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Assessment of Prescription Pattern of Chemotherapy in Subjects with Esophageal Cancer

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ABSTRACT

Esophageal cancer is a disease that arises when the tissues of the esophagus generate malignant cells. In terms of its prevalence, it ranks 13th among cancers in women and 7th among cancers in men. The goal of the study is to assess prescription pattern in subjects receiving chemotherapy for esophageal cancer and this research will provide guidance to healthcare professionals on ways to utilize medications effectively and improve subjects' quality of life and survival chances while reducing potentially dangerous side effects. This was a prospective observational study carried out in the Department of Oncology in ESI MC & PGIMSR, Rajajinagar, Bengaluru. A total of 35 samples were collected, of which 28 were selected for the study. Subjects for the study were identified by the investigator during ward rounds based on the inclusion and exclusion criteria. Relevant data collected were recorded on the Self-designed data collection form. All recorded data were entered using Microsoft excel software for determining the statistical significance. The results were expressed in descriptive statistics such as percentages were calculated for categorical variables. 71% (n=20) of the subjects involved in the study were prescribed with Carboplatin. Carboplatin with paclitaxel was the most preferred combination therapy. In the present study, we have concluded that the oncologists in this hospital prefer Cytotoxic drugs over Targeted drugs for the treatment of esophageal cancer. During the covid pandemic, subject previously diagnosed with EC discontinued their therapy and follow-ups due to restrictions imposed by the government and inability to travel during lockdowns. Hence, resulted in inadequate therapy which leads to spread of cancer among the subjects and there by the therapy is changed from dual therapy (carboplatin and paclitaxel) the triple therapy.

Keywords: Esophageal cancer, Chemotherapy and Prescribing pattern.

INTRODUCTION

Esophageal cancer (EC) arises when the tissues of the esophagus generate malignant cells [1]. EC is the world's eighth most common cancer with an annual incidence of 6,04,100 cases. In terms of its prevalence, it ranks 13th among cancers in women and 7th among cancers in men [2,3]. EC has an incidence rate of 5.04% in India, according to the WHO's globocan 2018 report. EC is ranked 5th among cancers in males and 6th among cancers in women. It is the 4th leading cause of cancer related death in India [4,5]. In India approximately 52,396 new cases of EC and 46,504 deaths are reported each year. Evidence suggests that men are more likely to develop EC than females [6,7]. The two most frequently observed categories of EC are Squamous Cell Carcinoma (SCC) and Adenocarcinoma (AC). Therapeutic decision on whether chemotherapy or chemoradiation therapy must be given includes careful consideration of potential benefits and possible risks associated with therapy being administered. The significant risks associated with cancer chemotherapy include development of secondary cancer, potential Adverse Drug Reactions (ADR), mental distress, worsening of Quality of life (QoL) and economic loss. According to the NCCN guidelines, systemic therapy is used in the treatment of esophageal cancer. Systemic therapy can be of 3 types, such as chemotherapy, targeted therapy (the drugs concentrate on specific features of cancer cell growth and by inhibiting those distinct features it kills the cancer cells. For example, ramucirumab, trastuzumab, etc.) and immunotherapy (eg. nivolumab) [8].

Prescription Patterns explain the extent to which the drug is being used, trends being followed, quality of drugs being used, and compliance with regional, state or national guidelines like standard treatment guidelines, usage of drugs from essential medicine list and use of generic drugs [9]. It is essential to develop and understand the possible and effective way of drug utilization for improving the quality of life of the subjects. This study can be used as a strategic method to collect and assess as much as possible information about prescribing trends of chemotherapeutic agents used in the treatment of esophageal cancer. Furthermore, this research will provide guidance to healthcare professionals on ways to utilize medications effectively and improve subjects' quality of life and survival chances while reducing potentially dangerous side effects.

MATERIALS AND METHODS

This was a prospective observational study carried out over a period of 6 months in the Department of Oncology ESI MC & PGIMSR, Rajajinagar, Bengaluru. Subjects for the study were identified by the investigator during ward rounds based on the inclusion and exclusion criteria. A total of 35 samples were collected, of which 28 were selected for the study. Relevant data collected were recorded on the Self-designed data collection form. The data thus obtained was entered into a Microsoft Excel sheet and analyzed appropriately. The study was approved in accordance with the guidelines issued by ICMR the Institutional Ethics Committee has issued ethical clearance to carry on the work.

