Drug Utilization and Evaluation Of Paclitaxel In Patients With Ovarian, Cervical And Breast Cancer

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ABSTRACT:

INTRODUCTION: Cancer is growing into a leading health and economic crisis worldwide causing over 10 million deaths in 2020.

AIMS AND OBJECTIVES:

- Assessment of treatment effectiveness of paclitaxel. (Primary objective)
- Assessing the drug utilization of paclitaxel in ovary, breast and cervical cancer.
- To determine the correlation between menarche and menopause with occurrence of cancer in women.
- To review and analyze the severity of drug associated ADRs

METHODS: Various methods were used to find out the objective of the study.

RESULTS: Out of 68 patients, 41 patients were having breast cancer, 22 patients with ovary cancer and 5 patients with cervical cancer.

CONCLUSION: Our study found that majority of the study population that is about 60% were affected by breast cancer, followed by 32% of population with the diagnosis of ovarian cancer and 7% with cervical cancer. The correlation of age at menarche and incidence of cancer in women showed the greater incidence of ovarian and breast cancer in women with early menarche. The ADR was analysed using naranjo's scale and CTCAE grading scale and most of them experienced drug induced burning or tingling sensation, peripheral neuropathy, myalgia and hypersensitivity reaction during the chemotherapy administration.

INTRODUCTION:

Cancer is growing into a leading health and economic crisis worldwide causing over 10 million deaths in 2020. The global cancer burden is estimated to have risen to 18.1 million new cases and 7.6 million deaths in 2018. One in 5 men and one in 6 women worldwide develop cancer during their lifetime and one in 8 men and one in 11 women die from the disease. Worldwide the total number pf people who are alive within 5 years of cancer diagnosis (5 years' prevalence) is estimated to be 43.8 billion. The increasing cancer burden is due to several factors including population growth and aging as well as the changing prevalence of certain causes of cancer linked to social and economic development. This is particularly true in rapidly growing economics, where a shift is observed from cancers related to poverty and infections to cancer associated with lifestyles more typical of industrialized countries. As per WHO Cancer is one of the leading causes of death globally. Especially in women, we have observed higher incidence of cervical & ovarian cancer over the years due to the unhealthy and unhygienic lifestyle.

Cancer being a dreadful disease in itself, the treatment is no less miserable. Over the years the incidence of cancer in women has skyrocketed to millions. Breast Cancer being one of the most common cancers has crossed the number of 2 million cases in the year 2020. With respect to Cervical cancer, it's observed in eight of ten and nine out of ten women die from the same condition especially in a moderate income surrounding like ours.

The treatment primarily aims to cure cancer or to considerably prolong life. There is, however a significant difference in the treatment approach between various countries based on favored protocol.

One among the treatment options which concerns us as pharmacists is Onco-Chemotherapy. Chemotherapy subdivided into Cytotoxic, Targeted and Hormonal domains of treatment. Cytotoxic drugs are in greater use, renowned for their fast and effective outcome in curbing cancer. Among all the different classes of

Cytotoxic drugs, Taxols have shown better effects in nominal doses.

Paclitaxel is prescribed in dose specific manner, based on either the BSA or BMI of Patient. Paclitaxel is prescribed either as a monotherapy or often combined with Carboplatin in various cancers more specifically breast and ovarian cancer. It's normally prescribed after an initial 4 cycles AC regimen and is also used in Adjuvant and Neo Adjuvant chemotherapy. Alongside the effects and pharmacological outcomes of Paclitaxel, it causes severe and often life threatening ADRs. Paclitaxel chemotherapy in a whole has benefited and also diminished quality of life in patients. Paclitaxel has been a remarkable source of healing in cancer patients but for a price of compromised quality of life. In this study, we are assessing the treatment efficacy and utilization evaluation by monitoring the health parameters.

MATERIALS AND METHODOLOGY:

Study site: Bharath hospital & institute of oncology, Mysuru.
Study design: This is a Prospective observational study
Study period: The study will be carried out for a period of **Six** months
Sources of data:
- Medical and Medication records of the patient.
- Interviewing patient and caretaker.
- Communicating with concerned clinicians and health care professionals.

