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Prospective Study on Pattern of Adverse Drug Reactions to Anti-Cancer Drugs at a Tertiary Care Hospital

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ABSTRACT

Cancer is a very complicated sequence of disease conditions progressing gradually with a generalized loss of growth control. There were only a few options of cancer treatment for patients for many decades which include surgery, radiation therapy, and chemotherapy as single treatments or in combination. The present study aimed to assess pattern of adverse drug reactions to anti-cancer drugs at a tertiary care hospital. The prospective observational study was carried out for a period of 6 months. The study was conducted in Pediatrics department in a tertiary care hospital. Mouth organs affected cancer patients were more 24(32 %) as compared to Brain organs affected patients were 14 (18.66%). In our study Surgery treatment patients were more 34 (45.33%) as compared to other chemo therapy patients. Prescribed drugs during the cancer treatment includes Pemitrexate prescribed drugs patients were more 18(24%) as compared to other prescribed drugs 126-133. The anti-cancer drugs ADR includes Nausea and vomiting patients were more 34 (45.33%), compared to Alopecia patients were 25 (33.33%), Numbness and Constipation patients were 16 (21.33%). Epidemiological information on cancer including the pattern and socio-demographic factors is fundamental in determining the priorities for cancer control in the given population group. The cancer registries in India take into account only a representative sample of the whole country. This study shows that there is marked difference in the cancer pattern of our hospital in comparison with the national statistics. Hence factors leading to such high incidence should be analyzed and steps towards prevention of this type of cancer should be taken to reduce the morbidity and mortality of cancer. Further, more such research can be conducted all over the country to find the cancer pattern of different areas and thus pave the way for effective preventive measures.

Keywords: Cancer, Epidemiological information, national statistics, cancer treatment

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

The emergence of immunotherapy has opened a new avenue of treatment and offered an opportunity to reduce cancer deaths. However, the long-standing challenges that faced targeted therapy (i.e., resistance and disease relapse) similarly pose a challenge to immunotherapy.The explosion in whole genome or exome sequencing of cancer has enhanced our knowledge of genomic changes that occur in cancer but has not translated into the identification of effective targets for therapy. If anything, the advancement of cancer sequencing has compounded the complexity of

cancer. Several mutations and genomic alterations are highlighted daily and touted as potential targets for therapy, but targets highlighted from these studies as breakthroughs have not led to transformative therapeutic options. The slow rate of progress in cancer treatment raises great concerns particularly with the significant investment made into research. The major success in several cancers is attributed to improved diagnosis at an early stage, occasioned by enhanced awareness of contributing factors and avoidance of major risk factors. These factors are in no way linked to advances in systemic metastasis management. Another strong piece of evidence of cancer as a genetic disease comes from the presence of mutations in the genome of cancer cells that do not occur in nearby normal tissues. Despite the hallmarks of cancer being shared by all cancers, not a single gene mutation is linked to all cancers. The gene commonly mutated in most types of cancers is the TP53 gene. Despite its high frequency, TP53 mutations are not found in every cancer. In several cancers (i.e., ovarian, esophageal, colorectal, head and neck, larynx, and lung cancer) with high rates of p53 mutations, the rate is about 38–50%. The mutational rate of p53 is even lower in other cancers (i.e., primary leukemia, sarcoma, testicular cancer, malignant melanoma, and cervical cancer) occurring at a rate of ~5%. This demonstrates that no single gene mutation is a feature in all cancers. The genetic theory postulates that alterations in different sets of genes ultimately result in the cancer phenotype. This explanation is not entirely supported by our current understanding of most genetic disorders where mutations in very different set of genes yield the same phenotypic outcome. Could the mutations that occur in cancers be an outcome of a deeper cause and not the main cause of the tumor. Subsequently, targeting and treating these mutations are just a surface approach. If this theory is true, then there would be a need to find the originating events and target that for therapy. This concept is not farfetched, as a recent study detailing the functions of commonly identified tumor suppressors and oncogenes linked their function to key roles in cellular metabolism. The unlimited mutations in cancer-associated genes affect three main metabolic pathways: the aerobic glycolytic pathway, the glutamine catabolic pathway, and one-carbon metabolism. These genetic alterations create an altered metabolic state allowing cancer cells to generate the large quantities of macromolecules (amino acids, nucleotides, and fatty acids) and metabolic intermediates required to fuel rapid cell growth and division.