Inclusion Criteria:

- Subjects diagnosed with different types of esophageal cancer of any stage attending outpatient department of Oncology of ESI-MC & PGIMSR, Rajajinagar, Bengaluru.
- Subjects willing to participate and ready to give consent will be included in the study and, during the personal interview, their demographic information will be collected.
- The subjects receiving chemotherapy for different type esophageal cancer.

- Subjects above the age of 18 years will be included in the study.
- Subjects of any gender will be included for the study.

Exclusion Criteria:

- Subjects with any other solid and liquid tumors will be excluded from the study.

Statistical Analysis:

All recorded data were entered and analyzed using MS Excel. Descriptive statistics were computed for quantitative variables. Frequencies and percentages were calculated for categorical values. Column charts, pie-charts, bar graphs were applied to find the nature of data distribution.

RESULTS & DISCUSSION

The study was conducted in the day care ward of the oncology department of ESI MC & PGIMSR, Rajajinagar, Bengaluru. A total of 35 samples were collected. Of these, 7 samples were dropped out due to insufficient data, so the overall sample size was 28.

Distribution Of Subjects According to Age and Gender

Subjects were categorized based on age and gender. Out of 28 participants from the day care ward of the oncology department, 46% (n=13) of subjects were in the age group of 61–70 years. Among these age group seven subjects were men and six were female. While the lowest number of 4% (n=1) subjects were found in the age group of 18-30 and 81-90. Also, no subjects were found in the age group of 31-40. In Table 1, the data are explained.

Table 1: Age - Gender distribution of subjects

Age Distribution (year)	Male	Female	No Of Subjects (n)	Percentage
18-30	0	1	1	4%
31-40	0	0	0	0%
41-50	4	0	4	14%
51-60	2	3	5	18%
61-70	7	6	13	46%
71-80	3	1	4	14%
81-90	1	0	1	4%

DISTRIBUTION OF SUBJECTS BASED ON RISK FACTOR

Out of 28 subjects, most of them presented with several risk factors. Among all the risk factors, the prevalence of smoking (n=15, 54%), metabolic disorder (n=14, 50%), and alcohol (n=12, 43%) were higher followed by family history of cancer (n=4, 14%), tobacco chewing (n=2, 7%) and obesity (n=2, 7%). While the lowest number of subjects (n=1, 4%) had ascites, cirrhosis, gutkha and pan chewing as risk factors respectively. In Table 2, the data are explained.

Table 2: Risk factor distribution of subject		
Risk Factor	**No. of Subjects (n)**	**Percentage**
Smoking	15	54%
Alcohol	12	43%
Pan Chewing	1	4%
Tobacco Chewing	2	7%
Gutkha Chewing	1	4%
Obesity	2	7%
Cirrhosis	1	4%
Fatty Liver	1	4%
Ascites	1	4%
Family History of cancer	4	14%
Metabolic Disorder	14	50%

DISTRIBUTION OF SUBJECT BASED ON PRESENTING COMPLAINT

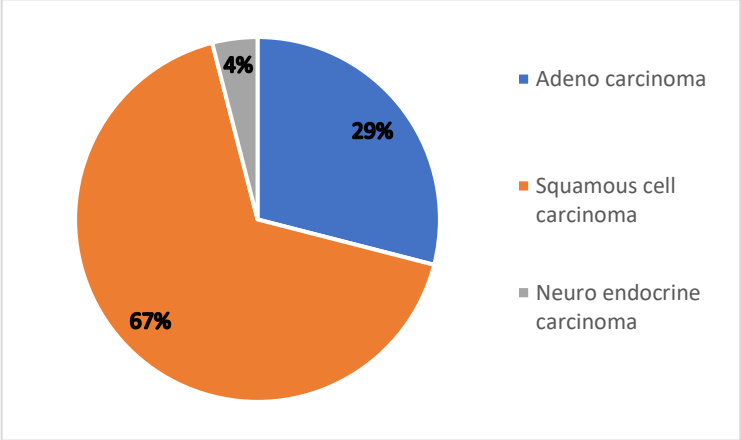
After analyzing the subject complaints, it was observed that the 75% (n=21) of the subject's complaints of dysphagia followed by weight loss (n=18, 64%), chest pain (n=4, 14%), painful swallowing (n=4, 14%), vomiting (n=4, 14%), abdominal pain (n=6, 21%), burning sensation (n=3, 11%), change in voice (n=3, 11%). Also, data represents Only 4% (n=1) subjects complain of throat pain and swelling of neck respectively. Table 3 clarifies the data.

