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RESEARCH ARTICLE

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Survey on adverse drug reactions in cancer patients and approaches for its management

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A R T I C L E I N F O

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A B S T R A C T

Introduction: Globally, Adverse drug reaction (ADR) reporting continues to be a challenge. It is estimated that about 95 % of AEs never get reported after pharmacotherapy necessitating strategies to improve it. The introduction of databases such as VigiAccess in which ADR data from Pharmacovigilance centers around the world can be assessed is an important step toward improving ADR reporting. This study assessed the therapeutic management of cancer patients in the Delhi-NCR region along with the reporting pattern of ADRs in VigiAccess, an open-access pharmacovigilance database.

Methods: Primarily, the cancer patients were investigated employing a questionnaire. Further, VigiAccess thoroughly searched for the categories of reported ADRs and the number and types of ADRs reported for a few selected drugs used in the treatment of cancer patients.

Results: After a thorough search through VigiAccess, 06 main categories of reported ADRs in the database were retrieved. These included blood and lymphatic system disorders, skin and subcutaneous tissue disorders, gastrointestinal disorders, psychiatric disorders, respiratory, thoracic, and mediastinal disorders, general disorders, and administration site conditions.

Conclusion: There is a need for vigilant ADR monitoring to decrease morbidity and mortality due to ADRs, which requires further studies on a larger population. This study demonstrated that monitoring of anticancer drugs given in chemotherapy-related ADRs is feasible in a cancer ward and can facilitate quality improvement initiatives, as well as potentially improve patient care.

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Introduction

Neoplasia, which refers to new growth, is also known as a tumor or a neoplasm. The processes of embryogenesis, regeneration and repair, hyperplasia, and hormonal stimulation are all instances of the new development of tissues and cells, therefore not all "new growths" are neoplasms. In healthy adults, the proliferation and maturation of cells are regulated, causing some cells to proliferate indefinitely (labile cells), others to proliferate very sparingly (stable cells), and still, others not duplicate at all (permanent cells). Neoplastic cells, on the other hand, are unable to regulate or control their rate of reproduction and develop into an aberrant mass of tissue.

An acceptable definition of a neoplasm or tumor is, therefore "a mass of tissue formed as a result of the pathological, rapid, uncontrolled, independent, and directionless proliferation of cells even after cessation of the stimulus for growth which caused it." Oncology is the name of the scientific field that deals with the study of neoplasms or tumors (oncos = tumor, logos = study). Neoplasms can be classified as "benign" when they are isolated, slow-growing, and do not pose a significant threat to the host, or "malignant" when they multiply quickly, spread throughout the body, and may ultimately result in the host's demise. Cancer is the umbrella word for all malignant tumours. Hippocrates (460–377 BC) first used the word "karkinos" to describe breast cancer. The term "cancer" means "crab," which accurately describes the disease since ‘it sticks to the part stubbornly like a crab’. All tumors, benign as well as malignant, have 2 basic components:

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- "Parenchyma," which is made up of expanding tumor cells, controls the type and course of the tumor.
- "Supportive stroma," which is made up of blood vessels and fibrous connective tissue, provides the foundation for the growth of parenchymal tumor cells.

The parenchymal component that makes up a tumor is the basis for the name given to it. Benign tumors are indicated by the prefix "-oma." Carcinomas are malignant tumors of epithelial origin, while sarcomas (from the Greek word for meaty) are malignant tumors of mesenchymal origin. Undifferentiated malignant tumors, on the other hand, are malignancies made up of extremely undifferentiated cells. Although this broad generalization about tumor nomenclature generally holds true in the majority of cases, some examples that go against this idea are melanoma for melanocytes cancer, hepatoma for hepatocytes cancer, lymphoma for lymphoid tissue malignant tumor, and seminoma for testis malignant tumor. The term "leukemia" refers to malignancy of the blood-forming cells (Mohan et al., 2010).

When aberrant cells proliferate uncontrolled, cross their normal boundaries to invade surrounding body parts, and/or travel to other organs, the condition known as cancer is caused. Cancer is a broad category of illnesses that can begin in nearly any organ or tissue of the body. The latter phase, known as metastasizing, is a significant contributor to cancer-related mortality. The terms "neoplasm" and "malignant tumor" are also used to describe cancer. An estimated 9.6 million fatalities, or one in every six deaths, were attributed to cancer in 2018, making it the second-highest cause of death worldwide. Men are more likely to get lung, prostate, colorectal, stomach, and liver cancer than women, who are more likely to develop breast, colorectal, lung, cervical, and thyroid cancer.

The physiological, psychological, and financial toll that cancer takes on people, families, societies, and healthcare systems throughout the world keeps rising. Numerous low- and middle-income nations' health systems are ill-equipped to handle this load, and many cancer patients worldwide lack access to prompt, effective diagnosis and treatment. The availability of early identification, high-quality treatment, and survivorship care in nations with robust health systems has improved the survival rates of several cancer forms (WHO, 2022).

