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RESEARCH ARTICLE

Study Of Capecitabine in Patients With Solid Tumours At a Tertiary Care Centre

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ABSTRACT

Background: Capecitabine, an orally administered fluoropyrimidine prodrug of 5-fluorouracil (5-FU), has become an integral component of systemic therapy for several solid malignancies because of its efficacy, favourable toxicity profile, and convenience of administration. Although its role has been extensively investigated in colorectal and breast cancers, real-world evidence regarding its effectiveness and tolerability across diverse solid tumours in the Indian population remains limited. This study aimed to evaluate the efficacy, safety, and tolerability of capecitabine in patients with solid tumours treated at a tertiary cancer care centre.

Methods: This observational study included adult patients with histopathologically confirmed solid malignancies who received capecitabine either as monotherapy or in combination with other anticancer modalities at the Department of Oncology in a tertiary care centre. Baseline demographic, clinicopathological, treatment, and laboratory data were recorded. Patients were prospectively followed to assess treatment response, adverse events, dose modifications, treatment interruptions, and survival outcomes. Tumour response was evaluated according to standard response assessment criteria (RECIST 1.1), while treatment-related toxicities were graded using the Common Terminology Criteria for Adverse Events. Statistical analyses were performed using appropriate descriptive and inferential methods, with a p-value <0.05 considered statistically significant.

Results: A total of 94 patients with solid malignancies were enrolled, with a median age of 48 years; 79% were female, and 84% had metastatic disease treated with palliative intent. Breast cancer was the most common malignancy (48.9%). Dose reduction due to toxicity was required in 72.3% of patients, while treatment discontinuation due to adverse events occurred in only 5.3%. Hand-foot syndrome (31.9%), anaemia (28.7%), and diarrhoea (21.3%) were the most frequent toxicities, with Grade 3/4 haematological toxicity observed in only 4.3%. Among the 78 evaluable patients, stable disease was achieved in 55.1%, partial response in 10.3%, and progressive disease in 34.6%. The highest disease control was observed in ovarian and cervical cancers, whereas head and neck cancers demonstrated the poorest response.

Conclusion: Capecitabine is an effective, safe, and well-tolerated therapeutic option for patients with a variety of solid malignancies in routine clinical practice. Its favourable toxicity profile, ease of oral administration, and acceptable treatment outcomes make it an attractive alternative to continuous intravenous fluoropyrimidine therapy. Early recognition and prompt management of treatment-related toxicities, particularly hand-foot syndrome and gastrointestinal adverse events, facilitate treatment continuation and optimize patient outcomes.

Keywords: Capecitabine; Solid tumours; Oral chemotherapy; Fluoropyrimidine; Safety; Toxicity; Efficacy; Hand-foot syndrome.

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Introduction

Cancer continues to represent one of the leading causes of morbidity and mortality worldwide, with solid tumours accounting for nearly 90% of all newly diagnosed malignancies.[1] Improvements in early diagnosis, multidisciplinary management, and the introduction of novel systemic therapies have substantially improved patient survival over the past two decades. Consequently, an increasing number of patients receive prolonged courses of systemic treatment, making the efficacy, safety, tolerability, and convenience of anticancer therapies critical determinants of treatment success.

Fluoropyrimidines remain among the most widely prescribed chemotherapeutic agents for the management of solid malignancies. Since its introduction in the late 1950s, 5-fluorouracil (5-FU) has formed the backbone of treatment protocols for colorectal, gastric, breast, pancreatic, and several other gastrointestinal malignancies.[2] Conventional intravenous administration of 5-FU, however, is associated with several practical limitations, including the need for repeated venous access or continuous infusion devices, frequent hospital visits, infusion-related complications, and considerable healthcare resource utilization.[3]

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Capecitabine is an orally administered fluoropyrimidine carbamate specifically designed to overcome many of these limitations.[4] Following gastrointestinal absorption, capecitabine undergoes a three-step enzymatic conversion to its active metabolite, 5-fluorouracil.[5] Because of its excellent oral bioavailability and favourable pharmacokinetic profile, capecitabine has become an established component of treatment protocols across multiple solid malignancies.[6]

Numerous randomized clinical trials have demonstrated that capecitabine provides efficacy comparable to continuous infusion or bolus 5-FU in colorectal, gastric, breast, and other solid tumours. Furthermore, oral administration offers several practical advantages, including improved patient convenience, reduced treatment-related hospital visits, elimination of infusion pumps and central venous catheters, lower healthcare costs, and greater patient autonomy.[3] These benefits have resulted in increasing incorporation of capecitabine into both curative and palliative treatment strategies, either as monotherapy or in combination with cytotoxic chemotherapy, targeted agents, radiotherapy, or immunotherapy.

