Chemotherapy in Patients with Recurrent or Refractory Epithelial Ovarian Cancer

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Objectives: *To evaluate the response rates, progression-free survival, and overall survival of patients with epithelial ovarian carcinoma who were treated with chemotherapy after being resistant to or had recurrence after first-line chemotherapy.*

Material and Method: *Clinical and pathological data of all patients with epithelial ovarian carcinoma who received chemotherapy in the second-setting at the Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital from January 1994 to December 2005 were reviewed.*

Results: *During the study period, 61 ovarian carcinoma patients met the inclusion criteria. All patients had primary surgery, not responded to or had recurrence after first-line chemotherapy, and received subsequent chemotherapy. Thirty-seven cases (60.7%) were considered as platinum-resistant and 24 cases as platinum-sensitive (39.3%). The overall response rate (RR) to subsequent chemotherapy was 23.0% (14 patients): complete response 18.0% (11 patients) and partial response 5.0% (three patients). Stable disease was achieved as the best response in 11 patients (18.0%). Thirty-six patients (59.0%) experienced disease progression. Median progression-free survival (PFS) of all 61 patients was 5.7 months (95%CI, 4.7-6.7 months) while median overall survival (OS) was 18.3 months (95%CI, 2.7-34.0 months). Some prognostic factors were studied and found that patients with platinum-sensitive had a better response rate, longer PFS and OS than those with platinum-resistant diseases.*

Conclusion: *Response rate of ovarian carcinoma to subsequent chemotherapy for resistant or recurrent diseases was modest. Median PFS and OS of the patients were less than and slightly longer than a year respectively. The patients who had platinum-sensitive diseases had a better prognosis in terms of RR, PFS, and OS than those with platinum-resistant disease.*

Keywords: *Epithelial ovarian carcinoma, Chemotherapy in the second-setting, Response rate*

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From the global cancer statistics of year 2002 which has been recently reported in 2005, ovarian cancer is the third most common gynecologic cancer in developed countries, with a lower incidence rate than breast and uterine cancer. While in developing countries, ovarian cancer ranks after breast and cervical cancer with the incidence of 108,000 new cases and 63,000 deaths in 2002[1]. In Thailand, although ovarian cancer ranks after cervical cancer among gynecologic malignancy, it is still the most common cause of death[2]. One reason for this high incidence of death may lie on the fact that most ovarian cancer patients present clinically when they are already in the advanced stages. These advanced stage diseases certainly have low response rates to adjuvant chemotherapy or have high rates of recurrences[3].

Generally, epithelial ovarian cancer (EOC) patients who have advanced stage diseases or those who have early stage diseases but with poor prognostic factor will receive adjuvant chemotherapy after primary surgery. This is to eradicate residual tumors or to

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prevent recurrence. Patients who have complete response to the primary chemotherapy would be followed up cautiously. Those patients who cannot achieve a complete remission, or have had it but develop recurrence later, certainly require additional chemotherapy. The drug may be the same regimen as the primary treatment or may be switched to other chemotherapeutic drugs. In selecting the type of chemotherapy in this setting, many factors must be taken into consideration.

The response rates of diseases to subsequent chemotherapy also vary depending on many factors e.g. efficacy of the drug itself, the response to first-line chemotherapy, the characteristic feature of recurrent disease etc.

The objective of the present study was to evaluate the overall efficacy of chemotherapy that was used in the second-line setting for epithelial ovarian cancer patients who had not responded to the first-line chemotherapeutic drugs or had recurrent diseases, who were treated in the authors' institution.

Material and Method

Patients

The present study included EOC patients who were treated at the Gynecologic Oncology Unit, Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital. The eligibility criteria were EOC patients who had primary surgery and received first-line chemotherapy in the authors' institution, or had complete history of primary treatment from other hospitals, had not responded or had disease recurrence after the first-line chemotherapy and received subsequent chemotherapeutic treatment in the authors' institution. The patients who had low malignant potential tumors were excluded.

