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A STUDY OF TOXICITY OF PACLITAXEL AND CARBOPLATIN CHEMOTHERAPY IN PATIENTS WITH CANCER OVARY

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ABSTRACT

Introduction: Ovarian cancer is one of the most common gynecologic cancers. The World Health Organization categorized ovarian cancer on the basis of tissue of origin. The prognosis for women with advanced stage disease is poor. Paclitaxel-platinum doublet chemotherapy and optimal cytoreductive surgery are the standard of care for advanced epithelial ovarian carcinoma. Neutropenia is the most serious hematologic toxicity of cancer chemotherapy. Neuropathy is often associated with Paclitaxel chemotherapy. Peripheral neuropathy negatively impacts quality of life in patients. The most common clinical neurotoxicity associated with paclitaxel administration is a predominantly sensory peripheral neuropathy. This study was undertaken to assess the safety of Paclitaxel Carboplatin chemotherapy regimen in patients with Cancer Ovary and to observe the toxicities.

Material and Methods: This was an observation study. All patients with epithelial cancer ovary and received Paclitaxel plus Carboplatin chemotherapy were included in this study. The patient characteristics like Age of patient, ECOG performance status, histopathology of the tumour, Stage of disease at presentation were recorded. The performance status was assessed before and after chemotherapy Staging was done using FIGO classification. Toxicities were recorded at the end of each cycle.

Results: A total of 78 patients were studied in three years. Mean age was 52.37 years. The majority of the patients presented with stage 3 disease and most of the patients were found to have serous carcinoma. Sensory peripheral neuropathy was seen in 25.64% patients and Motor Neuropathy11.54% of patients. Neutropenia was the most important haematological toxicity and 7 patients needed chemotherapy postponement.

Conclusion: Sensory neuropathy is more than motor neuropathy. Chemotherapy was well tolerated by most of the patients. Neutropenia was the most important toxicity which resulted in postponement of chemotherapy.

Key words: Cancer ovary, paclitaxel carboplatin, chemotherapy, toxicity.

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INTRODUCTION

Ovarian cancer is one of the most common gynecologic cancers that rank third after cervical and uterine cancer. It is the 7th cause of death and morbidity in females worldwide[1]. Women are at risk of developing ovarian cancer 1 in 75 and 1 in 100 will be at risk of death due to this fatal condition[2]. The World Health Organization categorized ovarian cancer on the basis of tissue of origin: Epithelial surface tumor (65%), ovarian germ cell (15%), sex cord tumor (10%), metastatic ovarian tumor (5%), and miscellaneous ovarian tumor (5%). In most of the population-based cancer registries in India, ovarian cancer is the third leading site of cancer among women, trailing behind cervix and breast cancer[3,4,5]. India with more than one billion population has a huge burden of cancer ovary. Most of the ovarian cancers are

initially operated by general gynecologists since trained gynecological oncologists are very few in the country[5,6].The hindrances for not diagnosing this tumor early are late presentation and ineffective screening modalities. According to National Comprehensive Cancer Network recommendations, monitoring of CA-125 concentration is not obligatory for follow-up, but it is common in everyday clinical practice. Ovarian tumors are often difficult to detect until they are advanced in stage or size, as symptoms are vague and insidious. Radical Surgery still remains the cornerstone towards cure in the management of cancer ovary[6,7,8].