Special Categories of Cancer

The following categories of tumors are examples that defy the generalization in nomenclature given above:

Mixed tumors

When two types of tumors are combined in the same tumor, it is called a mixed tumor. For example:

- **Adenosquamous carcinoma** is the combination of adenocarcinoma and squamous cell carcinoma in the endometrium.
- **Adenoacanthoma** is the mixture of adenocarcinoma and benign squamous elements in the endometrium.
- **Carcinosarcoma** is a rare combination of malignant tumors of the epithelium (carcinoma) and mesenchymal tissue (sarcoma) such as in the thyroid.
- **Collision tumor** is the term used for morphologically two different cancers in the same organ which does not mix.
- **Mixed tumor of the salivary gland** (or pleomorphic adenoma) is the term used for a benign tumor having a combination of both epithelial and mesenchymal tissue elements.

Teratomas

These malignancies are made up of a variety of different tissue types that are produced from totipotent cells found in the ectoderm, mesoderm, and endoderm germ cell layers. Ovaries and the testicles are the most typical locations for teratomas (gonadal teratomas). However, they also happen in non-gonad places, most often in the midline of the body, such as the head and neck area, mediastinum, retroperitoneum, sacrococcygeal region, etc. Most ovarian teratomas are benign or mature, whereas some are malignant or undeveloped (most testicular teratomas).

Blastomas (Embryomas)

A type of cancerous tumor known as blastomas or embryomas develops from cells that are embryonal or partly differentiated and would typically form blastema of the tissues and organs during development. These tumors are more common in young children and babies (under the age of five), and some cases of malignancies in this age range include pulmonary blastoma, hepatoblastoma, retinoblastoma, and neuroblastoma (also known as Wilms' tumor).

Hamartoma

A benign tumor called a hamartoma is comprised of fully developed, but disorganized, cells of tissues that are native to the affected organ, for example, a lung hamartoma is made of fully developed cartilage, smooth muscle, and epithelium. As a result, it has all of the adult differentiated tissue components that make up the bronchus, but they are mixed as a mass.

Choristoma

It is the designation given to the islands of normal tissue that are ectopic. Choristoma is hence heterotopia rather than a genuine tumor, although sounding like one (Mohan et al., 2010).

Carcinogenesis, also known as oncogenesis or tumorigenesis, is the process through which healthy cells turn into cancer cells, resulting in the development of a tumor. Atypical cell division and modifications at the cellular, genomic, and epigenetic levels define the process. A physiological process called cell division takes place in practically all tissues and under a range of conditions. To preserve the integrity of organs and tissues a balance between cellular proliferation and apoptosis, a sort of programmed cell death, is often maintained. The most widely recognized hypothesis of carcinogenesis, known as the somatic mutation theory, states that DNA mutations and epimutations that cause cancer to interfere with the programming governing these orderly processes, disturbing the natural balance between cell proliferation and cell death. Unchecked cell division and natural selection-based cell evolution in the body are the outcomes of this. While the majority of mutations do not cause cancer, some mutations do (Carcinogenesis, 2022). The beginning, promotion, and progression phases of carcinogenesis. Initiated cells with a mutant genotype are produced by genotoxic carcinogens; during promotion, these cells can be induced to proliferate by tumor-promoting carcinogenic substances to form clusters of initiated cells; the resulting lesion is predisposed to progress into cancer; however, additional exposure to genotoxic and tumor-promoting substances speeds up the advancement stage by continuing to increase genomic instability and cell proliferation rate, resulting in the transformation of a preneoplastic lesion into cancer.

Treatment of Cancer: Surgery, chemotherapy, radiation therapy, hormonal treatment, targeted therapy (including immunotherapeutics such as monoclonal antibody therapy), and synthetic lethality are all options for treating cancer; these therapies are often administered separately (e.g. chemotherapy before surgery). The location, severity, and phase of the disease, along with the patient's general health, all influence the therapeutic option (performance status). The most effective treatment for a patient's specific cancer can be determined with the use of cancer genome sequencing. A variety of investigational cancer therapies are also being developed (Type of cancers, 2022).

- **Surgery:** The goal of surgery is to remove cancer or as much of cancer as possible.
- **Chemotherapy:** Chemotherapy uses drugs to kill cancer cells.
- **Radiation therapy:** Radiation therapy uses high-powered energy beams, such as X-rays or protons, to kill cancer cells. Radiation treatment can come from a machine outside your body (external beam radiation), or it can be placed inside your body (brachytherapy).
- **Immunotherapy:** Immunotherapy, also known as biological therapy, uses your body's immune system to fight cancer. Cancer can survive unchecked in your body because your immune system doesn't recognize it as an intruder. Immunotherapy can help your immune system "see" cancer and attack it.
- **Hormone therapy:** Some types of cancer are fueled by your body's hormones. Examples include breast cancer and prostate cancer. Removing those hormones from the body or blocking their effects may cause the cancer cells to stop growing.
- **Targeted drug therapy:** Targeted drug treatment focuses on specific abnormalities within cancer cells that allow them to survive (Mayoclinic, 2022).

