Adverse affects of Paclitaxel and Carboplatin Combination Chemotherapy in Epithelial Gynecologic Cancer

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Objective: *To evaluate the adverse affects of paclitaxel and carboplatin combination chemotherapy.*
Design: *Descriptive cross sectional study*
Material and Method: *Patients with epithelial cancer of the ovary, fallopian tube and peritoneum treated with paclitaxel and carboplatin combination chemotherapy at Chiang Mai University Hospital between August 2003 and August 2004.*
Results: *Of 224 evaluable cycles in 63 patients treated with paclitaxel (175 mg/m^2) and carboplatin (AUC 5), grade 3 and 4 neutropenia occurred in 37.1% or 41.3% of patients. 4.8% of patients experienced febrile neutropenia. Grade 3 and 4 leukopenia occurred in 8.6% of courses and 12.6% of patients. Grade 3 anemia occurred in 5.2% of courses and 9.5% of patients. Grade 3 thrombocytopenia occurred in 2.8% of courses and 9.6% of patients. The nonhematologic adverse affects were rare, however, some adverse events may be potentially life threatening.*
Conclusion: *Adverse affects of paclitaxel and carboplatin combination chemotherapy are acceptable and manageable in the majority of patients.*

Keywords: *Adverse affects, Paclitaxel, Carboplatin, Epithelial gynecologic cancer*

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Despite advances in diagnostic techniques and therapy, the outcome of treatment for epithelial ovarian cancer is still poor. One of the main reasons is the advanced stage at presentation[1]. Comprehensive surgical staging is currently the intervention of first choice. However, adjuvant chemotherapy is usually required in 80-90% of patients because surgery cannot eradicate the microscopic and macroscopic diseases that frequently present due to the pattern of metastases that results in peritoneal carcinomatosis[2]. Currently, the chemotherapeutic regimen of choice consists of the combination of a platinum compound (preferably carboplatin) and paclitaxel[3].

Epithelial cancer of the fallopian tube and peritoneum are a rare disease, accounting for less than 1% of all gynecologic malignancies. These two tumors resemble epithelial ovarian cancer in its clinical behavior and response to treatment, specifically serous variety and are usually treated with the same surgical approach followed by combination chemotherapy[4-6].

As it is always important to balance the risk and benefit when setting out treatment plans, knowledge of the adverse affects is clearly necessary for an informed treatment decision to be made. The present study was undertaken to evaluate the adverse affects of paclitaxel and carboplatin combination chemotherapy with special consideration for myelosuppression.

Material and Method

Patients

Between August 2003 and August 2004, 63 patients (including 224 cycles) were treated with the combination chemotherapy consisting of paclitaxel and carboplatin for a total of 224 cycles. To be eligible for the present study, the patients had to have histologically documented epithelial cancer of the ovary,

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fallopian tube and peritoneum. Patients with a prior or concomitant malignancy and radiation therapy were excluded.

Treatment schedule

Before each treatment course, a complete history and physical examination were carried out. Baseline laboratory studies included serum chemistry, complete blood count, electrocardiography (ECG) and CA 125 determination. After each treatment course, serial complete blood count were investigated in all patients to determine the degree of myelosuppresion. A adverse affects survey using the questionnaire was recorded.

Paclitaxel was administered at a dose of 175 mg/m^2, infused over 3 hours, every 21 days. Premedication consisted of 20 mg intravenous dexamethasone, 200 mg intravenous cimetidine, 10 mg intravenous chlorpheniramine intravenously and 25 mg oral diphenhydramine given 30 minutes before paclitaxel treatment.

After complete infusion of paclitaxel, carboplatin was administered at an area under the concentration-time curve (AUC) of 5 which calculated according to the Calvert formula[7]. The glomerular filtration rate was calculated according to the Jelleffe formula[8].

Adverse affects were classified according to the National Cancer Institute Common Toxicity Criteria[9] (NCI CTC). Data were analyzed with the STATA program to describe descriptive statistics as mean, standard deviation, number, percentage and 95% confidence interval.

Results

The patients' characteristics are shown in Table 1. A total of 63 patients (mean age: 54 years: range 33-68 years) were enrolled into the present study. The diagnosis included epithelial ovarian cancer (55), epithelial primary peritoneal cancer (5) and epithelial fallopian tube cancer (3). Serous type was the most common histology found in 28 patients or 44.4%. About 88.9% (56 patients) received this chemotherapy regimen in the first line setting.

Among the 224 cycles of chemotherapy, the neutropenia was the most frequent grade 3 and 4 hematologic adverse affects occurring in 37.1% or 41.3% of patients, whereas the least frequent was thrombocytopenia occurring in 2.8% or 9.5% of patients. Despite the high frequency of grade 3 and 4 neutropenia, only 3 patients (4.8%) developed febrile neutropenia. Grade 3 anemia was observed in 5.2% of courses or 9.5% of patients and was manageable with blood transfusion (Table 2).

