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# DRUG UTILIZATION STUDY OF ANTICANCER AGENTS IN ONCOLOGY DEPARTMENT OF TERTIARY CARE TEACHING HOSPITAL IN NORTH INDIA

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**ABSTRACT:** Drug utilization studies provide basis for evidence based care decisions. In cancer therapy/oncology practice, safe use of drug plays a crucial role in reducing the disease and drug related burden. The prospective observational study was conducted at oncology department of Guru Gobind Singh Medical Hospital, Faridkot. A total of 100 prescriptions were analyzed. On analyzing the demographic pattern of cancer patient according to gender, the data represent that cancer was more prevalent in females (n=75) than males (n=25). In study usage of mono-therapy as management modality was observed in 15% of cancer patients while in other patients combination therapy (85%) was prescribed. Carcinoma breast was the most commonly observed carcinoma in the present study. Drug utilization studies need to be promoted and carried out on an ongoing basis. DUR is important to promote rational drug use. Its relevance to policy making and resource allocation needs to be emphasized.

**KEY WORDS** – DUE, ADR, NHL, Carcinoma, Anticancer drugs.

**INTRODUCTION:** DUS is defined as the marketing, distribution, prescription, and the use of drugs in a society with special emphasis on the resulting medical, social, and economic consequences.[1]Based on the design of the study, DU studies may be categorized as prospective, concurrent and retrospective, depending upon the timing of data collection.[2] Prospective DUR involves comprehensive review of patient's drug therapy before a medication was dispensed, pharmacist routinely perform reviews in their daily practice by assessing prescription medications.[2] Cancer is a broad term for class of diseases characterized by abnormal cells that grow and invade healthy cells in the body.[3] The practice of cancer medicine has changed dramatically in the past four decades, as curative treatments have been identified for a number of previously fatal malignancies such as

testicular cancer, lymphomas, and leukemia.[4] Several classes of drugs may be used in cancer treatment depending on the nature of the organ involved (For example breast cancers are commonly stimulated by estrogens and may be treated with the drugs that inactivate the sex hormones). Similarly, prostatic adenocarcinoma could also be treated with drugs that inactivate androgens the male steroid hormone.[5,6] Developing new anticancer drugs is the work of ongoing research. In 2003, a new technique was developed to streamline the search for effective drugs. Researchers pumped more than 23,000 chemical compounds through a screening technique to identify those that help fight cancer while leaving healthy cells unharmed.[5,7,8] According to WHO, cancer was responsible for 13% of overall mortality in 2005 worldwide. In India, cancer is responsible for 10% of total mortality in 2002 which was expected to rise up to 25-50% by 2020.[9] The main objective of the present study is to know the proportion of adjunctive drugs used, to assess the rational use of the drugs and to review prescribing patterns of the drugs.

## MATERIALS AND METHODS:

### Study Site

Study was carried out at Major referral hospital. Hospital has 100 bedded oncology department which is well equipped with modern apparatus. Hospital has various departments with well qualified staff (Medicine, Surgery, Gynecology, Psychiatrics, Pediatrics, Dermatology, Oncology and Orthopedics).

### Study Design

It is an observational prospective study.

### Study Duration

Study was conducted within time period of October 2015 to April 2016.

### Study Subjects

The Inclusion and Exclusion criteria for study are as follow:

**Inclusion Criteria:**

a) Newly diagnosed and known cases of cancer receiving chemotherapy

b) Both male and female patients of age group above 18 years

**Exclusion Criteria:**

a) Pregnant and lactating women

b) Patients in Intensive Care Unit

c) The patient who are not willing to sign the inform consent form

### Source of Data

All the relevant data was collected from

- Patients demographics
- Biochemical investigation
- Diagnosis and drug treatment chart
- Follow up chart

**Preparation of data collection form:**

A specially designed data collection form (Annexure-II) was developed. It includes demographic details like name, age, gender, medical history, height, weight, clinical data such as diagnosis, therapeutic details such as dose, type of treatment given, outcome, and management. The same details were documented electronically in specially design data base using SPSS v21.

**Patient enrolment**

Patients satisfied the inclusion and exclusion criteria were enrolled in the study.

**Data collection and documentation:** All relevant details of the enrolled patients were obtain from various data sources and documented in data collection form.