Side Effects of Cancer Treatment

Consider that side effects vary from person to person, even among people receiving the same type of cancer treatment (NIH, 2022).

Adverse Drug Reaction (ADR) is a response to a medical product, which is noxious and unintended, and which occurs for doses normally used in Human beings for the prophylaxis, diagnosis, or therapy of disease, or the modification of a physiological function (Bhise et al., 2021).

Method

Survey on Adverse effects of therapies and medications given to cancer patients in Delhi-NCR Region and approaches for the management of these adverse drug reactions in cancer patients. The objectives were as follows,

- Prepare of Questionnaire
- Direct interaction with Cancer patients
- Use "Vigiaccess.org" software for Adverse Drug Reactions worldwide data

The protocol was carried out from January 2022 to March 2022 in an in/outpatient setting in the Delhi-NCR region, for a time duration of 3 months. We have completed our survey on 156 Cancer. The project was carried out at various hospitals viz. All India Institute of Medical Sciences, New Delhi; Shree Jagannath Charitable Cancer Hospital, Duhai, Uttar Pradesh; Safdarjung Hospital, New Delhi; Max Institute of Cancer Care, Delhi. A questionnaire was prepared via a thorough literature search and approved by the institutional committee. The purpose of the survey questionnaire was explained in detail to the participants. Further interaction with patients was carried out physically, telephonically, and through emails along with the follow-up process. The participants filled out the questionnaire with or without the help of the authors. The patient's demographic details patient initial, age, sex, medication history, medical history, Adverse Drug Reactions, etc. were recorded and analyzed.

Results and Discussion

Direct interaction with cancer patients

We had a total of 156 subjects in our study with a male: female ratio of 77:79. As **Figure 1** shows, out of the 156 patients we accessed, there were 77 males representing 49 % of the total participants and 79 females contributing 51 % of the total subjects.

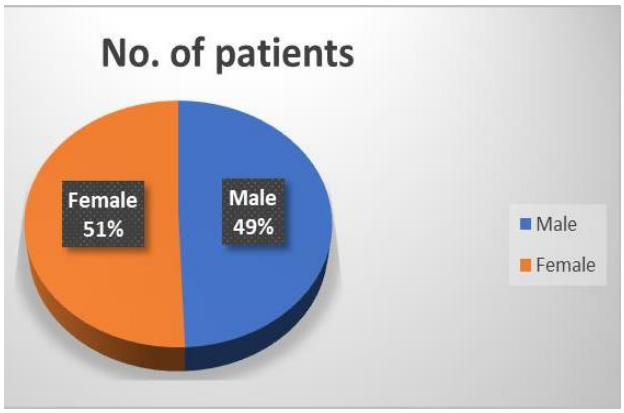


Figure 1: Pie Chart showing the proportion of males and females in the survey

Further, in this survey, there was a large difference in maximum and minimum age. The mean age of the subjects was 40 years, ranging between 2 to 87 years. As **Figure 2** shows, out of 156 patient's majority of the subjects (26.92 %) suffering from cancer comes under the range of 41-50 years while the 11-20 years range comprises the least cancer-suffering proportion, i.e., 3.20 % only.

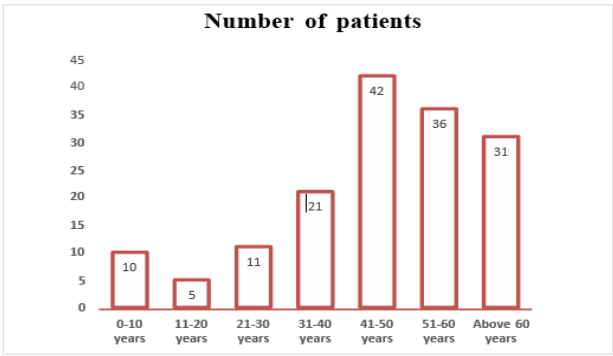


Figure 2: Histogram showing the proportion of subjects per age group

In which hospital you are getting treatment?

As in question no. 1 of our questionnaire, we covered hospitals where we had done our survey. We did most of our survey at All India Institute of Medical Sciences (AIIMS), New Delhi and there were some other hospitals too like Shree Jagannath Charitable Cancer Hospital, Max Super Specialty Cancer Hospital, Safdarjung Hospital, etc. of Delhi NCR Region.

What type of cancer do you have?

In response to the above question i.e., question no. 2 we have come across 25 types of cancer so far with which Head and Neck Cancer & Breast cancer comprise the largest proportion 26.92 % & 22.43 % respectively among the survey as shown in **Figure 3**.

