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A RETROSPECTIVE OBSERVATIONAL STUDY ON THE CLINICAL SAFETY OF CAPECITABINE IN CANCER AND ITS IMPLICATIONS

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Abstract
Cancer chemotherapy is frequently associated with adverse drug reactions that may compromise treatment adherence and clinical outcomes. Capecitabine, an oral fluoropyrimidine widely used in the management of breast, colorectal, gastric, pancreatic, and other solid malignancies, has demonstrated favourable efficacy but is commonly associated with treatment-related toxicities. The present retrospective observational study was conducted to evaluate the clinical safety of capecitabine and its implications in routine oncology practice. The study was carried out over a period of six months at a tertiary care hospital and included 60 patients receiving capecitabine-based chemotherapy. Demographic characteristics, cancer type, capecitabine brands, adverse drug reactions, and treatment-related safety outcomes were assessed from medical records and electronic databases. Female patients constituted 68.3% of the study population, and the highest proportion of patients belonged to the 61–70-year age group. Breast cancer was the most common indication for capecitabine therapy (41 patients). Hand-foot syndrome was the most frequently reported adverse drug reaction (37 patients), followed by nausea and vomiting, mouth ulcers, alopecia, and neuritis. Female patients experienced a slightly higher incidence of hand-foot syndrome than males. The findings indicate that capecitabine is generally safe when appropriately monitored; however, early recognition and management of adverse drug reactions are essential to minimize toxicity, improve treatment adherence, and optimise therapeutic outcomes in cancer patients.

Keywords: *Capecitabine, Cancer, Clinical safety, Hand-foot syndrome, Adverse drug reactions, Retrospective observational study, Chemotherapy***.**

INTRODUCTION

Cancer is one of the leading causes of morbidity and mortality worldwide, with an estimated 20 million new cases and approximately 9.7 million cancer-related deaths reported in 2022. The global burden of cancer continues to rise because of population aging, lifestyle changes, and increasing exposure to environmental risk factors. Chemotherapy remains a cornerstone in the management of several solid tumours, including colorectal, breast, gastric, and pancreatic cancers. Among fluoropyrimidine-based agents, capecitabine has become an important oral chemotherapeutic agent due to its efficacy comparable to that of intravenous 5-fluorouracil (5-FU), greater convenience, and improved patient compliance [1-3]. Capecitabine is an oral fluoropyrimidine carbamate that is preferentially converted to 5-FU within tumour tissues via thymidine phosphorylase, thereby enhancing selective antitumor activity while reducing systemic toxicity [4,5].

Capecitabine is approved for the treatment of metastatic colorectal cancer, adjuvant therapy for stage III colon cancer, metastatic breast cancer, and advanced gastric cancer, either as monotherapy or in combination with other cytotoxic agents [6]. Despite its established efficacy, capecitabine is associated with several clinically significant adverse drug reactions (ADRs), including hand-foot syndrome, diarrhoea, nausea, vomiting, mucositis, fatigue, myelosuppression, hepatotoxicity, and cardiotoxicity. The occurrence and severity of these toxicities vary considerably among patients and are influenced by factors such as age, renal function, treatment regimen, cumulative dose, pharmacogenetic variations, and comorbidities [7-9]. These ADRs often necessitate dose modification, treatment interruption, or discontinuation, potentially compromising therapeutic outcomes and patient quality of life. Therefore, continuous monitoring of capecitabine-associated toxicities is essential for optimising treatment safety and improving clinical outcomes.

Retrospective observational studies provide valuable real-world evidence regarding the safety profile of anticancer therapies by evaluating adverse drug reactions under routine clinical practice. Such studies complement randomised clinical trials by including broader and more heterogeneous patient populations and identifying toxicity patterns encountered in day-to-day oncology care [10]. Although several clinical trials have established the efficacy of capecitabine, real-world data describing its safety profile remain limited, particularly in developing countries. Therefore, the present retrospective observational study was undertaken to evaluate the clinical safety of capecitabine in patients with cancer by assessing the incidence and pattern of adverse drug reactions, identifying factors associated with toxicity, and examining their clinical implications. The findings of this study are expected to contribute to safer prescribing practices and improved pharmacovigilance in oncology settings [11,12].