**Computerization of data collection form:** The collected data and assessment form designed for use in the study was computerized using SPSS 21 (Annexure-IV).

**RESULTS**

The prospective observational study was conducted at oncology department in tertiary care hospital. A total of 100 prescriptions were analyzed.

**Demographic details-**

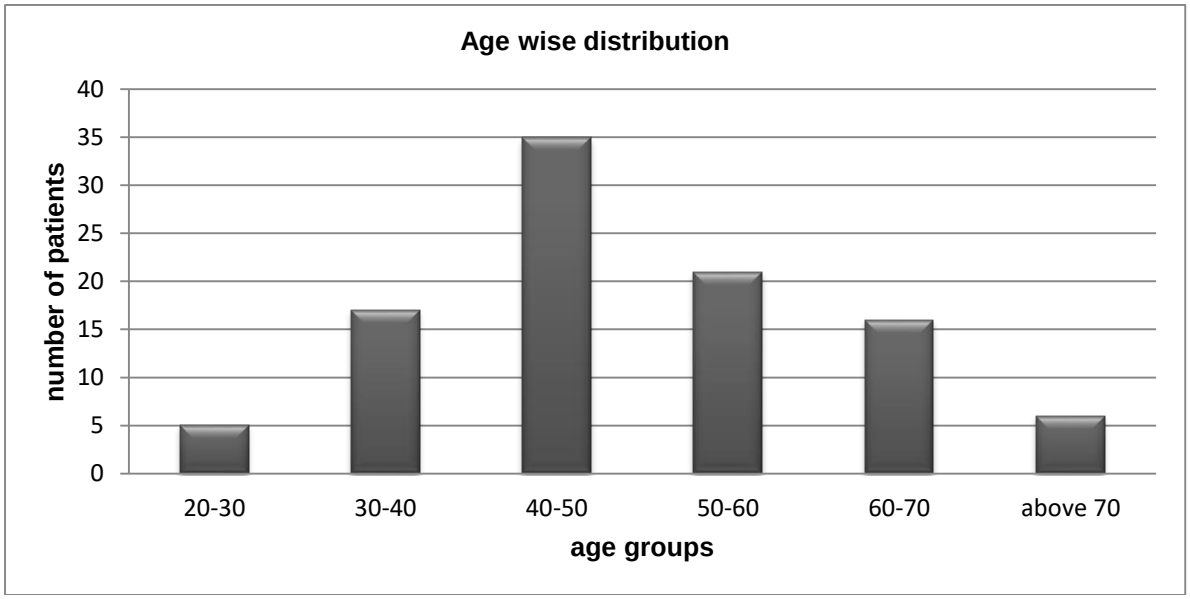
On analyzing the demographic pattern of cancer patient according to gender, the data represent that cancer was more prevalent in females (n=75) than males (n=25) as shown in table 1.

**Table 1: Gender wise distribution of patients**

| Gender | Frequency | Percentage |
|---|---|---|
| **Female** | 75 | 75 |
| **Male** | 25 | 25 |

From the analyzed data we found that the higher number of patient were at age group of 40-50 years (35%), followed by 50-60 years (21%), 30-40 years (17%), 60-70 years (16%), above 70 years (6%) and 20-30 years (5%) as shown in figure 1.

**Fig 1: Age wise distribution of cancer patients**



**Prevalence of carcinoma**

There were altogether 17 different types of cancer observed during the study period. The type of cancers observed with their corresponding number of patients were shown in table 2.

**Table 2: Prevalence of cancer**

| Cancer | Frequency | Percentage |
|---|---|---|
| Breast | 41 | 41 |
| Cervix | 8 | 8 |
| Lung | 4 | 4 |
| Ovary | 11 | 11 |
| Liver | 1 | 1 |
| NHL | 10 | 10 |
| Gall bladder | 3 | 3 |
| Head and neck | 12 | 12 |
| Pancreas | 4 | 4 |
| Urinary bladder | 1 | 1 |
| Endometrium | 1 | 1 |
| Esophagus | 3 | 3 |
| Rectum | 1 | 1 |
| Total | 100 | 100 |