Paclitaxel and carboplatin became the standard of care in the management of epithelial ovarian carcinoma. Complete resection of all macroscopic disease (optimal cytoreduction) is the single most important independent prognostic factor in advanced early ovarian cancer (EOC). Neoadjuvant chemotherapy followed by interval debulking surgery has been proposed in the management of advanced ovarian cancer. For Stage III and IV ovarian cancers, almost 2/3rd of the participants have the experience of complete cytoreduction after neoadjuvant chemotherapy[8,9]. Chemotherapy plays a pivotal role in the management of ca ovary. It is indicated in all patients with high grade disease irrespective of the stage of disease and in patients with stage 1c and above. Paclitaxel-platinum doublet chemotherapy and optimal cytoreductive surgery are the standard of care for advanced epithelial ovarian carcinoma. The Paclitaxel Carboplatin regimen has been studied as adjuvant therapy in ovarian cancer and primary treatment of relapsed platinum-sensitive ovarian cancer. The standard dose of this regimen is 175mg/m^2(Body surface area) of Paclitaxel and Carboplatin dose of Area Under Curve (AUC) 5 to 6 both given as IV administration. Both the drugs are repeated every 21 days[8,10,11,12]. Paclitaxel injection produces hypersensitivity reactions in about 10% of patients. Routine prophylactic pre-medications should be given prior to paclitaxel administration. Cytotoxic chemotherapy predictably suppresses the hematopoietic system, impairing host protective mechanisms. Neutropenia is the most serious hematologic toxicity of cancer chemotherapy, often limiting the doses of chemotherapy that can be tolerated. The degree and duration of the neutropenia determine the risk of infection. Because neutropenia reduces the signs and symptoms of infection, patients with neutropenia often may present with fever as the only sign of infection[11,12]. Neuropathy is often associated with Paclitaxel chemotherapy. Peripheral neuropathy negatively impacts quality of life in cancer patients and survivors. 20–100% of patients develop a condition known as chemotherapy-induced peripheral neuropathy (CIPN). CIPN occurs when peripheral nerves are damaged, resulting in abnormal sensory function, and pain or loss of motor control. The most common clinical neurotoxicity associated with paclitaxel administration is a predominantly sensory peripheral neuropathy. The neurotoxicity is dose- and infusion-duration related, and most frequently occurs when the dose of paclitaxel per administration exceeds 250 mg/m^2 infused over 24 hours[13,14,15,16]. This study was undertaken with the following objectives

To study the safety of Paclitaxel Carboplatin chemotherapy regimen in patients with Cancer Ovary and to observe the toxicities

To study the age distribution, performance status, histological type and stage of disease at presentation.

MATERIAL AND METHODS

This observation study was conducted at a Tertiary cancer care centre of South Kerala for a period of THREE years from August 2016 to July 2019 after getting clearance from the Institutional Research committee and the Institutional Ethics committee. The study was conducted at the cancer department where patients received chemotherapy mainly in the day care chemotherapy ward. All patients with epithelial cancer ovary who were having indication for chemotherapy and received Paclitaxel plus Carboplatin chemotherapy were included in this study after getting informed consent from all the patients. Patients above 75 years of age and with ECOG performance 3 and above were excluded from this study. The patient characteristics like Age of patient, ECOG performance status, histopathology of the tumour, Stage of disease at presentation were recorded. The performance status was assessed before and after chemotherapy Staging was done using FIGO classification 2014.

GRADE ECOG PERFORMANCE STATUS

0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair
5	Dead

FIGO staging for Ca Ovary

Stage 1A: Tumor limited to 1 ovary, capsule intact, no tumor on surface, negative washings.

Stage 1B: Tumor involves both ovaries otherwise like IA.

Stage 1C: Tumor limited to1 or both ovaries with surgical spill, and/or Capsule rupture before surgery or tumor on ovarian surface, and/or Malignant cells in the ascites or peritoneal washings

Stage 2A: Extension and/or implant on uterus and/or Fallopian tubes

Stage 2B: Extension to other pelvic intra peritoneal tissues

Stage 3A: Positive retroperitoneal lymph nodes and /or microscopic metastasis beyond the pelvis

Stage 3B: Macroscopic, extra pelvic, peritoneal metastasis $\leq$ 2 cm $\pm$ positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen.

Stage 3C: Macroscopic, extra pelvic, peritoneal metastasis >2 cm $\pm$ positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen

Stage 4A: Pleural effusion with positive cytology

Stage 4B: Hepatic and/or splenic parenchymal metastasis, metastasis to extra-abdominal organs (including inguinal lymph nodes and lymph nodes outside of the abdominal cavity

The dose of Paclitaxel was 175mg/m^2 of body surface area and the dose of Carboplatin was Area under curve (AUC) 5 to 6. Both the drugs were given as IV infusion on day 1 and Paclitaxel was given as three hour infusion prior to Carboplatin. All the patients received premedication with Steroids, Antiemetic andAntihistamine. Dexamethasone was the steroid of choice, and Pheniramine was used as antihistamine. Ondansetron and Granisetron were used as antiemetic. The chemotherapy regimen consists of 6 cycles of the drugs being repeated every 21 days. The response to the treatment was assessed by doing serum CA-125 and by doing USG-Abdomen. Toxicities were recorded at the end of each cycle and were graded accordingly using the National Cancer Institute- Common Terminology Criteria version 4. Peripheral sensory Neuropathy was graded as

Grade 1: Asymptomatic; loss of deep tendon reflexes or paresthesia

Grade 2: Moderate symptoms; limiting instrumental activity of daily living (ADL)

