Advanced Epithelial Ovarian Carcinoma in Thai Women: Should We Continue to Offer Second-Look Laparotomy?

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Abstract

Objective : To determine survival among patients with epithelial ovarian carcinoma (EOC) who underwent a second-look laparotomy (SLL) and those refusing the procedure. Also to analyze factor(s) influencing the survival of the patients.

Method and Material : Medical records were reviewed of patients with advanced EOC who were clinically free of disease after primary surgery and platinum-based chemotherapy between January 1, 1992, and December 31, 1998. All of them were offered SLL. Measurement outcomes include patient survival and disease-free survival.

Results : There were 50 patients with clinically complete remission after chemotherapy. Sixteen patients underwent SLL, and thirty-four patients refused the procedure (NSLL). Seven patients (43.8%) were reported to have positive SLL. After the median follow-up time of 35 months, 12 patients had died, and 5 patients were lost to follow-up. The median survival time for patients with SLL was about 60 months. Five-year survival rates of patients in the SLL, and NSLL groups were 37 per cent (95%CI = 7%-69%), and 88 per cent (95%CI = 65%-96%) respectively (P<0.001). The median time to relapse was about 25 months for patients with negative SLL. Five-year disease-free survival rates of patients in the negative SLL, and NSLL groups were 28 per cent (95%CI = 4%-59%), and 54 per cent (95%CI = 34%-70%) respectively (P=0.251). By Cox regression analysis, tumor grade was the only significant prognostic factor influencing patients' survival (HR = 6, 95%CI of HR = 1.2-34.2).

Conclusion : The second-look laparotomy doesn't have a favorable impact on overall and disease-free survival. Tumor grade is the only independent prognostic variable for survival of the patients.

Key word : Second-Look Laparotomy, Advanced Epithelial Ovarian Cancer

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Thailand is among countries with a low incidence rate (4.7 per 100,000) of ovarian cancer. An estimated 1,252 new cases are reported yearly, and approximately 70 per cent of the patients are diagnosed in the advanced stages[1]. The standard treatment for patients with epithelial ovarian cancer includes surgical staging followed by platinum-based chemotherapy. Second-look laparotomy (SLL) is the most accurate method of assessing the disease status in patients who have completed the initial therapy and who are clinically free of disease. It is not considered a "standard" or "mandatory" operation for all women with ovarian cancer[2]. Recently, the value of SLL has been questioned, while there are still advocates of the procedure, some have called for its abandonment[3-6].

In our institution, second-look laparotomy has been incorporated in the protocol treatment of advanced epithelial carcinoma. However, only a few patients who were candidates for SLL accepted the procedure. We were interested in reviewing the outcomes of patients in both groups, patients who underwent SLL and those refusing the surgery, in order to evaluate the value of the SLL. The purpose of this study was to determine survival among patients who underwent SLL and those refusing the procedure. Also to analyze factor(s) influencing survival of the patients.

METHOD AND MATERIAL

Medical records were reviewed of patients with advanced (FIGO-International Federation of Gynecology and Obstetrics-stage IIC, III or IV) epithelial ovarian carcinoma (EOC) who had full surgical staging and cytoreductive surgery, followed by platinum-based chemotherapy from January 1, 1992 to December 31, 1998. The protocol treatment and the dosage and schedules of the chemotherapeutic agents were previously described[7]. Only patients who were reported to be clinically free of disease and whose serum CA 125 levels <35 U/ml after scheduled adjuvant chemotherapy (clinical complete response) and were offered SLL were included in the study. Excluded from the study were patients having borderline tumors.

The SLL was performed four to six weeks after the conclusion of chemotherapy. Generally, SLL was performed through a midline incision. Upon entering the abdominal cavity, peritoneal fluid was collected from both paracolic gutters and cul de sac for cytologic examination and the entire peritoneal cavity and its contents were evaluated systematically for metastasis. Biopsies were taken from any suspicious area(s). In cases of no gross intraperitoneal disease, multiple random biopsies were taken of the peritoneum, especially from areas that previously contained cancer, and of the retroperitoneal lymph node. The average number of specimens taken for examination was 12. Secondary cytoreductive surgery would be performed if residual cancer were found at the time of SLL.

