

## A PROSPECTIVE OBSERVATIONAL STUDY OF BOTH MALE AND FEMALE PATIENTS WITH VARIOUS TYPES OF CANCERS

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### ABSTRACT

**Aim:** To evaluate the treatment options regarding different cancers, To study the Incidence, recurrence in cancer patients. To observe the adverse effect profile of different types of cancer patients. To assess the role of counseling and its outcome in cancer patients. To study the severity of the cancers & factors responsible for metastasis. To study therapeutic outcomes and mortality in cancer patients. **Method:** It is a prospective observational study involving 251 patients which has been conducted in ST.ANNS GENERAL AND CANCER HOSPITAL, kazipet. for 5 months i.e. (August 2018-December 2018). **Result:** During the study period a total of 251 patients data were collected. Head and Neck cancers are seen predominantly (61.75%) followed by Gastrointestinal cancers (19.92%), Respiratory cancers, penis cancer &

the least number of cancers are Skin cancers. **Conclusion:** Among 251 patients, majority was in age group of 41-50 years and was found to suffer with Head and Neck cancer. Of all cancers, head and neck cancer was more prevalent. Chewing tobacco and consumption of alcohol were the frequently seen risk factors for developing Head and neck cancers. Counseling the patients regarding ADRs was done. It creates awareness among physicians and prevents the further occurrence of similar ADRs. Evaluating the ADRs on daily basis helped in prevention and their recurrence in chemotherapeutic cycles. Regular counseling helped the patients enable them to return to normal living with positive attitude. Mortality rate was decreased and there is positive therapeutic outcome.

**KEYWORDS:** Incidence, cancer, mortality, metastasis.

## INTRODUCTION

Oncology is a branch of medicine that specializes in the diagnosis and treatment of cancer. It includes medical oncology (the use of chemotherapy, hormone therapy, and other drugs to treat cancer), radiation oncology (the use of radiation therapy to treat cancer), and surgical oncology (the use of surgery and other procedures to treat cancer).

### Neoplasm

The term 'neoplasia' means new growth; the new growth produced is called 'neoplasm' or 'tumour'. However, all 'new growths' are not neoplasms since examples of new growth of tissues and cells also exist in the processes of embryogenesis, regeneration and repair, hyperplasia and hormonal stimulation. Neoplastic cells lose control and regulation of replication and form an abnormal mass of tissue. Therefore, satisfactory definition of a neoplasm or tumour is 'a mass of tissue formed as a result of abnormal, excessive, uncoordinated, autonomous and purposeless proliferation of cells even after cessation of stimulus for growth which caused it'. Neoplasms may be 'benign' when they are slow-growing and localised without causing much difficulty to the host or 'malignant' when they proliferate rapidly, spread throughout the body and may eventually cause death of the host. The word 'cancer' means crab, thus reflecting the true character of cancer since 'it sticks to the part stubbornly like a crab' (Harsh mohan, 2010).

All tumours, benign as well as malignant, have 2 basic components:

- 'Parenchyma' comprised by proliferating tumour cells; parenchyma determines the nature and evolution of the tumour.
- 'Supportive stroma' composed of fibrous connective tissue and blood vessels; it provides the framework on which the parenchymal tumour cells grow.

## LITERATURE REVIEW

1. Goodarz Danaei et al, "Causes of cancer in world: Comparative risk assessment of nine behavioural & environmental risk factors". They have estimated the mortality from 12 types of cancer attributable to 9 risk factors in seven world regions for 2001. They have analyzed data from comparative risk assessment project & from new sources to assess exposure to risk factors & relative risk by age, sex and region.

2. Loic le Marchand et al, "Associations of sedentary life style, obesity, smoking, Alcohol use, and Diabetes with the risk of Colorectal cancer". They have conducted a population

based case –control study in the multiethnic population of Hawaii to evaluate associations between colorectal cancer and a number of characteristics of the western life style (high caloric intake, physical inactivity, Obesity, smoking, drinking) & some other associated diseases. They have interviewed with persons 698 male & 494 female united states –born or immigrant Japanese, Caucasian, Filipino, Hawaiian, & Chinese patients diagnosed in 1987-1991, with colorectal cancer, & 1192 population controls matched on the age, sex, ethnicity. Conditional logistic regression was used to estimate Odds ratio adjusting for dietary & non dietary risk factors.

3. Noe kyeong kim et al, “A Phase 3 randomized study of 5-Fluorouracil and cisplatin versus 5 Fluorouracil, Doxorubicin and Mitomycin C versus 5-Fluorouracil alone in the treatment of Advanced Gastric cancer”. With the introduction of cisplatin containing regimens in the treatment of advanced gastric cancer, promising clinical reports have been reported. A 61.5% response rate was observed with a combination of 5-fluorouracil (5-FU) infusion and bolus cisplatin; however the superiority of cisplatin –containing regimens to other regimens has not been clearly verified in any randomized controlled studies.

4. Mohandas K Mallath et al, “The growing burden of cancer in India: epidemiology and social context”. Cancer can have profound social and economic consequence for people in India, often leading to the family impoverishment young country. Slightly more than 1 million new cases of cancer are diagnosed every year in a population of 1.2 billion. In age-adjusted terms this represents a combined male and female incidence of about a quarter of that recorded in western Europe. However, an estimated 600000-700000 deaths in India were caused by cancer in 2012.