Table 1. Patient Characteristics (63 patients)

Patient Characteristics	N (%)
Mean age (range) year	54 (33-68) years
Type of gynecologic cancer	
Epithelial ovarian cancer	55 (87.3)
Epithelial peritoneal cancer	5 (8.0)
Epithelial fallopian tube cancer	3 (4.7)
Histology	
Serous	28 (44.4)
Clear cell	16 (25.4)
Endometrioid	13 (20.6)
Others	6 (9.6)
FIGO staging	
Stage I	14 (22.2)
Stage II	11 (17.5)
Stage III	26 (41.3)
Stage IV	12 (19.0)
Chemotherapy	
First line	56 (88.9)
Second line	6 (9.5)
Third line	1 (1.6)

Peripheral sensory neuropathy, myalgia and alopecia were common nonhematologic adverse affects. Peripheral sensory neuropathy and myalgia were noted in 79.3% and 50.9% of patients and most were mild (grade 1 and 2) adverse affects. All patients experienced alopecia and 93.7% of patients developed complete alopecia.

About grade 3 and 4 nonhematologic adverse affects, vomiting was observed in3.2% of patients while diarrhea, seizure and epidermal necrolysis occurred in 1.6% of patients, respectively. The clinico-radiologic diagnosis in patients experiencing seizure was posterior reversible encephalopathy syndrome (PRES) which spontaneously resolved after discontinuation of paclitaxel and well controlled blood pressure. Cardiac and circulatory effects were rare, grade 2 adverse affects being reported in 2 patients (3.2%) who developed palpitation without documented arrhythmia and treatment-related arrhythmia, respectively (Table 3).

Discussion

The most common hematologic adverse affects of paclitaxel and carboplatin combination chemotherapy was neutropenia and was noncumulative effects[10]. Du Boise et al reported 37% of grade 3 and 4 neutropenia of patients who received paclitaxel

Table 2. Hematologic adverse affects

	Set	N	NCI CTC grade (%)				Grade 3+4 (%)	95% CI
			1	2	3	4		
Neutropenia	C	224	32.1	30.8	26.8	10.3	37.1	30.7-43.7
	P	63	27.0	31.7	25.4	15.9	41.3	29.0-54.4
Leukopenia	C	208	72.1	19.3	6.7	1.9	8.6	5.2-13.3
	P	63	50.8	36.3	7.9	4.7	12.6	5.6-23.4
Anemia	C	189	65.6	29.1	5.2	-	5.2	2.5-9.5
	P	63	69.8	20.5	9.6	-	9.6	3.5-19.5
Thrombocytopenia	C	210	83.9	13.3	2.8	-	2.8	1.1-6.1
	P	63	80.8	9.6	9.6	-	9.6	3.5-19.5
Febrile neutropenia	P	63	-	-	4.8	-	4.8	0.9-13.3

Abbreviations: CI = Confidence Interval C = maximum grade over all course
P = maximum grade over all course within patient
N = number of courses in set C and number of patients in set P

Table 3. Nonhematologic adverse affects (N = 63)

	NCI CTC (%)				Grade 3+4 (%)	95% CI
	1	2	3	4		
Vomiting	33.3	6.3	3.2	-	3.2	0.3-11.3
Dermatitis	4.8	3.2	1.6	-	1.6	0.04-8.5
Diarrhea	9.5	6.3	1.6	-	1.6	0.04-8.5
Myalgia/Bone pain	39.7	9.6	1.6	-	1.6	0.04-8.5
Seizure	-	-	1.6	-	1.6	0.04-8.5
Alopecia	6.3	93.7	-	-	-	-
Peripheral sensory neuropathy	71.4	7.9	-	-	-	-
Constipation	15.8	-	-	-	-	-
Cardiac	12.9	3.2	-	-	-	-
Allergy	3.2	-	-	-	-	-
Creatinine	3.2	-	-	-	-	-
SGOT/SGPT/AP	9.5	-	-	-	-	-

Abbreviations: N = Number of patients, SGOT = Serum glutamic oxaloacetic transaminase
SGPT = Serum glutamic pyruvic transaminase, AP = Alkaline phosphatase
CI = Confidence Interval

(185 mg/m^2) as 3 hours infusion with carboplatin at an AUC of 6 mg/mL/min[11]. Additionally, Ozol et al reported 89% of grade 3 and 4 neutropenia of patients who received paclitaxel (175 mg/m^2) with carboplatin at an AUC of 7.5 mg/mL/min[12]. In the present study, grade 3 and 4 neutropenia was observed in 37.1% of courses and 41.3% of patients treated with paclitaxel (175 mg/m^2) as 3 hours infusion followed by carboplatin at an AUC of 5 mg/mL/min. The higher incidence in study of Ozol et al might be caused by using a higher dose of carboplatin which increased hematologic adverse affects. Although the effect of the neutropenia was significant, the duration of these events was generally short (7-10 days), and only 3 of 63 patients developed febrile neutropenia in the present study.