Post-operatively, patients with positive second-look would enter an investigational protocol treatment of second-line chemotherapy, which was running at the time, which included ifosfamide plus doxorubicin, high-dose paclitaxel, or oral megestrol acetate. Patients with negative SLL did not receive further treatment.

For the follow-up, patients with negative SLL and those refusing the procedure would be seen at 3 monthly intervals for the first two years and every 6 months thereafter. A complete general physical and pelvic examination and determination of serum CA125 level was carried out at each clinic visit. Chest X-ray and other imaging techniques such as ultrasonography, computed tomography (CT-scan), or magnetic resonance imaging (MRI) would be obtained when suspicion of recurrence had arisen. If recurrence occurred after 6 months from the last chemotherapy, the patient would receive reinduction therapy with the same platinum-based regimen. And if the treatment failed or recurrence occurred within 6 months, the patient would receive the second-line chemotherapy regimen as previously stated.

The main measurement outcomes were time to death (patient survival) and time to recurrence (disease-free survival). Patient survival time (months) was calculated from the date of diagnosis to the date of last follow-up[8]. Disease-free interval was calculated from the date of last chemotherapy to the date of recurrence. Time to relapse was considered in only negative SLL and in those refusing the surgery (NSLL). Patients who were still alive, or patients whose disease had not relapsed at the end of the study, December 2000, were dealt with as censored at that time. For patients without a measurable lesion, a rise of serum CA 125 levels to 100 U/ml was considered to be recurrence of disease. Prognostic variables of interest included the patient's

age, FIGO stage, histologic type, tumor grade, and residual disease (diameter of the largest residual implants) after initial surgery.

General characteristics among group, SLL and NSLL, were described using mean (standard deviation, SD) and frequency for continuous and categorical variables. Independent *t*-test and Fisher's exact test were used to compare characteristics among groups. Kaplan-Meier was applied to estimate the survival rates and Log-rank test was used to compare them. Cox proportional hazard was applied to estimate the risk of death separately for each variable such as patient age, FIGO stage, histologic type, tumor grade, and residual tumor. STATA version 6.0 was used through these analyses[9]. A P value of <0.05 was considered significant.

RESULTS

During the study period, there were 103 previously untreated patients with advanced stage epithelial ovarian carcinoma who had full staging surgery and adjuvant platinum-based chemotherapy. Fifty patients achieved a clinically complete response after six courses of chemotherapy and were offered SLL, they constituted the basis of this study. Sixteen of them (32%) underwent SLL while the remaining, 34 patients (68%), refused the procedure (NSLL-group). The general characteristics including age, FIGO staging, residual tumor, and histopathology of patients in both groups are shown in Table 1. Because of the limited number of study patients, those with histological diagnoses of endometrioid, mucinous, clear cell, and malignant Brenner tumor were evaluated as a single group of "non-serous". The same as tumor grade, those with moderately well, and poorly differentiated were grouped as "not-well differentiated".

For the SLL-group, 7/16 (43.8%) patients were reported to have positive SLL. In six of the 7 patients with positive SLL, the diameter of residual implants found was greater than 1 cm. The other patient had microscopic residual disease.

At the follow-up period (median = 35 months, range 6.7 - 99.4 months), 11 patients had died from the disease. One patient died from another cause, 5 patients were lost to follow-up. Thirty-three patients (66%) were still alive, 18 (36%) patients were alive without disease.