Despite the potential drawbacks associated with single marker evaluations, such as lower specificity in prognostic or predictive roles compared to comprehensive approaches like assessing co-occurring gene alteration patterns, there are pragmatic reasons for their continued use. The simplicity and cost-effectiveness of analyzing single markers make them attractive when resources are limited or when a straightforward diagnostic or prognostic tool is sufficient. Some single markers have undergone extensive clinical validation, showcasing their reliability and accuracy in specific contexts. These well-established markers may continue to play a crucial role in routine clinical settings where their clinical utility has been firmly established. Therefore, while acknowledging the limitations, single markers' practical advantages and validated efficacy support their continued relevance in specific molecular diagnostics and personalized medicine applications. Enzyme-linked immunosorbent assay (ELISA) is a commonly used immunological assay for detecting and measuring antibodies, antigens, and proteins in clinical practice, especially in blood and other body fluids. Newer techniques, such as electrochemical ELISA, have increased sensitivity for detecting low-abundance protein biomarkers. Some commonly used ELISA assays for detecting and estimating tumor marker levels include prostate-specific antigen and carcinoembryonic antigen (CEA) in patients with prostate cancer and pancreatic/colon cancer, respectively.

Tumour cells employ various immune evasion strategies, impacting immunotherapy responsiveness. These include increased PD-L1 expression, alteration in antigen presentation machinery (e.g. *B2M* or loss of heterozygosity in human leukocyte antigen (HLA LOH)), and loss of IFNγ sensitivity. To account for the multiple cell types within the immune microenvironment, as well as their activation and chemokine signaling, multiple transcriptomic signatures have been developed to predict response to checkpoint blockade.

In recent years, the study of blood-based biomarkers has advanced dramatically, especially in the area of circulating tumor DNA (ctDNA). Based on a large body of work, it is now clear that ctDNA most often comprises a variable, although small, fraction of the total circulating cell-free DNA (cfDNA) in the plasma of cancer patients. This fraction is correlated with a variety of biological factors including tumor type, histology, disease burden, cell proliferation, and genomic instability. The main clinical applications of ctDNA analysis include noninvasive tumor genotyping, monitoring response to therapy, detection of minimal residual disease (MRD) following treatment, and early cancer detection. Each of these applications targets a unique patient population with a distinct distribution of ctDNA concentrations, requiring careful consideration of the required limit of detection (LOD) for assays. Patients with advanced disease have the highest average ctDNA levels (often >1%), allowing tumor variant identification directly from the plasma with assays that have relatively less sensitive LODs. However, in the setting of MRD detection or screening for early-stage tumors, ctDNA levels can be below one part per million, necessitating much more sensitive assays.

The first ctDNA application that became part of the standard of care was non-invasive tumor genotyping to identify therapeutically actionable mutations in patients with advanced disease. Increasingly, liquid biopsies are performed in parallel with tumor tissue biopsies due to the combination identifying more actionable mutations and liquid biopsies having faster turnaround times[163,164]. One key advantage of liquid over tissue biopsies is that ctDNA

can contain contributions from multiple tumor deposits and may therefore better capture tumor heterogeneity than a tissue sample from a single site. Liquid biopsies can enable tumor genotyping in patients for whom a tissue biopsy is not available, or when the biopsy sample contains low tumor cellularity.

Early detection of cancers in asymptomatic individuals using approved screening modalities can decrease cancer-specific mortality and therefore there has been intense interest in recent years in developing liquid biopsy-based screening tests. However, as mentioned above, ctDNA levels in early-stage cancer patients are usually extremely low, often below one part per million. However, unlike MRD analysis, where prior knowledge of tumor mutations can be used to increase assay sensitivity, screening methods must employ tumor-naive approaches. For this reason, existing ctDNA early detection assays cannot attain the same LODs as the tumor-informed MRD assays and instead have LODs more similar to ct-DNA genotyping assays (~0.1%). Furthermore, screening assays require high specificity, since the majority of individuals being screened will not have cancer and therefore low specificity would result in the majority of positive tests being false positives.