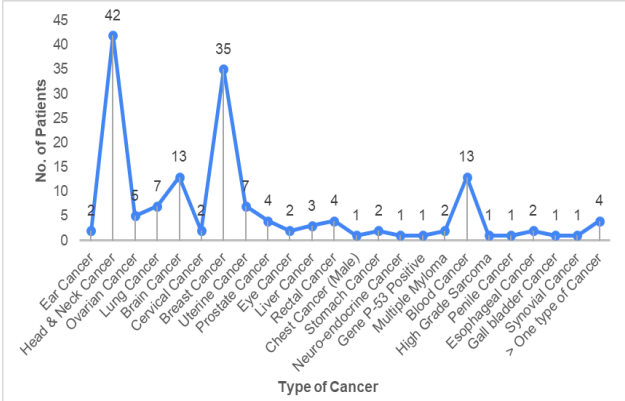


Figure 3: Graph showing the various types of cancer

What is the stage of your Cancer?

Concerning the above question, we categorized stages of cancer into I, II, III, IV & don't know. In response to that, we come to the result that the majority of patients (37 %) don't know about the stage of their cancer. As shown in **Figure 4**; 17 % of subjects are at stage I, 17 % of subjects are at stage II, 21 % of subjects are at stage III, and 7 % of subjects are at stage IV.

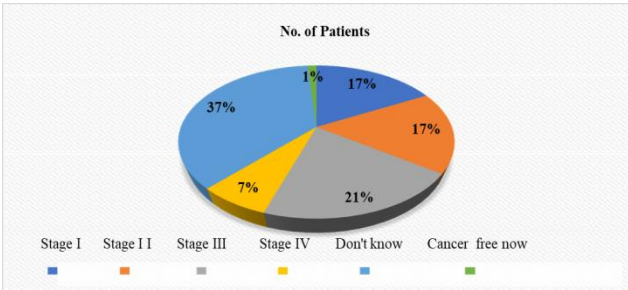


Figure 4: Pie chart representing different stages of cancer

Since how long have you been suffering from Cancer?

In response to the above question, we see that the maximum numbers of patients are getting treatment from 2-4 years but the range of duration of their cancer lies between 15 days to 10 years.

How do you get information about Cancer?

In response to the above question, the majority of patients got the information from Media (Television, newspapers, Billboards, etc.) and Family and Friends.

According to you, what may be the cause of your Cancer?

Regarding the causes of cancer, the responses varied. 12.5 % thought that smoking was the cause of cancer while 18.5 % thought that any tobacco product causes it. 14.8 % thought that infection causes cancer & 48 % don't know about the cause of their cancer.

Do you think Cancer is preventable?

Almost all of the patients we reached thought that cancer is preventable, only a few say 1-2% thought that it is not preventable.

What kind of treatment approach is prescribed by a doctor to you?

There were different kinds of approaches, patients had including Chemotherapy, Radiation therapy, surgery, a combination of two or three therapies, etc. As shown in **Figure 5** Chemotherapy is the most common approach which stands out at 29.4% alone followed by a combination of Radiation Therapy and Chemotherapy (17.3%) and a combination of Chemotherapy, Radiation Therapy & Surgery (14.74%). There are 5.12% of patients who aren't getting any treatment at that time.

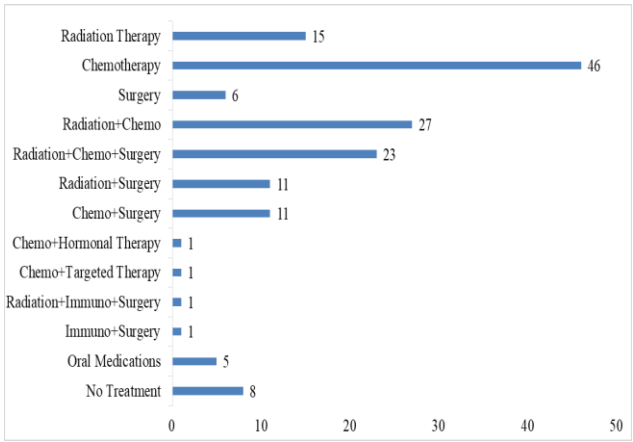


Figure 5: Graph representing different types of treatment approaches prescribed by a doctor

What do you think about the effectiveness of your Cancer treatment?

In response to question 9, 82.1% thought that cancer treatment is effective while 12.3% thought that it is partially effective.

After treatment, what are the Adverse Effects you are facing?

Many of the cancer patients who had cancer treatment are suffering from several side effects like alopecia, weight loss, nausea and vomiting, fatigue, fever, pain, appetite loss, etc. Out of which weight loss and nausea & vomiting top the list followed by constipation, anorexia, fatigue, and pain.

On a scale of 1 to 10, how would you rate your Pain?

Some of the patients felt pain before treatment while some of them felt pain after treatment. There were also cases where the patient felt no pain at all before or after treatment.

Have you taken Complementary and Alternative Medicine (CAM) Therapy?

In our survey, we find that only 1-2% of subjects have taken CAM Therapy including Yoga, Homeopathy medicines, Naturopathic medicines, Meditation, Ayurvedic medicines & Massage.