**Regimen for breast cancer**

Out of total 41 patients who develop breast cancer, majority of patient received combination of Docetaxel+Doxorubicin+Cyclophosphamide (13, 37.1%), followed by 5-FU+epirubicin+cyclophosphamide (8, 19.51), Gemcitabine+Cisplatin (3, 7.31%), Paclitaxel (2, 4.87%), Docetaxel+Cisplatin (2, 4.87%), Docetaxel+Capecitabine (2, 4.87%), Doxorubicin+Cyclophosphamide (2 ,4.87%), Docetaxel+Epirubicin+ Cyclophosphamide (2, 4.87%), 5-FU+Doxorubicin+Cyclophosphamide (2, 4.87%), Paclitaxel+Gemcitabine (1, 2.43%), Paclitaxel+Capecitabine (1, 2.43%), Paclitaxel+Trastuzumab (1, 2.43%), Docetaxel+Adriamycin (1, 2.43%), Docetaxel+Epirubicin (1, 2.43%) as shown in table 3.

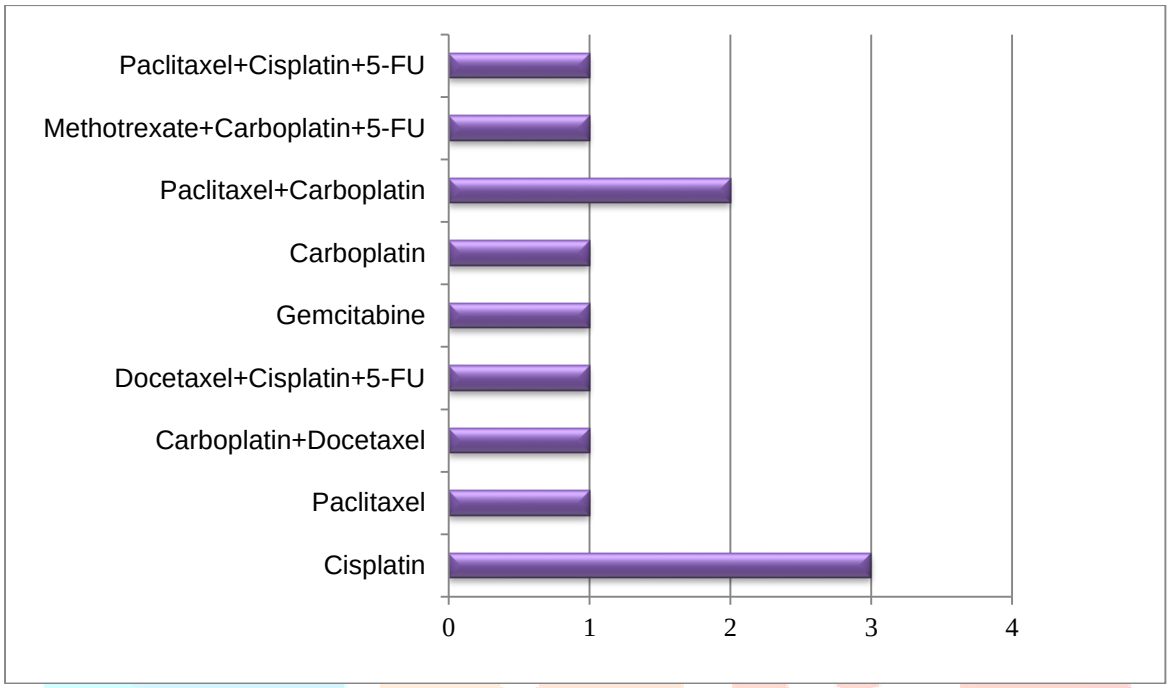
**Table 3: Type of regimen for breast cancer (n= 41)**

| Regimen | No. Of Patients | % Of Patients |
|---|---|---|
| Paclitaxel | 2 | 4.87 |
| Paclitaxel+Trastuzumab | 1 | 2.43 |
| Paclitaxel+Capecitabine | 1 | 2.43 |
| Paclitaxel+Gemcitabine | 1 | 2.43 |
| Docetaxel+Cisplatin | 2 | 4.87 |
| Docetaxel+Capecitabine | 2 | 4.87 |
| Docetaxel+Doxorubicin+Cyclophosphamide | 13 | 31.7 |
| Docetaxel+Epirubicin | 1 | 2.43 |
| Docetaxel+Epirubicin+Cyclophosphamide | 2 | 4.87 |
| Docetaxel+Adriamycin | 1 | 2.43 |
| Gemcitabine+Cisplatin | 3 | 7.31 |
| Doxorubicin+Cyclophosphamide | 2 | 4.87 |
| 5-FU+Epirubicin+Cyclophosphamide | 8 | 19.51 |
| 5-FU+Doxorubicin+Cyclophosphamide | 2 | 4.87 |

**Regimen for Head and Neck cancer -**

The second most occurring cancer observed in study was head and neck carcinoma. Cisplatin was prescribed more frequently (25%) followed by Paclitaxel+Carboplatin (16.66%) as shown in figure 2.