Table 3: Distribution of subject based on presenting complaint		
Complaints	**No. Of subjects (n)**	**Percentage**
Weight Loss	18	64%
Chest Pain	4	14%
Dysphagia	21	75%
Vomiting	4	14%
Swelling of Neck	1	4%
Painful Swallowing	4	14%
Burning Sensation	3	11%
Hiccups	3	11%
Abdominal Pain	6	21%
Melena	3	11%
Loss Of Appetite	7	25%
Change In Voice	3	11%
Throat Pain	1	4%
Reduce Tolerance Toward Hot	2	7%
Fatigue	3	11%
Abdominal Discomfort	5	18%

DISTRIBUTION OF SUBJECTS BASED ON THE TYPE OF ESOPHAGEAL CANCER CELL

On analyzing the distribution of cancer subjects according to type of esophageal cancer, the data showed that the number of subjects with SCC (n=19, 68%) is higher than the subjects presented with AC (n=8, 29%) and Neuro Endocrine Carcinoma (NEC) (n=1, 3%). Figure 1 provides a synopsis of the data.

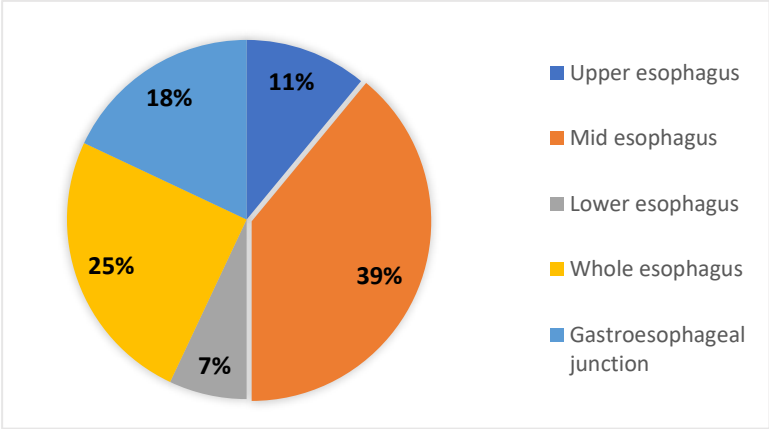
Figure 1: Type of esophageal cancer cell



DISTRIBUTION OF SUBJECTS BASED ON THE AFFECTED SITE OF ESOPHGUS

Out of 28 subjects, 48% (n=11) of the subjects suffered from mid esophagus cancer, followed by 30% whole esophagus (n=7), 13% upper esophagus (n=3) and 9% lower esophagus cancer (n=9%). In Figure 2 the data are explained.

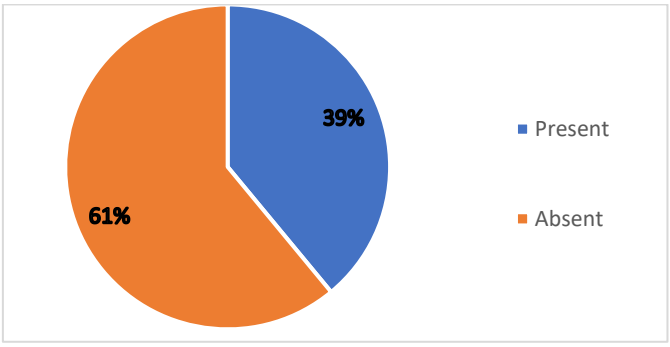
Figure 2: Affected site of esophagus



DISTRIBUTION OF SUBJECTS BASED ON METASTASIS:

Out of 28 subjects, 61% (n= 17) showed no evidence of metastatic disease, whereas 39% (n=11) did. Figure 3 clarifies the data.

