

## Evaluation of prescribing trends in patients with gastrointestinal cancers; a prospective observation study

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### Abstract

**Background:** To Evaluate the prescribing trends in patients with gastrointestinal cancers; A prospective observational study in Bharath Hospital and Institute of Oncology, Mysuru.

**Methodology:** Six hundred and seventy eight patients were screened and 111 were enrolled into the study based on inclusion and exclusion criteria and the same was taken for further analysis.

**Results:** Out of 111 patients with gastrointestinal carcinoma, 66 patients (54%) are between age of 41-50 years. In these study 78 patients (70.3%) were males, 91 patients (81.98%) are from rural area, in our study 69 patients were (62.16%) illiterate. In this study, the prevalence of GI cancer was 16.37% was observed. Doublet chemotherapy regimen (18.11%) was frequently prescribed, in which 71.11% of patients who received FOLFOX and ECF had carcinoma of GI while paclitaxel + carboplatin (8.10%). Singlet regimen 5-Fluorouracil (1.80%), Capecitabine (0.90%) were highly prescribed among the different cancer types. The most commonly prescribed supportive care medications Palonosetron (90.99%) dexamethasone (90.99%) and ranitidine (23.42%), filgrastim (83.33%) were prescribed among all cycles of chemotherapy.

**Conclusion:** Prevalence of gastrointestinal cancer in the study was 16.37% and more male were diagnosed gastrointestinal cancers.

**Keywords:** Gastrointestinal cancer, Chemotherapy, Prevalence.

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### Introduction

Cancer was becoming a leading cause of death worldwide among non-communicable diseases. Cancer is the leading cause of death in developed and developing nations and was responsible for 9.6 million deaths in 2018 [1]. In the year 2018, over 1.1 million new cancer cases, along with 0.78 million deaths, were reported in India and Gastric cancer is one of the common malignant *tumors types of adenocarcinomas* among worldwide population. Gastric cancer is diagnosed as fifth commonest cancer and also third leading cause of GI cancer-related mortality [2]. Most frequent carcinomas reported in India are Oral/ oropharynx, esophagus, Gastric carcinomas, and lungs in males while carcinoma of the mouth/ oropharynx, and esophagus in females [3]. Gastrointestinal (GI) cancer is a term used for the group of cancers that affect the gastrointestinal tract and other organs that are contained within the digestive system, including the esophagus, pancreas, stomach, colon, rectum, anus, liver, biliary system, and small intestine [4].

### Common Types of Gastrointestinal Cancers

Colorectal cancer starts in the colon or the rectum, most colorectal cancers begin as small, noncancerous (benign) clumps of cells, called polyps, on the inner lining of the colon or rectum. Regular screening is recommended for prevention since polyps don't usually produce symptoms [4].

- **Liver Cancer**

Liver cancer starts in the cells of the liver. While other cancers can affect the liver, only cancers that actually start in the liver are considered liver cancer [5].

- **Stomach Cancer**

Stomach cancer, also called gastric cancer, starts in the stomach. While stomach cancer can develop anywhere in the organ, most stomach cancers develop in the mucus-producing cells of the stomach's inner lining, these cancers are called adenocarcinomas [6].

- **Pancreatic Cancer**

Cancer that begins in the tissues of the pancreas an organ that sits behind the stomach pancreas control blood sugar levels [7].

- **Esophageal Cancer**

A cancer that occurs in the esophagus a hollow, muscular tube that connects the throat to the stomach. It is located behind the trachea (windpipe) and in front of the spine [8].

- **Anal Cancer**

Anal cancer starts in the anal canala short tube at the end of your rectum the inner lining of the anal canal is the mucosa most anal cancers start from cells in the mucosa [9].

- **Small Intestine Cancer**

There are four major types of small intestine which include adenocarcinomas, carcinoid tumors, lymphomas, and sarcomas. Small intestine cancer often begins with non-cancerous polyps, which over time, can change into cancer [10].