2. Methodology

The prospective observational study was carried out for a period of 6 months. The study was conducted in Pediatrics department in a tertiary care hospital. A written and informed consent was obtained from the recruited patients. A Total of 75 patients were enrolled in the study.

Study Design: It was Prospective observational study.

Study Period: The Present study was conducted for a period of six months.

Study site: The Present study was conducted in a oncology department of a tertiary care hospital.

Sample size: It was 75 Patients.

Inclusion criteria

- Patients who are willing to give consent.
- Patients with cancer symptoms.
- Patients of either sex, diagnosed with cancer.
- Patients with clinical profile of cancer.
- Patients receiving treatment for cancer.

Exclusion criteria

- Patients below 18 years.
- Patients who were not willing to join in the study.
- Patients who are not diagnosed with respiratory abnormalities.
- Special population including pregnant women and lactating women.
- Psychiatric abnormalities.

Institutional ethics committee (IEC) consideration:

The research protocol was submitted to ethical committee and ethical Committee was permitted to perform the research work in oncology department.

Patient data collection and management:

The data collection form contains information regarding age, sex, diagnosis, past medical history, laboratory data, and diagnostic results. The information about risk factors, clinical laboratory reports, treatment, dose and frequency of administration and duration of therapy was collected from the patients treatment chart.

Statistical analysis:

The data was represented as percentages. The $P<0.05$ was considered to indicate a statistically significant difference.

3. Results and Discussion

Table 1: Age wise distribution

In our study 30-35 years age patients were 25 (33.33%), 36-45 years age patients were 18 (24%),46-55 years age patients were 32 (42.66%).

S.No	Age	Total (N=75)	Percentage (%)
1.	30-35	25	33.33
2.	36-45	18	24
3.	46-55	32	42.66
	Total	**75**	

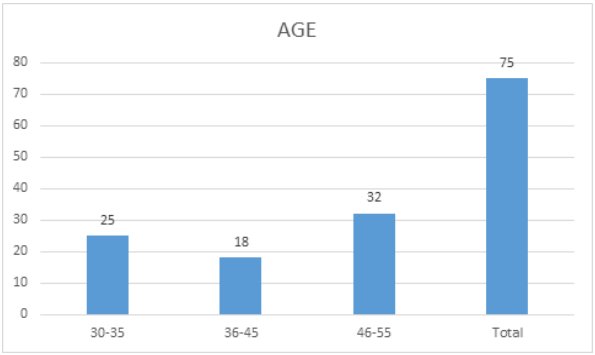

Fig 1: Age wise distribution

Table 2: Gender In our study male patients were 30 (40%), female patients were 45 (60%).

S.No	Gender	Total (N=75)	Percentage (%)
1.	Male	30	40
2.	Female	45	60
	Total	75	

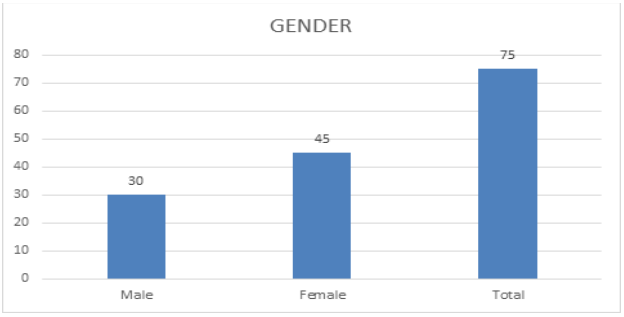

Fig 2: Gender

Table 3: Residential status

In our study Rural area patients were 50 (66.66 %), urban area patients were 25 (33.33%).

S.No	Residential status	Total (N=75)	Percentage (%)
1.	Rural	50	66.66
2.	Urban	25	33.33
	Total	**75**	

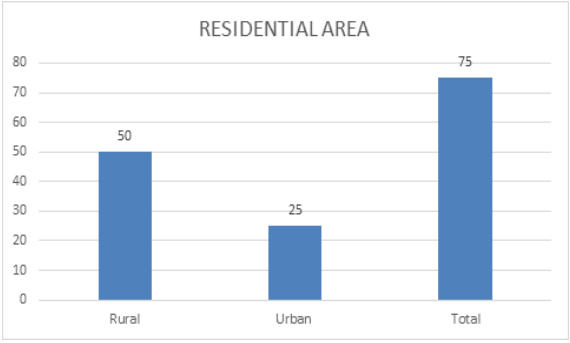

Fig 3: Residential status

Table 4: Marital status

In our study single patients were 18 (24%), married patients were 38 (50.66%), Divorce patients were 19(25.33%).