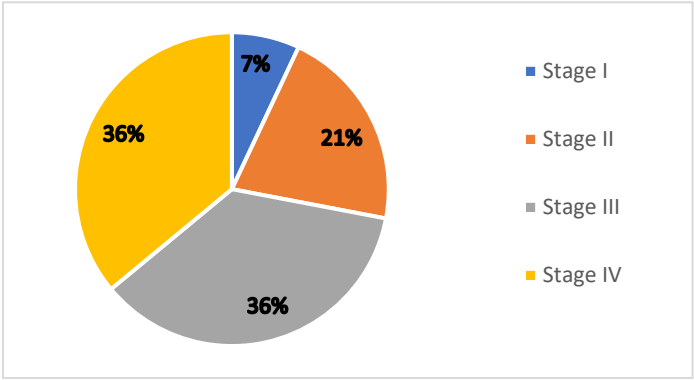
Figure 3: Distribution of subjects based on metastasis



DISTRIBUTION OF SUBJECTS BASED ON STAGE OF EC

Out of 28 subjects, 36% (n=10) of the subjects were in stage IV and stage III followed by stage II (n= 6, 21%) and stage I (n=2, 7%). In Figure 4, the data are explained.

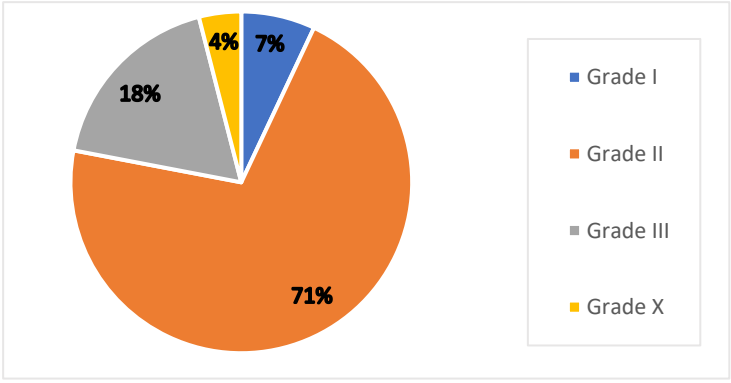
Figure 4: Distribution of subjects based on stage of EC



DISTRIBUTION OF SUBJECTS BASED ON GRADE OF EC

Among 28 subjects, majority of the subjects were in grade II (n= 20, 71%), followed by grade III (n=5, 18%), grade I (n= 2, 7%) and grade X (n=1, 4%). In Figure 5, the data are explained.

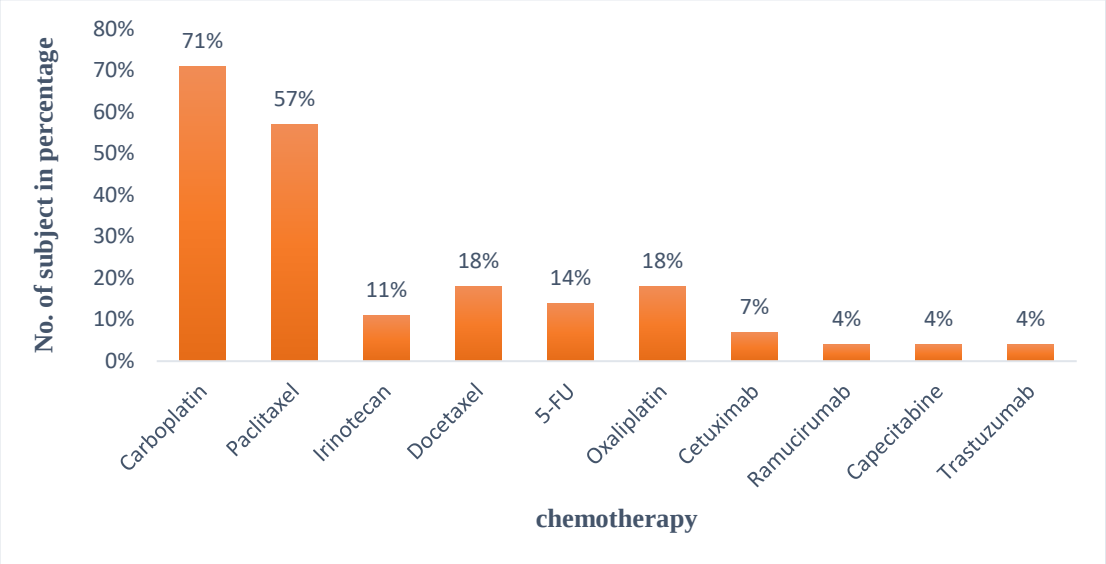
Figure 5: Distribution of subjects based on grade of EC



DISTRIBUTION OF SUBJECTS BASED ON CHEMOTHERAPY PRESCRIBED

Among 10 anticancer agents, 71% (n=20) of the subjects received carboplatin followed by paclitaxel 61% (n=17), docetaxel 18% (n=5), oxaliplatin 18% (n=5), 5-fluorouracil (FU) 14% (n=4), Irinotecan 11% (n=3), cetuximab7% (n=2), ramucirumab 7% (n=2) While only 4% (1) subject received capecitabine, trastuzumab, etoposide. In Figure 6, the data are explained.