5. Sheno R, Devrukhar V et al, “Demographic and clinical profile of oral squamous cell carcinoma patients: A retrospective study”. Oral cancers are one of the ten leading cancers in the world. However, in India, it is one of the most common cancer constitutes a major public health problem. The purpose of their study was to evaluate, retrospectively, the epidemiologic profile of patients with oral squamous cell carcinoma (OSCC). The cases were retrospectively analyzed from January 2008 to September 2010 for age, gender, occupation, duration of the symptoms, habits (tobacco and alcohol consumption), site of primary tumour, and TNM staging, and the findings were formulated to chart the trends in central India population.

**Aims and objectives****AIM**

An observational study in male cancer patients of Telangana Region.

**OBJECTIVES**

1. To study the Incidence, recurrence in cancer patients.
2. To evaluate the treatment options regarding different cancers.
3. To observe the adverse effect profile of different types of cancer patients.
4. To assess the role of counseling and its outcome in cancer patients.
5. To study the severity of the cancers & factors responsible for metastasis.
6. To study therapeutic outcome in cancer patients.
7. To study the mortality in cancer patients.

**METHODOLOGY PLAN OF THE STUDY**

**Study site:** ST.ANNS GENERAL AND CANCER HOSPITAL, kazipet.

**Study design:** prospective observational study.

**Study period:** 6 months.

**Study criteria*****INCLUSION CRITERIA***

8. Patients diagnosed with cancer and receiving treatment in oncology department.
9. Patients who are able to respond to the questionnaire.
10. Patients who had received atleast two cycles of chemotherapy.
11. Patients who had received atleast 5 days of radiation therapy.

***EXCLUSION CRITERIA***

←Pregnant women

3. Patients <20 years and >90 years.
4. Patients data without Histo-pathological examination reports.
5. Patients who didn't respond to the telephone calls for the survival rate have been excluded for this specific parameter.

**Source of data:** Patient records, laboratory data, radiation charts, direct communication with patients and their care takers in hospital, outside of the hospital via telephone calls.

**Parameters to be considered:** Demographics of patients, diagnosis, staging, treatment modality, social habits, family history, laboratory parameters which includes Biopsy, Histo-pathological study, Immuno-histology chemistry, complete blood picture, tumour markers (in specific) and results of radiology techniques.

The data collected is only used for the academics and the details of the patients collected are maintained confidential.

### Study protocol

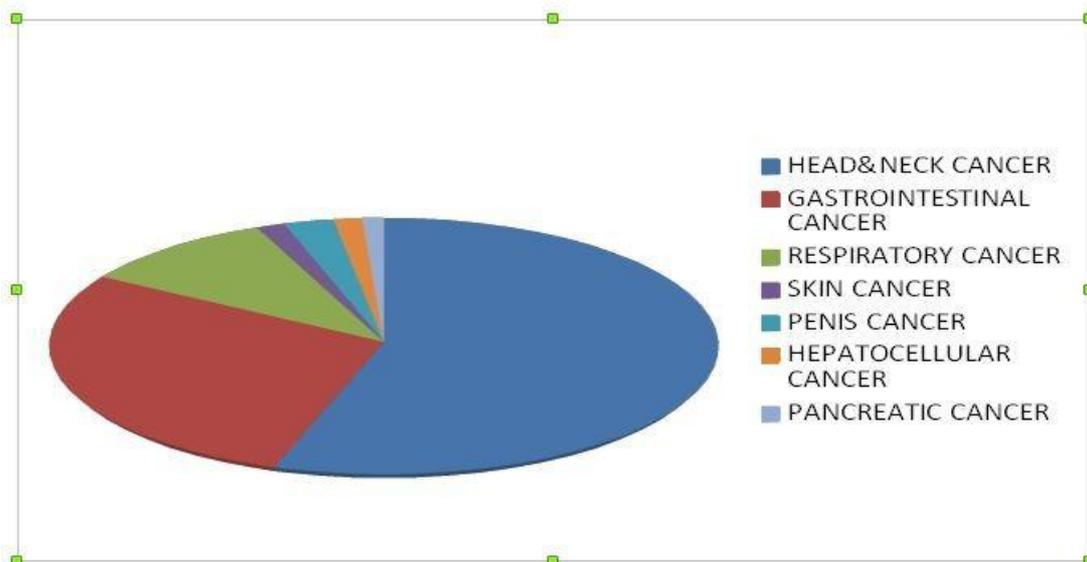
- Patients who are visiting oncology department on regular basis.
- Those patients who reach inclusion criteria are enrolled in the study.
- Necessary information was collected from the patient records, laboratory data, direct communication with patients and their care takers.
- All the required information is collected in appropriately designed data collection form with radiation chart.
- All the organized data will be subjected to statistical analyses based on requirement at the end of the study

### RESULTS

**Distribution based on type of Cancer:** During the study period a total of 195 patients data were collected. Head and Neck cancers are seen predominantly (52.8%) followed by Gastrointestinal cancers (29.2%), Respiratory cancers, penis cancer & the least number of cancers are Skin cancers.