Method

The present study was conducted after an approval of the Ethics Committee of the authors' institution. Between January 1994 and December 2005, patients with EOC who received chemotherapy after being resistant to or had recurrence after first-line chemotherapy were identified. The patients who met the eligibility criteria were included in the present study. Patient's clinical and pathological data were collected from the in-patient and outpatient charts. Data were collected on age, International Federation of Gynecology and Obstetrics (FIGO) stage, tumor histological cell type and grade, the type and outcome of primary surgery, the type and number of cycles of first-line chemotherapy and the disease response, treatment-free interval that was defined as the time interval between the end of first-line chemotherapy and the time at diagnosis of stable, progressive, or recurrent diseases, type and number of cycles of the second chemotherapy, and any chemotherapeutic drugs administered after the second chemotherapy treatment.

The main outcomes for efficacy of chemotherapy for persistent or recurrent diseases were the response rate (RR), progression-free survival (PFS), and overall survival (OS) of the patients. The clinical response was determined from the physical examinations, CA125, or radiological imaging according to Gynecologic Oncology Group response criteria[4]. The responses were defined as the following; complete response was defined when there was no clinical evidence of tumor after chemotherapy treatment, partial response was defined when tumor reduction was $\geq$ 50% and stable disease when a tumor that was unchanged in size or had decreased < 50% or increased < 25%. Progressive disease was defined as an increase in tumor size $\geq$ 25% or development of new lesion. PFS was obtained from the interval from the starting date of subsequent chemotherapy to the date of documented disease progression. For patients who were lost to follow-up, PFS data were right-censored at the time of the last evaluation or contact when the patient was known to be progression-free. OS was obtained from the interval from the date of subsequent chemotherapy started to the date of death or last follow-up visit. For patients who were alive at the end of the present study, overall survival data were right-censored at the time of the last evaluation or contact.

Platinum-sensitive was defined as recurrence of disease in patients who had experienced complete response to platinum-based therapy that is usually used as the first-line chemotherapy for $\geq$ 6 months after the end of treatment[5]. Platinum-resistance was defined when recurrence took place prior to 6 months or showed no response. Platinum-refractory was defined when disease had progression during the primary treatment. In the present study, the authors would categorize platinum-refractory together in the platinum-resistant group.

Data were analyzed using SPSS statistical software version 11.5 (SPSS, Chicago, IL). Descriptive statistics were used for demographic data and summarized as mean with standard deviation, median with range, or frequency with percentage. Data between groups were compared with Fisher's Exact or Chi-Square test as appropriate. Progression-free survival

and overall survival were analyzed with the Kaplan-Meier method. Survival data between groups were compared with the Log-rank test. The outcomes were significant only if $p \leq 0.05$.

Results

Between January 1994 and December 2005, the authors identified 61 EOC patients who experienced recurrence, or had persistent or progressive disease from primary chemotherapy, and who received subsequent chemotherapeutic treatment in the authors' institution. Mean age of the patients was 51.0 $\pm$ 10.1 years. Approximately half of the patients (31 patients or 50.8%) were in the postmenopausal state. The characteristic features of diseases, the type and result of primary surgery are shown in Table 1. The details of primary chemotherapy treatment and their responses are shown in Table 2.

Based on the primary responses and treatment-free interval, 24 patients (39.3%) had platinum-sensitive diseases, while 37 patients (60.7%) were considered as platinum-resistant. The median treatment-free interval of those who had platinum-sensitive diseases was 18.7 months (range, 7.0-83.4 months) compared to 1.5 months (range, 1.0-6.0 months) of those with platinum-resistant diseases. From 61 recurrent or persistent EOC, 15 patients (24.6%) underwent secondary cytoreduction. Nine of which had optimal surgery, one had residual diseases $\geq$ 2 cm, and five had no clear record of the residual tumor status.

From 24 patients with platinum-sensitive disease, 20 patients had re-induction treatment with platinum drug: as single agent carboplatin, carboplatin in combination with paclitaxel, or cisplatin and cyclophosphamide. The other four patients in this group received paclitaxel or oral etoposide. Thirty-seven patients with platinum-resistant diseases received other single non-platinum chemotherapy. The type, number of chemotherapy, and clinical response are shown in Table 3. Except one patient who received weekly paclitaxel for 19 cycles, the median number of second-line drug treatment in 60 patients was four cycles (range, 1-9). Among 37 patients who did not respond to this second chemotherapeutic treatment, the median time to progress was 4.5 months (range 1.0-56.6 months).