- **Gastrointestinal Stromal Tumors (GIST)**

GISTs start in special cells, called interstitial cells of Cajal (ICCs).The most common sites for GISTs are the stomach and small intestine [11].

Other Types of GI Cancers

- **Gall bladder & Biliary Tract Cancer**

Gallbladder cancer occurs when malignant cancer cells form in the tissues of the gallbladder. Biliary tract cancer (also known as cholangiocarcinoma), biliary tract cancer can form anywhere along the bile ducts [12].

### **Risk factors for Gastrointestinal (GI) cancer**

There are many causes of cancer and some are preventable, such as Nutritional risk high salt consumption, high nitrate, and consumption of Nitroso compounds, low dietary vitamin A & C , Low fat /protein diet with high complex carbs, low fresh fruits and vegetables Occupational risk factors like poor food preparation of smoked salt cured, lack of refrigeration, poor drinking water, rubbr workers coal workers, H.pylori infection , Epstein – barr virus, radiation exposure ,prior gastric surgery for benign gastric ulcer disease. Genetic factors blood group A, pernicious anaemia, family history, HNPCC, Precursor lesions like Adenomatous gastric polyps, chronic atrophic gastritis, dysplasia , intestinal metaplasia [24]. 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 [13] and also some cases normal cells affected by risk exposures mainly chronic viruses like Hep-B and C, Epstein Barr Virus (EBV), a mutation in the p53 gene increase the high risk of malignancies [14].

### **Diagnosis**

Some of the most common diagnostic tests for gastrointestinal cancers include colonoscopy, endoscopy, biopsy, and imaging.

- Colonoscopy and sigmoidoscopy: Used to screen for colorectal cancer
- Upper GI endoscopy: Examines the lining of the upper part of the gastrointestinal tract, including the esophagus, stomach, and duodenum.

### **Biopsy**

During a biopsy, we remove a sample of the abnormal tissue so it can be examined for cancer by a pathologist

### **Imaging**

Diagnostic imaging for GI cancers might include:

- Computedtomography (CT) scan: Using an X-ray that takes many pictures

- Ultrasound: Using sound waves and their echoes to produce a picture
- Magnetic resonance imaging (MRI): Using radio waves and magnets to produce an image
- Positron emission tomography (PET) scan: Using radioactive sugar that is injected into the blood and observed with a special camera [15].

#### **Treatment options**

Cancer treatments are divided into four main types: surgery, radiation therapy, chemotherapy, hormonal therapy, and biologic therapy [16]. Treatment varies based on the type of cancer and its stage [15]. Surgery can be used to diagnose, treat, or even help prevent cancer in some case and also Chemotherapy is the use of medicines or drugs to treat cancer [17] cancer treatment includes chemotherapy, hormonal therapy, immunotherapy, precision medicine, radiation therapy, stem cell transplant, surgery. The choice of therapy depends on patient factors, tumor factors, and treatment factors [18]. Chemotherapy is the treatment of cancer that uses one or more anti-cancer drugs as part of a standardized chemotherapy regimen [19]. Antineoplastic agents are also traditionally divided by their origin or mechanism of action. The main groups include Alkylating-like agents, Antimetabolites, Antitumour antibiotics, miscellaneous agents, Hormonal agents. Plant alkaloids bind to microtubule proteins during metaphase, causing mitotic arrest [21, 22]. There are different types of chemotherapy treatment that includes adjuvant chemotherapy, neoadjuvant chemotherapy, induction chemotherapy, consolidation chemotherapy, maintenance chemotherapy, and palliative chemotherapy. In the olden days, cancers were treated with a single drug; but, nowadays, combination of drugs is given to overcome the cancer cell heterogeneity and development of drug resistant cells to kill total tumor cells [23]. The utilization pattern of anticancer drugs has changed significantly in recent years because of better enhancement in the pathophysiology of carcinomas as well as the introduction of newer drugs. Significant variation in the response rate of individual anticancer drugs, availability of different regimens, and intolerability of combination regimens necessitate observation and evaluation of cancer chemotherapy. Such Information will help in optimizing malignancy therapy with improved efficacy and minimal toxicity [24]. The present study aimed to analyze and evaluate the trends and patterns of prescribing anti-Gastrointestinal carcinomas drugs. It also aimed to provide a review of prescribing practices to physicians, which can be used to promote cost-effective treatment and better health care delivery. The objectives of the study were to assess the rational use of anticancer drugs, identify the various types of cancer and the commonly prescribed drugs regimen mostly using in FOLFOX, FOLFERI, DCF.CF ECF, Cutixmab, Bevacizumab 5-Flurouracil , Capecitabine EOX . And analyze the prescribing indicators [25].