**Table 1: Distribution based on type of Cancer.**

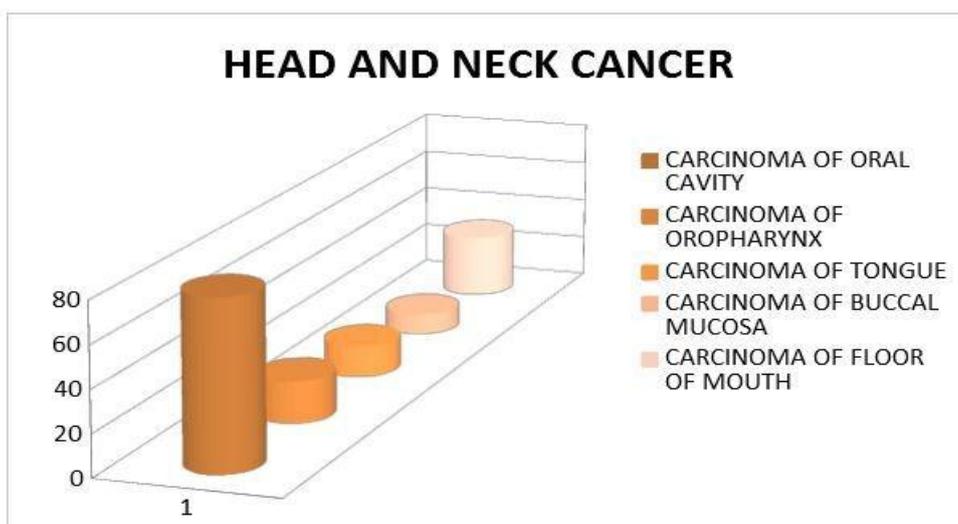
Type of Cancer	Number of Patients	Percentage
Head and Neck Cancers	155	61.75 %
Gastrointestinal cancers	50	19.92 %
Respiratory cancers	28	11.15 %
Skin cancer	4	1.5 %
Penis cancer	7	2.7 %
Hepatocellular carcinoma	4	1.5 %
Pancreatic cancer	3	1.1 %



**Distribution based on head and neck cancer:** A Total of 155 Head and Neck cancer cases were reported, most commonly seen cancers are Carcinoma of Oral cavity (33%), and least commonly seen cancers are Carcinoma of Floor of Mouth (10%).

**Table 2: Distribution based on head and neck cancer.**

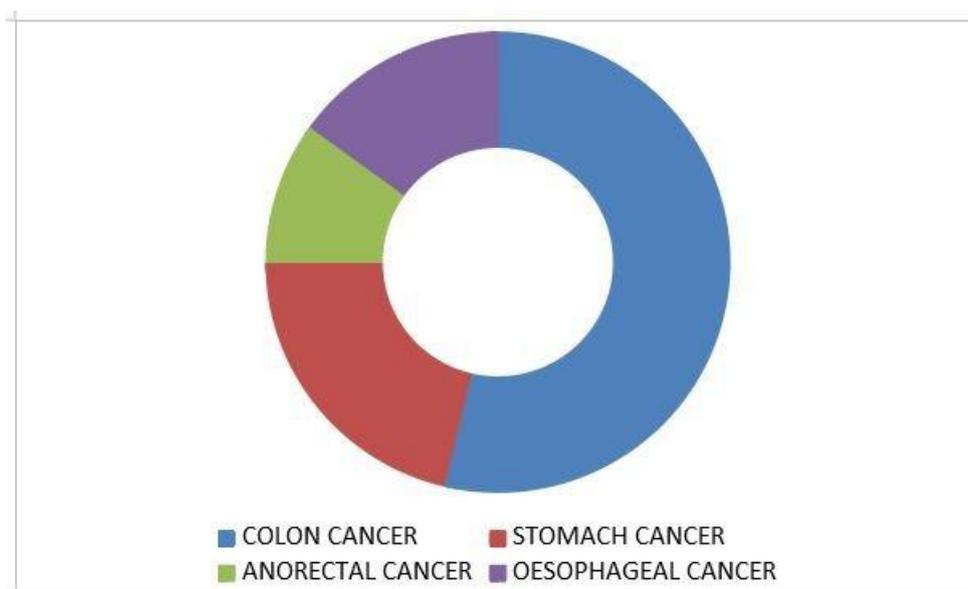
Type of cancer	Number of patients	Percentage
Carcinoma of Oral cavity	80	51.6 %
Carcinoma of oropharynx	20	12.9 %
Carcinoma of Tongue	15	9.6 %
Carcinoma of Buccal mucosa	10	6.4 %
Carcinoma of Floor of mouth	30	19.3 %



**Distribution based on gastrointestinal cancers:** A Total of 50 Gastrointestinal cancers have been reported. Among them the most frequently seen cancer were Colon cancer (46%) and the least number of cancers are Oesophageal cancers (14%).

**Table 3: Distribution based on gastrointestinal cancer.**

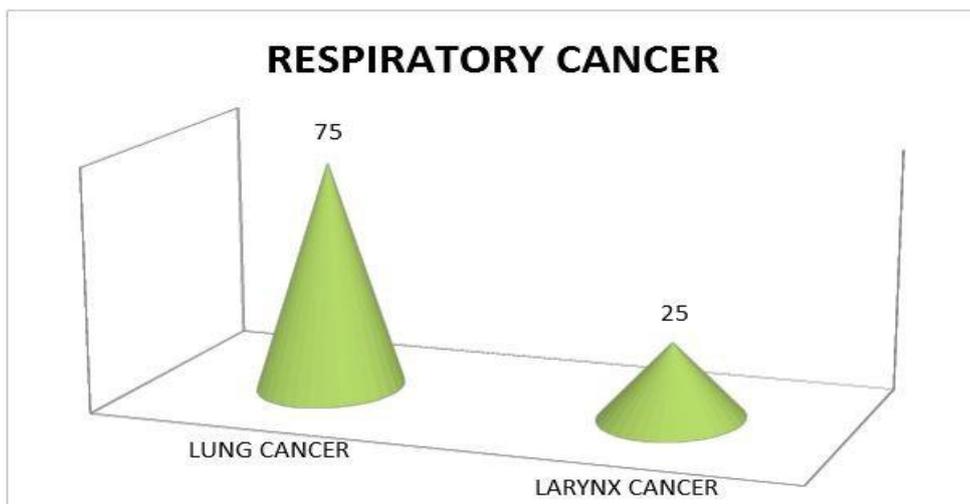
Type of Cancer	Number of Patients	Percentage
Colon Cancer	23	46
Stomach cancer	12	24
Anorectal cancer	8	16
Oesophageal cancer	7	14



**Distribution based on respiratory cancer:** A Total of 28 Respiratory cancers were seen among them Lung cancers are more predominantly seen with (26%), it is due to the presence of symptoms like Shortness of breath and fatigue and Comorbidites like TB, COPD, followed by carcinoma of larynx.