MATERIALS AND METHODS

Study Design

The present study was designed as a retrospective observational study to evaluate the clinical safety profile and associated adverse effects of Capecitabine in cancer patients receiving chemotherapy. The study primarily focused on assessing the occurrence and severity of adverse drug reactions, especially hand-foot syndrome, in routine clinical practice.

Study Site

The study was conducted at Gleneagles Hospitals, Lakdikapul, Hyderabad, Telangana, a tertiary care hospital providing comprehensive oncology services.

Study Duration

The study was carried out over a period of six months.

Sample Size

A total of 60 patients undergoing capecitabine-based chemotherapy were included in the study.

Eligibility Criteria

Inclusion Criteria

Patients fulfilling the following criteria were included in the study:

- Patients aged between 18–80 years
- Patients diagnosed with cancer and receiving chemotherapy where capecitabine was indicated
- Patients who had completed at least six cycles of chemotherapy
- Patients willing to participate and provide consent

Exclusion Criteria

The following patients were excluded from the study:

- Patients who were mentally unstable or unable to communicate
- Patients who did not complete the prescribed course of medication
- Pregnant and lactating women

Source of Data Collection

Data were collected from multiple sources to ensure comprehensive patient assessment, including [13-17]:

- Outpatient prescriptions
- Inpatient case records
- Electronic Medical Records (EMR) database
- Laboratory investigation reports
- Patient telephonic interviews

Data Collection Procedure

A structured patient data collection form was designed and developed according to the study requirements. Patient medical records were reviewed to identify eligible participants based on the inclusion and exclusion criteria. Demographic details, diagnosis, chemotherapy regimen, adverse drug reactions, laboratory findings, and treatment outcomes were documented. Telephonic interviews were conducted to obtain patient consent and to collect additional clinical information when required[18].

Assessment of Clinical Safety

The clinical safety of capecitabine was assessed by documenting the incidence and severity of adverse drug reactions such as:

- Hand-foot syndrome
- Nausea and vomiting
- Mouth ulcers
- Alopecia
- Neuritis
- Other treatment-related toxicities

Statistical Analysis

The collected data were compiled, tabulated, and analysed using Google Sheets and appropriate statistical tools. Results were expressed in the form of frequencies, percentages, and descriptive analysis [19].

Ethical Consideration

Before the initiation of the study, ethical clearance was obtained from the Institutional Ethics Committee of Gleneagles Hospitals. Patient confidentiality and privacy were maintained throughout the study in accordance with ethical guidelines.

RESULTS AND DISCUSSION

Gender-based Distribution of Study Population

A total of 60 cancer patients receiving Capecitabine therapy were included in the study. Among them, 41 patients (68.3%) were females, and 19 patients (31.7%) were males, as presented in Table 01. The higher prevalence among female patients may be attributed to the greater number of breast cancer cases included in the study population. This finding suggests that capecitabine is more frequently prescribed in female-dominant malignancies such as breast cancer.

Table 01: Gender-based distribution of study population

Gender	Number of Patients	Percentage (%)
Female	41	68.3
Male	19	31.7

Age-dependent Distribution of Study Population

The age-wise distribution showed that the majority of patients were in the 61–70 years age group (17 patients), followed by 41–50 years (14 patients) and 51–60 years (13 patients), as shown in Table 02 and Figure 01. This indicates that capecitabine therapy is commonly prescribed in middle-aged and elderly cancer patients, reflecting the increased incidence of cancer with advancing age.

Table 02: Age-dependent distribution of study population

Age Group (Years)	Number of Patients
30–40	6
41–50	14
51–60	13
61–70	17
71–80	8
81–90	2

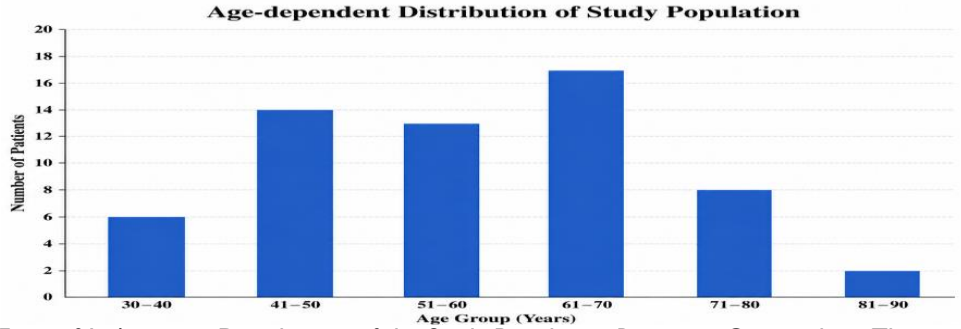

Figure 01: Age-wise Distribution of the Study Population Receiving Capecitabine Therapy

