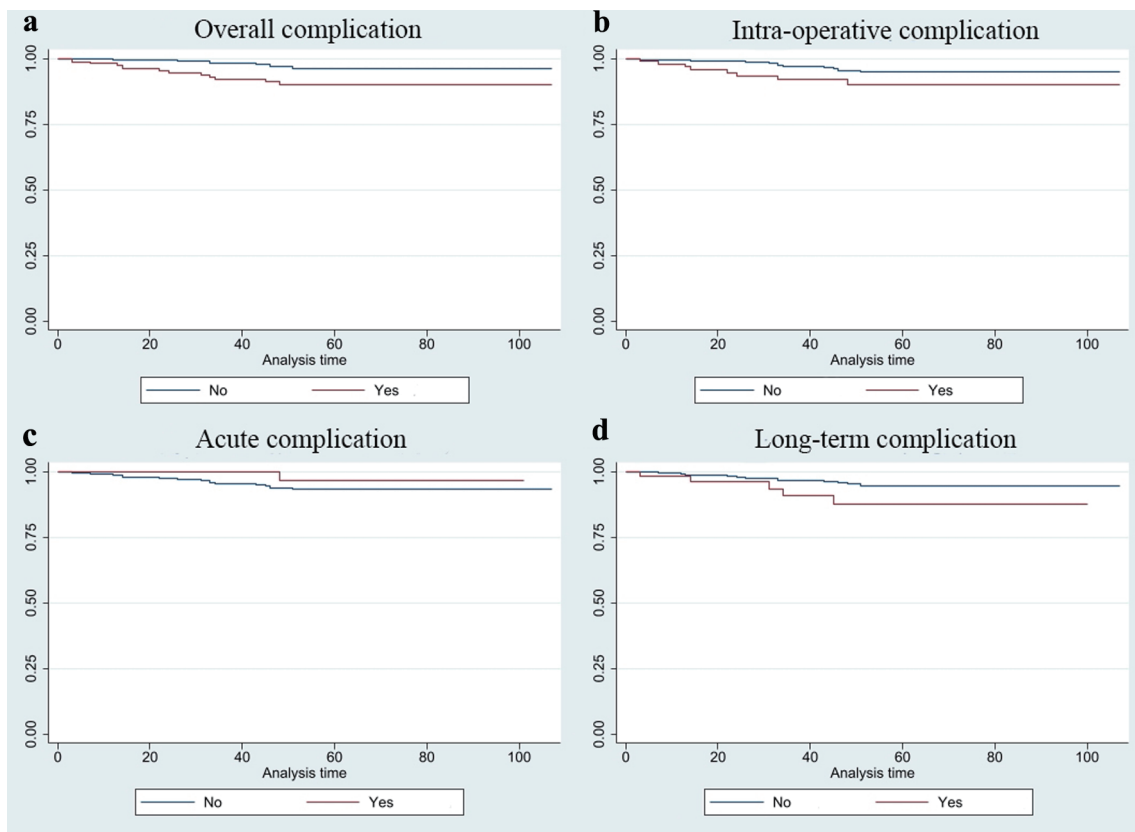


Figure 2. Kaplan-Meier survival estimates of the patients with or without complication. (a) Overall complication. (b) Intra-operative complication. (c) Acute complication. (d) Long-term complication.