A platelet-sparing effect of paclitaxel has been reported in both first line treatment and heavily pretreated patients when administered before the carboplatin infusion in the subsequent treatment[13-15]. This effect is not associated with changes in the pharmacokinetics of carboplatin[16]. Recently, Pertussini et al reported that P-glycoprotien-mediated efflux of paclitaxel, perhaps in association with glutathione S-transferase-mediated detoxification of carboplatin, resulted in the relative sparing of marrow colony-forming units-megakaryocytes after exposure to these chemotherapeutic agents[17]. Du Boise et al reported 3% grade 3 and 4 thrombocytopenia of courses and 13% of patients[11]. In the present study, the authors observed 2.8% and 9.6% grade 3 thrombocytopenia of courses and of patients, respectively.

None had grade 4 thrombocytopenia. This is consistent with the platelet-sparing effect of this combination chemotherapy.

In general, the proportion of patients experiencing grade 3 and 4 nonhematologic adverse affects remain below 10%[18,19]. These adverse affects are in accordance with the current study. Peripheral sensory neuropathy and myalgia were generally modest. No grade 3 and 4 peripheral sensory neuropathy were found and only 1.6% of patients experienced grade 3 myalgia. Du Bois et al reported an overall grade 3 and 4 peripheral sensory neuropathy and myalgia of 7.2% and 14.7% respectively[11]. Mayerhofer et al reported grade 3 peripheral neuropathy of 5%[20]. These comparable low incidence in the presented data might be explained by 2 possible reasons. First, the authors used a lower dosage of paclitaxel than that in the study of Du Bois et al. Second, these adverse effects were objective and difficult to evaluate. Thus, nerve conduction velocity testing such as current perception threshold (CPT) values proposed by Doi et al was advised to increase the accuracy of neurotoxicity evaluation[21].

Despite antiemetic prophylaxis consisting of both serotonin type 3 receptor antagonist and corticosteriod, 42.8% of the patients experienced at least one treatment cycle with vomiting of any grade and 3.2% of patients developed grade 3 vomiting. Du Bois et al reported an overall vomiting and severe (grade 3 and 4) vomiting in 48.5% and 2.8% of patients, respectively[11]. Bookman et al reported grade 3 vomiting in 2.8% of patients[12]. These accordant results demonstrated that vomiting was generally modest with mostly mild symptoms when treated with appropriate antiemetic prophylaxis. 1.6% of the presented patients suffered grade 3 diarrhea which is also in accordance with previous studies which reported grade 3 and 4 diarrhea in 0-2.8% of patients[11,12].

As with the majority of chemotherapeutic agents, alopecia is common with paclitaxel. Du Bois et al reported complete alopecia (grade 2) of 95.6%[11]. In the presented data, complete alopecia was noted in 93.7% of patients and affected approximately 14-21 days after the beginning of therapy. Although this adverse affects has significant effect on body image, it is acceptable and does not pose any clinical risk to the patients.

The rare adverse affects in the present study were extensive epidermal necrosis, treatment-related cardiac arrhythmia and seizure. Adverse cutaneous reactions to paclitaxel have been reported, namely bullous fixed drug eruption, onycholysis, acral erythma, erythema multiforme, pustular eruption and scleroderma-like cutaneous lesion[23-27]. The authors found 1 patient with platinum-sensitive recurrent epithelial ovarian cancer who developed extensive epidermal necrolysis requiring hospitalization and intravenous antibiotics administration.

Paclitaxel has been associated with cardiac adverse affects, ranging from asymptomatic tachy and brady arrhythmias to fatal myocardial infarction[28]. Nguyen et al reported a patient who suffered an acute myocardial infarction and cardiac arrest while receiving an intravenous infusion of paclitaxel. Coronary angiogram revealed only mild plaquing of the infarct-related artery without significant angiographic obstruction. They postulated that paclitaxel may have caused coronary vasospasm and myocardial infarction[29]. In the present study, the authors found 1 patient who experienced palpitation and fainted during the infusion of paclitaxel. Immediate ECG showed a pattern of sinus pause. 24-hour cardiac monitoring revealed a pattern of paroxysmal ventricular tachycardia. Persantin Thallium-201 myocardial perfusion study was further investigated and demonstrated a suspicious small area of myocardial ischemia. She was then treated with single-agent carboplatin. The role of paclitaxel retreatment in this patient has to be balanced between clinical risk and benefit. Markman et al reported 15 patients who had major cardiac risk factors prior to therapy. These risk factors included preexisting congestive heart failure, severe coronary heart disease, angina and patients who were being treated for rhythm disturbances with agent such as beta-blocker. No patients suffered a worsening of cardiac function following treatment with paclitaxel[30]. However, because of the very small number of patients in the present report, additional study is needed to evaluate the safe administration of intravenous paclitaxel in a clinical setting of retreatment in patients who experienced cardiac adverse affects or patients with preexisting cardiac risk factor.