Family History of Cancer

The family history analysis revealed that 61% of patients had a positive family history of different types of cancer, while 39% had no family history, as illustrated in Table 03. A positive family history may indicate genetic predisposition and increased susceptibility to cancer development.

Table 03: Distribution of study population based on family history

Family History	Number of Patients	Percentage (%)
Yes	37	61
No	23	39

Distribution Based on Brands of Capecitabine Used

Various brands of capecitabine were used among the study population. The most commonly prescribed brand was Xeloda R (37 patients), followed by Capibine (12 patients), as shown in Table 04 and Figure 02. This indicates the preference for certain brands based on availability, affordability, and physician prescribing patterns.

Table 04: Distribution based on brands of capecitabine used

Brand	Number of Patients
Cacit	0
Capsy	2
Capecit	4
Capetero	4
Capibine	12
Xeloda R	37
Capegard	3

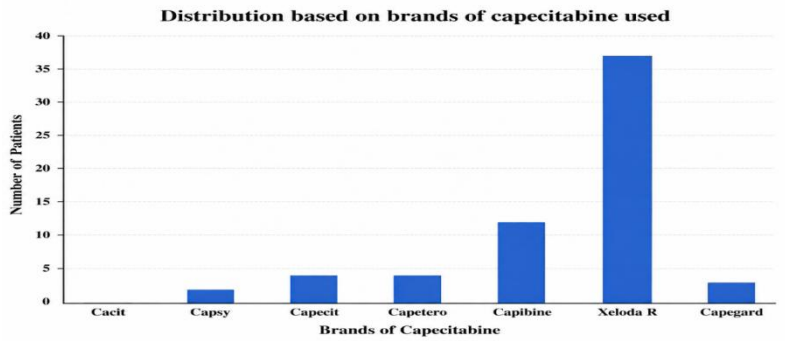

Figure 02: Distribution of Different Brands of Capecitabine Used Among the Study Population

Distribution Based on Side Effects

Among the 60 patients, Hand-Foot Syndrome (HFS) was the most commonly observed adverse effect, affecting 37 patients, followed by nausea and vomiting (13 patients) and mouth ulcers (10 patients), as shown in Table 05 and Figure 03. HFS remains the most significant toxicity associated with capecitabine therapy.

Table 05: Distribution based on side effects

Side Effects	Number of Patients
Hand Foot Syndrome	37
Nausea and Vomiting	13
Alopecia	6
Neuritis	4
Mouth Ulcer	10

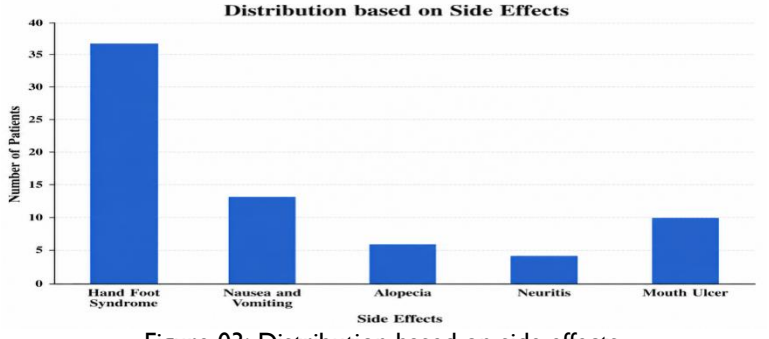

Figure 03: Distribution based on side effects

Gender-wise Distribution of Side Effects

The gender-based side effect analysis showed that female patients experienced a higher incidence of Hand-Foot Syndrome (21 cases) compared to males (16 cases), as represented in Table 06 and Figure 04. This may be related to the higher proportion of female patients in the study. Other side effects, such as nausea, alopecia, and mouth ulcers were distributed similarly between genders.