Study criteria:
Inclusion criteria:
-Patients meeting study criteria.
-Patients with age from 18years.
-Patients diagnosed with ovarian, cervix and breast cancers.
-Patients receiving chemotherapy.

Exclusion criteria:
-Incomplete case sheets.
-Incomplete medical or medication information.
-Patients not willing to participate in the study.
-Patient who are non-adherent to treatment.

Experimental design:
- The study involved the following steps:
- Step 1: Preparation of Informed Consent form An ICF was suitably designed in both English (Annexure 2) and Kannada (Annexure 3) to obtain consent from patients (Fulfilling the study criteria) to be included into the study. The ICF was reviewed and approved by an Institutional ethics committee. The patient was thoroughly explained about the study in their regional languages and the consent was taken by taking their signature or thumb impression respectively.
- Step 2: Preparation of Data Collection Form A specially designed data collection form (Annexure 1) was devised for the study. The form included demographic details like name, age, gender, family history, social habits, address, contact number. Clinical data such as diagnosis, past medication history, co-morbidities, allergy status, therapeutic data such as name of the drug prescribed, dose, frequency, route and duration of administration, concurrent medications were taken. The same details were documented electronically in specially designed google forms (Link: https://docs.google.com/forms/d/e/1FAIpQL Sdyzg7eXAriJs5VFdCPPWIy1Isfu2HidbRhq _RjL2vxT36gXg/viewform?usp=sf_link). To report, document and assess adverse drug reaction due to Paclitaxel, a standardized *Naranjo algorithm in English* (Annexure 4).
- Step 3: Patient enrolment: Patients fulfilling the study criterion were enrolled into the study after obtaining their informed consent after translating to their regional language/preferred language. Patients were enrolled during their outpatient visits. All the documents used in the study were translated to their regional language/preferred language
- Step 4: Data Collection: All relevant details of the enrolled patients were obtained from a fore mentioned data sources and documented in the data collection form (Annexure 1)
- Step 5: Statistical analysis Statistical analysis was performed by using SPSS Software for the evaluation of data. Descriptive statistics (Percentage, mean standard deviation, tables and graphs) is used to resemble the results.
- Step 6: Interpretation: The prescription audit of drugs was performed according to NCCN Guidelines and Adverse drug reaction due to Antipsychotics can be assessed by using *Naranjo algorithm*.

RESULTS:

Bar Chart (Paclitaxel)

Bar Chart (Paclitaexl+Carboplatin)
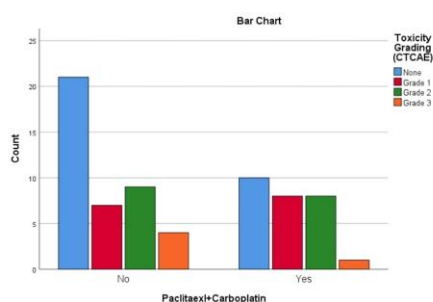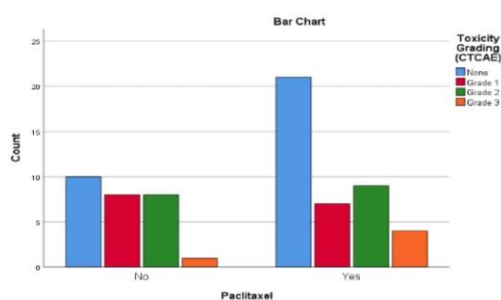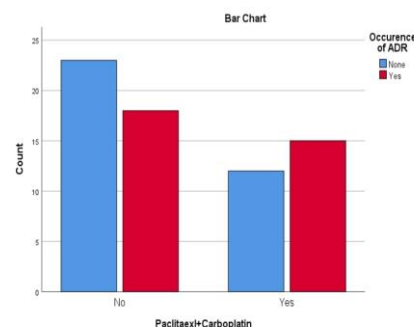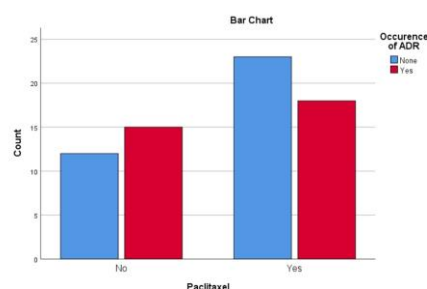
Distribution of CTCAE Grading:

Among 27 patients receiving chemotherapy of Paclitaxel+Carboplatin among the 68 of study population, 8 of them were computed to have grade 2 toxicity according to CTCAE toxicity grading. 8 patients were observed with grade 1 toxicity and only 1 patient with grade 3 toxicity according to CTCAE grading respectively.