#### **Objectives of the study**

- To assess prescription patterns for the chemotherapeutic agents in GI cancers.
- To assess the Prevalence of gastrointestinal cancers.
- To identify chemotherapy drug induced toxicities, management.

#### **Methodology**

##### **Materials and Methods**

**Study site:** The study will be conducted in both in patients and Day care patients at Bharth Hospital and institute of oncology, Mysuru.

**Study design:** Prospective Observational Study.

**Study period:** The study will be carried out for a period of six months.

##### **Study criteria**

##### **Inclusion criteria:**

- Patients those who are willing to participation in this study
- Patient those who are positively diagnosed with gastrointestinal cancer
- All the patients receiving chemotherapy drugs and biological therapy (Hormonal and targeted therapy).
- Those who are having >18years were included
- Patients those who are receiving anticancer drugs in hospital admission, as well as day-care patients, were included.
- Patients those who are having other co morbidities conditions were included.

**Exclusion criteria:**

- Patients those who are not willing to participate in these study
- Those patients who are treated with only radiation, and surgical interventions.
- Patients those who are having less than 18 years were excluded.
- Patient those who are having other than the gastrointestinal cancer.

**Preparation of data collection form**

A specially designed data collection form was devised for the study. The Particulars included demographic details like name, age, gender, medical history, height, Weight, body surface area; clinical data such as diagnosis, stage of cancer, therapeutic details such as chemo-radiotherapy, type of chemotherapy received; Chemotherapy details such as dose, cycles , duration, type of Chemotherapy , adverse event observed, grade and type of event, treatment given, The same details were documented electronically in specially Designed database using Google forms and Microsoft excel 2007.

**Study procedure and data collection:**

**Patient enrolment**

Patients fulfilling the study criteria were enrolled into the study. Patients were enrolled from In-patients, general wards, private wards, day care centre and prescribing patterns of chemotherapy were analyzed by collecting the details of drug usage including drug name, dose, indication, dosage form, and frequency, and duration, route of administration, chemotherapy cycles, and chemotherapy regimens and were recorded in the data collection form. Similarly, prescribing pattern of Anti-cancer chemotherapy drugs used along with supportive drugs was also recorded from the drug treatment chart and convened in the data collection form. Fig:1