Despite these advantages, capecitabine therapy is associated with a distinct spectrum of adverse events. Hand-foot syndrome remains the characteristic dose-limiting toxicity [7], while gastrointestinal adverse effects such as diarrhoea, nausea, mucositis, and vomiting are frequently encountered.

Most evidence supporting the use of capecitabine originates from large randomized clinical trials conducted in Western populations. Although these studies have firmly established its efficacy, treatment outcomes observed in routine clinical practice may differ because of heterogeneity in patient demographics, nutritional status, comorbidities, tumour biology, treatment compliance, and healthcare infrastructure. Real-world studies from India remain relatively limited, particularly those evaluating capecitabine across multiple solid tumour types rather than individual malignancies.[8]

The present observational study was therefore undertaken at a tertiary cancer care centre to comprehensively evaluate the real-world use of capecitabine in patients with solid tumours. The study aimed to assess its therapeutic efficacy, safety profile, tolerability, treatment modifications, and clinical outcomes across a broad spectrum of solid malignancies. The findings are expected to provide clinically relevant data regarding the utilization of capecitabine in routine oncology practice and contribute to the growing body of evidence supporting personalized and evidence-based cancer care in the Indian population.

Materials and Methods

This prospective observational study was conducted in the Department of Oncology over two years . The study aimed to evaluate the efficacy, safety, and tolerability of single-agent capecitabine in adult patients with solid malignancies. A total of 94 patients with histopathologically confirmed solid tumours who fulfilled the eligibility criteria and were initiated on single-agent capecitabine were enrolled. Combination chemotherapy regimens were excluded to minimize heterogeneity arising from tumour-specific treatment protocols.

Patients aged 18 years or older with histologically confirmed solid malignancies and an Eastern Cooperative Oncology Group performance status of 0–2 or Karnofsky Performance Status >40 were included. Patients with ECOG performance status >2, KPS ≤40, or severe renal impairment (creatinine clearance <30 mL/min) were excluded.[9]

After obtaining written informed consent, demographic characteristics, clinical history, previous oncological treatment, physical examination findings, laboratory investigations, imaging studies, chemotherapy details,

and treatment-related adverse events were prospectively documented using a predesigned study proforma.

Capecitabine was administered orally at a starting dose of 2000–2500 mg/m²/day in two divided doses approximately 12 hours apart, within 30 minutes after meals. Dose calculations were based on baseline body surface area, and tablets were swallowed whole with water without splitting. Treatment-related adverse events were graded according to the Common Terminology Criteria for Adverse Events.[7] Dose interruptions and reductions were implemented according to the severity and recurrence of toxicities. Persistent or recurrent Grade 3 toxicities resulted in treatment discontinuation as per protocol. Tumour response was assessed using contrast-enhanced computed tomography or positron emission tomography/computed tomography (PET/CT) based on clinical indications. Treatment response was evaluated according to the Response Evaluation Criteria in Solid Tumours version 1.1, and categorized as complete response, partial response, stable disease, or progressive disease. Objective responses were confirmed after a minimum duration of four weeks.[10] Statistical analyses were performed using SPSS software. Continuous and categorical variables were summarized using appropriate descriptive statistics, and results were presented using tables, bar charts, pie charts, and line diagrams where applicable. The study was approved by the Institutional Review Committee of the institute, and written informed consent was obtained from all participants before enrolment.