S.No	Marital status	Total (N=75)	Percentage (%)
1.	Single	18	24
2.	Married	38	50.66
3.	Divorce	19	25.33
	Total	**75**	

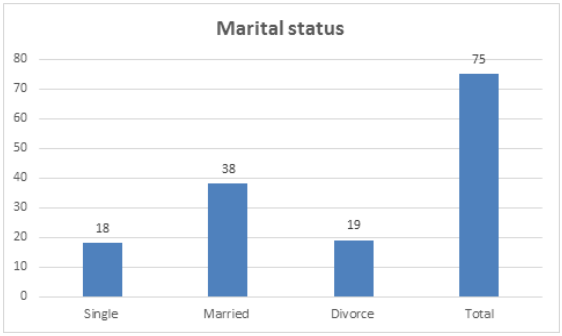

Fig 4: Marital status

Table 5: Duration of hospitalization

1-2 days hospitalized patients were 34 (45.33%), 3-4 days hospitalized patients were 22 (29.33%),5-6 days hospitalized patients were 19 (25.33%).

S.No	Duration	Total (N=75)	Percentage (%)
1.	1--2 days	34	45.33
2.	3--4 days	22	29.33
3.	5—6 days	19	25.33
	Total	**75**	

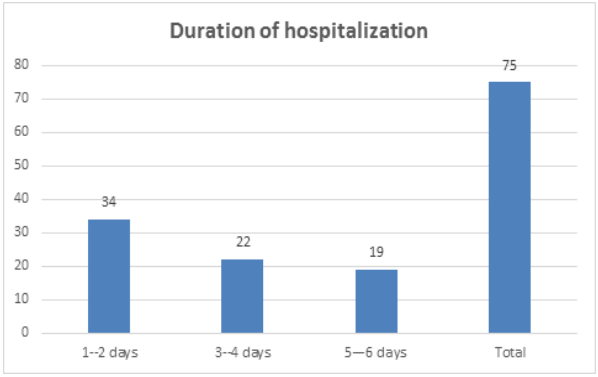

Fig 5: Duration of hospitalization

Table 6: Types of cancer

Lung cancer patients were 16 (21.33%), Ovarian cancer patients were 19 (25.33%), Bladder cancer patients were 22 (29.33%), Leukemia patients were 18 (24%).

S.No	Types of cancer	Total (N=75)	Percentage (%)
1.	Lung cancer	16	21.33
2.	Ovarian cancer	19	25.33
3.	Bladder cancer	22	29.33
4.	Leukemia	18	24
	Total	**75**	

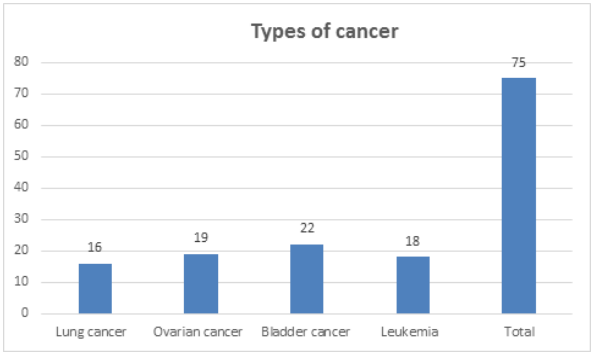

Fig 6: Types of cancer

Table 7: Stage of cancer

In our study the stage of cancer patients includes stage I cancer patients were 14 (18.66%), stage II cancer patients were 17 (22.66%), stage III cancer patients were 15 (20%), stage IV cancer patients were 29 (38.66%).