Patient survival rate among the group was estimated and shown in Table 2. In the SLL-group, all 7 patients with positive SLL had progression of disease in a short period of time after receiving second-line chemotherapy. Five patients died of the disease. Of the 9 patients with negative SLL, 6 (67%) patients developed recurrent diseases within five years, all were in the abdomen or pelvis. Six

Table 1. General characteristics of patients who underwent the second-look laparotomy (SLL) *versus* those refusing second-look laparotomy (NSLL).

Characteristics	Group		P-value
	SLL (N=16)	NSLL (N=34)	
Age, years, mean (sd)	48 (9)	51 (11)	0.431
FIGO staging			
IIC	2 (25)	6 (75)	0.999
III + IV	14 (33)	28 (67)	
Residual tumor, cm			
< 2	8 (23)	27 (77)	0.049
≥ 2	8 (53)	7 (47)	
Histological diagnosis			
Serous	7 (33)	14 (67)	0.999
Non-serous	9 (31)	20 (69)	
Tumor grade			
Well differentiated	3 (15)	17 (85)	0.053
Not-well differentiated	7 (54)	6 (46)	
Unknown	6 (35)	11 (65)	

Continuous variable: mean (sd); *t*-test
Categorical variable: frequency (%), Fisher's exact test

Table 2. Two-year, and five-year survival rates of CA ovary patients according to SLL.

Survival rate	Group		Log-rank Test P-value
	SLL	NSLL	
Two-year, % (95%CI)	67 (38 - 85)	94 (77 - 98)	<0.001
Five-year, % (95%CI)	37 (7 - 69)	88 (65 - 96)	

SLL : second-look laparotomy, NSLL : no second-look laparotomy

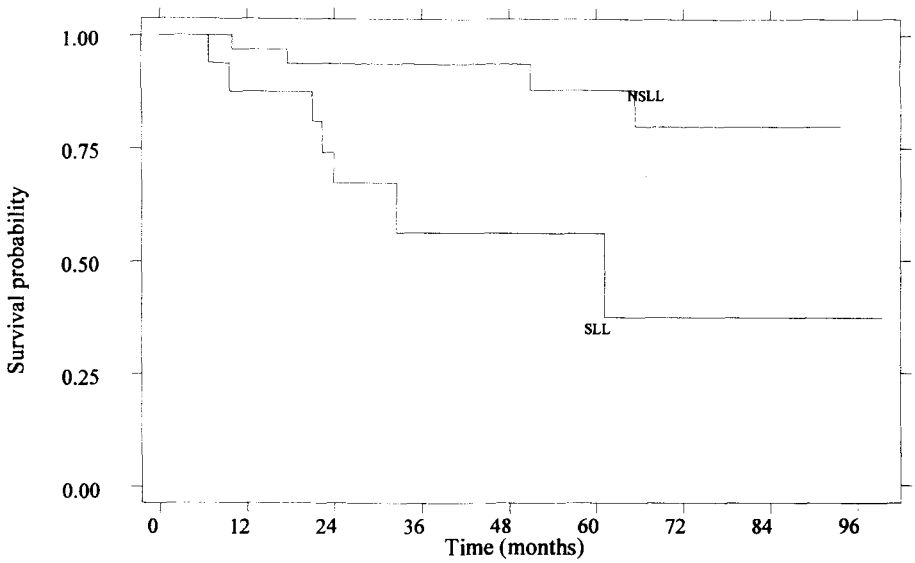

Fig. 1. Survival time of CA ovary patients by SLL.

patients were still alive, 2 without disease at the time of report. Two, and five-year survival rates were 67 per cent (95%CI = 38%-85%) and 37 per cent (95%CI = 7%-69%). The median survival time for patients in the SLL-group was about 60 months.

In the NSLL-group, 14 of the 34 (41%) patients had relapse and fifteen patients were still alive without disease. Two, and five-year survival rates were 94 per cent (95%CI = 77%-98%) and 88 per cent (95%CI = 65%-96%). Survival curves among the group are displayed in Fig. 1. We found that the survival rate of SLL-group was statistically shorter than survival rates in the NSLL-group (P< 0.001).