Grade 3: Severe symptoms; limiting self-care ADL

Grade 4: Life-threatening consequences;urgent intervention indicated

Grade 5: Death

Peripheral Motor Neuropathy was observed and graded as

Grade 1: Asymptomatic; clinical or diagnostic observations only; intervention not indicated

Grade 2: Moderate symptoms; limiting instrumental ADL

Grade 3: Severe symptoms; limiting self-care ADL; assistive device indicated

Grade 4: Life-threatening consequences; urgent intervention indicated

Grade 5: Death

According to the National Cancer Institute-Common Toxicity Criteria, Nausea was graded from 0 to 3 and vomiting was graded from 0 to 4.Anaemia, Neutropenia and Thrombocytopenia were graded from 1 to 4. Note was taken of all the other adverse events related to this chemotherapy regimen. All the data were compiled and analysed on Microsoft Excel. For all qualitative variables proportion or percentage were calculated. For all quantitative variables, mean and standard deviation was calculated and test of significance was done using Inferential Analysis.

RESULTS

A total of 78 patients with radiological and pathological diagnosis of epithelial carcinoma ovary and received Paclitaxel Carboplatin chemotherapy were included in the study. Most of the patients received chemotherapy in the day care ward of our hospital.

The age of patients in this study ranged from 30 to 69 and the mean age was 52.37 years. The youngest patient was 30 years of age at diagnosis. The maximum number of patients was in the age group 51-60 years. The age distribution was 21-30 years - 1 patient (1.28%); 31-40 years there were 8 patients (10.26%); 41-50 years there were 18 patients (23.08%); 51-60 years there were 35 patients (44.87%) and in age group >60 there were 16 patients (20.51%). (Figure 1)

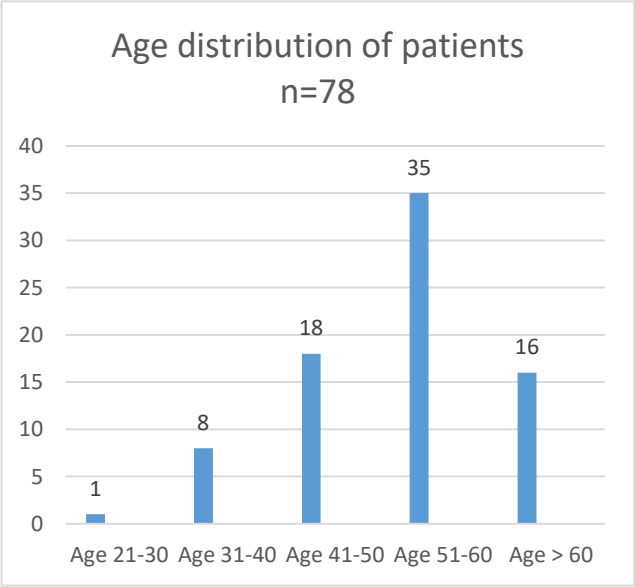

Figure 1: Age distribution of patients

Staging of the disease was done using the FIGO 2014 staging system. Out of the 78 patients at presentation Stage 1 was seen in 6(7.69%), stage 2 in 13(16.67%), stage 3 in 48(61.54%) and stage 4 in 11(14.10%) patients. The majority of the patients presented with stage 3 disease. (Figure 2)

The patients were classified according to the histopathology of the tumours and the result showed that the majority (39) of the patients had Serous carcinoma (50%). There were 10 patients with Mucinous carcinoma (12.82%). There were 18 patients with Endometrioid carcinoma (23.08%) and Clear cell carcinoma were found in 6 patients (7.69%) and 5 patients (6.41%) had Brenner carcinoma. The majority of the patients were found to have serous carcinoma of the ovary. (Figure 3)

