# STUDY OF THE ADVERSE DRUG REACTIONS IN CANCER PATIENTS IN GOVERNMENT HEAD QUARTERS, KRISHNAGIRI

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## ABSTRACT

Pharmacovigilance plays a vital role in ensuring that cancer patients receive appropriate medical products that are safe and effective, but very few studies has been done in past on Clinical oncology setup . Adverse drug reactions (ADRs) are an important clinical issue and a serious public health risk. ADRs leading to hospitalization or occurring during hospital stay contribute significantly to cancer patient morbidity and mortality as well as representing an additional cost for healthcare systems. Chemotherapy, a multimodal approach to oncological treatment, involves highly complex regimens and hence accounts to high susceptibility toward ADRs. The study was conducted in the North eastern part of Tamilnadu with less literacy rate and high rate of incidence in sexually transmitted disease. Understanding the underlying mechanisms by the Clinical Pharmacist is critical for clinical diagnosis and management of different ADRs at its early stage in oncology departments. The present study was conducted to assess the chemotherapy induced adverse drug reactions in patients of cancer of oncology department patients in Government Head Quarters Hospital, Krishnagiri and Tamilnadu for a period of 6 months from December 2015 to May 2016.

## INTRODUCTION

Primary Objective is to assess the chemotherapy induced adverse drug reaction of oncology patients in Government Head Quarters Hospital, Krishnagiri to evaluate the Adverse Drug Reactions by using ADR Probability Scale (Naranjo assessment scale) and to find out the most commonly occurring Adverse Drug Reactions to cancer patients during our investigation period. Also to rule out the relation between clinical stage of the cancer and occurrence of the ADR. Secondary Objectives is to evaluate the type and gender wise distribution of adverse drug reactions and which gender is more prone to cancer. To find out the most frequently used anti-cancer drug and its combination. To assess the co morbidity conditions with cancer, supportive therapy given along with the chemotherapy and the stage wise distribution of cancer patients.

## MATERIALS AND METHODS

This was a prospective observational, single centered study conducted among the cancer patients age above 20 of oncology department patients in Government Head Quarters Hospital, Krishnagiri, Tamil Nadu for a period of 6 months from December 2015 to May 2016. All the patients meeting the inclusion and exclusion criteria were informed the details of the study, consent were obtained and included in the study were reviewed every five days of week. About 150 cancer patients irrespective of age and sex with established cancer were medication history interviewed during the time period of 6 months from Dec 2015 to May 2016 using self-prepared protocol and structured questionnaire. Naranjo's adverse drug reaction probability scale was used to assess the adverse drug reactions. A regular ward round participation with oncologist and staff nurse to collect the data in suitable self-designed protocols and distribute filled ADR Alert form to them after individual prescription analysis. The suitable statistical analysis with Microsoft Excel and SPSS Software was done.

## RESULTS AND DISCUSSION

A total of 150 established cancer patients were enrolled in the prospective single centered observational study in the oncology department of age above 20 where, females of 82 (54.7%) are more affected than males of 68 (45.3%), the most number of patients were in the age group of 50- 59 years [48 (32%)] and least number of patients were in

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the age group of 20-29 years [7 (4.67%)] and the month April of 40 (26.7%) has the most number of admission while the month May of 16(10.6%) has the least number of admission, the most number of days of hospitalization in which 8 -14 days was found to be more with 34.67% and Stage II of 52(34.66%) was observed to be highest and Stage I of 25 (16.67%) was found to be the lowest and Diabetes Mellitus+ Hypertension [21(14%)] was observed to be the major Co morbidity followed by Diabetes [18(12%)], Hypertension [8(5.3%)], COPD [7(4.66%)] and Bronchial Asthma [6(4%)]from the study population. Socio-economic status of collected cases, Marital status [Married {115 (76.66%)}, Unmarried {35(23.33%)}], Place of living [Rural {134(89.33%)}, Urban {16(10.66%)}], Family expenses [Lower middle {16 (10.66)}, Upper middle {36(24%)}, Poor {98(65.33%)}, Education qualification [Illiterate {106(71.33%)}, Basic education {31(20.66)} Graduate {12(8%)}], Occupation [Unemployed {8(5.33%)}, Technical{22(14.66%)}, Housewife {73(48.66%)}, Farmer {31(20.66%)}, Professional {16(10.66%)}], Smoking habits [Never{21(30.88%)}, Ex-smoker {32(47.05%)}, Current {15(22.05%)}],