The median time to relapse in patients with negative SLL was about 25 months while for patients in NSLL it was undefinable. The disease-free survival was estimated for the negative SLL and NSLL group, Table 3. Five-year disease-free survival rates for negative SLL and NSLL group were 28 per cent (95%CI = 4%-59%), and 54 per cent (95%CI = 34%-70%) respectively (P = 0.251). The disease-free survival curves of patients with negative SLL and NSLL are shown in Fig. 2.

All clinical and pathological factors such as age, FIGO stage, residual tumor, histological diagnoses, and tumor grade were separately assessed whether they were associated with patient survival using the Cox hazard model. Only the tumor grade was significantly associated with survival time in the univariate model. Patients whose tumor grade was not-well differentiated were about 6 (95%CI = 1.2-34.2) times more likely to die compared to patients with a well differentiated tumor. Patients with a residual tumor >2 cm at the initial surgery were at risk of death about 0.8 (95%CI = 0.2-3.9) times compared to those with residual tumor <2 cm. For patients whose tumor histology were non-serous were at

Table 3. Two-year, and five-year disease-free survival rates of CA ovary patients among negative SLL and NSLL group.

Disease-free survival rate	Group		Log-rank Test P-value
	Negative SLL	NSLL	
Two-year, % (95%CI)	56 (20 - 80)	69 (51 - 82)	0.251
Five-year, % (95%CI)	28 (4 - 59)	54 (34 - 70)	

SLL : second-look laparotomy, NSLL : no second-look laparotomy

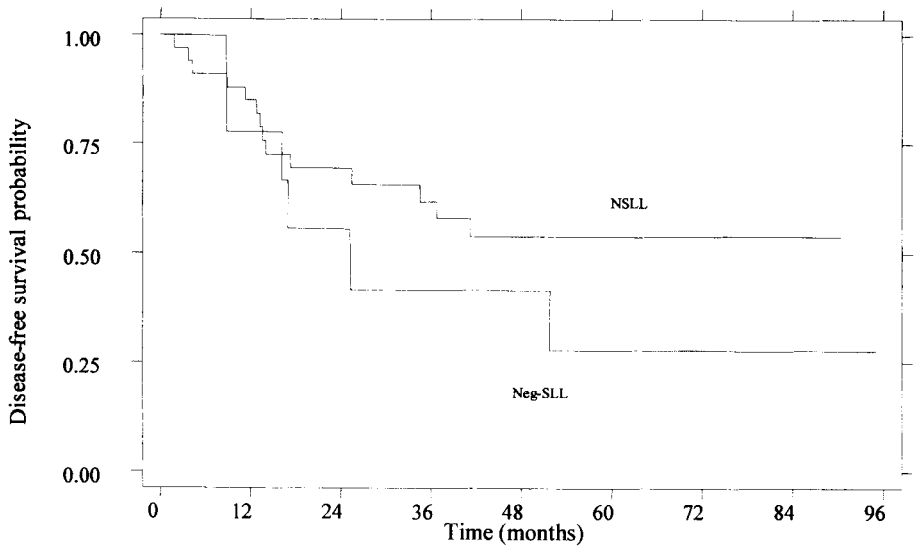

Fig. 2. Disease-free survival of CA ovary patients.

risk of death about 0.8 (95%CI = 0.2-3.1) times compared to patients with serous type.

DISCUSSION

The second-look laparotomy was defined as a systematic surgical re-exploration in asymptomatic patients who have no clinical evidence of tumor following initial surgery and completion of a planned program of chemotherapy for ovarian cancer[10]. The number of patients who underwent SLL (SLL-group) was small in this study. Thirty-four of the 50 SLL candidates (68.0%) did not undergo the surgery (NSLL-group). However, the percentage of patients refusing the second-look surgery in our unit was not much different from that of other centers in Thailand.