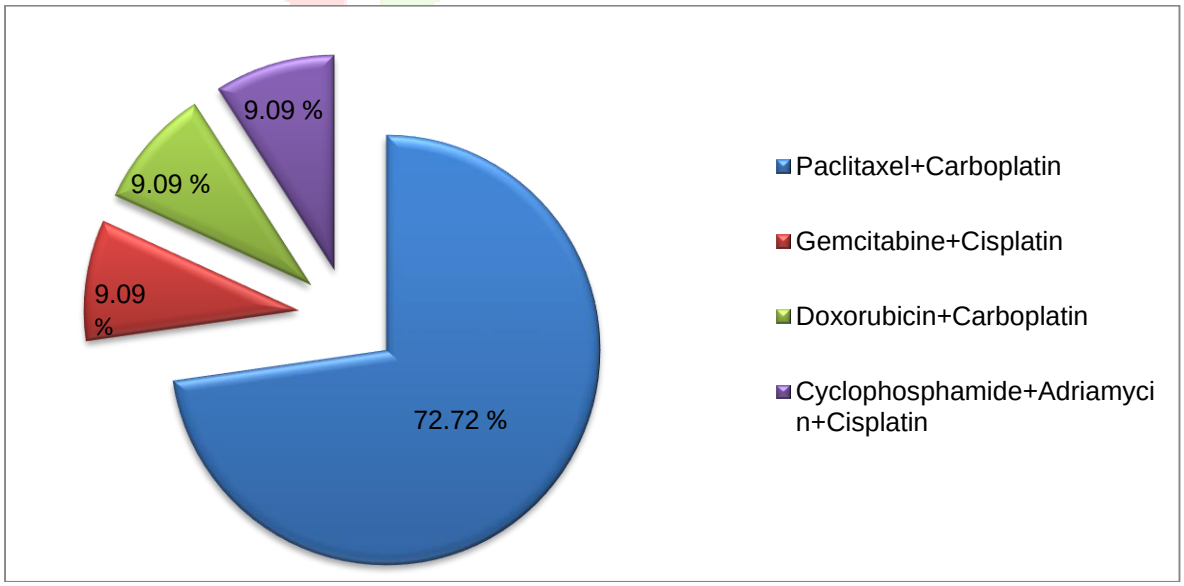
**Fig 2: Type of regimen for head and neck cancer**




**Regimen for carcinoma ovary**

Carcinoma ovary is occurring in 11 patients out of 100 as observed in study. The most frequently used regimen for this cancer is Paclitaxel+Carboplatin (8, 72.72%) followed by Gemcitabine+Cisplatin (1, 9.09%), Doxorubicin+Carboplatin (1, 9.09%) and Cyclophophamide+Adriamycin+Cisplatin (1, 9.09%) as shown figure 3.

**Fig 3: Type of regimen for carcinoma ovary**



**Regimen for Non-Hodgkin's Lymphoma**

Non-hodgkin's lymphoma is also one of the common type of cancer occurring in patients with different type of drug regimen. Regimen Rituximib+Cyclophosphamide+Vincristine+Doxorubicin is prescribed in 40% patients followed by other regimens as shown in table 4.