Figure 6: Subject distribution based on chemotherapy



DISTRIBUTION OF SUBJECTS BASED ON SUPPORTIVE THERAPY GIVEN WITH CHEMO

The most received supportive therapy were ondansetron and pheniramine maleate for all subjects followed by pantoprazole and 0.9% sodium chloride (n=27, 96%), dexamethasone (n=26, 93%), hydrocortisone succinate (n=14, 50%), ranitidine (n=6, 21%), leucovorin (n=4, 14%) and filgrastim (n=3, 11%). While only 4% (n=1) subject received hyoscine butyl bromide, metoclopramide, olanzapine, and erythropoietin respectively. In Figure 7, the data are explained. In Figure 7, the data are explained.

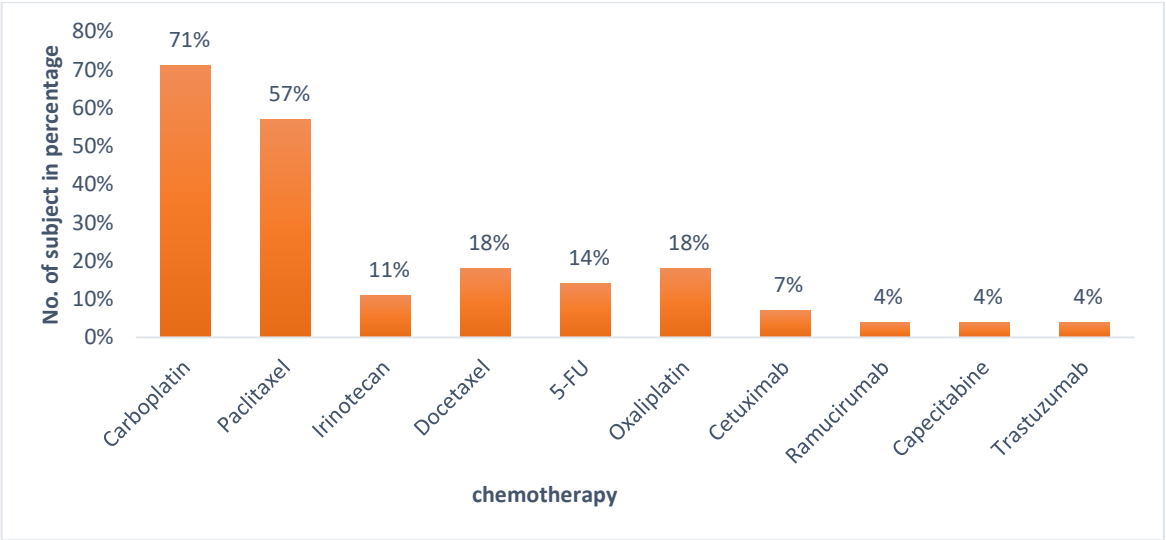


Figure 7: Subject distribution based on supportive therapy

DISTRIBUTION OF CHEMOTHERAPY S BASED ON CANCER CELL

Out of 28 subjects palclitaxel based regimen followed by Capox (Capecitabine + oxaliplatin) and FLOT (5 fu+ docetaxel+ oxaliplatin) therapy were prescribed or the treatment AC subjects. Also, subjects with SCC were treated with carboplatin based regimen (Carboplatin + paclitaxel, Carboplatin + irinotecan, Carboplatin + docetaxel etc.) and FLOT therapy. Subject with NEC treated with carboplatin-based regimen (Carboplatin + irinotecan). In Table 4, the data are explained.