This study showed that about 43 per cent of patients with advanced stage disease who were clinically free of disease after completion of primary induction chemotherapy had persistent disease. The accuracy in predicting the presence or absence of disease by noninvasive techniques, such as evaluation of tumor marker levels, and imaging of the abdomen and pelvis with ultrasonography, CT-scan, or MRI, are still unsatisfactory[11]. Senapad S et al reported the combined serum CA 125 and tissue polypeptide specific antigen (TPS), using cut-off value of 10 U/ml and 50 U/ml respectively, had a negative predictive value for pathological CR of 88.9 per cent (95%CI, 63.9-89.1) among 33 patients with advanced non-mucinous epithelial ovarian cancer[12]. This interesting result requires confirmation in a larger population study.

With the advance of new technology in endoscopy, second-look laparoscopy may be an alternative mean to assess the residual ovarian can-

cer after completion of adjuvant chemotherapy. However, its reliability compared to SLL has been controversial[13,14]. Fujiwara et al showed that cytologic evaluation of peritoneal fluid obtained from the implantable port system (IPS) could detect intraperitoneal persistent disease in patients with unmeasurable residual ovarian cancer[15].

Most studies showed that patients with positive SLL had a short survival time especially among those with macroscopic residual disease[16-18]. In this study, the median time of survival in the positive SLL group was 24 months with a two-year survival rate 36 per cent (95%CI = 5%-70%) (not shown). This can be explained that, at present, there are still no effective second-line therapies available. It is, therefore, evident that SLL is not beneficial for patients in this group.

Patients with negative SLL are known to have long term survival rates. We achieved five-year overall survival rates of 59 per cent (95%CI = 8%-90%). Ten-year recurrence-free survival rate of 40 per cent among patients with negative SLL has been reported, and those who remain disease free at 5 years have excellent long-term survival rates[19]. In this study, the recurrence rates were 44 per cent at two years and 67 per cent at five years. The median time to relapse was about 25 months. The results were comparable to previous studies[5,6,16]. The disease-free survival rates at two and five years in this study were 56 per cent (95%CI = 20%-80%) and 28 per cent (95%CI = 4%-59%). In order to improve the disease-free interval for this group of patients, clinical trials that are investigating consolidation therapies (radiation, chemotherapeutic, or biologic) should be encouraged.

Tumor grade and residual disease at the time of initial surgery were the prognostic factors for survival of patients who underwent SLL often cited in previous studies[3,4,20,21]. Patients with well differentiated tumors and a small residual tumor mass at the first operation had a good prognosis after SLL[21]. Our study only confirmed the tumor grade to be a prognostic factor.

The preliminary result of the GOG 158 study showed that second-look surgery does not influence recurrence-free survival in patients with optimal (no residual tumor nodule >1 cm) stage III ovarian cancer, compared to those in whom second look was not performed[22]. Patients in the NSLL group in this study had a 5-year overall survival rate of 88 per cent (95%CI = 65%-96%). The median time to relapse was over 40 months compared to 39.1 months reported by Friedman RL et al[3]. The 2-year, and 5-year disease-free survival were 69 per cent (95%CI = 51%-82%) and 54 per cent (95% CI = 34%-70%) respectively which were comparable to that of the negative SLL group. It should be noted that the NSLL group had a greater proportion of patients with good prognostic characteristics i.e. well differentiated tumor than the SLL group.

Finally, should we continue to offer SLL? Currently, without the effective second-line therapies available, SLL is not beneficial for patients with residual disease found at the surgery. In addition, for patients with negative SLL, there should be an investigational protocol treatment available, such as consolidation therapy. Otherwise, the second-look laparotomy should be terminated.

In summary, the second-look laparotomy doesn't have a favorable impact on overall and disease-free survival. Tumor grade is the only independent prognostic variable for survival of the patients.

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มะเร็งรังไข่ชนิดเอปิธีเลียม คาร์ซิโนมาระยะลุกลามในผู้ป่วยคนไทย: เป็นการสมควรที่จะทำการผ่าตัด second-look ต่อไปหรือไม่?

