

Assessment of Prescribing Pattern of Chemotherapy Drugs and Monitoring Of Adverse Drug Reaction in Cancer Patients

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ABSTRACT: Cancer is one of the leading causes of death worldwide with estimated 12% deaths annually. By evaluating and comparing the prevailing pattern with the existing standards, necessary steps should be taken to optimise the drug therapy. Hence, our study was conducted with the aim to observe and evaluate the prescribing trends of anticancer drugs and possible avenues for improving cancer management. Primary objectives are; To evaluate the prescribing pattern of chemotherapy drugs and to monitor adverse drug reaction in the cancer patients receiving chemotherapy. The study was conducted for a period of six months. A hospital based retrospective and prospective observational study. Sources of data and materials are including Patient case sheet, Laboratory data reports, Medication/treatment chart, Hospital Database, Suitable design documentation form. Patients diagnosed with cancer and receiving treatment in outpatient and inpatient oncology department during study period irrespective of age, sex, diagnosis, and treatment were considered for inclusion. Out of 260 patients included in the study, 60% were females and 40% were males. The majority of patients were from IP department and the age group between 41-50 years. In this study anticancer prescription in chemotherapy, was not rational as there is polypharmacy, overuse and inappropriate use.

Keywords: Chemotherapy, 5-FU, Anticancer, CINV, ADR, Drug use pattern.

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I. INTRODUCTION

Cancer is a life-threatening disease which causes to lose cohesiveness and orderliness of normal tissue.¹ Apoptosis or programmed cell death in normal tissues is replaced by uncontrolled cell growth in cancer cells. The cells which grow uncontrollably are called malignant cells and the phenomenon of converting a normal cell to malignant cell is called “malignancy.” These malignant cells can spread to any other organ through blood flow or lymphatic flow and develop malignancy over there, this phenomenon is called metastasis.² Cancer was becoming a leading cause of death worldwide among the non-communicable diseases. There was 14.1 million new cancer cases and 8.2 million cancer deaths worldwide in 2012.³ The estimated number of new cancers in India is about 1.1 million per year.⁴ More than 0.6 million people die of cancer each year⁴ and approximately 42% cancers are tobacco related.⁵ Most frequent carcinomas reported in India are mouth/ oropharynx, oesophagus, stomach and lungs/bronchus/trachea in males while carcinoma of cervix, breast, mouth/oropharynx and oesophagus in females.⁶ The most common cancer in the world was lung cancer and the most common for women was breast cancer.³ There are many causes of cancer and some are preventable, such as tobacco smoking, heavy alcohol consumption, excess body weight, physical inactivity, poor nutrition, pollution, UV, ionizing radiation etc. But age is the most significant unpreventable risk factor currently.

The main modalities used for cancer treatment include chemotherapy, hormonal therapy, immunotherapy, precision medicine or personalized medicine (a newer or developing approach), radiation therapy, stem cell transplant, surgery. The choice of therapy depends upon patient factors, tumour factors and treatment factors.⁷ Chemotherapy is the treatment of cancer that uses one or more anti-cancer drugs as part of a standardized chemotherapy regimen.⁸ A number of Cytotoxic drugs such as 5-fluorouracil, epirubicin, doxorubicin, cyclophosphamide, cisplatin, docetaxel, paclitaxel, carboplatin, vinblastin, fosfamide, mytomycin C, etoposide etc. are prescribed to tackle cancer patients.⁹

5-fluorouracil and cisplatin are the most commonly prescribed anticancer drugs followed by cyclophosphamide.¹⁰ However, till date, there is no universally accepted guidelines for better therapeutic management. Thus, there is need to explore the drug prescribing pattern of those cancer patients.⁹

Antineoplastic agents are also traditionally divided by their origin or mechanism of action. The main groups include: ¹⁶ Alkylating and alkylating-like agents, Antimetabolites, Antitumour antibiotics, Plant alkaloids, Miscellaneous agents, Hormonal agents.

Plant alkaloids bind to microtubule proteins during metaphase, causing mitotic arrest. The cell cannot divide and dies. This group is mainly cell cycle phase specific for M phase.