S.No	Stage of cancer	Total (N=75)	Percentage (%)
1.	I	14	18.66
2.	II	17	22.66
3.	III	15	20
4.	IV	29	38.66
	Total	**75**	

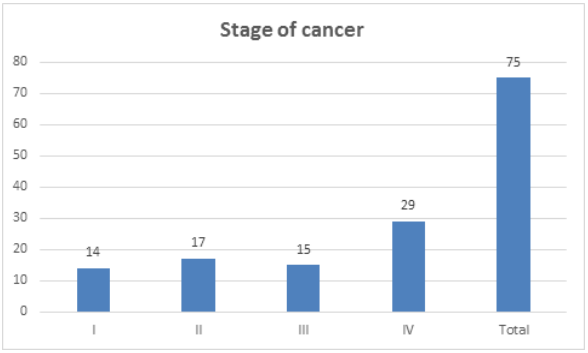

Fig 7: Stage of cancer

Table 8: Lab test for cancer

S.No	Lab test	Total (N=75)	Percentage (%)
1.	CT scan	23	30.66
2.	Blood test	16	21.33
3.	CA-125 test	19	25.33
4.	Biopsy	17	22.66
	Total	**75**	

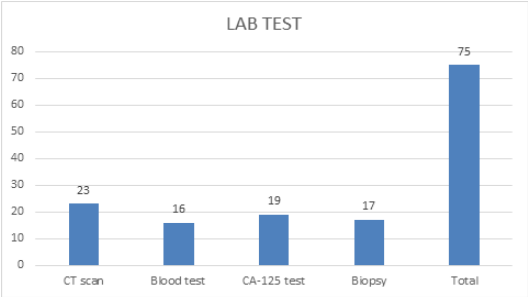

Fig 8: Lab test for cancer

Table 9: Organs involved in the cancer

Lungs organs affected patients were **18** (24%), Bladder organs affected patients were 19(25.33%), Mouth organs affected patients were 24(32 %), Brain organs affected patients were 14 (18.66%).

S.No	Organs involved in cancer	Total (N=75)	Percentage (%)
1.	Lungs	18	24
2.	Bladder	19	25.33
3.	Mouth	24	32
4.	Brain	14	18.66
	Total	**75**	

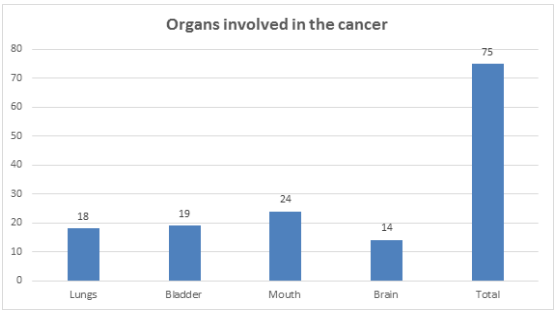

Fig 9: Organs involved in the cancer

Table 10: Treatment for cancer

In our study Chemotherapy treatment patients were 18 (24%), Radiotherapy treatment patients were 23 (30.66%), Surgery treatment patients were 34 (45.33%).

S.No	Treatment for cancer	Total (N=75)	Percentage (%)
1.	Chemotherapy	18	24
2.	Radiotherapy	23	30.66
3.	Surgery	34	45.33
	Total	**75**	

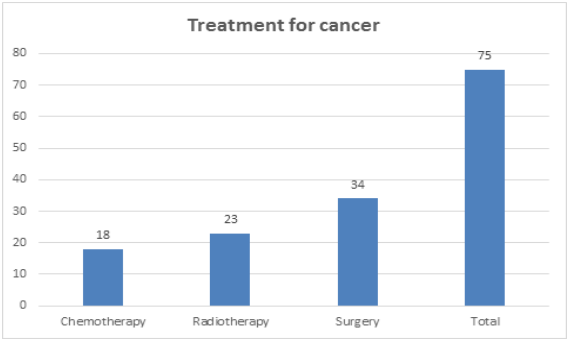

Figure 10: Treatment for cancer

Table 11: Prescribed drugs during the cancer treatment

S.No	Prescribed drugs	Total (N=75)	Percentage (%)
1.	Vincristine	14	18.66
2.	Docetaxel	12	16
3.	Ifosfamide	15	20
4.	Dactinomycin	16	21.33
5.	Pemitrexate	18	24
	Total	**75**	