Table 4: Distribution of chemotherapy s based on cancer cell

Type of cell	Combination base	Drug regimen	No. Of subject	Percentage
AC	Paclitaxel based regimen	Paclitaxel + cetuximab	1	4%
		Paclitaxel + ramucirumab	1	4%
		Paclitaxel + trastuzumab	1	4%
	Capox	Capecitabine + oxaliplatin	1	4%
	FLOT therapy	5 fu+ docetaxel+ oxaliplatin	3	11%
NEC	Carboplatin based regimen	Carboplatin + irinotecan	1	4%
SCC	Carboplatin based regimen	Carboplatin	3	11%
		Carboplatin + paclitaxel	12	43%
		Carboplatin + irinotecan	2	7%
		Carboplatin + docetaxel	1	4%
		Carboplatin + paclitaxel + trastuzumab	1	4%
	Flot therapy	5 fu+ docetaxel+ oxaliplatin	1	4%

DISTRIBUTION OF THERAPY BASED ON EC STAGE

out of 28 subjects, 4% (n=1) carboplatin + irinotecan combination was prescribed in stage IV of NEC subject. In case of AC, subjects with stage IA (n=1, 4%) treaded with capecitabine + oxaliplatin. Also, FLOT therapy was prescribed for the subject with stage IIB (n=2, 7%) stage IIIB (n=1, 4%). For AC subjects with stage IV were mostly received paclitaxel-based combinations. In case of SCC subjects with stage IA (n=1, 4%) was treated with monotherapy of carboplatin. Also, FLOT therapy was prescribed for the subject with stage IIA (n=1, 4%). Carboplatin + paclitaxel was prescribed for subjects with stage IIB (n=3, 11%), IIIA (n=4, 14%), IIIB (n=3, 11%), IVA (n=1, 4%) and IVB (n=1, 4%). In Table 5, the data are explained.

Table 5: Distribution of therapy based on EC stage

Cell type	Stage	Drug regimen	No. Of patient	Percentage
NEC	IV B	Carboplatin + irinotecan	1	4%
AC	I A	Capecitabine + oxaliplatin	1	4%
	II B	5 fu+ docetaxel+ oxaliplatin	2	7%
	III B	5 fu+ docetaxel+ oxaliplatin	1	4%

	IV B	Paclitaxel + cetuximab	1	4%
		Paclitaxel + trastuzumab	1	4%
		Paclitaxel + ramucirumab	1	4%
SCC	I A	Carboplatin	1	4%
	II A	5 fu+ docetaxel+ oxaliplatin	1	4%
	II B	Carboplatin +paclitaxel	3	11%
	III A	Carboplatin	1	4%
		Carboplatin + paclitaxel	4	14%
	III B	Carboplatin + paclitaxel	3	11%
		Carboplatin + paclitaxel + cetuximab	1	4%
	IV A	Carboplatin	1	4%
		Carboplatin + paclitaxel	1	4%
	IV B	Carboplatin	1	4%
		Carboplatin + paclitaxel	1	4%
		Carboplatin + irinotecan	2	7%

DISTRIBUTION OF SUBJECT BASED ON THE THERAPY TYPE AND AREA OF CANCER

Out of 28 subjects, mid esophagus cancer subjects mostly received dual therapy of carboplatin + paclitaxel (n= 7, 25%) followed by carboplatin + docetaxel (n=1, 4%), carboplatin + irinotecan ((n=1, 4%) and monotherapy on carboplatin (n=2, 7%). For the subjects with upper esophagus cancer received monotherapy of carboplatin (n=1, 4%) dual therapy of carboplatin + paclitaxel (n= 1, 4%) and triple therapy of carboplatin + paclitaxel + cetuximab (n= 1, 4%).

In case of lower esophagus cancer subjects received dual therapy of carboplatin + paclitaxel (n= 1, 4%) and triple therapy combination of FLOT (n= 1, 4%). For subjects with whole esophageal cancer received dual therapy combination of carboplatin + paclitaxel (n= 3, 11%) followed by carboplatin + irinotecan ((n=2, 7%), paclitaxel + cetuximab (n= 1, 4%) and paclitaxel + trastuzumab (n= 1, 4%).

For subjects with GEJ cancer received dual therapy of paclitaxel + ramucirumab (n= 1, 4%) and paclitaxel + cetuximab (n= 1, 4%) and capecitabine + oxaliplatin (n=1, 4%) and triple therapy of FLOT combination (n=2, 7%). In Table 6, the data are explained.