Tobacco Users [Never{34(22.6%)}, Ex-user{17(11.33%)}, Current {99(66%)}], Other forms of tobacco [Never{72(48%)}, Ex-user{52(34.66%)}, Current {26(17.33%)}], Alcohol users [Never{16(10.66%)}, Ex-Alcoholic {20(13.33%)}, Current {32(21.3%)}] and the most commonly occurred was Breast cancer of 32(21.33%), Cervix cancer of 23(15.33%), Ovarian cancer of 17 (11.33%) and Lung cancer of 10 (6.66%) are seen in the collected distribution of data. Total number of ADRs observed greatest in Female of 216(66.05%) than in Male of 111(33.95%) and According to Naranjo Probability ADR Assessment Scale, Definite category [65(43.33%)] was with highest observations along with probable [50(33.33%)], Possible [35(23.33%)] and Doubtful [0(0%)].

In type and gender wise distribution of ADR, most common was Nausea and vomiting of 92 [female {48}, male {44}] followed by Alopecia of 60 [female {31}, male {29}]. The most frequently prescribed anticancer drugs were Cisplatin [101(67.33%)], Fluorouracil [79(52.6%)], Paclitaxel [59(39.33%)], Doxorubicin [42(28%)] Cyclophosphamide [33(22%)] and Carboplatin [17(11.33%)] and the most commonly used chemo protocol

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combination was Cisplatin+5-Flurouracil [47(31.3%)], Cyclophosphamide + Doxorubicin + 5-Flurouracil [32(21.3%)], Paclitaxel+Cisplatin [17(11.3%)] and Cisplatin+ Gemcitabine [12(8%)]. The most commonly prescribed Antibiotics [Cefotaxim {24(16%)}, Ciprofloxacin {18(12%)} Ceftriazone {16(10.67%)}, Ampicillin {14(9.33%) and Amikacin {12(8%)}], Nutritional Supplement [Multivitamin {56(37.33%)}, Iron Supplement {42(28%)}, BCT {31(20.66%)}, Calcium supplement {12(8%)}] and Supportive Care Perinorm {89(59.33%)}, Ranitidine {87(58%)}, Metoclopramide {75(50%)}, Dexamethasone {46(30.66%)} and Ondasetron {44(29.33%)}]. According to SPSS software the p value was found to be 0.006 (highly significant) & Chi-square value was 18.04, which shows an association between ADR score & stages of cancer, as ADR increases with stages of cancer.

## CONCLUSION

Antineoplastic drugs were mostly prescribed for cancer patients which has greater susceptibility towards ADRs. The major hospitalized stage of cancer was Stage II where more prone gender was females who were tobacco chewers by Breast cancer, ovarian cancer and Cervix cancer while males who were alcoholic and smokers by Lung and Uro-reproductive organ cancer was found out. Most of observed ADR was in Definite category by using Naranjo Probability ADR Assessment Scale, the most number of patients were in the age group of 50- 59 years, the most number of admission done in the month April, the most number of days of hospitalization in which 8 -14 days, the major Co morbidity was Diabetes Mellitus+ Hypertension and highest ADR observed was Nausea and Vomiting.

The most frequently prescribed anticancer drugs were Cisplatin, the most commonly used chemo protocol combination was Cisplatin+5-Flurouracil, the most commonly prescribed Antibiotics was Cefotaxim { Nutritional Supplement was Multivitamin and Supportive Care was Perinorm from the study population.

The p value of the study was found to be 0.006 (highly significant). & Chi-square value was 18.04, which shows an association between ADR score & stages of cancer, as ADR increases with rise in stages of cancer. Assessment of Chemotherapy induced adverse drug reaction can greatly help in

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improving quality of life and reducing economic burden.

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