Are you suffering from any other disease besides Cancer?

We asked patients about any other disease(s) besides cancer they are suffering from and come to a shocking result that 79.48% were not suffering from any other major disease besides cancer. As shown in **Figure 6**, out of 156, 7.05% are suffering from Diabetes, 3.84% from Hypertension, 2.56% from Diabetes & Hypertension both, 3.20% from Thyroid, 1.28% from Tuberculosis, 0.64% from Diabetes, Hypertension & Thyroid, 0.64% from Vitiligo, 0.64% from Asthma & Hypertension both and 0.64% from Diabetes, Hypertension & Piles.

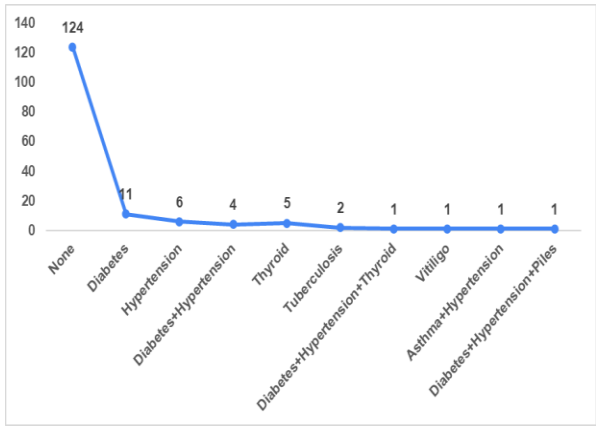


Figure 6: Graph representing different types of diseases patients were suffering from besides cancer

Did you suffer from Covid?

As shown in **Figure 7**, only 17% of patients suffered from COVID-19 while 83% were not affected by the virus.

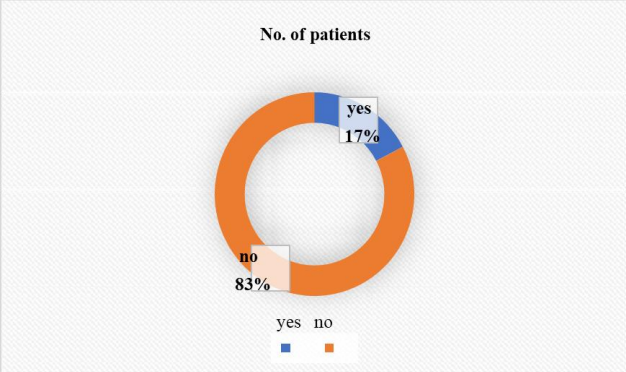


Figure 7: Pie chart showing no. of patients who suffered from COVID-19

How much are you able to accomplish in daily activities?

We have a scale of one to five to know about the ability of the patient to accomplish daily activities where one represents not being able at all & five represents fully accomplished. We came to mixed results where most of the patients were able to do /her daily activities on levels three and four.

Do you sleep well?

Like question no. 15, we gave a scale of one to five to know about the sleep cycle of patients, where one represents chronic insomnia & five represents sleeping well. We came to mixed results where most of the patients were getting sleep on levels three and four but very few patients are unable to sleep at night.

During your hospital visit, did you find someone on the hospital staff to talk to about your worries and fears?

Almost all the subjects were able to find someone on the hospital staff to talk properly or to some extent. Only one or two patients (s) found no person on the staff to talk to about their worries & fears.

Were you given enough privacy when discussing your conditions and treatment?

Out of 156, 98-99 % felt that they have been provided with enough privacy by the medical professionals while discussing their condition and treatment. Only 1-2 % were facing privacy issues.

Use of "VigiAccess.org" Software for Adverse Drug Reactions Worldwide Data

Pharmacovigilance centers are mandated by the WHO to submit adverse drug reaction reports including ADR reports from various countries to a large pool of adverse drug reaction electronic database called VigiBase (Ampadu et al., 2016). VigiBase categorizes safety data into sex, disease condition for which a particular medicine was given as well as other relevant features on ICSR forms on which safety data of patients are recorded before submission. These features make the database a good resource for the UMC and other stakeholders of pharmacovigilance as it indicates the number of safety reports submitted by each country from the time, they joined the PIDM.

The WHO has an alternative database called VigiAccess which is open to the general public and serves as a repository of reported adverse drug reactions (Shankar et al., 2016). VigiAccess can serve as a powerful tool for quick reference of adverse drug reactions by both HCPs and the general public due to its open-access nature. This study assessed the reporting pattern of AEFIs from the various continents of the world in VigiAccess. It is hoped that findings from the study will serve as baseline data based upon which future researchers will build toward improving vaccine safety and the quality of VigiAccess data.