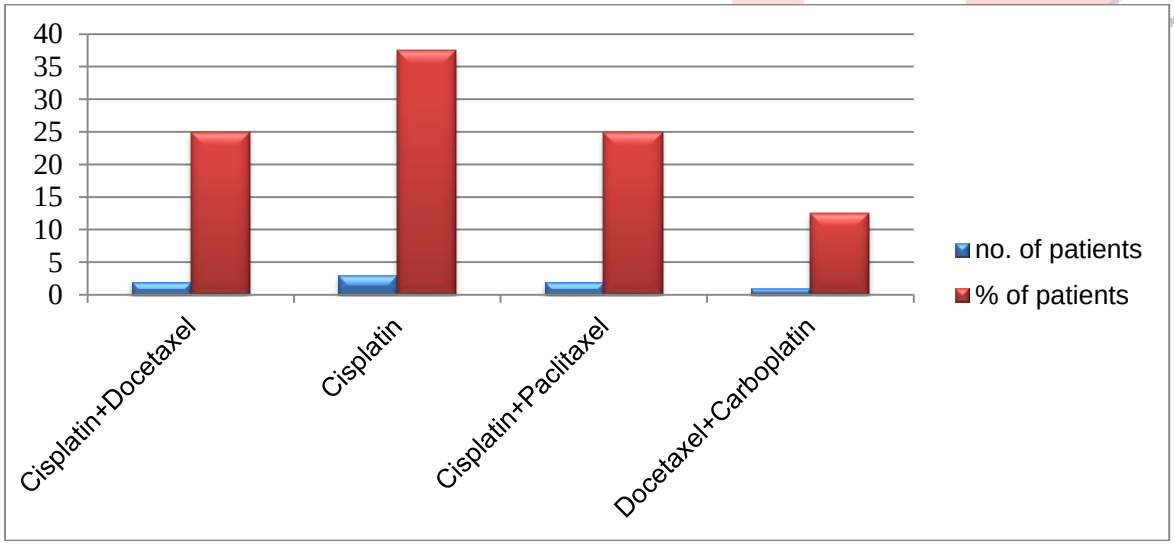
**Table 4: Type of regimen for non-hodgkin's lymphoma**

| Regimen | No. Of Patients | % Of Patients |
|---|---|---|
| Bendamustine | 1 | 10 |
| Bendamustine+Cyclophosphamide | 1 | 10 |
| Bleomycin+Etoposide+Cisplatin | 1 | 10 |
| Adriamycin+Cyclophosphamide | 1 | 10 |
| Cyclophosphamide+Doxorubicin+Vincristine | 1 | 10 |
| Rituximib+Cyclophosphamide+Vincristine+Doxorubicin | 4 | 40 |
| Rituximib+Cyclophosphamide+Doxorubicin | 1 | 10 |

**Regimen for cervix cancer**

In carcinoma of cervix the mostly prescribed drug is Ciplatin (3, 37.5%) followed by combinations of Cisplatin+Docetaxel (2, 25%), Cisplatin+Paclitaxel (2, 25%), Docetaxel+Carboplatin (1, 12.25%) as shown in figure 4.

**Fig 4: Type of regimen for cervix cancer**




**Other carcinomas**

Apart from above mentioned carcinomas, other cancers observed during study in remaining 18 patients were lung cancers (4, 22.22%) followed by cancers such as pancreas (4, 22.22%), gall bladder (3, 16.66%), esophagus (3, 16.66%), urinary bladder (1, 5.55%), rectum (1, 5.55%), endometrium (1, 5.55%), and liver (1, 5.55%) as shown in following table 5.

**Table 5: Type of regimen for other carcinomas**

| Other carcinoma(N=18) | No of patient |
|---|---|
| **Lung cancer** | |
| Paclitaxel+Carboplatin | 3 |
| Cisplatin+Premetexed | 1 |
| **Gall-Bladder Cancer** | |
| Gemcitabine+Cisplatin | 2 |
| Gemcitabine+Oxaliplatin | 1 |
| **Urinary Bladder Cancer** | |
| Gemcitabine | 1 |
| **Rectum Cancer** | |
| Irinotecan+Capecitabine | 1 |
| Carcinoma Esophagus | |
| Paclitaxel+Carboplatin | 1 |
| Paclitaxel | 1 |
| Paclitaxel | 1 |
| Carcinoma Endometrium | |
| Paclitaxel+Carboplatin | 1 |
| **Pancreas Cancer** | |
| Gemcitabine+Cisplatin | 1 |
| Gemcitabine+Oxaliplatin | 2 |
| Gemcitabine+Carboplatin | 1 |
| **Liver Cancer** | |
| Paclitaxel+Carboplatin | 1 |

**Types of anticancer drugs prescribed**

Different anticancer drugs were prescribed in cancer patients. Mostly prescribed drugs were taxanes (54%) followed by platinum analogs (47%), antibiotics (39%), alkylating agents (37%), antimetabolites (32%), monoclonal antibodies (6%) and epipodophyllotoxins and topoisomerase inhibitors were prescribed in 1% patients only as shown in table 6.