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ความเป็นมา : การผ่าตัด second-look (SLL) เป็นส่วนหนึ่งของกระบวนการรักษาตาม protocol ในผู้ป่วยมะเร็งรังไข่ระยะลุกลาม ของหน่วยมะเร็งนรีเวช โรงพยาบาลรามาธิบดี พบว่ามีผู้ป่วยจำนวนไม่น้อยที่ปฏิเสธไม่ยอมรับการผ่าตัดนี้ คณะผู้วิจัยมีความประสงค์ที่จะทราบว่าการผ่าตัด SLL มีประโยชน์ต่อผู้ป่วยหรือไม่

วัตถุประสงค์ : หาอัตราการรอดตาย (survival rate) ของผู้ป่วยที่ได้รับการทำผ่าตัด SLL กับของผู้ป่วยที่ไม่ได้รับการผ่าตัด และศึกษาหาปัจจัยที่มีอิทธิพลต่อการรอดตาย (survival) ของผู้ป่วย

วิธีการศึกษา : จากเวชระเบียนผู้ป่วยมะเร็งรังไข่ระยะลุกลาม ในช่วง มกราคม พ.ศ. 2535 ถึง ธันวาคม พ.ศ. 2541 ที่ได้รับการทำผ่าตัด (surgical staging) และได้รับยาเคมีบำบัดครบ และได้รับการประเมินทางคลินิกแล้วไม่พบว่ามีโรค (complete remission) ,ผู้ป่วยกลุ่มนี้ทั้งหมดได้รับคำแนะนำให้ทำการผ่าตัด SLL นำข้อมูลมาวิเคราะห์ หา overall และ disease-free survival

ผลการศึกษา : มีผู้ป่วย 50 รายที่ได้รับการประเมินทางคลินิกว่า มี complete remission ในจำนวนนี้ 16 ราย ได้รับการทำผ่าตัด (SLL-group) อีก 34 ราย ปฏิเสธการผ่าตัด (NSLL-group) จากการผ่าตัดพบว่า 7 ราย (43.8%) ยังมีโรคหลงเหลืออยู่ (positive SLL) หลังจากการติดตามผู้ป่วยเป็นระยะเวลาเฉลี่ย (median) 35 เดือน มีผู้ป่วย 12 ราย เสียชีวิต 5 รายขาดการติดต่อ ระยะเวลาการรอดตายเฉลี่ยของผู้ป่วย SLL-group เท่ากับ 60 เดือน Survival rate ที่ 5 ปี ของผู้ป่วยในกลุ่ม SLL, และ NSLL เท่ากับ 37% (95%CI = 7%-69%), และ 88% (95%CI = 65%-96%) ตามลำดับ ($P<0.001$) ระยะเวลาเฉลี่ยที่ตรวจพบโรคกลับเป็นซ้ำในกลุ่ม negative SLL เท่ากับ 25 เดือน Disease-free survival rate ที่ 5 ปีในกลุ่ม negative SLL และ NSLL เท่ากับ 28% (95%CI = 4%-59%), และ 54% (95%CI = 34%-70%) ตามลำดับ ($P=0.251$) จากการวิเคราะห์ทางสถิติโดย Cox regression analysis พบว่า tumor grade เป็นปัจจัยที่มีอิทธิพลต่อการรอดตายของผู้ป่วย (HR = 6, 95%CI of HR = 1.2-34.2)

สรุป : จากการศึกษานี้พบว่า การผ่าตัด second-look ไม่ได้มีผลทำให้ overall และ disease-free survival ของผู้ป่วยดีขึ้น และ tumor grade เป็นปัจจัยที่มีอิทธิพลต่อการรอดตายของผู้ป่วย

คำสำคัญ : การผ่าตัด second-look, มะเร็งรังไข่ชนิดเอปิธีเลียม คาร์ซิโนมาระยะลุกลาม

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