Bar Chart (Paclitaexl+Carboplatin, Naranjo's scale)

Bar Chart (Paclitaxel, Naranjo's scale)
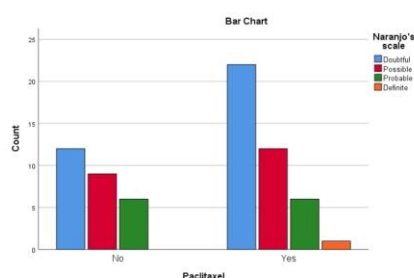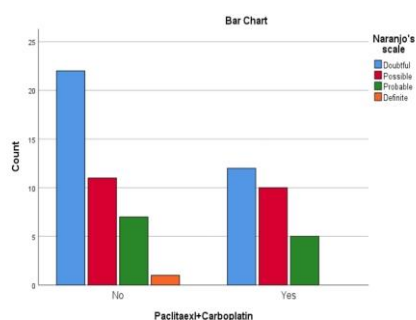
Naranjo's Scale Score:

Among the 27 patients receiving chemotherapy of Paclitaxel+Carboplatin in the study population of 68 patients, 12 were screened with doubtful ADRs and 10 with possible ADRs. 5 patients showed signs of probable ADRs and no patient was observed with definite ADRs as per the Naranjo's scoring.

Among the 41 patients receiving chemotherapy of Paclitaxel in the study population of 68 patients, 22 were screened with doubtful ADRs and 12 with possible ADRs. 6 patients showed signs of probable ADRs and only 1 patient was observed with definite ADRs as per the Naranjo's scoring.

Bar Chart (Paclitaxel, Occurence of ADR)

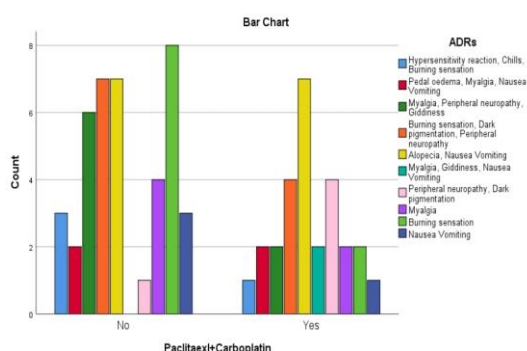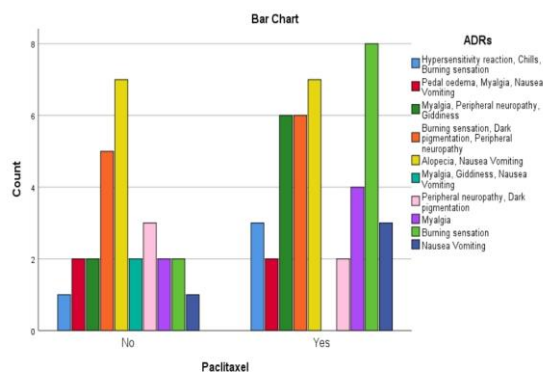Bar Chart (Paclitaexl+Carboplatin, Occurence of ADR)

Among the 68 patients study population, among which 41 patients receiving Chemotherapy of Paclitaxel about 43.9% of them were observed with occurrence of ADRs (n=18). Whereas among the 27 patients receiving chemotherapy of Paclitaxel+Carboplatin about 55% of them were observed with the occurrence of ADRs.