Table 06: Gender-wise distribution of side effects

Side Effects	Male	Female	Total
Hand Foot Syndrome	16	21	37
Nausea and Vomiting	7	6	13
Alopecia	2	4	6
Neuritis	2	2	4
Mouth Ulcer	7	3	10

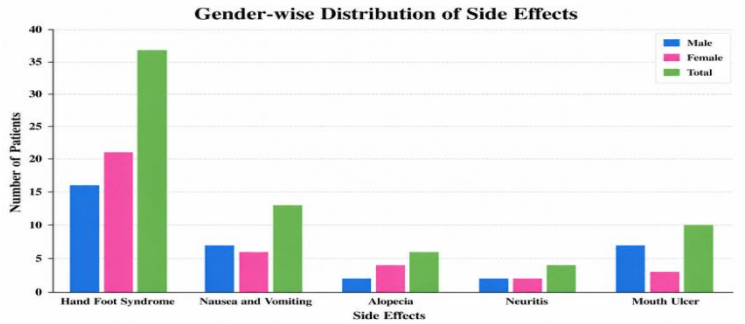

Figure 04: Gender-wise Distribution of Capecitabine-induced Side Effects Among the Study Population

Distribution Based on Cancer Types for Capecitabine Prescription

Among the study population, capecitabine was predominantly prescribed for breast cancer (41 patients), followed by GI cancer (7 patients) and pancreatic cancer (6 patients), as shown in Table 07 and Figure 05. This finding indicates that capecitabine remains an important chemotherapeutic agent in breast cancer management.

Table 07: Distribution of cancer types where capecitabine was prescribed

Cancer Type	Number of Patients
GI Cancer	7
Colorectal Cancer	3
Pancreatic Cancer	6
Breast Cancer	41
Prostate Cancer	3

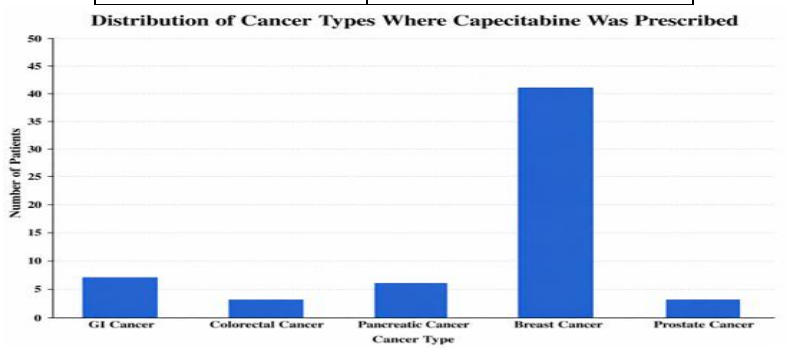

Figure 05: Distribution of Malignancies Managed with Capecitabine in the Study Population

CONCLUSION

The present study concludes that stroke is more prevalent in elderly patients, particularly those above 50 years of age, with males being more commonly affected than females. Ischemic stroke was identified as the predominant type among the study population. Hypertension emerged as the most significant risk factor, followed by smoking, alcohol consumption, diabetes mellitus, and dyslipidemia.The findings emphasise that the presence of multiple risk factors substantially increases the likelihood of stroke occurrence. Early screening, timely diagnosis, and proper management of these modifiable risk factors are essential in reducing the incidence and severity of stroke. Public awareness programs and lifestyle interventions such as smoking cessation, reduced alcohol intake, and healthy dietary practices should be encouraged. Overall, effective preventive strategies can significantly reduce the burden of stroke and improve the quality of life in affected patients.

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Nil

CONFLICT OF INTEREST
The authors declare that there are no conflicts of interest regarding the publication of this paper.

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AUTHOR CONTRIBUTIONS
B.E. Evangileen conceived and supervised the study and critically reviewed the manuscript. Nashra Fatima, Y. Harish, and N. Mounika contributed to data collection, data analysis, literature review, manuscript preparation, and revision. All authors read and approved the final version of the manuscript.

ETHICAL STATEMENT
The ethical committee clearance was obtained from Gleneagles Global Hospital before initiating the study. Reference number: AIPS/ 04/ IEC/05

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