

## Monitoring of Adverse Drug Reactions To Anti-Cancer Drugs In Cancer Patients (A Prospective Hospital Based Study From A Tertiary Care Hospital Of North India)

Sameena Farhat, Parvaiz A.Shah,Shaheena Rasool.

### Abstract:

**Background:-**Chemotherapy involves highly complex regimens and hence accounts to high susceptibility towards Adverse Drug Reactions. All antineoplastic drugs have potential to cause one or more Adverse Drug Reactions which may vary from mild to severe form.

**Objectives:** The aim of study was to find out the frequency of adverse drug reactions among patients treated with anticancer drugs and to ascertain the causality and severity of these adverse drugs reactions.

**Methods and Results:** This prospective and observation study was conducted between 1st April 2015 to October 2016. Naranjo's monitoring Scale was used for causality assessment. Most of the adverse drug reactions were encountered in the age group of 40-50 years.As per Naranjo's monitoring scale out of 840 adverse drug reactions 330 (39.28%)were definite, 286 (34.04%) were probable, 213 (25.35%) were possible and 11 (1.30%) were doubtful.

**Conclusion:** All antineoplastic drugs have potential to cause one or more adverse drug reactions, which may vary from mild to severe form. These drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's rapidly proliferating cells. Measures need to be put into place to reduce the physical, emotional and economic burden on the patient due to adverse drug reactions.

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### Introduction

Cancers are a large family of diseases that involve abnormal cell growth with the potential to invade or spread to other parts of the body.<sup>1,2</sup>They form a subset of neoplasms. A neoplasm or tumor is a group of cells that have undergone unregulated growth, and will often form a mass or lump, but may be distributed diffusely.<sup>3,4</sup> Chemotherapy is employed as part of a multimodal approach to the treatment of many tumors.<sup>5</sup> Chemotherapy regimens are immensely complex, and cancer patients are a susceptible population with little tolerance.<sup>6</sup> The magnitude of adverse drug reactions (ADR's) endured by oncology patients is colossal making them almost synonymous with the treatment.<sup>7</sup> An adverse drug reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis and treatment of disease or for modification of physiological function.<sup>8</sup> Adverse drug reactions are considered among the leading causes of morbidity and mortality causing hospital visits and admissions. Chemotherapeutic drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's

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Anti Cancer Drugs, Adverse drug  
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rapidly proliferating cells. The normal tissues adversely affected by these drugs are those which are rapidly dividing: the bone marrow, gastrointestinal tract and hair follicles. The aim of the study was to find the occurrence of various adverse drug reactions caused by anti cancer drugs used in different malignancies. To correlate the adverse drug reactions caused by anti-cancer drugs with age and sex of the patients. To assess severity assessment of the reported adverse drug reactions. To assess the causality assessment of the reported adverse drug reactions. Our study was a prospective observational study which was conducted in the Department of Pharmacology in association with Department of Radiation Oncology and Department of Medicine, Government Medical College, Srinagar and associated SMHS Hospital, Srinagar between April 2015 to October 2016.

**INCLUSION CRITERIA**

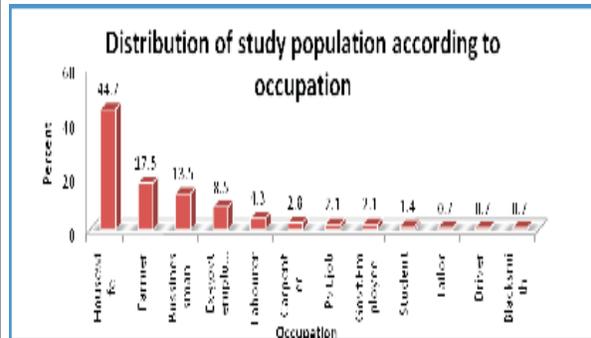
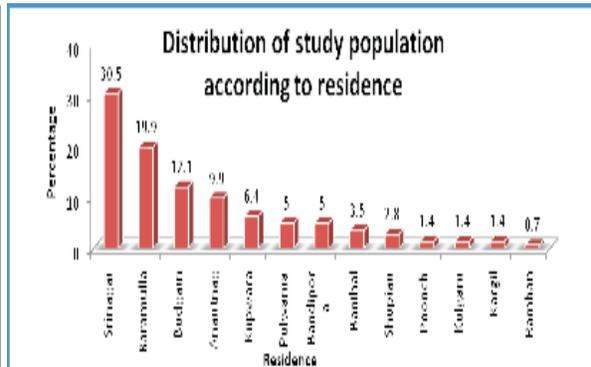
All the patients of either sex and any age receiving anti cancer drugs in the inpatient department of radiation oncology were included.