Table 1. Characteristic features of diseases and primary surgery

Tumor characteristics and details of surgery	Number	Percent
Stage (n = 59)		
I	12	20.3
II	1	1.7
III	40	67.8
IV	6	10.2
Histology (n = 61)		
Serous cystadenocarcinoma	21	34.5
Mucinous cystadenocarcinoma	6	9.8
Clear cell carcinonoma	12	19.7
Endometrioid adenocarcinoma	13	21.3
Adenocarcinoma, not otherwise specified	6	9.8
Mixed epithelial tumor	3	4.9
Tumor grade (n = 50)		
I	2	4.0
II	13	26.0
III	35	70.0
Presence of ascites (n = 57)		
Presence	22	38.6
Absence	35	61.4
Type of primary surgery (n = 61)		
Complete surgical staging	26	42.6
Incomplete surgical staging	35	57.4
Result of primary surgery (n = 42)		
Optimal surgery	26	61.9
Suboptimal surgery	16	38.1

Table 2. Types and numbers of primary chemotherapy treatment, their responses, and platinum sensitivity status after primary chemotherapy treatment (n = 61)

Chemotherapy	Number	Percent
Type of chemotherapeutic drugs		
Platinum plus cyclophosphamide		
Cisplatin plus cyclophosphamide	44	72.1
Carboplatin plus cyclophosphamide	6	9.8
Platinum, not otherwise specified plus cyclophosphamide	3	5.0
Paclitaxel plus carboplatin	8	13.1
Number of chemotherapeutic treatment (cycle)		
1	2	3.3
2	1	1.6
3	5	8.2
4	6	9.8
5	4	6.6
6	36	59.0
> 6	7	11.5
Responses to primary chemotherapy		
Complete response	31	50.8
Partial response	2	3.3
Stable diseases	4	6.6
Progressive diseases	24	39.3
Platinum sensitivity		
Platinum-sensitive*	24	39.3
Platinum-resistant**	37	60.7

* 24 patients in the platinum-sensitive group were those who had complete response and had recurrence > 6 months after primary chemotherapy

** 37 patients in the platinum-resistant group comprised of 24 patients who had progress or refractory, 6 patients who had partial response or stable disease and 7 patients who had recurrence ≤ 6 months after primary chemotherapy

Table 3. Types and numbers of second-line chemotherapy treatment and responses rates (n = 61)

Chemotherapy	Number	Percent
Type of chemotherapeutic drugs		
Platinum plus cyclophosphamide	11	18.0
Paclitaxel plus carboplatin	9	14.8
Paclitaxel	11	18.0
Carboplatin	3	4.9
Gemcitabine	1	1.6
Ifosfamide	1	1.6
Oral etoposide	20	32.8
Megestrol acetate	2	3.2
Liposomal doxorubicin	3	4.9
Number of chemotherapeutic treatment (cycle)		
1	8	13.1
2	11	18.0
3	8	13.1
4	5	8.2
5	5	8.2
6	16	26.3
> 6	8	13.1
Responses to second-line chemotherapy		
Complete response	11	18.0
Partial response	3	5.0
Stable diseases	11	18.0
Progressive diseases	36	59.0

Table 4. Response of patients to second-line chemotherapy according to various characteristics

Characteristic features (n*)	Number of patients with response	Overall response rate (%)	p-value
Stage IC-IV, n = 59			
Early stage (I-II) (n = 13)	2	15.4	0.712**
Advanced stage(III-IV) (n = 46)	11	23.9	
Tumor grading, N = 50			
Well differentiated (n = 2)	0	0.0	1.000**
Moderate-poor differentiated (n = 48)	10	100.0	
Histology subgroup, n = 61			
Serous carcinoma (n = 21)	8	38.1	0.042*
Non-serous carcinoma (n = 40)	6	15.0	
Presence of ascites at primary diagnosis, n = 57			
Presence (n = 22)	3	13.6	0.179**
Absence (n = 35)	10	28.6	
Result of primary surgery, n = 42			
Optimal surgery (n = 26)	6	23.1	1.000**
Suboptimal surgery (n = 16)	3	18.8	
Platinum sensitivity, n = 61			
Platinum sensitive (n = 24)	9	37.5	0.030*
Platinum resistant (n = 37)	5	13.5	
Largest recurrent tumor size, n = 41			
$\leq$ 5 cm (n = 28)	7	25.0	1.000**
> 5 cm (n = 13)	3	23.1	
Site of recurrent tumor, n = 58			
$\leq$ 2 sites (n = 52)	11	21.2	0.608**
> 2 sites (n = 6)	2	33.3	
Liver involvement, n = 61			
No liver involvement (n = 44)	11	25.0	0.738**
Liver involvement (n = 17)	3	17.6	