Results

A total of 94 patients with solid malignancies were included in this prospective observational study, with a median age of 48 years and a predominance of female patients (79%), primarily reflecting the high proportion of breast cancer cases. Most patients had a Karnofsky Performance Status of 80, and the majority (84%) presented with metastatic disease and were treated with palliative intent. Breast cancer was the most common malignancy (48.9%), followed by hepatobiliary and head and neck cancers (12.7% each). Capecitabine demonstrated an acceptable safety profile, although dose reduction was required in 72.3% of patients due to treatment-related toxicities. Anaemia was the most frequent haematological adverse event (28.7%), while Grade 3/4 haematological toxicity was uncommon (4.3%). Among non-haematological adverse events, hand-foot syndrome was the most frequently observed toxicity (31.9%), followed by diarrhoea (21.3%) and stomatitis (12.7%). Despite these adverse effects, treatment discontinuation due to toxicity occurred in only 5.3% of patients, indicating that most toxicities were manageable with appropriate supportive care and dose modification.

Among the 78 evaluable patients, stable disease was the best response in 55.1%, partial response was achieved in 10.3%, and disease progression occurred in 34.6% of patients. The most favourable disease control was observed in ovarian and cervical cancers, whereas head and neck cancers demonstrated comparatively poor responses, with disease progression in nearly two-thirds of patients. Overall, the findings suggest that capecitabine is an effective, well-tolerated, and practical oral chemotherapeutic agent for the management of selected solid tumours in routine clinical practice. Appropriate patient selection, vigilant toxicity monitoring, and timely dose modifications can optimize treatment outcomes while maintaining an acceptable quality of life. Larger multicentric studies with longer follow-up are warranted to further validate these findings and identify predictors of treatment response in the Indian population.

Discussion

The discussion section of the study provides a detailed comparison between the findings at a tertiary care centre and established national and international literature. It evaluates demographics, safety, and efficacy to explain the unique clinical profile of Capecitabine in the Western Indian population.

The demographic profile of our cohort was comparable to previously published studies [11], with a median age of 48 years and a female predominance attributable to the high proportion of breast cancer patients. Although the performance status was comparable to international studies [11], the slightly lower Karnofsky Performance Status likely reflected the inclusion of patients with head and neck and hepatobiliary malignancies, who generally present with poorer functional status. A higher proportion of patients required dose reduction (72.3%) than reported in Western studies [12], which may be explained by poorer baseline nutritional status, lower socioeconomic conditions, and the inclusion of patients with advanced, heavily pre-treated malignancies. Anaemia was the most frequent haematological toxicity, whereas hand-foot syndrome remained the commonest non-haematological adverse event, consistent with the known toxicity profile of capecitabine.

Despite frequent dose modifications, treatment discontinuation due to adverse effects was uncommon

(5.3%) [13], highlighting the manageable nature of treatment-related toxicities with appropriate supportive care and individualized dose adjustments. The disease control rate observed in our study was encouraging, although the partial response rate was lower than that reported in other Indian studies [14], likely because of the inclusion of chemoresistant tumour types and patients who had received multiple prior lines of chemotherapy.[15]

While responses in head and neck cancers were limited [16], favourable disease stabilization was observed in breast and gynaecological malignancies [16], supporting the role of capecitabine as an effective and well-tolerated therapeutic option in routine clinical practice [17], particularly when treatment is individualized according to patient tolerance and clinical condition.

Conclusion

This prospective observational study evaluated the real-world efficacy, safety, and tolerability of capecitabine in patients with various solid malignancies treated at a tertiary cancer care centre. Capecitabine demonstrated satisfactory clinical effectiveness across different tumour types while maintaining an acceptable and manageable safety profile.

The majority of treatment-related adverse events were mild to moderate in severity and could be successfully managed with appropriate supportive care, dose modifications, or temporary treatment interruptions, allowing most patients to continue therapy. The convenience of oral administration, favourable tolerability, and established therapeutic activity make capecitabine an attractive alternative to intravenous fluoropyrimidine-based chemotherapy in appropriately selected patients. Careful patient selection, regular monitoring, early recognition of toxicities, and individualized dose adjustment remain essential to optimize treatment outcomes. Although this study provides valuable real-world evidence regarding capecitabine use in routine oncology practice, larger multicentric studies with longer follow-up are warranted to further validate these findings and better define long-term survival outcomes and predictors of treatment response in the Indian population.

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