**Table 4: Distribution based on respiratory cancer.**

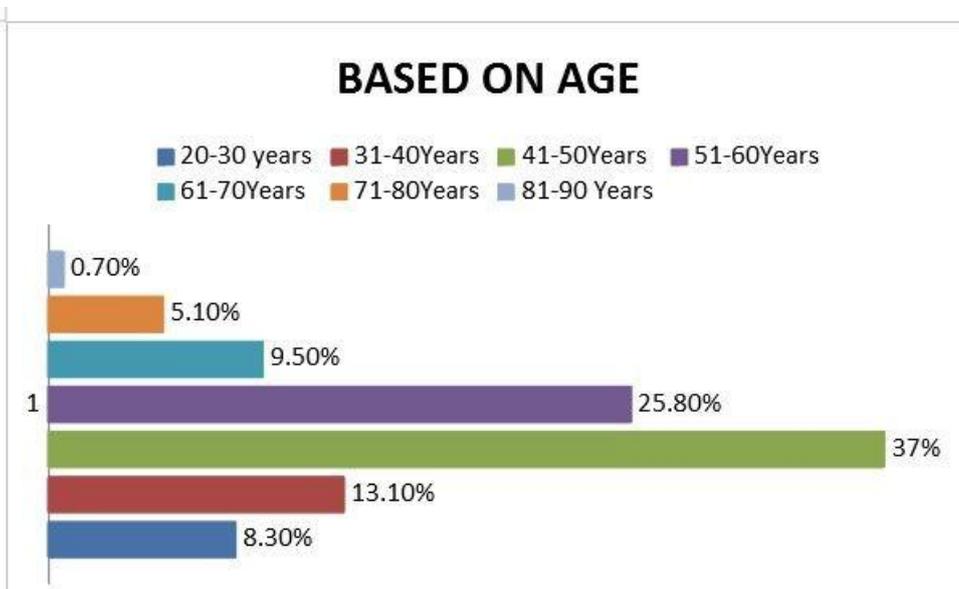
Type of Cancer	Number of Patients	Percentage
Lung Cancer	21	75%
Larynx Cancer	7	25%



**Distribution based on age wise:** Out of 251 patients, 41-50 years age group is prone to suffer with cancer with a 32.3% followed by 81-90 years with 0.5%.

**Table 5: Distribution based on age wise.**

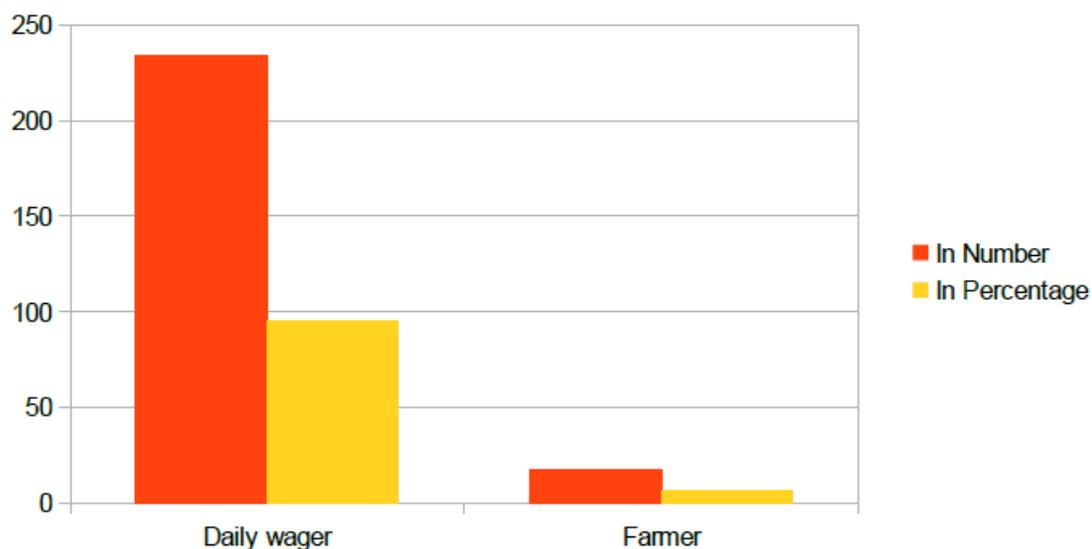
Age	Number of Patients	Percentage
20-30 years	21	8.3%
31-40 years	33	13.1%
41-50 years	93	37%
51-60 years	65	25.8%
61-70 years	24	9.5%
71-80 years	13	5.1%



**Distribution based on occupation status:** Most of the patients are daily wagers they are with 94% when compared to Farmers.