Miscellaneous agents differ from any of the major classes of cytotoxic agents. Common miscellaneous agents are asparaginase and hydroxyurea. Topoisomerase inhibitors prevent realigning of DNA strands and maintain single-strand breaks. ^{17, 18, 19} Hormonal agents alter the internal / extracellular environment. ¹⁹

Antineoplastic agents are commonly administered in various combinations of dosages and timing; the specific regimen is referred to as a protocol. A protocol may use one or as many as five or six different antineoplastic agents. Selection of an appropriate protocol should be based on type of tumor, grade or degree of malignancy, stage of the disease. ¹⁶

Adverse drug reactions (ADRs) are a worldwide problem associated with the use of drugs for curbing the ailments. According to World Health Organisation (WHO), ADR can be defined as 'A response to a drug, which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. ²⁵ The common side effects of these medicines include loss of appetite, nausea or vomiting, skin rash (which may itch), diarrhoea or constipation, sores in the mouth or throat, hair loss, changes in the way foods taste, weakness or fatigue, decreased red blood cell count, decreased white blood cell count, alopecia, loss of libido etc. ¹¹ Cytotoxic agents do not differentiate between healthy and cancerous cells. All dividing cells exposed to these agents are killed resulting in significant adverse drug reactions (ADRs) in patients. ¹² ADRs occurring due to cancer chemotherapy significantly increase the cost of healthcare as well as an increase in morbidity and mortality. This leads to further increase in the suffering of the patient. ¹³

Chronic pain is extremely prevalent among patients with cancer. Approximately one-third of patients have pain while undergoing active therapy for the disease, and more than three-quarters have pain during the last stages of illness. ²⁷

The WHO realized the importance of having the efficient, dynamic surveillance system to monitor the occurrence of ADRs, which was the basis for starting the international Drug Monitoring Program, thereby, the Pharmacovigilance program was started in India in 2010 with the objectives of monitoring drug safety and creating an ADR database for our population. ¹⁴ Pharmacists must play a crucial role in developing, maintaining and evaluating a program to reduce the risk of ADRs through detecting, reporting and assessing any suspected ADR. ¹⁵

Cancer is one of the leading causes of death worldwide with estimated 12% deaths annually. ²⁶ There is a dearth of ADRs data associated with chemotherapy drugs in countries like India. The present study of monitoring the ADRs is to collect data and estimation of incidence of ADRs receiving treatment in a tertiary care hospital. So, the study was aimed to determine the adverse drug reactions of the anticancer drugs prescribed (either alone or in combination) for the treatment. By evaluating and comparing the prevailing pattern with the existing standards, necessary steps should be taken to optimise the drug therapy. Hence, our study will be conducted with the aim to observe and evaluate the prescribing trends of anticancer drugs and possible avenues for improving cancer management.

II. MATERIALS AND METHODS

Study design:

This study was a hospital based prospective and observational study conducted at Sapthagiri Institute of Medical Sciences & Research Centre (SIMSRC) (Sapthagiri Hospital), a 1200 bedded multispecialty tertiary care teaching hospital and Prakriya Hospital over a period of 6 months (November 2018 – April 2019).

Study population:

The study was done in the Department of oncology of two different tertiary care hospital. The data was collected from the patients admitted to IP and OP oncology department. The hospital caters to both urban and rural population. Most of the patients belong to middle and upper strata of the society.

Sampling method:

All the patients irrespective of age, sex, diagnosis, and treatment who were on anticancer prescription and were willing to give consent were included in the study. 260 patients were selected based on the criteria. The oncology wards were visited on all five days of the week and information regarding the patient demographics and drug use were recorded in a suitably designed proforma.

Study criteria:

Inclusion criteria:

Patients diagnosed with cancer and receiving treatment in outpatient and inpatient oncology department during study period irrespective of age, sex, diagnosis, and treatment were considered for inclusion.

Exclusion criteria:

The patients who were pregnant or lactating, HIV positive patients, patients with psychiatric illness were excluded from the study.

Study materials:

Patient Consent Form:

Consent was collected by using self-designed Patient Consent Form. Consent of each patient/guardian was taken.

Data Collection Form:

Data was collected by using a self-designed data collection form, which was used to record all the necessary data including patient demographic details, patient medication history, reason for admission, medication details and lab investigation. The pattern of drug dosing was recorded.