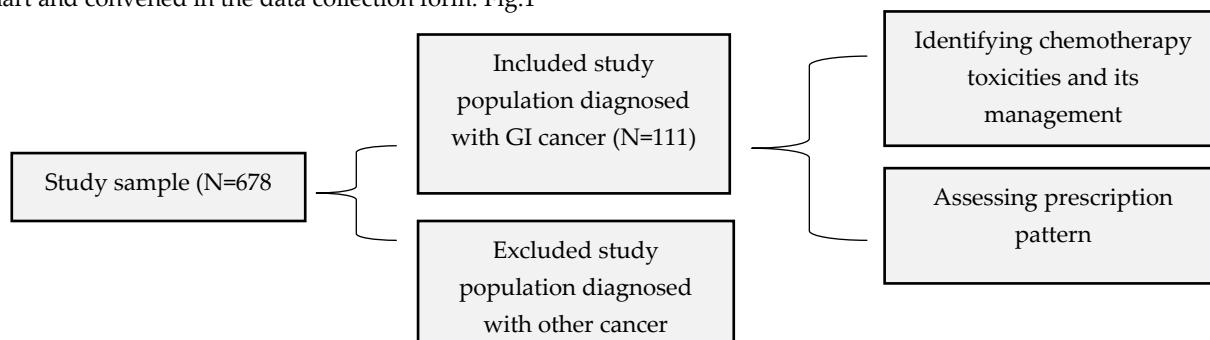


Fig: 1

**Results**

Out of 678 study sample, 111 were enrolled into the study based on inclusion and exclusion criteria and the same was taken for further analysis.

**Demographic details of study population with GI cancer**

In the Data were obtained prospectively from 111 patients with gastrointestinal carcinoma for chemotherapy in inpatients, receiving chemotherapy in Bharath hospital & institute of Oncology (BHIO) Mysore .whereas, 66 patients (54%) are between age of 41-50 years. In these study 78 patients (70.3%) were males, 91 patients (81.98%) are from rural area, in our study 69 patients were (62.16%) illiterate. Demographic details of prospective study sample were represented in Table 1

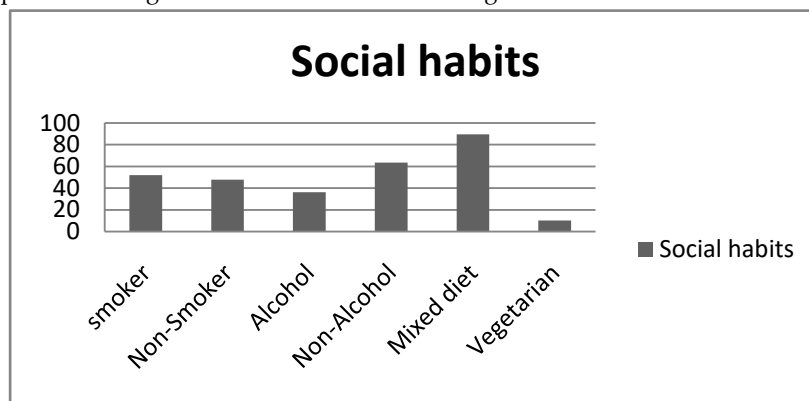
**Table 1: Demographic details of the study population with GI cancer**

Demographic details	No of Patients (n)	Percentage (%)
<b>Age:</b>		
31-40	3	2.7%
41-50	66	54%
51-60	27	24%
61-70	10	9%
71-80	5	4.5%

<b>Gender:</b> Male Female	78 33	70.30% 29.72%
<b>Residence:</b> Rural Urban	91 20	81.98% 18.01%
<b>Education Status :</b> Literate Illiterate	42 69	37.83% 62.16%

**Life style habits of the study population**

In our study, among 111 patients, 52.2% were alcoholic, 53.1% were smokers and 92.79% having mixed, and details were noted as per life style in patients with gastrointestinal carcinomas in fig 2