**Table 6: Distribution based on occupation status.**

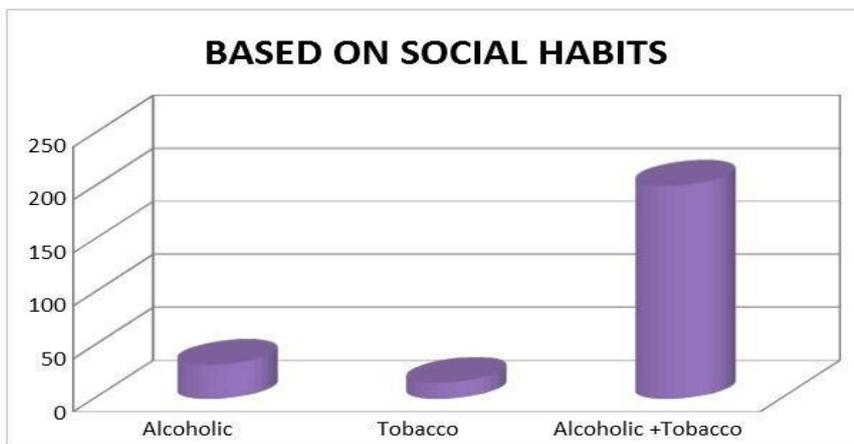
Type of Occupation	Number of Patients	Percentage
Daily Wager	234	94.8%
Famer	17	6.1%



**Distribution based on social habits:** Out of 251 patients, social history of Alcoholic and Tobacco are more when compared to alcoholic, tobacco chewers.

**Table 7: Distribution based on social habits.**

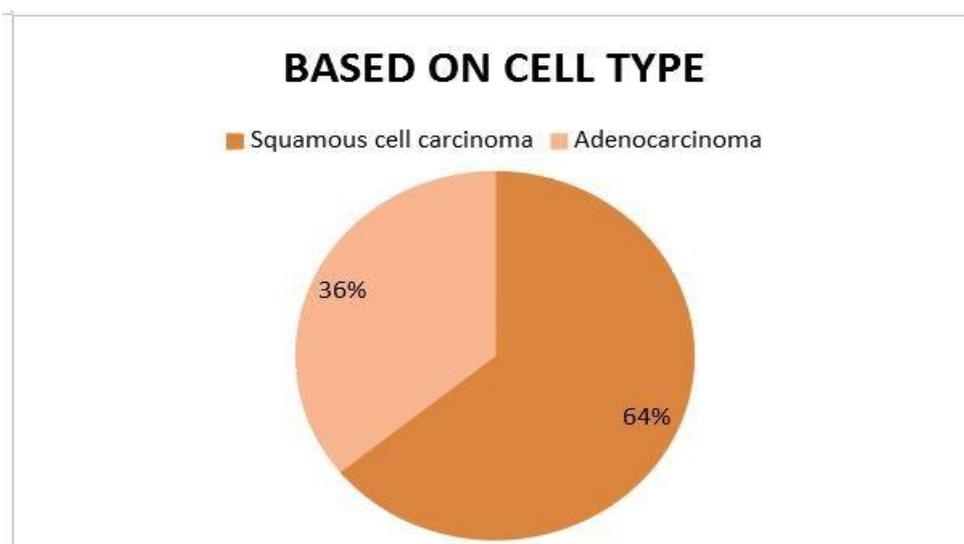
Social History	Number of Patients	Percentage
Alcoholic	32	12.7%
Tobacco	15	4.7%
Alcoholic+Tobacco	201	80.0%



**Distribution based on cell type:** As most of the carcinomas are confined to the epithelial layers of the cell squamous cell carcinomas are most commonly seen when compared to Adenocarcinoma.

**Table 8: Distribution based on cell type.**

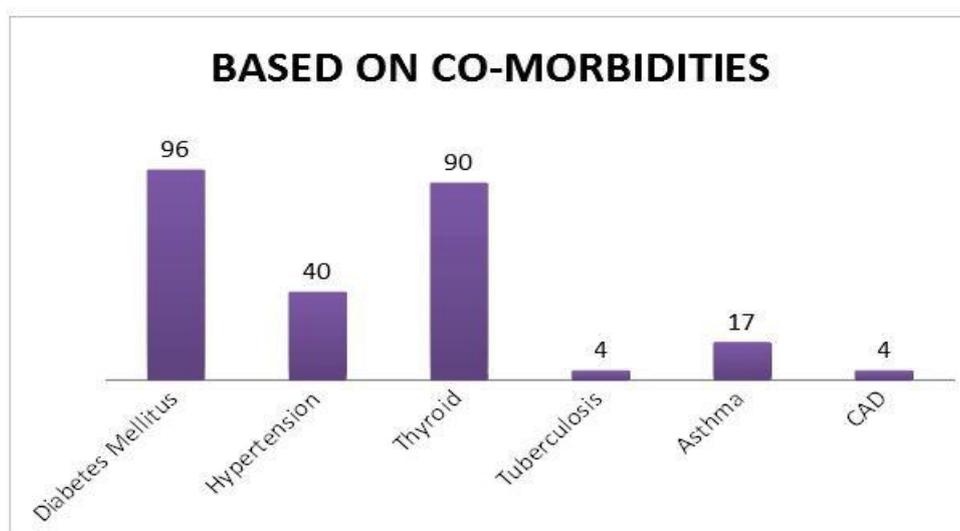
Cell Type	Number of Patients	Percentage
Squamous cell Carcinoma	175	69.7%
Adenocarcinoma	76	30.2%



**Distribution of cancers based on co-morbidities:** Out of 251 patients Diabetes mellitus is most commonly seen comorbidity, followed by low number of coronary artery disease.