Ethical approval:

The study was approved by the Institutional Ethical Committee of R R college of pharmacy.

Data analysis:

The prescriptions were analyzed for the percentage of IP and OP according to the type of cancer, percentage of adjuvant drugs prescribed per patient, percentage of encounters with classification of other drugs prescribed per patient, percentage of most common anticancer drugs received and found out inappropriate prescriptions and percentage of adverse drug reaction in various study groups, the data was pooled and descriptive analysis done. This data was analyzed by using Microsoft Excel. The results were presented as mean and percentages. To assess the appropriateness of supportive care for chemotherapy, the National Comprehensive Cancer Network (NCCN) guidelines 2017 version 4, 2018, were used. ²⁸

III. RESULTS

Distribution of gender in patients observed in this study:

Out of 260 patients included in the study, 156 (60%) were females and 104 (40%) were males. This result also shows that majority 149 (57.3%) of patients were from IP department which 38.92% were male and 61.07% were female, followed by 111 (42.69%) were from OP department which 41.44% were male and 58.55% were female. [Table 1, Figure 1.1 & 1.2]

Table 1: Patient distribution based on gender and department

Gender	No of IP	No of OP	Total
Male	58 (38.92%)	46 (41.44%)	104 (40%)
Female	91 (61.07%)	65 (58.55%)	156 (60%)
Total	149 (57.3%)	111 (42.69%)	260