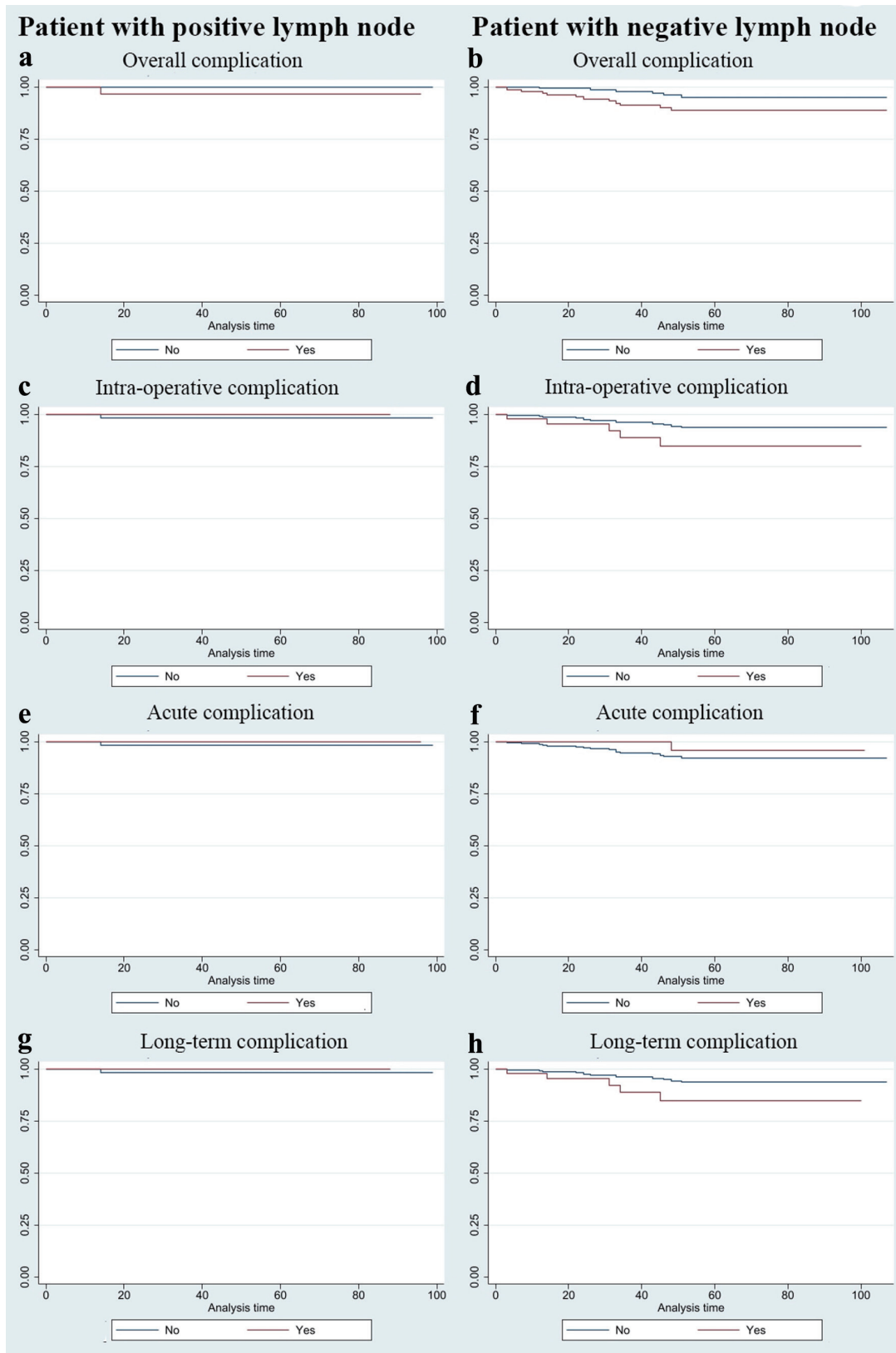


Figure 3. Kaplan-Meier survival estimates of the subgroup of patients with or without positive lymph node. (a, b) Overall complication. (c, d) Intra-operative complication. (e, f) Acute complication. (g, h) Long-term complication.

tion rate of 33.8% (45/133) in endometrial cancer patients [17]. The post-operative complication rate of ovarian cancer patients, depending on the extension of surgical procedures, ranged from 13.3% to 29.9% [18-20]. In our subgroups analysis, the overall complication rates in cervical cancer, endometrial cancer and ovarian cancer patients were 39.5%, 29.9% and 59.3%, respectively.

A large cross-sectional study revealed that the procedures for gynecologic cancer (adjusted OR: 1.60, 95% CI: 1.27 - 2.0) and disseminated cancer (adjusted OR: 2.57, 95% CI: 1.64 - 4.03) were predictors of 30-day major composite morbidity in gynecologic surgery [14]. In subgroup analysis of 1,463 cancer patients, predictors of major complications after surgery included functional status, pre-operative systemic infection, ascites, known bleeding disorder, and disseminated cancer. The number of removed lymph nodes is associated with post-operative complication. Franchi et al reported that the removals of > 14 nodes and > 19 nodes were significantly associated with one and two post-operative complications, respectively [17]. In our study, the predictors for overall and intra-operative complications are positive lymph node and operative time \geq 240 min. Positive lymph node represents advanced disease, leading to longer operative times and higher rate of complications. In our study, mean operative time is higher than previous studies because our institute is a tertiary so the majority of patients referred from primary or secondary hospitals were advanced stage. In our practice, the patients with ovarian cancer (89.3%) and endometrial cancer (86.8%) underwent pelvic and para-aortic lymphadenectomy. Additionally, our institute is a university hospital so fellowship training might affect the operative time, even all operations were under supervision of experienced surgeons.