**Table 9: Distribution of cancers based on co-morbidities.**

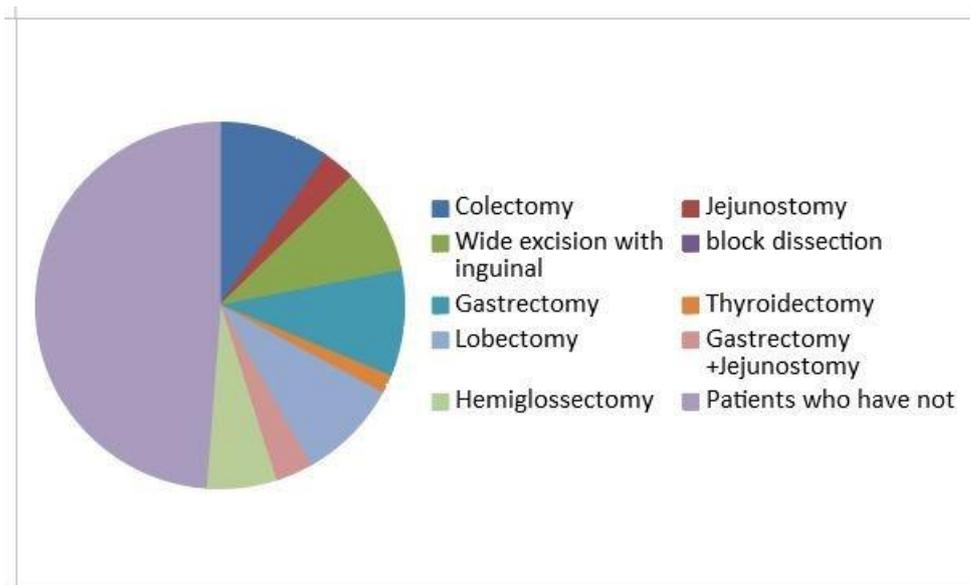
Co-Morbidites	Number of Patients	Percentage
Diabetes Mellitus	96	38.2%
Hypertension	40	15.9%
Thyroid	90	35.8%
Tuberculosis	4	1.5%
Asthma	17	6.7%
CAD	4	1.5%



**Distribution of cancer based on surgery profile:** Colectomy is most commonly seen surgical profile when compared to other surgical profiles.

**Table 10: Distribution of cancer based on surgery profile.**

Surgical Profile	Number of Patients	Percentage
Colectomy	24	9.5%
Jejunostomy	11	4.3%
Wide excision with inguinal dissection	23	9.1%
Gastrectomy	23	9.1%
Thyroidectomy	8	3.1%
Lobectomy	22	8.7%
Gastrectomy+Jejunostomy	9	3.5%
Hemiglossectomy	15	5.6%
Patients without Surgery	120	47.8%



**Distribution based on staging of oral cancer:** Most of the patients are with last stage when compared with the initial stages.

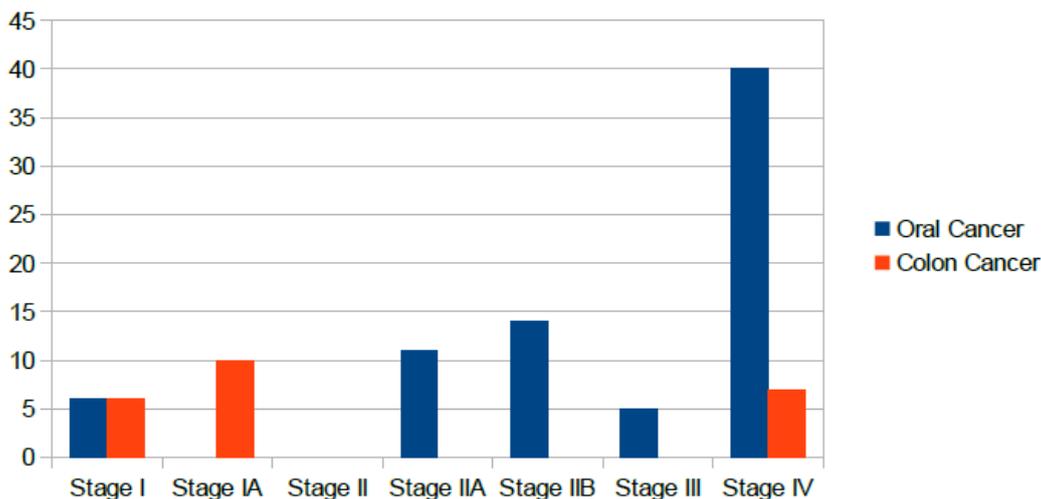
**Table 11: Distribution based on staging of oral cancer.**

Staging	Number of Patients	Percentage
Stage I	10	12.5%
Stage IIA	11	13.7%
Stage IIB	14	17.5%
Stage III	5	6.2%
Stage IV	40	50%