Abbreviations: N, number of all patients with available data in each category; n, number of patients in each subcategory
* p-value by Chi-Square
** p-value by Fisher's Exact

The authors studied the response rate according to the interesting factors with available clinicopathological data (Table 4). The number of patients who had known result of secondary surgery was too small so the authors did not include them in the subgroup analysis. Only histological type and platinum-sensitivity had significant impact on the response rate. No statistically significant differences were observed among other subgroups evaluation.

Overall, 31 patients (50.8%) were treated further with other chemotherapy: 28 patients who did not respond and three patients who had partial response or recurrence after chemotherapy in this second setting. The other half had poor performance status, or preferred to undergo only palliative care without further salvage treatment. Median PFS of all 61 patients was 5.7 months (95% confidence interval [CI], 4.7-6.7 months). The 2-year PFS was 30.5% (95%CI, 16.7-44.3%). At the time of the present study, 39 of the 61 patients (64.5%) had died: 36 patients died of their cancer and the other three from intercurrent diseases. Median OS of all patients who had chemotherapy in the second setting was 18.3 months (95%CI, 2.7-34.0 months) with 2-year survival of 45.7% (95%CI, 31.5-55.9%).

The authors studied the PFS and OS according to platinum-sensitivity and the response to chemotherapy in the second setting. The authors found that median PFS of platinum sensitive group was significantly longer than that of the platinum resistant group. Median PFS of platinum-sensitive patients had not been reached while that of the platinum-resistant group was 5.1 months (95%CI, 4.1-6.1 months (p = 0.015)). The 2-year PFSs were 53.6% (95%CI, 32.3-74.8%) and

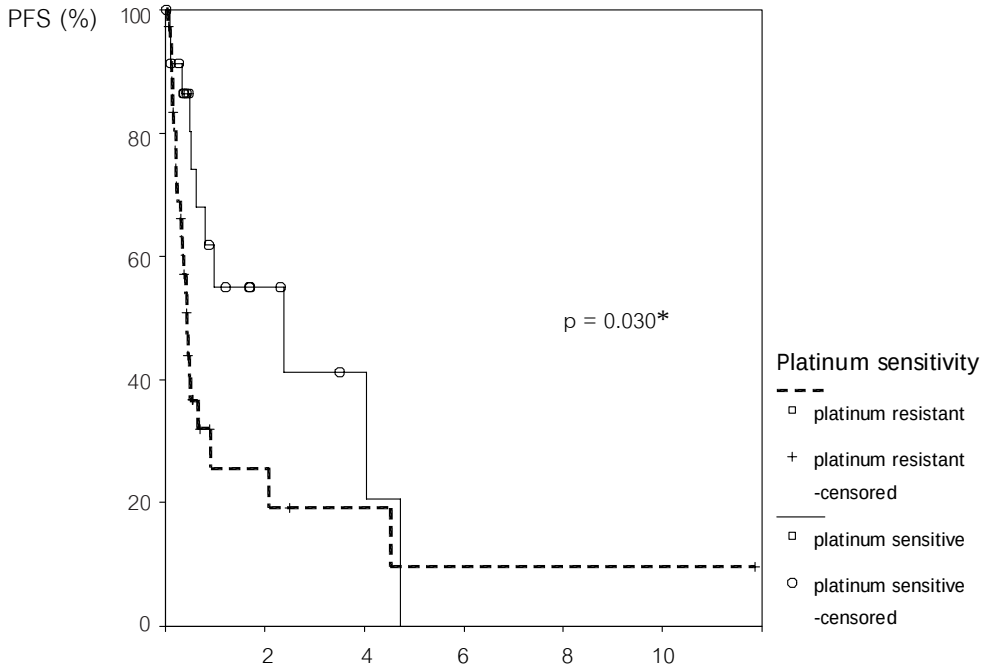

Fig. 1 Progression-free survivals of platinum-sensitive and platinum-resistant epithelial ovarian cancer patients receiving second-line chemotherapy (n = 61)
* p value obtained by Log-rank test