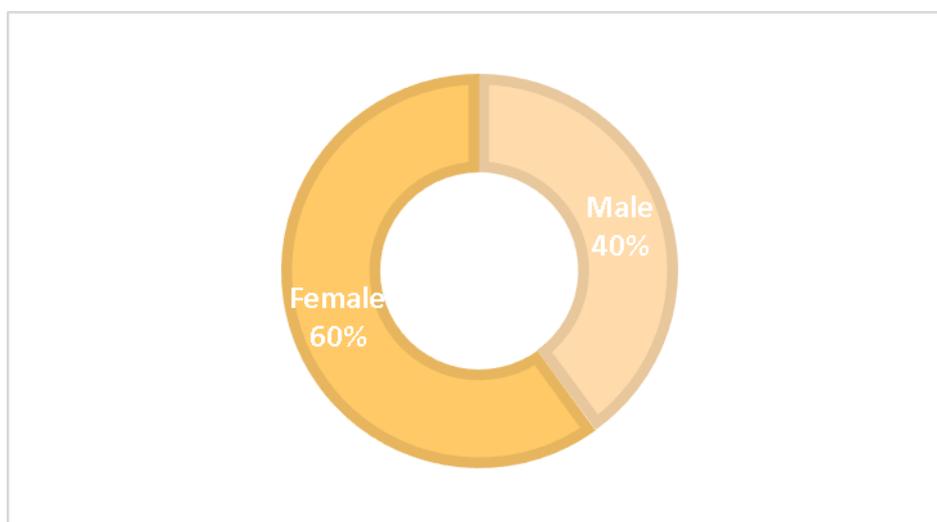


Figure 1.1: Pie chart of patient distribution based on gender

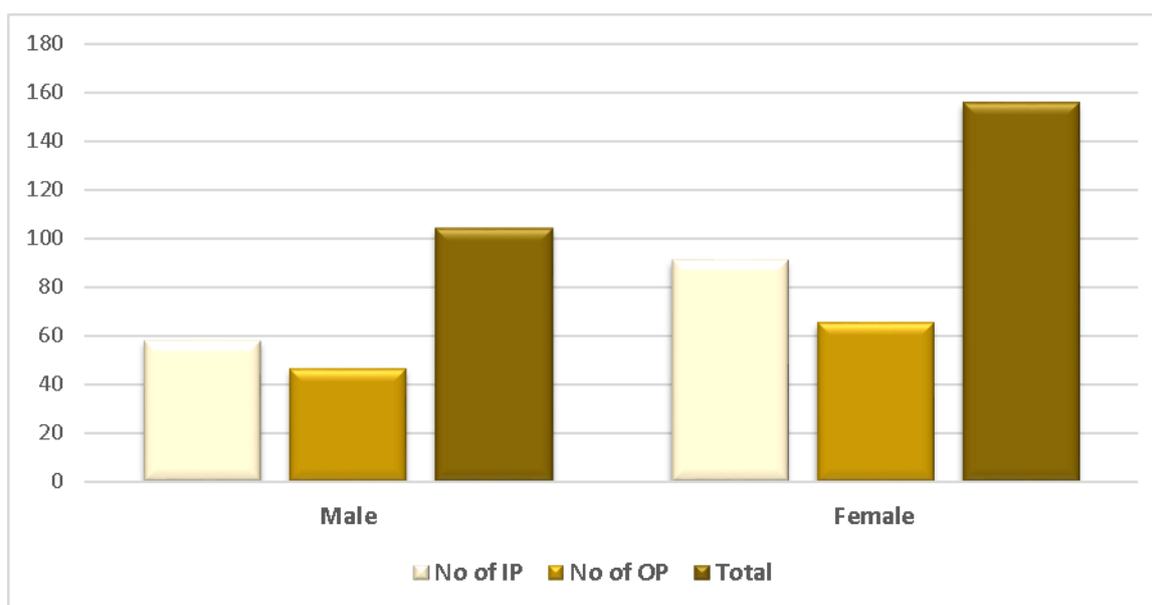


Figure 1.2: Patient distribution based on gender and department

Patient distribution with respect to their age groups:

Patients were categorized according to their age groups. Out of 260 patient's majority 114 (43.84%) of them were found in the age group between 41-50 years, followed by 72 (27.69%) in the age group between 51-60 years, 51 (19.61%) in the age group between 61-70 years, then 18 (6.92%) were found between 30-40 years and 5 (1.92%) were found >70 years. [Table 2, Figure 2.1 & 2.2]

Table 2: Patient distribution with respect to their age groups

Age group of patients	No. of Male Patients (n=104)	No. of Female Patients (n=156)	Total No. of Patients (n=260)
31-40	8 (7.69%)	10 (6.41%)	18 (6.92%)
41-50	41 (39.42%)	73 (46.79%)	114 (43.84%)
51-60	22 (21.15%)	50 (32.05%)	72 (27.69%)
61-70	32 (30.76%)	19 (12.17%)	51 (19.61%)
>70	1 (0.96%)	4 (2.56%)	5 (1.92%)