In our study, out of 156, 46 subjects were on Chemotherapy only and 64 were on a combination of therapies along with chemotherapy, which makes 110 patients (46 + 64). Rest 46 patients didn't interact with the therapy provided. We listed six drugs that were most commonly given to patients in Chemotherapy. Out of 110 subjects that were on Chemotherapy, Docetaxel (16.36 %) was the most commonly prescribed anticancer drug in our study followed by paclitaxel (15.45 %), carboplatin (13.63 %), capecitabine (12.72 %), Trastuzumab (9.09 %) & Abiraterone (7.27 %) as shown in **Figure 8**. These six drugs comprise more than 50 % i.e., 74.54 % out of the other anticancer drugs prescribed by doctors.

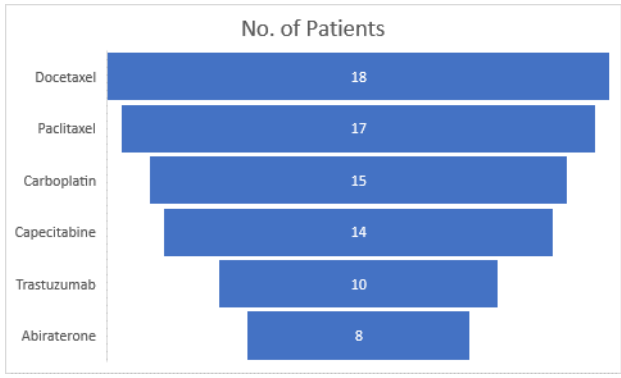


Figure 8: Funnel Chart showing the most prescribed anticancer drugs

With the reference of *"Vigiaccess.org"* which is maintained by the Uppsala Monitoring Centre (Programme of WHO), we studied the number of ADRs recorded globally of above mentioned six common anticancer drugs of our study. As shown in **Figure 9**, the total number of records obtained globally for Docetaxel is highest i.e., 133861 in number followed by Paclitaxel (132608), Carboplatin (90800), Capecitabine (72095), Trastuzumab (41253) & Abiraterone (29298).

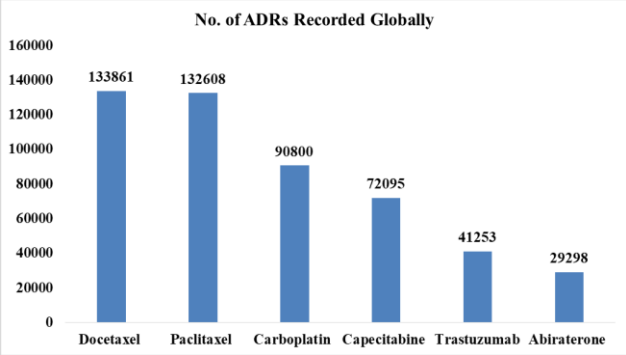


Figure 9: Graph showing the no. of ADRs recorded globally

By taking the reference of ***Vigiaccess.org***, we listed out the six types of ADRs that are reported most of the time for the most prescribed drug in our study i.e., Docetaxel which shows, Blood and lymphatic system disorders which represents 26.50% (35476) out of total records listed for docetaxel, Skin and subcutaneous tissue disorders: 31.81% (42586), General disorders and administration site conditions: 22.22% (29750), Gastrointestinal disorders: 16.81% (22515), Psychiatric disorders: 10.84% (14512) & Respiratory, thoracic and mediastinal disorders: 10.35% (13867) as shown in **Figure 10**.

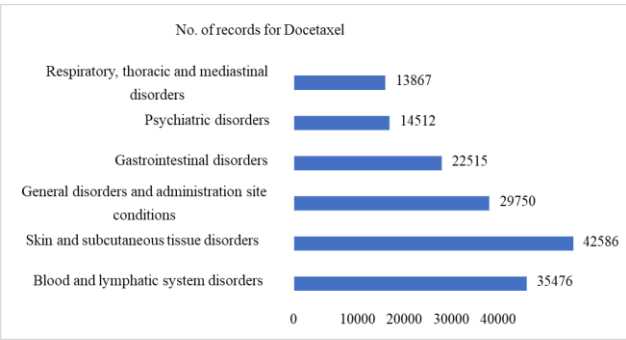


Figure 10: Graph showing the Different types of ADRs of Docetaxel and their numbers recorded globally

Similarly, we listed out the recorded numbers of the same ADRs (that we noted out for Docetaxel) of our remaining five major drugs i.e., Paclitaxel, Carboplatin, Capecitabine, Trastuzumab & Abiraterone. The number of the same ADRs as of Docetaxel recorded for other drugs are shown in **Figures 11, 12, 13, 14 & 15** separately.