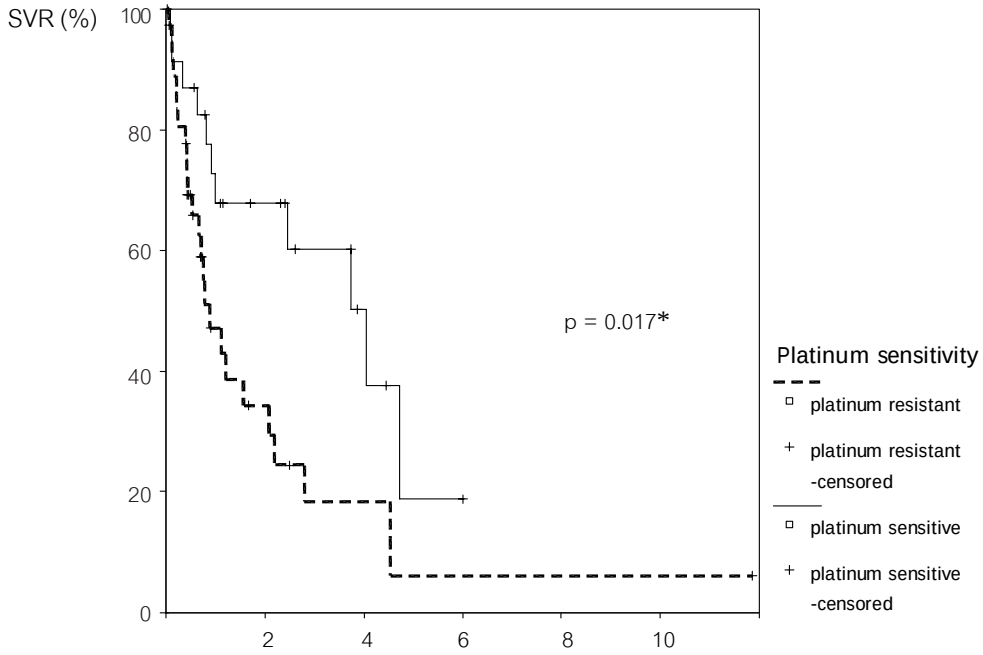

Fig. 2 Survival of platinum-sensitive and platinum-resistant epithelial ovarian cancer patients receiving second-line chemotherapy (n = 61)
* p-value obtained by Log-rank test

15.3% (95%CI, 0.3-30.0%) respectively. In the same directions as PFS, median OS of platinum-sensitive patients was significantly longer than that of the platinum resistant; 47.3 months (95%CI, 23.4-71.2 months) versus 10.3 months (95%CI, 4.2-16.4 months) ($p = 0.017$) with 2-year OS of 67.8% (95%CI, 48.1-87.6%) and 29.4% (95% CI, 11.6-47.2%) respectively.

Discussion

Ovarian cancer is considered one of the most chronic and difficult-to-treat gynecologic cancers. Many patients who have been treated with surgery and primary chemotherapy frequently experienced recurrence, especially those with advanced stage diseases. Secondary surgery has a limited role in recurrent diseases and is considered only in certain groups of patients, while chemotherapy appears to play a major role of treatment in this setting. This salvage or subsequent chemotherapy would be given after the secondary surgery, or given directly to those with a disease resistant to primary chemotherapy.

One important consideration to decide the type of chemotherapy for recurrent epithelial ovarian cancer is the platinum sensitivity status of recurrent diseases. Generally, the response rates to chemotherapy are generally higher in platinum-sensitive diseases than those with platinum-resistant diseases. Patients whose tumors are platinum-sensitive are usually re-treated with platinum drug. Those platinum-resistant patients are usually treated with other single non-cross resistant agent.