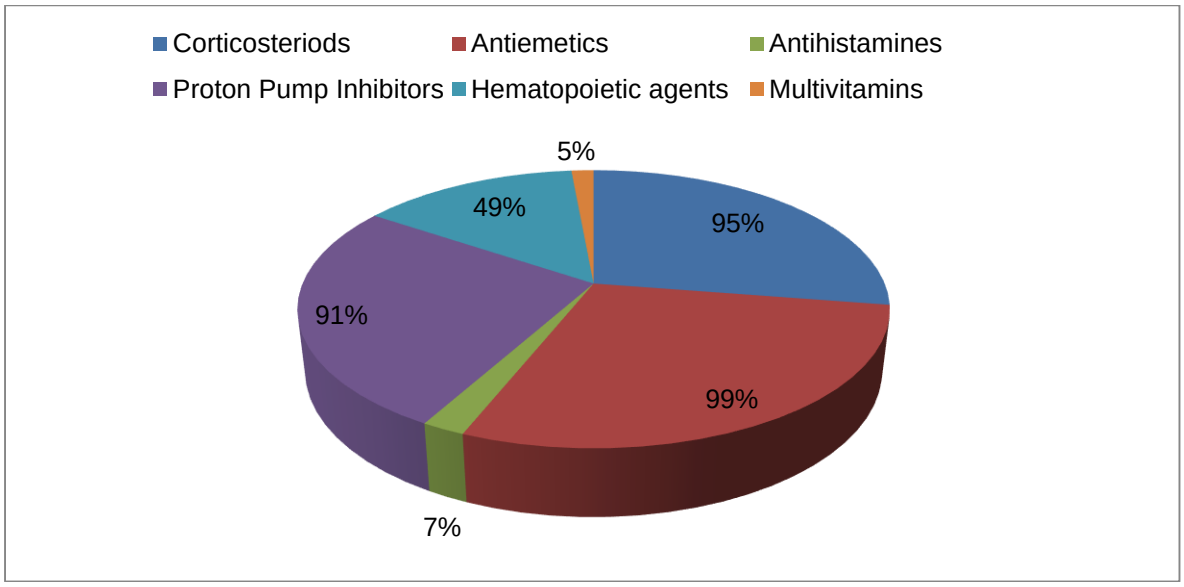
**Table 6: Use of anticancer agents in cancer patients**

| Use Of Anticancer Drugs | No. Of Patients | % Of Patients |
|---|---|---|
| Alkylating Agents | 37 | 37 |
| Antimetabolites | 32 | 32 |
| Antibiotics | 39 | 39 |
| Taxanes | 54 | 54 |
| Platinum Analogs | 47 | 47 |
| Monoclonal Antibodies | 6 | 6 |
| Epipodophyllotoxins | 1 | 1 |
| Topoisomerase Inhibitors | 1 | 1 |

**Class of adjuvant drug therapy**

Apart from anticancer agents there are many other drugs which are used to prevent or treat the adverse effects of the chemotherapy such as corticosteroids, antiemetics, antibiotics, antihistaminics, multivitamins and hematopoietic agents as depicted in figure 5.

**Fig 5: Class of adjuvant drug therapy in cancer patients**




**Use of adjuvant drug therapy**

The adjuvant drugs used to treat side effects of the chemotherapy are depicted in the above fig. the most commonly used antiemetic drug is ondansetron (67%) followed by 20% granisetron. Dexamethasone is given in 91% patients and proton pump inhibitor (pantoprazole) is prescribed in 84% as shown in below table 7.

**Table 7: Use of adjuvant drug therapy**

| Use of adjuvant drug therapy | No of patients | % of patients |
|---|---|---|
| Dexamethasone | 91 | 91 |
| Granisetron | 27 | 27 |
| Ondansetron | 67 | 67 |
| Pantoprazole | 84 | 84 |
| Ranitidine | 5 | 5 |
| Omeprazole | 7 | 7 |
| Palonosetron | 5 | 5 |
| Prednisolone | 4 | 4 |
| Filgrastim | 49 | 49 |
| Pheniramine maleate | 1 | 1 |
| Astymin | 5 | 5 |

**Type of therapy**

Usage of mono-therapy as management modality was observed in 15% of cancer patients while in other patients combination therapy (85%) was prescribed as shown in table 8.