**Staging of colon cancer:** patients with end stage are more in number when compared to the initial stages.

**Table 12: Staging of colon cancer.**

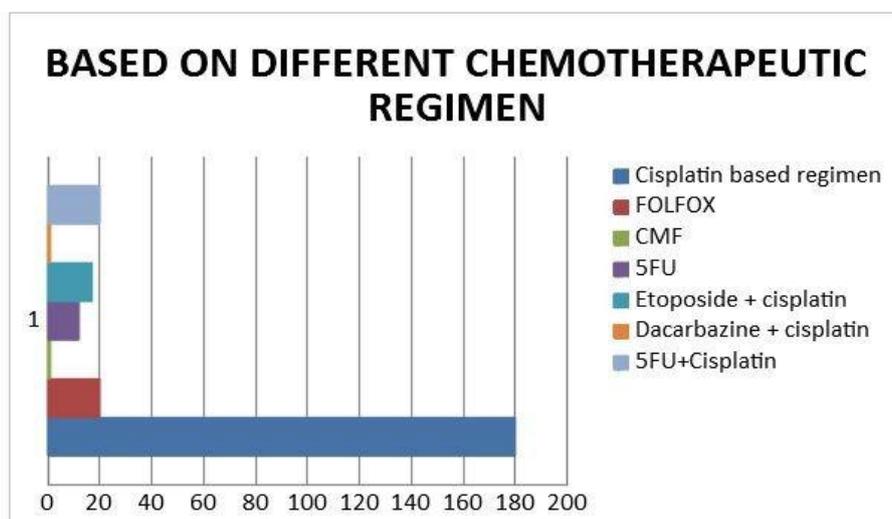
Staging	Number of Patients	Percentage
Stage I	6	26%
Stage IA	10	43.4%
Stage II	-	-
Stage III	-	-
Stage IV	7	30.4%



**Distribution based on different chemotherapeutic regimen:** Most commonly seen chemotherapeutic regimen was Cisplatin based chemotherapeutic regimen, followed by least chemotherapy regimen is Dacarbazine +cisplatin.

**Table 13: Distribution based on different chemotherapeutic regimen.**

Chemotherapeutic Regimen	Number of Patients	Percentage
Cisplatin based regimen	180	71.1%
FOLFOX	20	7.9%
CMF	1	0.3%
5FU	12	4.7%
Etoposide + Cisplatin	17	6.7%
Dacarbazine + Cisplatin	1	0.3%
5FU + Cisplatin	20	7.9%



**List of ADRs:** A total of 3043 ADRs have discoloration of skin, body pains and mouth ulcers been reported. Out of them Hoarseness of voice, are most predominantly seen.

**Table 27: Distribution of ADRs.**

Adverse Drug Reaction	Number of Patients	%
Vomiting	85	2.7
Alopecia	40	1.3
Nausea	85	2.7
Discoloration of skin	170	5.5
Pain in limbs	10	0.3
Weight Loss	132	4.3
Discoloration of nails	97	3.1
Abdominal Pain	89	2.9
Numbness	48	1.5
Cough	79	2.5
Fever	68	2.2
Fatigue	90	2.9
Cold	55	1.8
Anemia	102	3.3
Pain in site of radiation	128	4.2
Diarrhea	92	3.02
Body Pains	132	4.33

Backache	99	3.25
Epigastric Pain	100	3.28
Itching in perianal Region	18	0.5
Pain during defecation	92	3.2
Thrombophlebitis	45	1.47
Burning Micturation	102	3.35
Giddiness	77	2.5
Headache	85	2.7
Constipation	99	3.25
Bleeding	75	2.46
Pedal Edema	120	3.94
Throat Pain	99	3.25
Mouth Ulcers	102	3.35
Indigestion	84	2.76
Epistaxis	114	3.7
Hoarseness of voice	175	5.75
SOB	55	1.8

**16. Distribution of Adverse Drug Reactions in Gastrointestinal System:** A Total of 890 ADRs have been reported, among them weight loss, mouth ulcer, are more predominantly seen followed by pain during defecation, fatigue, nausea, vomiting.

**Table 28: Distribution of Adverse Drug Reactions in Gastrointestinal System.**

Adverse Drug Reaction	Number of Patients	%
Nausea	85	9.5
Vomiting	85	9.5
Constipation	120	13.4
Weight loss	132	14.8
Mouth Ulcer	102	11.4
Indigestion	84	9.4
Fatigue	190	21.3
Pain during defecation	92	10.3

**17. Distribution of Adverse Drug Reactions in Musculoskeletal System:** Out of 479 ADRs, body pains are majorly seen followed by pain at the site of radiation.

**Table 29: Distribution of Adverse Drug Reactions in Musculoskeletal System.**

Adverse Drug Reaction	Number of Patients	%
Pain in limbs	100	20.8
Pain at site of radiation	128	26.7
Body Pains	132	27.5
Backache	99	20.6
Chest Pain	20	4.17

**18. Distribution of Adverse Drug Reactions in Respiratory System:** Out of 364 ADRs most commonly seen ADRs are Hoarseness of voice, followed by cough and Shortness of breath.

**Table 30: Distribution of Adverse Drug Reactions in Respiratory System.**

Adverse Drug Reaction	Number of Patients	%
Hoarseness of voice	175	48
SOB	55	15.1
Cold	55	15.1
Cough	79	21.7

**19. Distribution of Adverse Drug Reactions in Skin Appendages:** Out of 352 ADRs Discoloration of skin & Discoloration of nails are seen majorly followed by Alopecia.

**Table 31: Distribution of Adverse Drug Reactions in Skin Appendages.**

Adverse Drug Reaction	Number of Patients	%
Alopecia	40	11.3
Discoloration of skin	170	48.2
Discoloration of nails	97	27.5
Thrombophlebitis	45	12.7

**20. Distribution of Adverse Drug Reactions in Nervous System:** Out of 310 ADRs Headache & Giddiness are majorly seen followed by fever, numbness & insomnia.

**Table 32: Distribution of Adverse Drug Reactions in Nervous System.**

Adverse Drug Reaction	Number of Patients	%
Insomnia	32	10.3
Headache	85	27.4
Fever	68	21.9
Numbness	48	15.4
Giddiness	77	24.8

**21. Distribution of Adverse Drug Reactions in Circulatory System:** Out of 411 patients, pedal edema and epistaxis are most commonly seen followed by anaemia and bleeding.