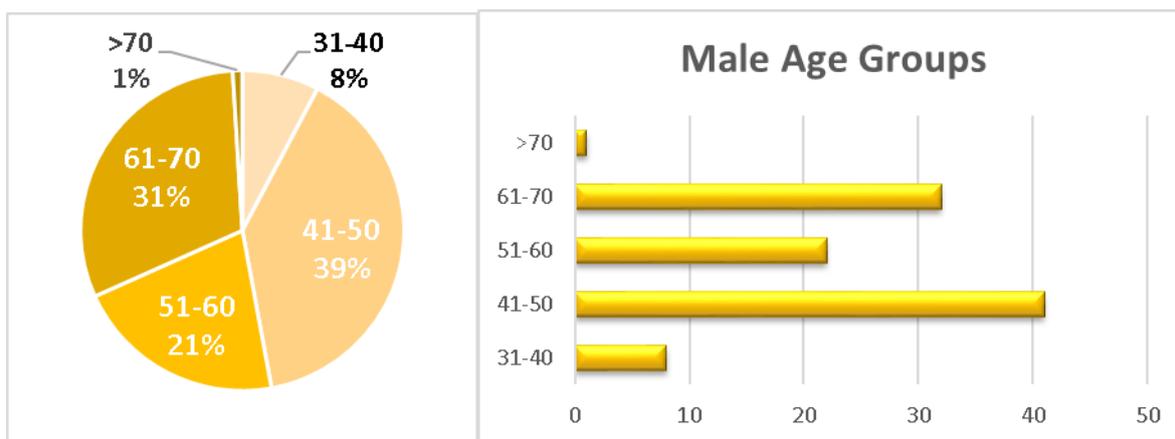


Figure 2.1: Male patient distribution with respect to their age groups

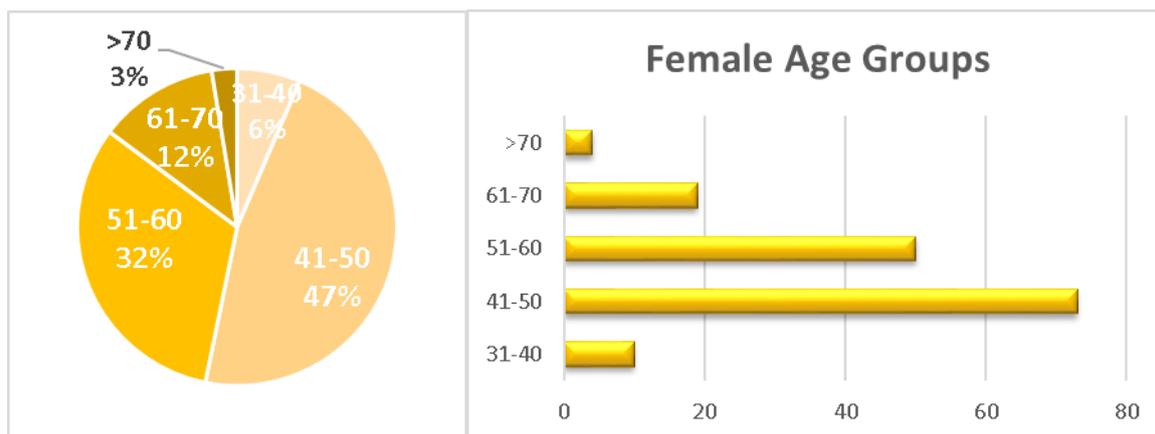


Figure 2.2: Female patient distribution with respect to their age groups

Distribution of in patients and out patients according to the type of cancer:

Out of 149 IP enrolled in the study, it was observed that Stomach Cancer 31 (20.8%) followed by Breast Cancer 21 (14.09%), And Gall bladder Cancer 17 (11.4%). Out of 111 OP enrolled in the study, it was observed that Mastalgia 32 (28.82%) followed by Zuska Disease 18 (16.21%), And Fibroadenosis 17 (15.31%). [Table 3]

Table 3: IP and OP distribution based on type of cancer

Type of Cancer	No of Male Patients	No of Female Patients	Total
IP Distribution Based on Type of Cancer			
Breast	1 (1.53%)	20 (23.8%)	21 (14.09%)
Gall bladder	5 (7.69%)	12 (14.28%)	17 (11.4%)
Stomach	22 (33.84%)	9 (10.71%)	31 (20.8%)
Small intestine	2 (3.07%)	10 (11.9%)	12 (8.05%)
Duodenum	1 (1.53%)	6 (7.14%)	7 (4.69%)
Rectum	4 (6.15%)	6 (7.14%)	10 (6.71%)
Lymphoma	4 (6.15%)	8 (9.52%)	12 (8.05%)
Pancreas	5 (7.69%)	4 (4.76%)	9 (6.04%)
Blood	11 (16.92%)	5 (5.95%)	16 (10.73%)
Lung	6 (9.23%)	4 (4.76%)	10 (6.71%)
Prostate	4 (6.15%)	0 (0.0%)	4 (2.68%)
OP Distribution Based on Type of Cancer			
Mastalgia	5 (27.77%)	27 (29.03%)	32 (28.82%)
Fibroadenosis	0 (0.0%)	17 (18.27%)	17 (15.31%)
Fibroadenoma	1 (5.55%)	14 (15.05%)	15 (13.51%)
Zuska Disease	0 (0.0%)	18 (19.35%)	18 (16.21%)
Breast Abscess	2 (11.11%)	7 (7.52%)	9 (8.1%)
Mastitis	0 (0.0%)	8 (8.6%)	8 (7.2%)
Ductal Adenocarcinoma	4 (22.22%)	2 (2.15%)	6 (5.4%)
Meningioma	6 (33.33%)	0 (0.0%)	6 (5.4%)

Distribution of classification of other drugs prescribed per patient:

The most commonly used other drugs in our study are Antibiotics, Normal Saline, Vitamins, Diuretics and Anticoagulant. [Table 5]

Table 5: Distribution of total number of other drugs prescribed

Drugs	Total NO.	Percentage (%)
Antibiotics	112	21.17
Normal Saline	75	14.17
Anticoagulant	60	11.34
Diuretics	66	12.47
Antiestrogens	32	6.04
Dopamine Receptor Agonists	17	3.21
Antifungal	29	5.48
Electrolyte Replenisher	12	2.26
Protein Powder	32	6.04
Antifibrinolytics	22	4.15
Vitamins	72	13.61