One patient in the presented data receiving paclitaxel for recurrent epithelial ovarian cancer developed the clinical-radiologic syndrome of posterior reversible encephalopathy syndrome (PRES). She had clinical manifestation of hypertension, headache and tonic-clonic seizure during the infusion of paclitaxel. CT brain scan showed bilateral interstitial brain edema and ill-defined patchy hypodense lesions involving occipital, frontal and parietal lobes of both

cerebral hemisphere without enhancing the lesion on the post contrast study. After well-controlled blood pressure was achieved, repeated CT brain scan 19 days later showed disappearance of the previous ill-defined patchy hypodense lesions. The posterior reversible encephalopathy has been reported with the use of cyclosporine, gemcitabine, cytarabine and cisplatin[31-34]. The pathophysiology remains incompletely understood. Impairment in cerebrovascular autoregulatory control is a major hypothesis[35,36]. PRES is rare but a recognized complication of cisplatin therapy. It has been observed as late as 3 months after repeated infusion of the chemotherapeutic agent[34]. It might be the cause in the presented patient since she received her last dose of cisplatin only 4 months prior to the development of the syndrome. Nevertheless, the contributory effect of previous administration of cisplatin to the development of PRES with the institution of paclitaxel cannot be excluded in the present case.

In conclusion, neutropenia occurred in the majority of patients in the present study but its consequence was manageable with a few patients having documented febrile neutropenia. Regarding other hematologic adverse affects, the proportion of patients experiencing grade 3 and 4 adverse affects remained low. The grade 3 and 4 nonhematologic adverse affects were rare but some adverse events may be potentially life threatening and require early recognition and treatment.

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ผลข้างเคียงจากการใช้ Paclitaxel and Carboplatin ยาเคมีบำบัดในผู้ป่วยมะเร็งนรีเวชชนิดเยื่อบุผิว

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วัตถุประสงค์: ศึกษาผลข้างเคียงของ Paclitaxel และ Carboplatinในผู้ป่วยมะเร็งนรีเวชชนิดเยื่อบุผิว
วัสดุและวิธีการ: ผู้ป่วยมะเร็งเยื่อบุผิวรังไข่ ท่อนำไข่และเยื่อบุช่องท้องที่ได้รับ Paclitaxel และ Carboplatin ที่โรงพยาบาลมหาราชนครเชียงใหม่ ระหว่างสิงหาคม พ.ศ. 2546 ถึงสิงหาคม พ.ศ. 2547
รูปแบบการศึกษา: การศึกษาเชิงพรรณนาแบบตัดขวาง
ผลการศึกษา: จากการรักษา 224 รอบ ในผู้ป่วย 63 ราย ที่ได้รับ Paclitaxel (175 mg/m^2) และ Carboplatin (AUC 5) พบเม็ดเลือดขาวชนิด neutrophil ต่ำระดับ 3 และ 4 ร้อยละ 37.1 หรือร้อยละ 41.3 ของผู้ป่วย ร้อยละ 4.8 ของผู้ป่วยเกิด febrile neutropenia พบเม็ดเลือดขาวต่ำระดับ 3 และ 4 ร้อยละ8.6 ของรอบหรือร้อยละ12.6 ของผู้ป่วย พบเกล็ดเลือดต่ำระดับ 3 ร้อยละ5.2 ของรอบหรือร้อยละ9.5ของผู้ป่วย ภาวะซีดระดับ 3 พบได้ร้อยละ 2.8 ของรอบหรือร้อยละ 9.6 ของผู้ป่วย ผลข้างเคียงในกลุ่มที่ไม่ใช่ผลข้างเคียงทางโลหิตวิทยาพบได้น้อย แต่บางภาวะอาจทำให้เกิดอันตรายที่รุนแรงถึงแก่ชีวิตได้
สรุป: ผลข้างเคียงจาก Paclitaxel และ Carboplatin อยู่ในเกณฑ์ยอมรับได้และส่วนใหญ่ไม่ก่อให้เกิดภาวะแทรกซ้อนรุนแรง