Among 41 patients receiving chemotherapy of paclitaxel among the 68 of study population, 9 of them were computed to have grade 2 toxicity according to CTCAE toxicity grading(n=9). 7 patients were observed with grade 1 toxicity and 4 others with grade 3 toxicity according to CTCAE grading respectively.

6 of the patients were observed with peripheral neuropathy and pigmentation along with major complaint of burning sensation.6 other patients experienced myalgia and giddiness along with peripheral neuropathy. 3 of the patients

experienced hypersensitivity reaction and chills during the administration of the chemotherapy. Very few were observed with pedal oedema(n=2) and the others experienced one of the above mentioned ADRs (n=7).


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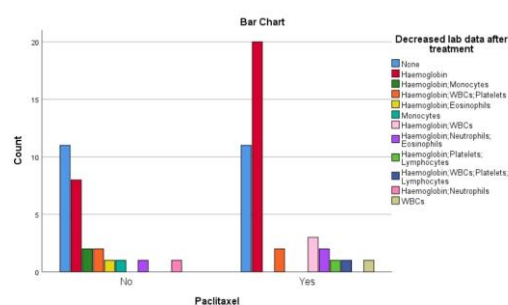
Among 27 patients receiving chemotherapy of Paclitaxel+Carboplatin among the 68 of the study population, Majority of them experience drug induced nausea and vomiting along with alopecia(n=7). Followed by several other experiencing burning sensation(n=4) and observed to have peripheral neuropathy and pigmentation(n=4).2 patients experienced myalgia and 2 others were observed with pedal oedema along with the above mentioned ADRs. Other patients experienced one of these ADRs only.
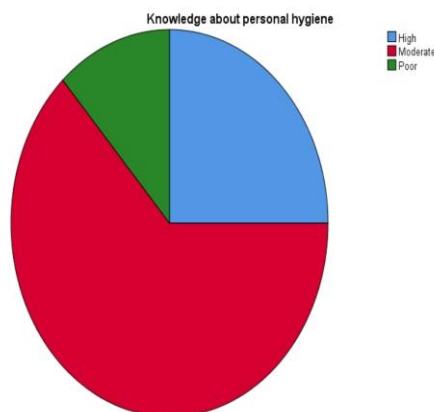
DISTRIBUTION OF KNOWLEDGE OF PERSONAL AND MENSTRUAL HYGIENE:

Among the women of our study about 63.2% of them had moderate level knowledge of menstrual and personal hygiene. A total of 25% high knowledge on menstrual hygiene and personal hygiene and practice. Only about 11.8% of women of the study had poor knowledge and understanding of hygiene.
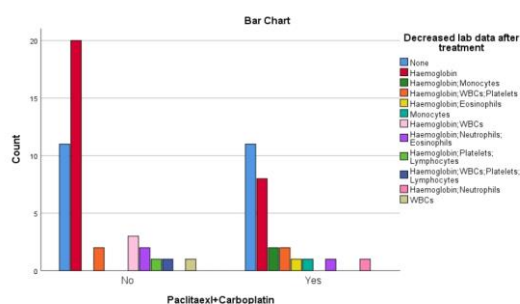
Lab data variation:

In Patients receiving Paclitaxel and Pacli+Carbo chemotherapy there was considerable decrease in Haemoglobin levels. Followed by a gradual decrease in WBCs, Platelets, neutrophils, lymphocytes and eosinophils.

The chemotherapy induced anaemia was quite evident.

CONCLUSION:

Drug prescribing patterns of different regimens of Paclitaxel were observed for the varying effect on target patients. The individual patient response and also the possible ill-effects of a drug was analysed using standard scales such as CTCAE toxicity grade and Naranjo scale scores, in order to draw an inference on the fashion of adverse reactions and events occurring in study population. Along with this primary approach to study the evaluation of drug utilization and its beneficence, certain other correlations of menarche age and menopause age with diagnosis of cancer was strived to establish pertaining to some of the prominent factors of the considered study subject. Statistical analysis of each variable and data collected during the study and its accurate application into computing the results of the intended study, helps to validate and rely on the findings of the study. Thus, the performed research satisfactorily met the needs to understand the beneficence of chemotherapy of paclitaxel and its combination regimen by comparative and correlative approach.

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