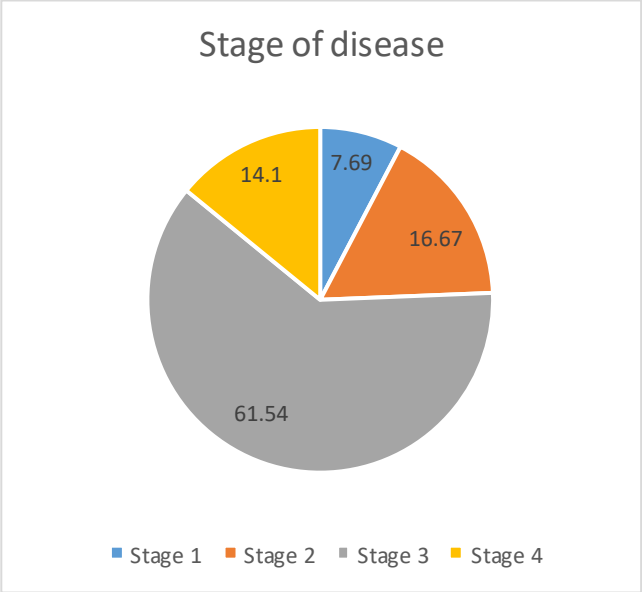

Figure 2: Distribution of patients as per Stage of disease

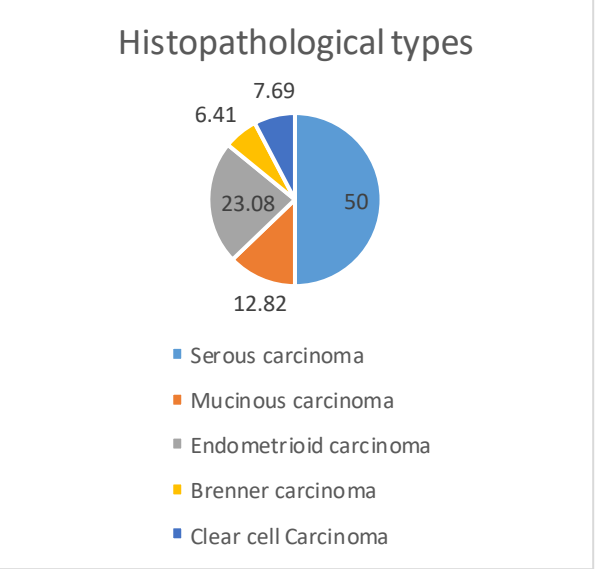

Figure 3: Distribution of patients as per Histological types

The performance status of the patient was assessed before and after chemotherapy using the ECOG performance scale. Pre Chemotherapy the performance status was ECOG 0- 8 (10.26%) patients, ECOG 1- 42 (53.84%) patients and ECOG 2- 28 (35.9%) patients. The majority of patients had a performance scale ECOG 1. After chemotherapy the performance scale was found to be ECOG 1 – 26 (33.33%) patients, ECOG 2- 32 (41.03%) patients, ECOG 3- 16 (20.51%) patients and ECOG

4 in 4 (5.13%) patients. The patients were found to have performance status 3 and 4 post chemotherapy whereas the majority of patients had ECOG 1 before chemotherapy. (Figure 4)

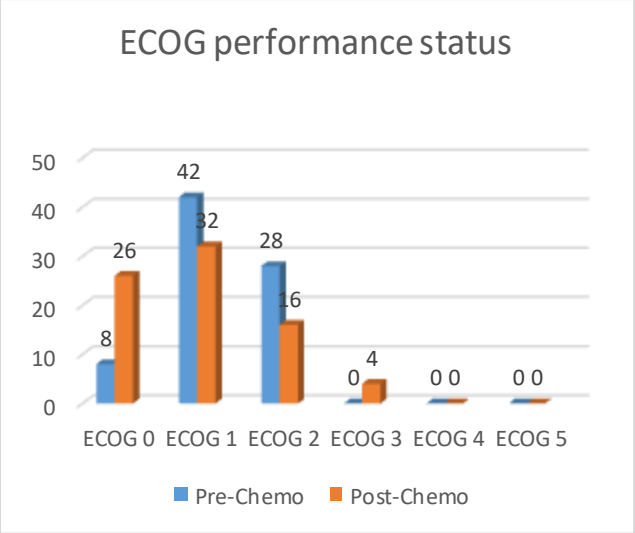

Figure 4: Distribution of patients according to ECOG performance status

On studying the occurrence and pattern of both Sensory and Motor Neuropathy the following was the result. Sensory peripheral neuropathy was seen in 20 (25.64%) patients and Motor Neuropathy was seen in 9 (11.54%) patients. Out of the sensory neuropathy patients 12 had Grade 1, 6 had Grade 2, and 2 had Grade 3 sensory neuropathy. Out of the 12 patients with motor neuropathy there were 5 patients with Grade 1, 3 patients with Grade 2 and 1 patient had Grade 3 motor neuropathy. (Figure 5)