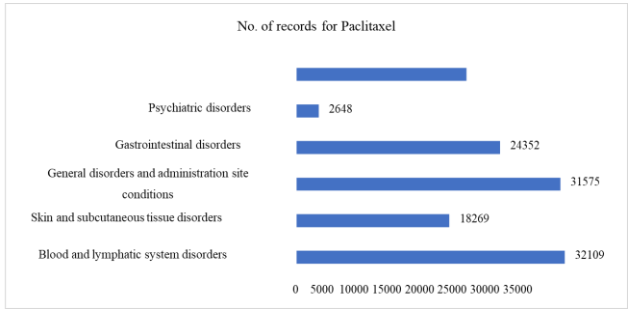


Figure 11: Graph showing No. of different types of ADRs of Paclitaxel recorded globally

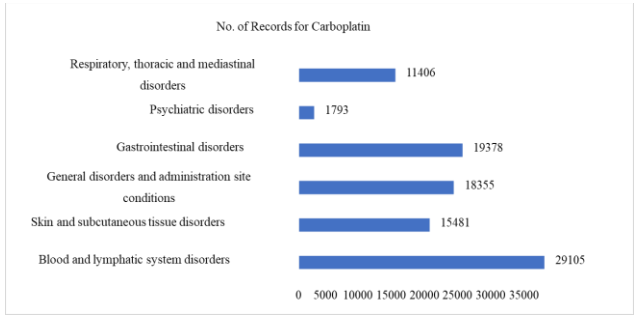


Figure 12: Graph showing No. of different types of ADRs of Carboplatin recorded globally

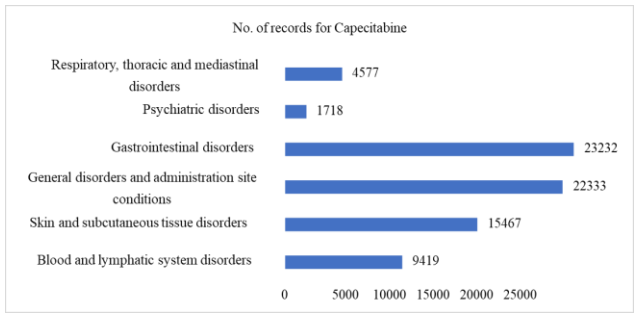


Figure 13: Graph showing No. of different types of ADRs of Capecitabine recorded globally

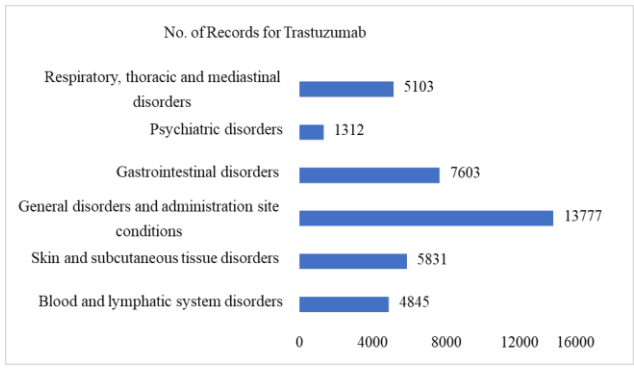


Figure 14: Graph showing No. of different types of ADRs of Trastuzumab recorded globally

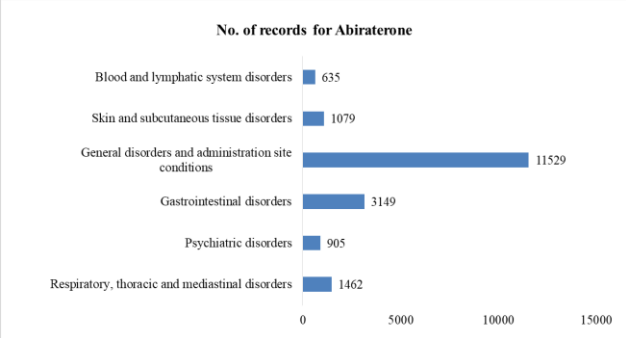
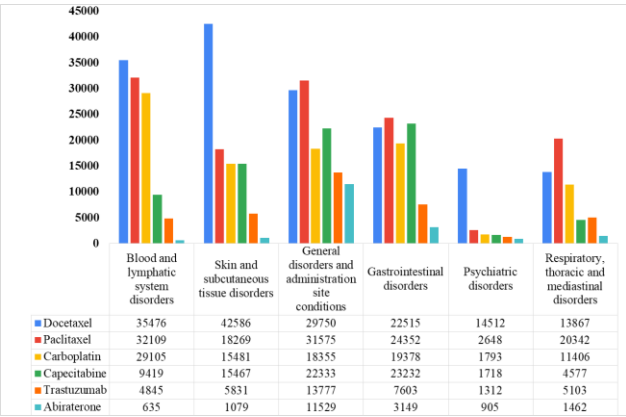


Figure 15: Graph showing No. of different types of ADRs of Abiraterone recorded globally

Discussion

We compared the anticancer drugs that we listed against the Adverse Drug Reactions that are common in all of them as shown in **Figure 16** and some of the interpreted results are, Blood and lymphatic system disorders; Skin and subcutaneous tissue disorders & Psychiatric disorders are more in number for Docetaxel while General disorders and administration site conditions; Gastrointestinal disorders & Respiratory, thoracic and mediastinal disorders are more in number for Paclitaxel. Abiraterone has the lowest number of ADRs in each category which is probably due to being less prescribed in comparison to the other five drugs.