**Fig 2: Social habits of the study population with GI cancer**

**Co-morbidities of the study population**

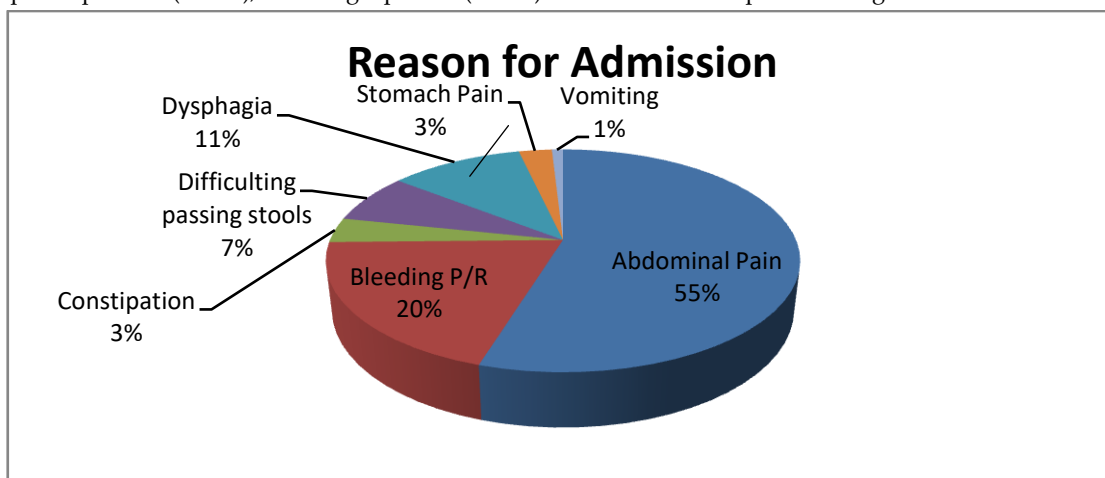
Out of 111 patient’s was found to be more compare with disease population, 43 patients (38.73%) are also known with Diabetes mellitus and Hypertension and 48 patients (43%) are diagnosed with Gastrointestinal carcinomas without any Co-morbidities, these details are presented in Table 2

**Table: 2 Co-morbidities of the study population**

Co – morbidities	No of Patients (n)	Percentage (%)
DM+ HTN	43	38.73%
HTN	19	17%
DM	01	0.9%
Nil	48	43%

**Reason for admission in study population:**

In our study mostly Admitted with chief complaint of abdominal pain 61(55.0%) patient’s and followed by P\R bleeding 22(20.0%), Dysphagia 12 patients (11.0%), Difficulting passing stools 8 patients (07%) , Constipation (4) patients (3.60%) Stomach pain 3 patients (2.70%), vomiting 1 patient (0.90%) these details are represent in fig 3



**Fig: 3 Reasons for Admission**

**Type of Cancer in Study Population**

In this study, the occurrence of Stomach cancer was more pre dominate 27 patients’ (24.32%), followed by 19 patient’s (17.11%) ca colon, 17patients (15.31%) Ca Rectum, 9patients (8.10%) Ca oesophagus,6 patients (5.40%) Ca Colon with Liver Mets,5 patients (4.50%)Ca GE Junction ,5 patients (4.50%)Ca Pancreas,4 patients (3.60%)Ca periampullary ,4 patients (3.60%) Cholangiocarcinoma, 4 patients (3.60%) Ca stomach with liver mets ,3 patients (2.70%) Ca Rectum with liver, 2 patients (1.80%) patients, Ileocecal ,2(1.80%) Caecum, 2 patients (1.80%), ca Anal 2 patients (1.80%), ca liver mets 1 patient (0.90%), Ca Gastric lymphoma 1 patient(0.90%) . these details are represented in Table 3

**Table 3: Type of Cancer in Study Population**

Type of Cancer	No of Patients (n)	Percentage (%)
Ca. Stomach	27	24.32%
Ca. Colon	19	17.11%
Ca. Rectum	17	15.31%
Ca. Esophagus	9	8.10%
Ca. Colon with liver mets	6	5.40%
Ca. GE Junction	5	4.50%
Ca Pancreas	5	4.50%
Ca. periampullary	4	3.60%
Ca. Cholangio	4	3.60%
Ca. Stomach with liver mets	4	3.60%
Ca. Rectum with liver mets	3	2.70%
Ca. Ileocecal	2	1.80%
Ca. Caecum	2	1.80%
Ca. Anal	2	1.80%
Ca. Liver mets	1	0.90%
Ca. Gastric Lymphoma	1	0.90%

**Prevalence:**

The overall prevalence was found to be 16.37% (111) for GI Cancer. Prevalence for Ca stomach 3.98%, Ca colon 2.80%, Ca Rectum 2.50%, Ca esophagus 1.32%, Ca colon with liver mets 0.88%, Ca GE Junction 0.73%, Ca Pancreas 0.73%, Ca

Periampulary 0.58%, Ca cholangio 0.58%, Ca stomach with liver mets 0.58%, Ca Rectum with liver mets 0.44%, Ca .Ilececal 0.29%, Ca cacum 0.29%, Ca Anal 0.29% Ca Liver mets 0.14% , Ca Gastric Lymphoma 0.14% details are presented below fig 4.