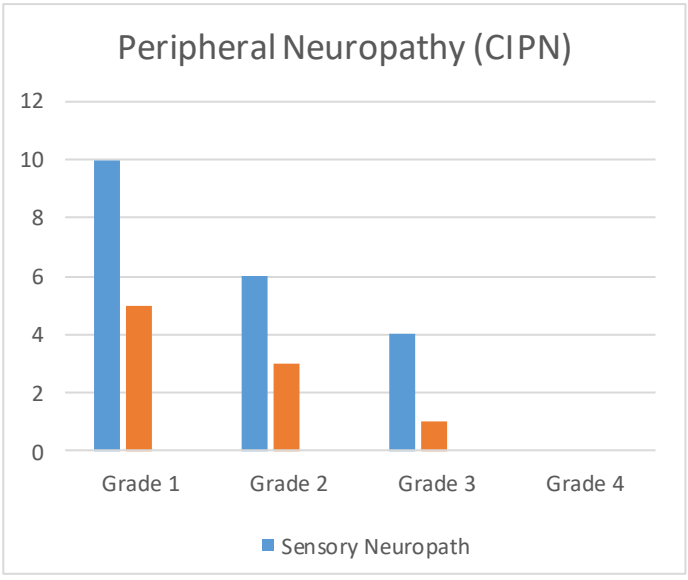

Figure 5: Distribution of patients according to Peripheral Neuropathy

The haematological toxicity of this chemotherapy regimen was studied and the result found was Anemia in 6 (7.69%) patients, Neutropenia in 15 (26.24%) patients and Thrombocytopenia was found in 2 (2.56%) patients only. Out of the 6 patients with Anemia 4 had Grade 2 and 2 patients had Grade 3 Anemia. Out of the 15 patients with Neutropenia 8 patients had Grade 2 and 7 patients had Grade 3 Neutropenia. Thrombocytosis of Grade 2 was seen in 2 patients. All the 7 patients with grade 3 neutropenia required postponement of chemotherapy.

Alopecia was seen in all the patients receiving chemotherapy and this was seen significantly after the second chemotherapy. Nausea was another major symptom and was found to be Grade 0 in 40(51.28%) patients, Grade 1in 28(35.90%) patients, Grade 2 in 9(11.54%) patients and only 1(1.28%) patient developed Grade 3 Nausea. Out of the 38 patients who had nausea, 7 had diarrhoea.

Vomiting was also graded and we found Grade 0 in 32(41.03%) patients, Grade 1 in 20 (25.64%) patients, Grade 2 in 25 (32.05%) patients and Grade 3 in 1(1.28%) patient.

The other symptoms that were associated with this chemotherapy regimen were Myalgia which was seen in 34 (43.59%) patients, Arthralgia in 23 (29.49%), Fatigue in 44 (56.41%) patients, Mucositis was seen in 16 (20.51%) patients and Diarrhoea in 7(8.97%) patients. 1 patient had developed Grade 1 hypersensitivity reaction but none of the patients had developed any severe allergic reaction.

DISCUSSION

This study was done to assess the toxicity of Paclitaxel Carboplatin chemotherapy regimen in patients with carcinoma ovary and also to study the Age, performance status, histological type and stage of disease at presentation. The study was done in 78 patients with epithelial carcinoma ovary who received chemotherapy with Paclitaxel and Carboplatin.

The age of the patients in the study population ranged from 30 to 69 years and the mean age was 52.37 years. In our study the stage of the patients at presentation was stage 1 in 6(7.69%), stage 2 in 13(16.67%), stage 3 in 48(61.54%) and stage 4 in 11(14.10%) patients. In the study by P Basu et al[9] in

218 patients with ca ovary the mean age at presentation was 48.8 years and more than 80% of the patients had stage 3 or 4 disease at the time of registration. Characteristics of patients in the Scottish Randomised Trial in Ovarian Cancer 1 by Paul A et al[17] the median age was found to be 59 in the 1077 patient population and 80.5% of patients had stage 3 or 4 disease.

The majority of the patients had serous carcinoma ovary (50%). There were 18 (23.08%) patients with Endometrioid carcinoma. Mucinous carcinoma was diagnosed in 10 (12.82%) patients, Clear cell carcinoma were found in 6 patients (7.69%) and Brenner carcinoma in 5 patients (6.41%). In the study by Paul A et al, 44% of the patients had serous carcinoma, 12% had Endometrioid cancer, 4% of Mucinous carcinoma and 5% had clear cell carcinoma.