	Blood and lymphatic system disorders	Skin and subcutaneous tissue disorders	General disorders and administration site conditions	Gastrointestinal disorders	Psychiatric disorders	Respiratory, thoracic and mediastinal disorders
Docetaxel	35476	42586	29750	22515	14512	13867
Paclitaxel	32109	18269	31575	24352	2648	20342
Carboplatin	29105	15481	18355	19378	1793	11406
Capecitabine	9419	15467	22333	23232	1718	4577
Trastuzumab	4845	5831	13777	7603	1312	5103
Abiraterone	635	1079	11529	3149	905	1462

Figure 16: Graph showing a comparative study among the six most commonly prescribed anticancer drugs and their most reported six categories of ADRs.

We saw the prescriptions of some of the patients we reached and come to the outcome that subjects having Docetaxel was also prescribed other medications like Inj. GCF, Emeset, Dexa, Pantop, Wysolone, Ultracet, ORS, Rantac, Imodium, etc. shows that they were facing some adverse effects of chemotherapy like vomiting, pain, acidity, etc.

Inj. GCF is used for blood and lymphatic system disorders; Emeset, Pantop, ORS, Rantac & Imodium are used for gastrointestinal disorders; Ultracet for general disorders and administration site conditions and Dexamethasone and Wysolone for respiratory, thoracic, and mediastinal disorders & skin and subcutaneous disorders.

Similarly, patients getting Paclitaxel, Trastuzumab, Carboplatin, and Abiraterone were also prescribed with Inj. GCF, Dexorange syrup for blood & lymphatic system disorders; Pantocid, Cremaffin Syrup, Emeset, Rantac, Ondansetron, Tab. Loperamide, Zofer, Perinorm for gastrointestinal disorders; Tab. Pyridoxine, Calcium, Tramadol, PCM for general disorders & administration site conditions; Tab. Pregabalin, Lanzapine, and Gabapentin for psychiatric disorders; Avil for skin and subcutaneous disorders and Dexamethasone for respiratory, thoracic & mediastinal disorders.

Conclusion

Most of the anticancer drugs were prescribed in combination for better therapy. Among several anticancer drugs we come across in our survey, Docetaxel was the most commonly prescribed. Chemotherapy has a high potential to cause ADRs in cancer patients. The most frequently observed ADRs were Blood and lymphatic system disorders & General Disorders and administration site conditions. The most common adverse effects were vomiting, constipation, and anorexia (appetite loss). These can be preventable, so there is a need to improve the management of these adverse effects since the rates of prevention of these adverse effects were poor. In the current study, the causality of adverse effects was poor due to the presence of co-administered drugs. Since cancer chemotherapy has a high potential to cause ADRs, measures need to be put into place to reduce the physical, emotional, and economic burden on the patient due to adverse drug reactions.

Measures to improve the detection and reporting of ADRs should be taken to enhance our understanding of the nature and impact of these ADRs. By implementing the ADR monitoring and reporting system, pharmacists can promote drug safety and thereby assist healthcare professionals in better patient care. Regular evaluation of ADR in anticancer drugs is very important as its impact on patients receiving chemotherapy is severe. ADR monitoring process helps in better prescribing habits for the safe and effective use of anticancer drugs. This may improve the quality of life of cancer patients.

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Competing Interests

The authors declare that there is no conflict of interest regarding the publication of this paper.

References

Ampadu, H. H., Hoekman, J., de Bruin, M. L., Pal, S. N., Olsson, S., Sartori, D., Leufkens, H. G., & Dodoo, A. N. (2016). adverse drug reaction reporting in africa and a comparison of individual case safety report characteristics between africa and the rest of the world: Analyses of Spontaneous Reports in VigiBase. *Drug safety*, *39*(4), 335–345.

Bhise S.B., Bhise M.S. (2021). A Textbook of pharmacovigilance, First Edition, Nirali Prakashan, Page No. 1.16-1.17.

Carcinogenesis. (2022). Wikipedia. Retrieved from https://en.wikipedia.org/wiki/Carcinogenesis

Mayoclinic. (2022). Test procedures. Retrieved from https://www.mayoclinic.org/tests-procedures/cancer-treatment/about/pac-20393344

Mohan Harsh, ed. (2010) Textbook of pathology, Sixth Edition, Jaypee Brothers Medical Publishers (P) Ltd. Pg No. 192-193.

NIH (2022). Cancer treatment. Retrieved fromhttps://www.cancer.gov/about-cancer/treatment/side-effects

Shankar P. R. (2016). VigiAccess: Promoting public access to VigiBase. *Indian journal of pharmacology*, *48*(5), 606–607.

Types of cancer. (2022). Wikipedia. Retrieved from https://en.wikipedia.org/wiki/Treatment_of_cancer

WHO. (2022). Cancer. Health topics. Retrieved from https://www.who.int/health-topics/cancer