Table 6: Distribution of subject based on therapy type and area of cancer

Area of cancer	Drug regimen	No. Of patient	Percentage
Upper esophagus	Carboplatin	1	4%
	Carboplatin + paclitaxel	1	4%
	Carboplatin + paclitaxel + cetuximab	1	4%
Mid esophagus	Carboplatin	2	7%
	Carboplatin + irinotecan	1	4%
	Carboplatin + paclitaxel	7	25%
	Carboplatin + docetaxel	1	4%
Lower esophagus	Carboplatin + paclitaxel	1	4%

	5 fu+ docetaxel+ oxaliplatin	1	4%
Whole esophagus	Carboplatin + irinotecan	2	7%
	Carboplatin + paclitaxel	3	11%
	Paclitaxel + cetuximab	1	4%
	Paclitaxel + trastuzumab	1	4%
Gastro esophageal junction (GEJ)	Paclitaxel + ramucirumab	1	4%
	Paclitaxel + cetuximab	1	4%
	Capecitabine + oxaliplatin	1	4%
	5 fu+ docetaxel+ oxaliplatin	2	7%

DISTRIBUTION OF THERAPY BASED ON METASIS AREA OF THE SUBJECTS

Among the subject's majority of them had lung metastasis and received dual therapy of carboplatin + docetaxel (n=1, 4%), carboplatin + irinotecan ((n=3, 11%), of paclitaxel + trastuzumab (n= 1, 4%) and paclitaxel + cetuximab (n= 1, 4%). For the subjects with liver metastasis received dual therapy of carboplatin + paclitaxel (n=1, 4%) and Paclitaxel + ramucirumab (n= 1, 4%). Subjects with breast metastasis received dual therapy of carboplatin + paclitaxel (n= 1, 4%) and triple therapy of FLOT combination (n=1, 4%). Subjects with brain metastasis received carboplatin monotherapy (n=1, 4%). In Table 7, the data are explained.

Table 7: Distribution of therapy based on metastasis area of the subjects

Metastasis area	Therapy	No. Of patient	Percentage
Lung	Carboplatin + irinotecan	3	11%
	Paclitaxel + cetuximab	1	4%
	Paclitaxel + trastuzumab	1	4%
	Carboplatin + docetaxel	1	4%
Liver	Carboplatin + paclitaxel	1	4%
	Paclitaxel + ramucirumab	1	4%
Breast	Carboplatin + paclitaxel	1	4%
	5 fu+ docetaxel+ oxaliplatin	1	4%
Brain	Carboplatin	1	4%

DISCUSSION

Out of the 28 subjects included in the study, the majority were in the age range of 51–80 years. The age wise distribution of the subjects showed that the prevalence of esophageal cancer was higher in the age group of 61–70 years, which is similar to the age group of participants in the study of **Mary Rohini Pentareddy et al.**, in which it was observed that age-related events are responsible for the higher prevalence of cancer in the elderly [10].

After analyzing the subject data, results indicated that the prevalence of esophageal cancer is higher in male participants than that in female participants, which is similar to the findings in the study conducted by **VT Annapurna et al.,** in 2017 [11].

Our study showed that the majority of subjects had both metabolic diseases (32% HTN, 18% DM) and social habits (54% smoking, 43% drinking, 7% chewing tabaco, 4% chewing pan, and 4% chewing gutkha). This differs from the study by **VT Annapurna et al.,** in which social habits were found to be the primary factor responsible for EC in males [11].

On analyzing the data analysis, the majority of subjects (67%) had squamous cell carcinoma, whereas just 29% had adenocarcinoma and 4% neuro endocrine carcinoma. Which is similar to the cancer cell type in the study by **Inian Samarasam et al.,** in which the author observed that 76% had SCC and 24% AC [12].

In this study, out of 28 subjects, the majority 39% had mid esophageal cancer, followed by 25% whole esophagus, 18% GEJ, 11% upper esophagus and 7% lower esophageal cancer. This result differs from the study by **VT Annapurna et al.,** in which the author observed that the majority of their subjects had whole esophageal carcinoma (32%), followed by stomach carcinoma (29%), mid-esophageal carcinoma (19%), GEJ carcinoma (12%), and upper esophageal carcinoma (9%) [11].