Distribution of adjuvant drugs prescribed per patient:

The most commonly used adjuvant drugs in our study are ondansetron, paracetamol, pethidine, phenargan, pantoprazole, lactulose, ranitidine and peptard. [Table 6]

Table 6: Distribution of adjuvant drugs prescribed per patient

Drugs	Total NO.	Percentage (%)
Pethidine	47	4.75
Phenargan	47	4.75
Ondansetron	69	11.38
Paracetamol	49	8.08
Pantoprazol	38	6.27
Dexamethasone	26	4.29
Ranitidine	29	4.78
Metoclopramide	27	4.45
Tramadol	25	4.12
Ketorolac	30	4.95
Lactulose	29	4.78
Ibuprofen	19	3.13
Betahistine	13	2.14
Fentanyl Citrate	4	0.66
Hydrocortisone	14	2.31
Magnesium Sulfate	4	0.66
Metoclopramide	28	4.62
Morphine	24	3.96
Peptard	29	4.78
Potassium Chloride	14	2.31
Eterocoxib	13	2.14
Rabeprazole	28	4.62

Distribution of most common anticancer drugs received:

Among 412 drugs 23 drugs were inappropriately prescribed. The category of drugs like 5-Fluorouracil, Capecitabine, Methotrexate and Doxorubicin drugs required more dosage adjustment when compared to other category of drugs. [Table 7, Figure 7]

Table 7: Number of drugs requiring cancer patients

Drug Category	Total N= 412	Inappropriate	Percentage (%)
5-Fluorouracil	64	5	15.53
Bevacizumab	21	0	5.09
Capecitabine	36	3	8.73
Carboplatin	27	1	5.58
Cisplatin	19	0	4.61
Cyclophosphamide	26	2	6.31
Docetaxel	18	0	4.36
Doxorubicin	28	2	6.79
Etoposide	15	0	3.46
Gemcitabine	20	1	4.85

Oxaliplatin	16	1	3.88
Paclitaxel	17	0	4.12
Vincristine	22	1	5.33
Epirubicin	17	0	4.12
Ifosfamide	19	2	4.61
Dacarbazine	14	1	3.39
Methotrexate	33	4	8