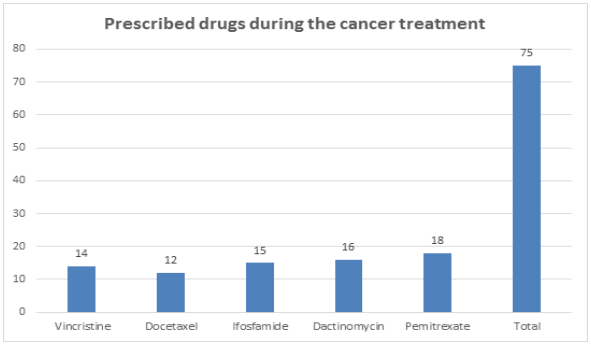

Fig 11: Prescribed drugs during the cancer treatment

Table 12: Anti-cancer drugs ADR's

S.No	Prescribed drugs	Total (N=75)	Percentage (%)
1.	*Nausea and vomiting*	34	45.33
2.	*Alopecia*	25	33.33
3.	*Numbness and Constipation*	16	21.33
	Total	**75**	

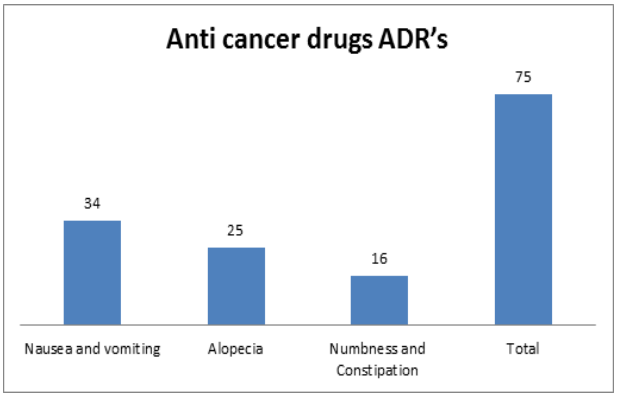

Fig 12: Anti-cancer drugs ADR's

Discussion

- In our study 46-55 years age patients were more 32 (42.66%) as compared to other age groups.
- In our study female patients were more 45 (60%) as compared to males 30 (40%).
- In our study Rural area patients were more 50 (66.66 %), as compared to urban area patients were 25 (33.33%).
- In our study married patients were more 38 (50.66%) as compared to Divorce patients were 19(25.33%).

- In our study 1-2 days hospitalized patients were more 34 (45.33%) as compared to 3-4 days hospitalized patients were 22 (29.33%).
- Bladder cancer patients were more 22 (29.33%), as compared to Leukemia patients were 18 (24%).
- In our study stage IV cancer patients were more 29 (38.66%) as compared to other cancer stages.
- In our study CT scan patients were more 15 (11.36%) as compared to other lab test.
- Mouth organs affected cancer patients were more 24(32 %) as compared to Brain organs affected patients were 14 (18.66%).
- In our study Surgery treatment patients were more 34 (45.33%) as compared to other chemo therapy patients.
- Prescribed drugs during the cancer treatment **i**ncludes Pemitrexate prescribed drugs patients were more 18(24%) as compared to other prescribed drugs[126-133].
- The anti-cancer drugs ADR includes Nausea *and vomiting* patients were more 34 (45.33%), compared to *Alopecia* patients were 25 (33.33%), *Numbness and* Constipation patients were 16 (21.33%).

4. Conclusion

The study had shown that the external support given by the physician and family members had a greater influence on cancer patients to adapt well to the situation of having had a life-threatening disease and to undergo their treatment more positively. Our study revealed that the cancer cases are high and it showed increasing trend which suggests that the population based cancer registries to be made at all levels of health care to identify the time trends so that prevention measures can be implemented at the community level. Epidemiological information on cancer including the pattern and socio-demographic factors is fundamental in determining the priorities for cancer control in the given population group. The cancer registries in India take into account only a representative sample of the whole country. This study shows that there is marked difference in the cancer pattern of our hospital in comparison with the national statistics. Hence factors leading to such high incidence should be analysed and steps towards prevention of this type of cancer should be taken to reduce the morbidity and mortality of cancer. Further, more such research can be conducted all over the country to find the cancer pattern of different areas and thus pave the way for effective preventive measures

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