**Table 8: Type of therapy given in cancer patients**

| Type of therapy | No of patient | % of patient |
|---|---|---|
| Mono-therapy | 15 | 15 |
| Combination Therapy | 85 | 85 |

**DISCUSSION-**

Drug utilization studies are found to be a potential tool to evaluate the prescription pattern and rational use of drugs. The present study is the observational prospective study conducted at hospital among inpatients suffering from cancer. The purposed study helps to find out the current prescribing pattern of anticancer drugs with respect to their diagnosis and type of cancer. Chemotherapy is used to treat many cancers. More than 100 chemotherapy drugs are used today – either alone or in combination with other drugs or treatments. Factors to be consider in choosing which drugs to use include:

- The type of cancer
- The stage of the cancer (how far it has spread)
- The patient's age
- The patient's overall health
- Other serious health problems (such as heart, liver, or kidney diseases)
- Types of cancer treatments given in the past

In present study usage of chemotherapy alone as management modality was observed in 15% of patients which are quiet less than an observational study done in 2014.[10] Carcinoma breast was the most commonly observed carcinoma in the present study. Other commonly observed carcinomas are of head and neck, ovary, NHL and cervix which are almost similar with the study of Pentareddy M R *et al* done in 2015[11]. Female to male ratio (75:25) was high in this study which is similar to ICMR study. The greater prevalence of cancer in females can be because of the involvement of their reproductive system such as cervical cancer, ovarian cancer and breast cancer which occupy the major portion among all other forms of cancer. In study majority of patients (35%) were of age group 40-50 years followed by 21% patients of age group 50-60 years but according to 1994 Surveillance, Epidemiology, and End Results Program of the National Cancer Institute, over 50% of all cancers occur in patients who are older than 65 years of age. Incidence of cancer increases as the age advances. Anticancer drugs were mostly prescribed in combination (85%) in current study. Among combinations chemotherapeutic regimens, Taxanes+platinum based combinations were mostly prescribed (24%). Breast carcinoma is one of the most common neoplasms in women and is a leading cause of deaths worldwide. The most frequently prescribed regimen of breast cancer in females is docetaxel+doxorubicin+cyclophosphamide (13, 31.70%) which is similar to the study of Darshan J. D *et al* (2014)[10]. Taxanes are the fundamental drugs used in the treatment of breast cancer which is similar to the study of Pentareddy M R *et al* (2015)[11]. Platinum is combined with taxel in most of the cases of cancer cervix, cancer lung, carcinoma of liver and endometrium and head and neck cancer. Gemcitabine and platinum combination is preferred in gall bladder and pancreas cancer. These results are in comparison with an observational study by Pentareddy M R *et al* (2015)[11]. In carcinoma of urinary bladder, gemcitabine monotherapy is given. In esophagus cancer, taxane monotherapy was prescribed in 2 patients while taxane+platinum based combination were given in one patient. Taxanes are the most frequently prescribed anticancer drug (54%) followed by prescription of platinum analogs (47%) but in comparison to Siddiqua A *et al* (2014)[12] study platinum analogs are more prescribed instead of taxanes. To treat the side effects of the chemotherapy such as nausea and vomiting which are most commonly occurring in cancer patients, the antiemetic drugs are prescribed in nearly about all patients (99%) and most commonly and frequently prescribed drug is ondansetron (67%) which is consistent to the results of Sneha G. *et al* study done in 2015[13].Dexamethasone was given in almost all the patients (91%). Addition of dexamethasone to 5-$HT_3$ antagonists has been shown to improve the control of acute phase of chemotherapy induced vomiting and these results are similar to the study of Pentareddy M. R *et al* (2015).[11]

## CONCLUSION

In conclusion, we have conducted this study in the routine clinical practice setting with no intervention from us in the clinical process. This study is relevant as it shows the drug utilization review the way it is generally performed in Indian setting may not be sufficient to improve the quality of prescribing. A concurrent drug utilisation evaluation with direct feedback to prescriber seems effective to improve the appropriateness with regard to the indication for use. Drug utilization studies need to be promoted and carried out on an ongoing basis. Drug utilization research is important to promote rational drug use. Its relevance to policy making and resource allocation needs to be emphasized.

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