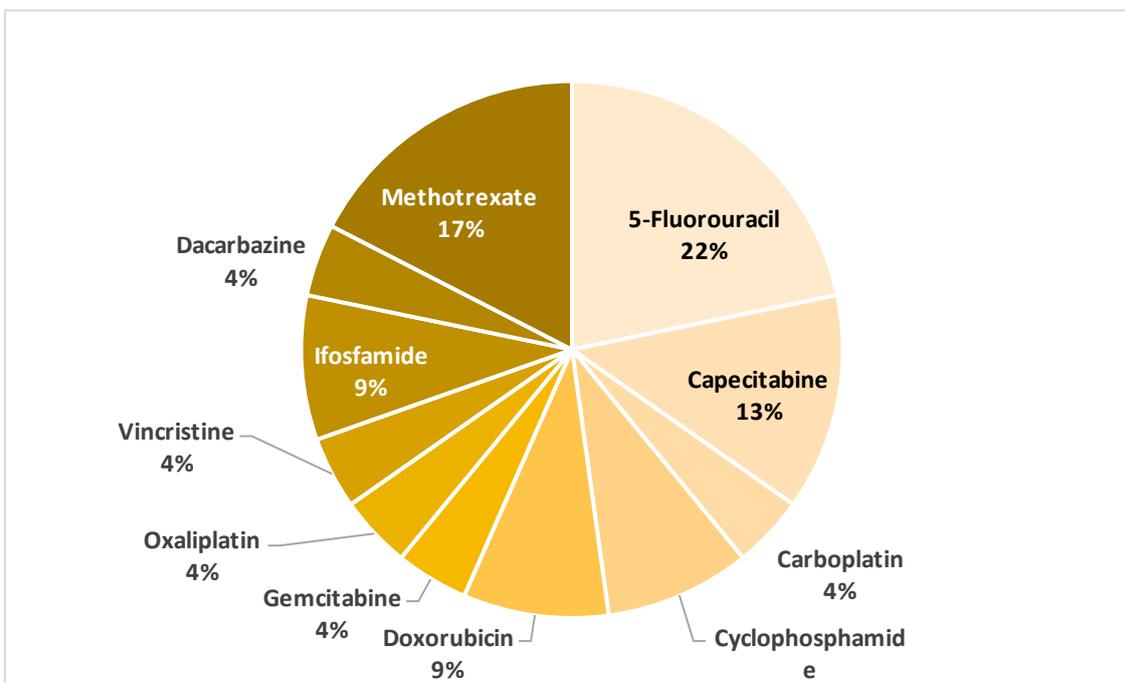


Figure 7: Pie chart representation of inappropriate prescribed medications

Description of adverse drug reaction in various study groups:

In the study population the most common ADRs were Body Pain 37 (14.23%) followed by nausea 23 (8.84%), Fatigue 19 (7.3%), Vomiting 18 (6.92%) and Diarrhea 16 (6.15%). [Table 8]

Table 8: Description of adverse drug reaction in various patients

Adverse Effect	Male CTP	Female CTP	Total
Body Pain	15 (14.42%)	22 (14.1%)	37 (14.23%)
Nausea	7 (6.73%)	16 (10.25%)	23 (8.84%)
Headache	6 (5.76%)	8 (5.12%)	14 (5.38%)
Joint Pains	4 (3.84%)	5 (3.2%)	9 (3.46%)
Vomiting	9 (8.65%)	9 (5.76%)	18 (6.92%)
Fatigue	10 (9.61%)	9 (5.76%)	19 (7.3%)
Insomnia	8 (7.69%)	5 (3.2%)	13 (5%)
Tremors	7 (6.73%)	6 (3.84%)	13 (5%)
Anorexia	3 (2.88%)	6 (3.84%)	9 (3.46%)
Changes in Weight	7 (6.73%)	0 (0.0%)	7 (2.69%)
Unable to Concentrate	0 (0.0%)	4 (2.56%)	4 (1.53%)
Blurred Vision	0 (0.0%)	4 (2.56%)	4 (1.53%)
Fever	3 (2.88%)	7 (4.48%)	10 (3.84%)
Shortness of Breath	4 (3.84%)	2 (1.28%)	6 (2.3%)
Heart Burn	4 (3.84%)	6 (3.84%)	10 (3.84%)
Hearing Problems	2 (1.92%)	3 (1.92%)	5 (1.92%)
Constipation	1 (0.96%)	3 (1.92%)	4 (1.53%)
Loss of Hair	2 (1.92%)	12 (7.69%)	14 (5.38%)
Diarrhea	5 (4.8%)	11 (7.05%)	16 (6.15%)
Leukoplakia	0 (0.0%)	5 (3.2%)	5 (1.92%)
Peripheral Neuropathy	2 (2.88%)	4 (2.56%)	6 (2.3%)
Missed Menstrual Periods	0 (0.0%)	3 (1.92%)	3 (1.15%)
Stomach Pain	5 (4.8%)	6 (3.84%)	11 (4.23%)

*CTP: Chemotherapy Patients

IV. DISCUSSION

The principal aim of a drug utilization study is to promote the rational use of drugs in populations. In our study, we found that majority of the patients were female (60%) which is similar to many studies^{20, 21} while it is in contrast with Vijay M. Motghare, Nikhil H. Dhargawe, et al.²² where majority of the patients were males (73.05%). Though the exact reason for this is unknown, increased exposure to hormones [estrogens which increases risk of uterine and breast cancers], lack of physical activity and dietary habits could be the main risk factors.

In our study, majority of the patients belonged to the age group of 41-50 years (44%) which was similar to the study conducted by Manushi Aggarwal, Shalini Chawla, et al.¹⁴ Cancer is more common as we age because of gene mutations and slow progression of cancer, usually it can occur at any age but the risk increases as we get older.