The authors included 61 EOC patients who had persistent or recurrent diseases and were treated in the authors' institution. The authors included patients who received re-induction treatment with platinum drug and other second-line drug in the present study to have an overview of chemotherapy efficacy in the second setting. Almost all patients with platinum-sensitive disease in the present study were retreated with platinum agent. One important issue regarding treatment of recurrent platinum-sensitive EOC with platinum drug is about the platinum regimen - as a single agent or in combination with other drugs. In the authors' institution, the authors tended to use platinum combination for this particular group of patients. From 20/24 platinum-sensitive patients who were re-treated with platinum drugs in the present study, almost all had platinum in combination with cyclophosphamide. A few large randomized trials with positive results in favor of combination therapy of platinum with epidoxorubicin, or paclitaxel, or gemcitabine were evidenced in terms of symptom control, improvement of RR, PFS, and probably OS[6-8]. These reports deemed to support the authors' practice. Nevertheless, the other two platinum-sensitive patients were treated with paclitaxel to avoid repeated toxicity of platinum drugs from the primary treatment and the other two received oral etoposide based on their own preference to have oral chemotherapy as an outpatient basis. In platinum-resistant patients, various types of non-platinum agents were used. Many factors are taken into consideration in this group of patients, when the aim of treatment and expected outcome might be somewhat different or lesser than the platinum-sensitive group. These factors are for example the efficacy of the drug, status of recurrent or persistent diseases, performance status of the patients including co-morbidity and the residual side effects from previous treatment. Cost is also another important issue, especially during the past few years when the new public health care system has been employed. Nevertheless, benefit to the patients is the most important consideration for the final decision for chemotherapy treatment.

From various types of chemotherapy used for the presented patients with persistent or recurrent diseases after first line chemotherapy, the response rate to chemotherapy in this second-setting was 23.0%. This was in the range with the other studies, which reported the efficacy of each particular single or combination chemotherapy regimens which varied from 10-30%[9]. Many factors might influence the response of recurrent diseases to chemotherapy. One large study by Eisenhauer et al reported predictors of response to subsequent chemotherapy in patients with ovarian cancer[10,11]. Of the potential prognostic factors analyzed on univariate analysis, some were found to be significant-age, tumor grade, histology (serous versus non-serous type), presence of ascites at primary surgery and residual disease after primary cytoreduction, drug used, response to last chemotherapy, time since last treatment, number of disease sites (> 2), tumor size and liver metastasis.

The authors also studied response rates according to the interesting factors with available data. The authors study also showed that patients with platinum-sensitive diseases had a 37.5% response rate compared to 13.5% in those with platinum-resistant diseases ($p = 0.030$). While tumors of serous histology also showed a higher response rate than those of other histologic cell types, 57.1% compared to 42.9% respectively ($p = 0.042$). Patients with the absence of ascites at primary diagnosis, the largest recurrent

tumor size ≤ 5 cm, or number of recurrent tumors ≤ 2, or absence of liver parenchyma involvement had higher response rates than the other corresponding groups. The differences did not have any statistical significance.

Median progression-free survival (PFS) and overall (OS) of the patients who received chemotherapy in the second-setting in the present study were only modest, only in the number of months: 5.7 months and 18.3 months respectively. Regarding the survival outcome in recurrent EOC, many prognostic factors have been studied. Segna et al reported size of residual tumors after secondary surgery and an interval between primary surgery and secondary surgery for recurrent cancer as being important[14]. They found that median survival was significantly longer if the interval between initial and secondary surgery was ≥ 12 months. Other favorable factors included optimal surgery, previous response to cisplatin therapy, and age < 55 years. The strongest predictor of survival was residual tumor < 2 cm[12]. Eisenkop et al. also reported factors that might be predictors of better survival in their large series of recurrent ovarian cancer patients: long disease-free interval (DFI) after primary treatment, completeness of the secondary surgical cytoreduction, and the use of salvage chemotherapy[15]. The authors did not focus on secondary surgery as a prognostic factor because only a few EOC patients in the present study had surgery for their recurrent diseases. The authors found that the patients with platinum-sensitive (long disease-free interval > 6 months) had a significantly longer PFS and OS than those with platinum-resistant. The present study was limited due to the small number of patients, yet, they were also in agreement with the study by Eisenkop et al and Segna et al[12,13].