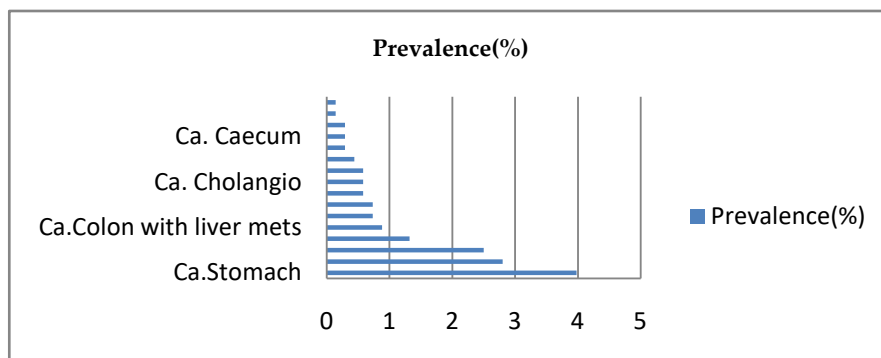


Fig: 4 Prevalence of in the study population

**Chemotherapy Regimen using in study population**

In the study FOLFOX 50(45.90%) patients was the most frequently prescribed regimen as triple combination followed by ECF 13(11.71%) regimen. The most used combined regimen were Paclitaxel + carboplatin 9(8.10%) patients,5-fluorouracil 2(1.8%) Patients and capecitabine 1(0.90%) patients were used as single agent regmin and other Regimen FOLFOX+ Bevacizumab 3(3.33%). The data are reported in Table 5

Table: 5 Chemotherapy Regimen using in study population

Regimen	No of Patients (n)	Percentage (%)
<b>Triple combination</b>		
FOLFOX	51	45.90%
FOLFORI	2	1.80%
DCF	6	5.40%
ECF	13	11.71%
EOC	2	1.80%
CAPOX	5	4.5%
<b>Double combination</b>		
GEMOX	2	1.80%
Paclitaxel+ Carboplatin	9	8.10%
5-Flourouracil+ Mitomycin	1	0.90%
Gemcitabin + Cisplatin	1	0.90%
Gemcitabin + Paclitaxel	1	0.90%
Irinotecan + Capecitabine	1	0.90%
Oxaliplatin+5-Flourouracil	3	2.70%
Oxaliplatin+ Capecitabine	2	1.80%
Pemetrexate+ Carboplatin	1	0.90%
<b>Single Combination</b>		
5-Flourouracil	2	1.80%
Capecitabine	1	0.90%
Gemcitabin	2	1.80%
Cisplatin	2	1.80%

<b>Others</b>		
FOLFOX+ Bevacizumab	3	3.33%
R-Chop	1	0.90%

**Prescription patterns of Anti-Neoplastic Drugs**

In our study most frequently prescribed anti neoplastic agents, 80% of patients were received 5-Fu and 80(72.07%) of patients received Oxaliplatin 64(57.65%) of 111 patients, the data were reported and presented in Table 6

**Table: 6 Prescription patterns of Anti-Neoplastic Drugs**

Class of Drugs	Cytotoxic drugs	No of prescriptions (%)
Platinum compounds	Carboplatin	10(9.00%)
	Cisplatin	22(19.81%)
	Oxaliplatin	64(57.65%)
Taxanes	Paclitaxel	11(9.90%)
	Docetaxel	4(3.60%)
Antimetabolites	5-Flurouracil	80(72.07%)
	Capecitabin	12(10.81%)
	Gemcitabine	7(6.30%)
	Pemetrexed	1(0.90%)
Alkylating agents	Cyclophosphamide	1(0.90%)
Antibiotics	Epirubicin	17(15.31%)
	Mitomycin	1(0.90%)
Topoisomerase inhibitors	Ironotecan	2(1.80%)
Targeted therapy	Bevacizumab	4(3.60%)
Monoclonal Antibodies	Rituximab	1(0.90%)
Chemotherapy enhancer	Leucovorin	80(72.07%)
Vica Alkloids	Vincristin	1(0.90%)