The present study was carried out in 260 prescriptions which 149 of them belongs to In Patients, it was observed that Stomach Cancer (20.8%) out of 11 different cancers, was most common cancer, irrespective of age and sex, followed by Breast Cancer and Gall bladder Cancer. In Smita Khandelwal et al²⁹ study shows gastrointestinal cancers were more prevalent followed by breast, genitourinary, lung, head & neck, thyroid, lymphoma and leukemia, myeloma, bone, brain cancers and similar to present study. But in many studies observed that breast cancer was most common.^{21, 23, 11} The main reason is because breast cancer is the most common cancer among the females of world wide.

In present study, it was observed that Mastalgia (28.82%) followed by Zuska Disease and Fibroadenosis was most common diagnosed out of 111 of outpatients who attended to the OP department of hospital irrespective of age and sex.

The most commonly used adjuvant drugs in our study are ondansetron, paracetamol, pethidine, phenargan, pantoprazole, lactulose, ranitidine and peptard. Similar findings were observed in studies Vinodkumar Mugada, Aswinichand Paruchuri, et al.¹⁰ The most commonly used other drugs in our study are Antibiotics, Normal Saline, Vitamins, Diuretics and Anticoagulant.

The most common anti-cancer drugs prescribed per patient was 5-Fluorouracil followed by Capecitabine, Methotrexate, Doxorubicin and Cyclophosphamide. Among 412 drugs 23 drugs were inappropriately prescribed. The category of drugs like 5-Fluorouracil, Capecitabine, Methotrexate drugs required more dosage adjustment when compared to other category of drugs. This result is similar with Vinodkumar Mugada, Aswinichand Paruchuri, et al¹⁰ which observed that 5-Flurouracil and Cisplatin are most commonly prescribed anticancer drugs.

In the study population out of 23 ADRs, the most common ADRs were Body Pain (14.23%) followed by nausea, Fatigue, Vomiting and Diarrhea. In Deepti Chopra, Harmeet S. Rehan, et al²³ the frequently observed ADRs included nausea and vomiting, hair fall, leukopenia followed by diarrhea, gastritis. In Shruti Singh, DC Dhasmana, et al²⁴ shows the reactions appearing commonly after every cycle were nausea and vomiting, gastritis, constipation, diarrhea, fever, peripheral nervous system (PNS) manifestations, alopecia, and musculoskeletal pain which is disagree with present study.

Majority of adverse drug reaction were preventable. As common ADRs like body pain, nausea, vomiting can be effectively controlled, the treating physician should anticipate and counsel the patient adequately prior to starting of therapy. Chemotherapy related nausea and vomiting remains a problem in many patients despite the use of antiemetic and dexamethasone.

Thus present study emphasizes the need to improve management of ADRs and pharmacovigilance program should be promoted which is highly effective in increasing the ADRs reporting and help to detect infrequent ADRs caused by drugs, which will be beneficial for better outcome of anticancer treatment in future.

V. CONCLUSION

In our study anticancer prescription in chemotherapy, IP and OP, was not rational as there is polypharmacy, overuse and inappropriate use. This study observed that 23 of anticancer drugs were inappropriately prescribed and most of them required more dosage adjustment when compared to other category of drugs.

Our study has shown that science of ADRs like Body Pain which related to nerves system is gaining more importance in the hospital setting, especially in the oncology field. However, the most common ADRs between cancer patients are nausea and vomiting and loss of hair. It was observed that oncology patients present several ADRs, including mild to severe reactions, which should be reported in the pharmacovigilance system. However, these reactions pass by unreported, which contributes to the underreporting in oncology.

Most of the adjuvant drugs prescribed in this study were related to digestive system which used to relief the ADRs arising from anticancer drugs. Most of these patients were complaint of pain. However, most common drug prescribed was ondansetron which used to treat nausea and vomiting.

Our study also found out that most of the patients were suffering from stomach cancer which could be related to their nutrition.

Cancer is more common as we age because of gene mutations and slow progression of cancer. Usually it can occur at any age but the risk increases as we get older, as we can see in this study, patients majority were found in the age group between 41-50 years.

Since cancer chemotherapy has a high potential to cause ADRs, measures need to be put into place to reduce the physical, emotional and economic burden on the patient due to adverse drug reactions. There is a need for vigilant ADR monitoring to reduce morbidity and mortality due to adverse drug reactions, which requires further studies on larger population. By implementing the ADR monitoring and reporting system, pharmacists can promote drug safety and there by assist health care professionals for a better patient care.

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