In conclusion, the response rate chemotherapy in the second-setting of epithelial ovarian cancer in the present study was only modest and was in the range with other reports of any specific drug. The median PFS and OS were not very long either. Although cost-benefit must be one important factor of concern in taking care of the patients, the patients' need must also be respected. The median time to progress of the non-responders to chemotherapy in the second-setting of 4.5 months might be meaningful to the patient and her family. These results might provide basic information to the caregivers and in counseling the patients for optimal decision-making.

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การใช้ยาเคมีบำบัดในผู้ป่วยมะเร็งรังไข่ชนิดเยื่อบุผิวที่ดื้อยาเคมีบำบัดขั้นแรกหรือที่กลับเป็นซ้ำ

ดาราวดี สัทธาพงศ์, ศิริวรรณ ตั้งจิตกมล, สุมนมาลย์ มนัสศิริวิทยา, กมล ภัทราดูลย์

วัตถุประสงค์: *เพื่อศึกษาอัตราการตอบสนองต่อเคมีบำบัด ระยะเวลาที่โรคไม่ดำเนินต่อและระยะเวลาการอยู่รอดของผู้ป่วยมะเร็งรังไข่ชนิดเยื่อบุผิวที่กลับเป็นซ้ำและดื้อยา*

วัสดุและวิธีการ: *รวบรวมศึกษาข้อมูลของผู้ป่วยมะเร็งรังไข่ชนิดเยื่อบุผิวที่กลับเป็นซ้ำที่ได้รับยาเคมีบำบัดที่ภาควิชาสูติศาสตร์-นรีเวชวิทยา วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล ตั้งแต่เดือนมกราคม พ.ศ. 2537 ถึง เดือนธันวาคม พ.ศ. 2548*

ผลการศึกษา: *ในช่วงเวลาที่ศึกษา พบผู้ป่วยมะเร็งรังไข่ชนิดเยื่อบุผิวที่ตรงตามเกณฑ์การคัดเลือก จำนวน 61 ราย ผู้ป่วยทุกรายได้รับการผ่าตัดและไม่ตอบสนองหรือมีการกลับเป็นซ้ำหลังได้รับยาเคมีบำบัดขั้นแรก ผู้ป่วยจัดเป็นกลุ่มที่ดื้อต่อยาพลาตินั่ม 37 ราย (60.7%) และตอบสนองดีต่อยาพลาตินั่ม 24 ราย (39.3%) ผลอัตราการตอบสนองโดยรวมของผู้ป่วย 61 รายต่อยาเคมีบำบัด คือ 23.0% (14 ราย) โดยเป็นการตอบสนองโดยสมบูรณ์ 18.0% (11 ราย) การตอบสนองเป็นบางส่วน 5.0% (3 ราย) การอยู่คงที่ของโรค 18.0% (11 ราย) และการดำเนินเพิ่มของโรค 59.0% (36 ราย) ค่ามัธยฐานของระยะเวลาที่โรคไม่ดำเนินต่อเท่ากับ 5.7 เดือน (95%CI, 4.7-6.7 เดือน) ค่ามัธยฐานของระยะเวลาการอยู่รอดเท่ากับ 18.3 (95% CI, 2.7-34.0 เดือน) พบว่าในกลุ่มที่ตอบสนองดีต่อยาพลาตินั่มจะมีการตอบสนองต่อยาเคมีบำบัดที่ดีกว่าระยะที่ไม่ดำเนินต่อของโรคและระยะเวลาการอยู่รอดจะยาวกว่าในกลุ่มที่ดื้อต่อยาพลาตินั่ม*

สรุป: *อัตราการตอบสนองต่อเคมีบำบัดของผู้ป่วยมะเร็งรังไข่ชนิดเยื่อบุผิวที่กลับเป็นซ้ำค่อนข้างต่ำ ระยะที่ไม่ดำเนินต่อและระยะเวลาการอยู่รอดประมาณ 1 ปี กลุ่มที่ตอบสนองดีต่อยาพลาตินั่มจะมีการพยากรณ์โรคที่ดีกว่ากลุ่มที่ดื้อต่อยาพลาตินั่มทั้งในแง่ของอัตราการตอบสนอง ระยะที่ไม่ดำเนินต่อ และระยะเวลาการอยู่รอด*