**EXCLUSION CRITERIA**

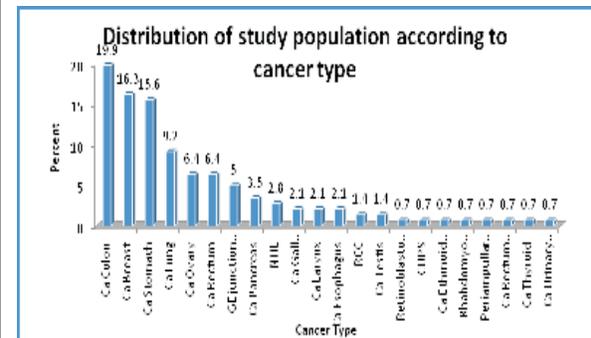
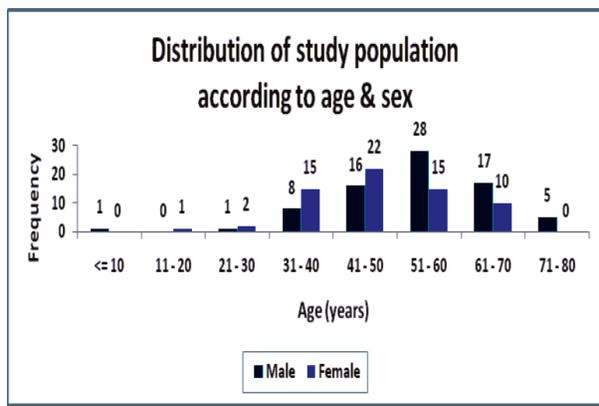
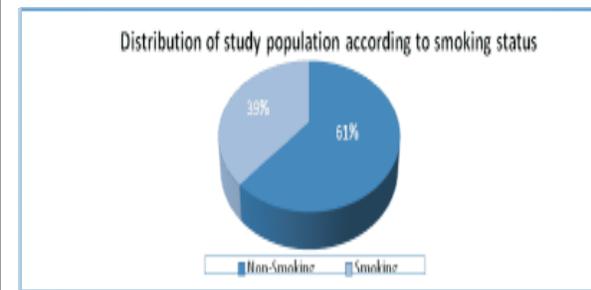
Patients who did not offer consent to participate in the study.

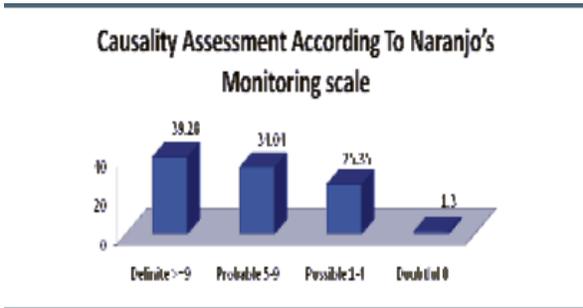
**RESULT**

A total number of 141 patients were enrolled and followed who were treated for different malignancies with different chemotherapeutic agents. Out of a total of 141 patients, there were 76 (53.9%) males and 65 (46.1%) females. In our study, most of the patients i.e. 43 (30.1%) were in the age group of 50-60 years. Majority of the patients i.e. 98 (69.5%) were from rural areas and most of them were from district Baramulla, while there were only 43 (35.5%) from urban areas. Most of the patients in our study were housewives.



Most of the patients i.e. 87 (67.1%) were non-smokers. Carcinoma colon 19.9% was the most common malignancy in the study population followed by carcinoma breast 16.3%, stomach 15.6%, lung 9.2%, ovary and rectum 6.4%. According to Naranjo's causality assessment scale, 39.28% ADR's were definite, 34.04% probable and 25.35% were possible.





## DISCUSSION

Adverse drug reactions significantly diminish quality of life, increase hospitalizations, prolong hospital stay and increase mortality.<sup>9</sup> Our study was an observational and prospective study conducted in the Department of Pharmacology in association with the Department of Radiation Oncology and Department of Medicine to determine the frequency, pattern and severity of chemotherapy induced adverse drug reactions and to determine their relationship with age and sex of the patients. Similar type of study was conducted by Kirti et al & Dr. Vikneshwaran et al.<sup>10,11</sup> A total number of 141 patients were enrolled and followed during this period who were treated for different malignancies with different chemotherapeutic agents. Out of a total of 141 patients, there were 76 (53.9%) males and 65 (46.1%) females. So number of males was more than the number of females. In our study, most of the patients i.e. 43 (30.1%) were in the age group of 50-60 years. This is comparable to study conducted by Anju Prasad et al.<sup>12</sup>. Majority of the patients i.e. 98 (69.5%) were from rural areas and most of them were from district Baramulla, while there were only 43 (35.5%) from urban areas. Similar reports were found in a study conducted by Poddar et al Bangladesh<sup>13</sup>. Most of the patients i.e. 87 (67.1%) in our study were non-smokers. Similar finding was found in a study conducted by Poddar et al<sup>13</sup>. Most common malignancies in our study were carcinoma colon (19.1%), carcinoma breast (16.3%) and carcinoma stomach (15.6%). However in other studies breast cancer and bronchogenic carcinoma were found to be commonest. Deepti Chopra et al<sup>14</sup> and Anju Prasad et al<sup>12</sup>. On the basis of Naranjo's monitoring scale for causality assessment, 330 (39.28%) Adverse drug reactions were definite, 286 (34.04%) Adverse drug reactions were probable, 213 (25.35%) were possible and 11 (1.30%) were doubtful.

## SUMMARY

This study was a prospective and observational

study conducted between 1st April 2015 to October 2016 with the aim of finding out the frequency of adverse drug reactions among patients treated with anti-cancer drugs and to ascertain the causality and severity of these adverse drug reactions. Naranjo's monitoring Scale was used for causality assessment. Most of the adverse drug reactions were encountered in the age group of 40-50 years. As per Naranjo's monitoring scale out of 840 adverse drug reactions 330 (39.28%) were definite, 286 (34.04%) were probable, 213 (25.35%) were possible and 11 (1.30%) were doubtful.

## CONCLUSION

All antineoplastic drugs have potential to cause one or more adverse drug reactions, which may vary from mild to severe form. These drugs have a narrow therapeutic index and the dosage needed to achieve a therapeutic response usually proves toxic to the body's rapidly proliferating cells. Measures need to be put into place to reduce the physical, emotional and economic burden on the patient due to adverse drug reactions. Modification of dose of the drug and appropriate treatment measures should be implemented to further improve the benefit:harm ratio of the drugs. Therefore there is a need for vigilant ADR monitoring to decrease morbidity and mortality due to ADR's which require further studies on large populations.

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