After analyzing the data, the result indicated that 36% of the subjects are in Stage III & Stage IV followed by 21% Stage II, 7% Stage I. The grade of the cancer helps to assess the prescription trend among esophageal cancer subjects. After analyzing the EC grade of 28 subjects, the data represented, majority of subjects had Grade II (71%) EC, followed by Grade III (18%), Grade I (7%), Grade X (4%) which is similar to the histological grade of EC in the study by **Li-Ling Luo et al**., [13].

A total of 10 anticancer agents were used in our study for the treatment of EC. The majority of subjects received carboplatin (71%), followed by paclitaxel (57%), docetaxel (18%), oxaliplatin (18%), 5 fluorouracil (14%), irinotecan (11%), trastuzumab (4%). This result is similar to the study by **Manushi Aggarwal et al**., in which cisplatin was the most common drug used for the treatment followed by paclitaxel (19.8%), 5-fluorouracil (16.4%) [14].

Anticancer drugs were administered either singly or in combination. In our study, the majority of patients received dual therapy (75%) followed by and 11% triple therapy, 4% monotherapy, but this result differs from the study by **Ravindra S. Beedimani et al.,** in which the author found that the majority (63%) of patients received monotherapy while 37% received a combination of anticancer drugs [15].

On analysing the prescription, the majority of SCC subjects received a carboplatin based dual drug therapy (combination of carboplatin and irinotecan or docetaxel or paclitaxel) followed by triple drug therapy (combination of docetaxel, 5-fluorouracil, and oxaliplatin or carboplatin, paclitaxel and trastuzumab) and the majority of AC subjects received a FLOT therapy followed by paclitaxel based dual therapy (combination of paclitaxel + cetuximab or ramucirumab or trastuzumab) and CAPOX also, NEC subjects received carboplatin and irinotecan combination. The result of this study differs from the study by **Mary Rohini Pentareddy et al**., in which the author found that the majority of the patients received Paclitaxel and carboplatin, Oxaliplatin and 5-FU [15].

Our study also observed that the most commonly received supportive therapies were ondansetron and pheniramine maleate for all subjects, followed by pantoprazole and 0.9% sodium chloride (96%), dexamethasone (93%), hydrocortisone succinate (50%), ranitidine (21%), leucovorin (14%), and filgrastim (11%). While only 4% of the subjects received hyoscine butyl bromide, olanzapine, and erythropoietin. This result was similar to the supportive care given in the study by **Manichavasagam M et al.,** in which the author found that Chlorpheniramine maleate (86%), Dexamethasone (60%), anti-emetics (70%) [16].

CONCLUSION:

The study found that the majority of esophageal cancer cases occurred between the ages of 61 and 70. Also, number of male subjects with EC was higher than females. This leads to the conclusion that incidence of esophageal cancer increases with an increase in age.

It was found that subjects were exposed to metabolic disorders, smoking, and alcohol consumption as the risk factors. Also, weight loss, dysphagia, chest pain, vomiting, painful swallowing, burning sensations, and abdominal pain were the most common symptoms seen in the subjects. The study also revealed that squamous cell carcinoma was higher in number than subjects with AC. It was also found that the majority of the subjects had cancer in the mid esophagus, followed by the lower part of the esophagus along with GEJ. According to the study findings, the majority of subjects were prescribed carboplatin, paclitaxel, docetaxel, oxaliplatin, 5-fluorouracil, irinotecan, and other esophageal cancer treatments. The most commonly used supportive therapies in our study were ondansetron, pantoprazole, dexamethasone, pheniramine maleate, 5% dextrose, 0.9 % sodium chloride, hydrocortisone succinate, ranitidine, filgrastim, etc. Subjects diagnosed with EC and the treatments initiated before covid had included both monotherapy (carboplatin) and dual therapy (carboplatin and paclitaxel) based on the severity of the cancer among different subjects.

During the covid pandemic, subject previously diagnosed with EC discontinued their therapy and follow-ups due to restrictions imposed by the government and inability to travel during lockdowns. Hence, resulted in inadequate therapy which leads to spread of cancer among the subjects and therefore the therapy is changed from dual therapy (carboplatin and paclitaxel) the triple therapy (FLOT therapy). Here, the pharmacist can play a crucial role by keeping track of each patient, scheduling. Chemotherapy appointments, counselling the cancer patients regarding the therapy process, type of therapy, diet, etc. To enhance the patients' quality of life, pharmacists can also keep a close eye on the adverse effects of chemotherapy.

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