Laparotomy is one of the predictors for overall and intra-operative complications. Querleu et al studied 1,000 gynecologic cancer patients who underwent laparoscopic pelvic and/or para-aortic lymphadenectomies [21]. The intra-operative and early post-operative complication rates, as well as the lymphocyst formation rate were 2.0% and 2.9%, respectively [20]. Although laparoscopic lymphadenectomy is considered safe, laparoscopic equipment is available in only some tertiary hospitals due to a lack of financial support; hence, 89% of this population underwent exploratory laparotomy.

The specific complications associated with lymphadenectomy are lymphocyst formation and lymphedema which are commonly detected during long-term period. The incidence of asymptomatic lymphocele ranged from 17.3% to 20.2% [8, 9], but the incidence of symptomatic cases is 4.0-7.1% [8, 9, 21]. The surgical approach is not associated with the occurrence of symptomatic lymphocele. Volpi et al reported that 10 out of 249 endometrial cancer patients (4%) developed symptomatic lymphocele [8]. In their population, 45.4% underwent laparoscopic lymphadenectomy. Querleu et al studied 1,000 patients with laparoscopic lymphadenectomy, and the incidence of symptomatic lymphocele was 7.1% [21]. Zikan et al reported an incidence of 5.8%. In this study, 82.5% of enrolled cases underwent laparotomy for lymphadenectomy, which is comparable with our population (laparotomy 88.7%). In our study, 24 patients (6%) developed symptomatic lymphocele. Ultrasonography or other imaging studies are not included in our routine post-operative care, so the incidence of asympto-

matic cases was not reported. In terms of lymphedema, the incidence ranged from 11.4% to 36.9% in previous studies [7, 8]. In our study, the incidence of lymphedema is very low (2%) because most patients do not have any symptoms or have mild symptoms, so both patients and physicians might not be concerned about it. These reasons led to the loss of the record and a lower incidence. Kuroda et al reported that the cumulative incidence of lower lymphedema was 23.1% at 1 year, 32.8% at 3 years, and 47.7% at 10 years post-surgery, and lymphedema developed after a median of 13.5 months [22]. Eight cases in our study developed lymphedema 24 - 870 days after surgery.

This study includes all gynecologic cancers and all major and minor post-operative complications. Additionally, our study reports the complications divided by the time of adverse events occurring. The limitation of this study is its retrospective nature, so some information was not recorded. In addition, grouping of three types of cancer together may have some disadvantages due to the heterogeneous nature of the population, which may exhibit differences in specific characteristics. Despite the retrospective nature of our study posing limitations, we propose future prospective studies in collaboration with multiple centers to enhance the population diversity and encompass a broader spectrum of cancers and surgical procedures. Such studies would contribute valuable insights into refining risk stratification and optimizing patient care strategies in gynecologic cancer surgeries.

Conclusion

Our study comprehensively investigated the outcomes of pelvic and/or para-aortic lymphadenectomy in gynecologic cancer patients. Although the overall complication after gynecologic surgery was found in almost half of all cases, the rate of major complications was 13.5%. The major factors associated with complications included surgical approach, lymph node status, and mean operative time. Laparotomy emerged as a significant predictor for both overall and intra-operative complications. However, the heterogeneous nature of the three types of cancer makes it difficult to draw conclusions regarding the effect of lymphadenectomy on complications.

The analysis of specific complications directly related to lymphadenectomy revealed occurrences primarily in the long-term period. Symptomatic lymphocele and lymphedema were identified in 6.0% and 2.0% of patients, respectively. Notably, the majority of symptomatic lymphocele cases exhibited spontaneous regression, while lymphedema cases were characterized by mild symptoms and managed with self-bandaging and physical therapy. Lymphadenectomy in gynecologic cancer surgery can be performed with safety.

Supplementary Material

Suppl 1. Factors related to overall, intra-operative, acute post-operative and long-term post-operative complications in 399 patients who underwent pelvic and/or para-aortic lymphadenectomy.

Suppl 2. Univariate and multivariate analysis of the factors related to overall, intra-operative, acute post-operative and long-term post-operative complications.

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None to declare.

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There was no financial support for the research of this article.

Conflict of Interest

The authors declare no potential conflict of interest.

Informed Consent

This retrospective study was approved by the Vajira Institutional Review Board (Ethics Committee) of Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Thailand, and the requirement of obtaining written informed consent was waived.

Author Contributions

Conceptualization: TS and WC. Methodology: TS and WC. Data curation: TS. Formal analysis: TS and WC. Original draft preparation: TS. Writing-review and editing: WC. All authors have contributed equally, read and agreed to the published version of the manuscript.

Data Availability

All data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

CI: confidence interval; FIGO: International Federation of Gynecology and Obstetrics; OR: odds ratio; SD: standard deviation; SLN: sentinel lymph node; VTE: venous thromboembolism

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