**Prescription pattern using Pre-medication in study population**

In our study, most commonly prescribed pre-medication before receiving chemotherapeutic regimen, patients were Palanosetron 101 patients (90.99%) and Dexamethasone 101 (90.99%) of 111 patients. the data were reported in Table 7.

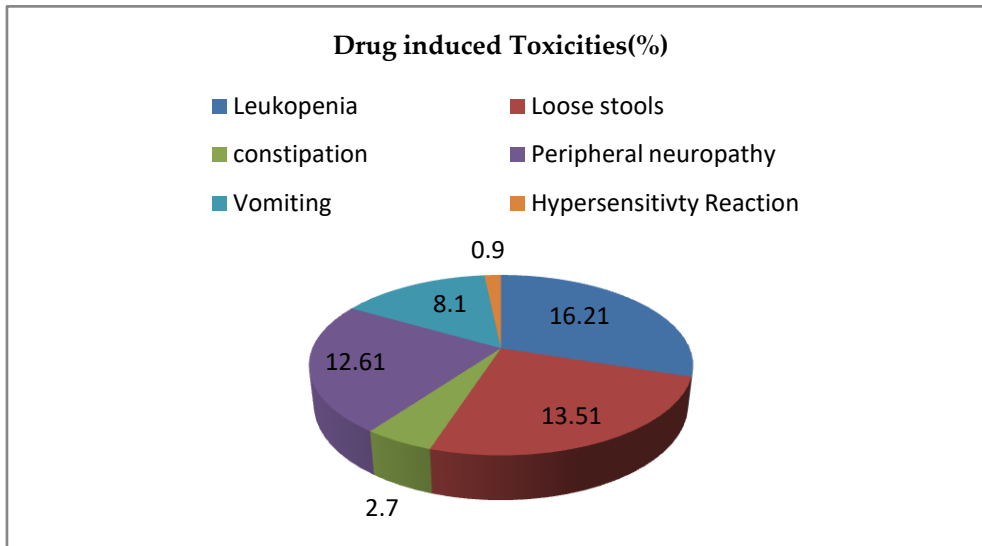
**Table: 7 Prescription pattern using Pre-medication in study population**

Class of Drug	Pre-medication	No of prescription Percentage (%)
Steroids	Dexamethasone	101 (90.99%)
	Prednisone	1 (0.90%)
Proton pump Inhibitors	Pantoprazole	43 (38.73%)
5HT3 Antagonist	Palanosetrone	101 (90.99%)
	Ondensetron	5 (4.50%)
Anti-Histamine	Rantidin	26 (23.42%)
	Pheniramine malate	3 (2.70%)
Pre-medication	MgSo4+ KCL	5 (4.50%)
Osomtic Diuritics	Mannitol	12 (10.81%)



**Drug induced Toxicities in study population**

Nevertheless, poly therapeutic regimen is unavoidable in some patients, though it adversely effects the quality of life and increase the burden of drug related problem, they are predictable and dose dependent and are explain by known pharmacological proprieties in individual agents. They were 60 drug toxicities from 111 patients, toxicities was maximum with Oxaliplatin 11(9.90%) patients, causality assessment of drug reaction were probable as assessment using WHO probability scale and naranjoj scale respectively. The data was reported and Presented in Fig 4



**Fig: 4 Drug Induced Toxicities**

**Chemotherapy Induced Toxicities and its management in study population**

In our present study, most of the intervention were seen as drug toxicity by using various chemotherapeutic agents, the most frequent drug toxicity were said to be myelosuppression such as leukopenia 18(16.21%) of 111 patients, whereas 15(83.33%) patients received Filgrastim of 18 patient’s, and Diarrhea 15 of patients where as 15 patients received Lopramide and Diphenoxylate+ Atropin the data was reported and presented in Table 8.