**Table 33: Distribution of Adverse Drug Reactions in Circulatory System.**

Adverse Drug Reaction	Number of Patients	%
Anemia	102	24.8
Bleeding	75	18.2
Epistaxis	114	27.7
Pedal edema	120	29.1

**22. Distribution of Adverse Drug Reactions based on Naranjo scale:** Of 2403 ADRs, majority are in Definite, with a 51% followed by probable with 30% & possible with 18%.

**Table 34: Distribution of Adverse Drug Reactions based on Naranjo scale.**

Adverse Drug Reaction	Number of Patients	%
Definite	1229	51.1
Probable	732	30.4
Possible	442	18.3

**23. Distribution of Adverse Drug Reactions based on severity scale:** Out of 2223 ADRs majority are in moderate scale with 78%, followed by mild with 20%, followed by severe with 32%.

**Table 35: Distribution of Adverse Drug Reactions based on severity scale.**

Adverse Drug Reaction	Number of Patients	%
Mild	450	20.2
Moderate	1741	78.3
Severe	32	1.43

- The total number of metastatic patients observed in our study was found to be 12.

## DISCUSSION

In our study a total of 251 patients data was collected. Head and neck cancers are seen predominantly followed by gastrointestinal cancers, respiratory cancers followed by penis & pancreatic cancer.

According to Anil.K. Chaturvedi et al, oral cancers are among the most common cancer worldwide with an estimated 4, 00,000 incident cases and 2, 23,000 deaths during 2008. According to Annahwys, et al head and neck cancers are among the most common cancers worldwide with nearly 6,00,000 new cases and 30,000 deaths occurring globally each year. These include cancers of oral cavity, pharynx, and larynx. Estimated numbers of chemical compounds in cigarette smoke are 7,357. Number of compounds with confirmed carcinogenic activity is 70 and it contains nicotine, acetaldehyde, N-nitrosamines, 1, 3 butadiene, benzene, acrolen, aromatic amines, and polyaromatic compounds. In our study, Head and neck cancer were predominantly seen with the incident rates of 61.1%.

The incidence of Head and neck cancers in our study was found to be 52% & the age groups prone to suffer with Head and Neck cancers are more in 41-50 years age group & least in 71-80 year patients. It is because of the social history of the patient like chewing tobacco and alcohol which are common risk factors for developing Head and neck cancers. Due to the intake of tobacco and alcohol, the entire regular aero digestive tract epithelium may be exposed to these carcinogens.

In general, patients undergoing surgery for resection of the primary tumor should undergo dissection of the ipsi lateral side of the neck that is at greatest risk factor for metastasis. Patients with advanced lesions involving the anterior tongue, floor of mouth or lip that approximate or cross the midline should undergo contralateral submandibular dissection as necessary to achieve adequate tumor resection followed by intensity modulated radiation

therapy, which is followed similar to NCCN guidelines. In our study, the surgical management of regional lymphatics is dictated by the extent of tumor at initial tumor staging and was done as per the NCCN guidelines. According to Liviu et al, The highest incidence & prevalence of Oral SCC is found in the Indian subcontinent where the risk of developing Oral SCC is increased by prevalent habits such as tobacco chewing, betelquid & arecanut. In our study, the incidence of Oral SCC patients is 90% which is similar to their study. The mutagenic effects of tobacco, betelquid & alcohol or arecanut are dependent upon dose, frequency, duration of use & are accelerated by concurrent use of 2 or more of these agents.

About 8% of patients with oral SCC are with distant metastases at the time of diagnosis most frequently to lungs. Surgery is the preferred first line treatment of small accessible Oral SCCs. However, advanced stage Oral SCC is usually treated by Chemotherapy, Radiation therapy and surgery.

In our study, the radiation dose given for patients with oral cancer was  $\geq 50\text{Gy}$  92.0Gy / day) which is similar to NCCN guidelines. According to NCCN Guidelines it stated that newly diagnosed unrespectable tumours should be treated with induction chemotherapy (5FU + cisplatin) followed by radiation therapy which is similar to our study.

### **LIMITATION**

The duration of study period was short.

### **CONCLUSION**

Among 195 patients, majority was in age group of 41-50 years and was found to suffer with Head and Neck cancer. Of all cancers, head and neck cancer was more prevalent. Chewing tobacco and consumption of alcohol were the frequently seen risk factors for developing Head and neck cancers. Many of the patients were on mixed diet. Most of the patients were daily wage employees and were from rural background. Histopathological evaluation reveals more cases of Squamous cell Carcinoma compared to Adenocarcinoma. Most commonly seen treatment modality is chemotherapy & Radiation therapy. Screening tests were performed for all types of cancers except Lung cancer. In our study Treatment modalities were similar to NCCN guidelines except for metastasis of Lung cancer wherein ESMO guidelines were followed. ADRs have probably been prevented in patients with hoarseness of voice, vomiting, nausea and hiccups by medicating the patients and proper counseling. Counseling the patients regarding ADRs was done. It creates awareness among physicians

and prevents the further occurrence of similar ADRs. Evaluating the ADRs on daily basis helped in prevention and their recurrence in chemotherapeutic cycles. Regular counseling helped the patients enable them to return to normal living with positive attitude. Mortality rate was decreased and there is positive therapeutic outcome.

### **FUTURE PROSPECTS**

Multi centered, long term follow up studies can be carried out. Patient volume can be increased.

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