The performance status of the study population was assessed before and after chemotherapy using the ECOG performance scale. Pre Chemotherapy the performance status was ECOG 0- 8 (10.26%) patients, ECOG 1- 42 (53.84%) patients and ECOG 2- 28 (35.9%) patients. The majority of patients had a performance scale ECOG 1 during the pre-chemotherapy assessment with no patients in the ECOG 3 or 4 performance scale. During post-chemotherapy the performance scale was found to be ECOG 1 – 26 (33.33%) patients, ECOG 2- 32 (41.03%) patients, ECOG 3- 16 (20.51%) patients and ECOG 4 in 4 (5.13%) patients. The patients were found to have performance status 3 and 4 post chemotherapy whereas the majority of patients had ECOG 1 before chemotherapy. In the study done by Shawky H et al[18], 55.6% of the patients presented with ECOG 1 status whereas Paul et al found 87% patients to have ECOG 0-1.

Peripheral neuropathy is the most important dose limiting toxicity of this chemotherapy regimen as reported in many literatures. We studied the sensory and motor neuropathy that occurred in our study population and found that sensory peripheral neuropathy was seen in 20 (25.64%) patients and Motor Neuropathy was seen in 9 (11.54%) patients. Out of the sensory neuropathy patients 12 had Grade 1, 6 had Grade 2, and 2 had Grade 3 sensory neuropathy. Out of the 12 patients with motor neuropathy there were 5 patients with Grade 1, 3 patients with Grade 2 and 1 patient had Grade 3 motor neuropathy.In the study by Shawky et al the incidence of peripheral neuropathy is found to be 12.5%. In the study by Paul et al, he has reported the incidence of neurosensory as 78% and neuromotor as 16%.

Haematological toxicities included Anemia in 6 (7.69%) patients, Neutropenia in 15 (26.24%) patients and Thrombocytopenia in 2 (2.56%) patients only. Out of the 6 patients with Anemia 4 had Grade 2 and 2 patients had Grade 3. Out of the 15 patients with Neutropenia 8 patients had Grade 2 and 7 patients had Grade 3. All the 7 patients with grade 3 neutropenia required postponement of chemotherapy. Postponement of chemotherapy may affect the overall outcome of the treatment but was not studied in our study[19,20]. Thrombocytosis of Grade 2 was seen in 2 patients. In a recent study by Chen Yu Huang et al[21] with weekly paclicarbo chemotherapy he has a reported incidence of Anemia 22.7%. Thrombocytopenia 13.6% and Neutropenia 77.3%. The study by Shawky et al reported Grade 3 Anemia in 9.4%, Grade 3 Thrombocytopenia in 6.3%. Grade 3 and 4 neutropenia was seen in 25% and 3.1% respectively.

Alopecia was seen in all patients who received Paclitaxel Carboplatin chemotherapy and this was significant after the second chemotherapy. Most of the literatures have observed the same finding.

Nausea was another major symptom and was found in 48.72% of the study population. Out of this 35.90% patients had Grade 1, 11.54% had Grade 2 and only 1.28% had Grade 3 Nausea. In the study by Paul A et al he reported nausea Grade 1 in 7.62%, Grade 2 in 4.28% and Grade 3 in 0.93% of the study population who received Paclitaxel Carboplatin chemotherapy regimen[17,22]. In our study 7 patients who had nausea later had diarrhoea. Most of the patients who had nausea progressed to have vomiting. It was found to be Grade 0 in 32(41.03%) patients, Grade 1 in 20 (25.64%) patients, Grade 2 in 25 (32.05%) patients and Grade 3 in 1(1.28%) patient. In the study by Shawky et al, 9.4% patients had Grade 3 vomiting.

Other problems seen in the study population included Myalgia in 43.59% patients, Arthralgia 29.49%, Fatigue in 56.41% patients, Mucositis was seen in 20.51% patients and Diarrhoea in 8.97% patients. Grade 1 hypersensitivity developed in 1

patient but none of the patients had developed any severe allergic reaction.

Study Limitation- This study did not analyse the deterioration of overall prognosis due to postponement of chemotherapy due to neutropenia.

CONCLUSION

Surface epithelial cancer of Ovary mainly affects the middle aged women. The commonest histopathology is serous carcinoma and most of the patients present in an advanced stage of the disease. The most important non haematological toxicity is peripheral sensory and motor neuropathy. Sensory neuropathy is more than motor neuropathy. Neutropenia is the major haematological toxicity followed by Anemia and Thrombocytopenia. This chemotherapy was well tolerated by most of the patients. Neutropenia was the most important toxicity which resulted in postponement of chemotherapy. This may even affect the result of the chemotherapy treatment.

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