**Table: 8 Chemotherapy Induced Toxicities and its management in study population**

Toxicities(n)	Management of toxicities	No of Patients (%)
Leukopenia (18)	Inj. Filgrastim	15 (83.33%)
Diarrhea (15)	Lopramide Diphenoxylate+ Atropin	10 (66.66%) 5 (33.33%)
Peripheral Neuropathy (14)	Gabapentin Pregabalin	11 (78.57%) 3 (21.42%)
Vomiting (9)	Ondansetron Metaclopramide	6 (66.66%) 3 (33.33%)
Constipation (3)	Lactulose	3 (100%)
Hypersensitive Reaction (1)	Hydrocortisone	1(100%)

**Discussion**

Patient prescribing trends from the Oncology Department have been analysed. In this research, 70.30 percent of males were recruited and Tjulandin SA, et al, performed a similar study where 70.8 percent of males were enrolled in their study. We may also assume that males are more likely to develop gastrointestinal cancer because, relative to females, the incidence of carcinoma in males is greater than that of females and has been addressed in his research paper [39]. As the risk of cancer rises with age.

Present study also elucidated similar results with stomach 27(24.32%) cancer being most common, followed by Ca colon 19(17.11%) patients and Ca Rectum 17 (15.3%). Chemotherapy is one of the main management strategies along with radiotherapy and surgery in cancer. In malignant diseases drugs are used with the aim of cure or prolonged remission, palliative care or adjuvant chemotherapy. In present study Oxaliplatin was the most commonly used drug, followed by 5-Fluorouracil, Capecitabine, Paclitaxel, Doxorubicin, Cyclophosphamide and Carboplatin. Oncologists are using more injectable (especially intravenous) drugs than oral formulations.

Anticancer drugs were administered with both single agent and in combination with FOLFOX, ECF, doublet as Paclitaxel + Carboplatin where as single regimen are mostly 5-Fluorouracil and Capecitabine. The fundamental principle of combination chemotherapy is that different drugs act through different cytotoxic mechanisms and prevent /or slow with the subsequent development of cellular drug resistance. A major issue with this cytotoxicity is that it is not specific, normal cells may also be damaged along with the tumour cells.

Anti-neoplastic agents are mostly highly emetogenic in nature, inducing extreme vomiting of mutagenicity and carcinogenicity. In our research, we found that 6 drugs Toxicity inducing and grading causing extreme vomiting (grades 1 & 2), peripheral neuropathy (grades 1 & 2), leucopenia (grades 1 & 2) caused toxicity and managed to provide supportive drugs that were most likely due to the judicious use of drugs such as ondansetron and dexamethasone (for nausea and vomiting), ranitidine, and many others. Cyto-protective drugs have also been used in particular along with anti-metabolites, Gabapentin (peripheral neuropathy) and Filgrastim (Leukopenia) has often been used in our research.

### **Conclusion**

In the present study, majority of patients were in the age group of 41–50 years (54.0%). Females (29.72%) were predominant than males (70.30%). GI cancer (16.37%) was mostly observed. Doublet chemotherapy regimen (18.11%) was frequently prescribed, in which 71.11% of patients who received FOLFOX and ECF had carcinoma of GI while paclitaxel and carboplatin (8.10%), Singlet regimen 5-Fluorouracil (1.80%), Capecitabine (0.90%) were highly prescribed among the different cancer types. The most commonly prescribed supportive care medications Palonosetron (90.99%) dexamethasone (90.99%) and ranitidine (23.42%), filgrastim (83.33) were prescribed among all cycles of chemotherapy.

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