RESEARCH ARTICLE

# A Prospective Study of Risk Factor Analysis and Treatment Outcomes of Chemotherapy in Cancer Patients



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**Abstract:** Cancer treatment outcomes are significantly influenced by patient-specific risk factors and chemotherapy regimen effectiveness. A hospital-based prospective study was conducted to evaluate the relationship between various risk factors and chemotherapy treatment outcomes in 150 cancer patients. Patient data was collected using standardized assessment tools including the Barthel Index for physical functioning, Cumulative Illness Rating Scale for comorbidities, Hospital Anxiety and Depression Scale for psychological assessment, and Medical Social Support Survey Scale for social support evaluation. Treatment effectiveness was assessed using Response Evaluation Criteria in Solid Tumors (RECIST). The mean age of patients was 50.57±12.62 years, with females comprising 66.7% of the study population. Reproductive system cancers were predominant (50.66%), followed by digestive system malignancies. Physical functioning analysis revealed 62% of patients were independent in daily activities. Gastrointestinal adverse effects were most common (27.5%), followed by hematological (24.5%) and dermatological complications (21%). Progressive disease was observed in 37.3% of patients, while 35.4% showed stable disease. Significant associations were found between treatment outcomes and age (p=0.027), physical functioning (p=0.0076), comorbidities (p<0.00001), anxiety and depression (p<0.000072), and adverse reactions (p<0.00001). Social support levels did not show significant correlation with treatment outcomes (p=0.918619). The results of this study indicate that early identification and management of modifiable risk factors could improve chemotherapy outcomes and patient care quality.

Keywords: Chemotherapy, Cancer; Risk factors; RECIST criteria; Treatment effectiveness; Patient assessment.

## 1. Introduction

Cancer represents a complex group of diseases characterized by uncontrolled cellular proliferation and tissue invasion. The term originates from the Latin word for crab, reflecting the invasive nature of malignant growths [1]. Currently, over 200 distinct types of cancer have been identified, each demonstrating unique patterns of cellular differentiation, survival, proliferation, and death [2]. The global cancer burden has reached significant proportions, with approximately 19.3 million new cases diagnosed in 2020. Cancer remains the second leading cause of death worldwide, accounting for nearly 10 million deaths annually [3]. Lung cancer leads mortality statistics with approximately 1.8 million deaths, followed by colorectal (935,000), liver (830,000), stomach (769,000), and breast cancer (685,000) [4]. In pediatric populations, leukemia represents 34% of cases, followed by central nervous system tumors (23%) and lymphomas (12%) [5]. Chemotherapy plays a vital role in modern cancer treatment as a systemic therapeutic approach. It functions through various mechanisms to target rapidly dividing cells, though this action affects both malignant and normal cells [6]. The primary objectives of chemotherapy include tumor mass reduction, metastasis prevention, symptom management, and in some cases, complete disease eradication [7]. The administration of chemotherapy follows carefully planned cycles to maximize therapeutic efficacy while allowing normal tissue recovery. These cycles typically span several months, with rest periods between

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treatments enabling the regeneration of healthy cells [8]. The timing and duration of these cycles are crucial, as they allow for the targeting of cancer cells in different phases of their growth cycle while minimizing damage to normal tissues [9].

Treatment success depends heavily on various patient-specific factors. Age significantly influences treatment tolerance and outcomes, with elderly patients often experiencing increased toxicity due to altered drug metabolism and reduced physiological reserves [10]. Gender differences have been observed in treatment responses and adverse effects, particularly with certain chemotherapeutic agents [11]. Comorbidities can substantially impact treatment decisions and outcomes through drug interactions and altered physiological functions [12]. Psychological factors, particularly anxiety and depression, can significantly influence treatment adherence and outcomes. These conditions may affect immune function and impact overall survival rates [13]. Social support systems play a crucial role in treatment adherence and quality of life during chemotherapy, potentially influencing survival outcomes [14]. The effectiveness of chemotherapy requires careful monitoring through standardized criteria such as the Response Evaluation Criteria in Solid Tumors (RECIST). This system provides objective measures for assessing tumor response to treatment, enabling consistent evaluation across different cancer types and treatment protocols [15].

# 2. Methodology

## 2.1. Study Design

A prospective observational study was conducted at the Department of Oncology, Koringa College Hospital, Kakinada, India, from January 2024 to December 2024. The study followed the STROBE guidelines for observational studies [16]. The study protocol received approval from the Institutional Ethics Committee (IEC/KCP/2024/001), and written informed consent was obtained from all participants in accordance with international research standards [17].

## 2.2. Study Population

A total of 150 cancer patients receiving chemotherapy were enrolled in the study. The sample size was calculated using G\*Power analysis with an effect size of 0.3,  $\alpha$  error of 0.05, and power of 0.95, following standard statistical protocols for clinical research [18].

## 2.3. Patient Selection Criteria

Patients aged 16 years and above of either gender diagnosed with primary or secondary cancer receiving chemotherapy as the primary treatment modality were included. The selection criteria were based on established oncology guidelines [19]. Patients receiving concurrent radiotherapy, those with severe psychiatric disorders preventing reliable assessment, and patients unable to tolerate chemotherapy were excluded. The exclusion criteria were determined based on previous similar studies and clinical practice guidelines [20].

#### 2.4. Assessment Tools and Methods

## 2.4.1. Clinical Assessment

A structured data collection form, validated through pilot testing [21], was used to gather information regarding age, gender, educational level, marital status, employment status, household composition, cancer type, and chemotherapy regimen details.

# 2.4.2. Evaluation of Physical Functioning

The Barthel Index, with established reliability (Cronbach's  $\alpha = 0.89$ ) [22], was employed to evaluate patients' functional status. This validated tool assessed ten activities of daily living, with scores ranging from 0-100, categorized according to standardized criteria [23].

# 2.4.3. Comorbidity Assessment

The Cumulative Illness Rating Scale (CIRS), validated for oncology patients [24], was utilized to evaluate comorbidities across 14 organ systems. The scale demonstrated high inter-rater reliability ( $\alpha = 0.85$ ) in previous studies [25].

# 2.4.4. Psychological Status

The Hospital Anxiety and Depression Scale (HADS), validated in multiple languages [26], was administered to evaluate psychological status. This scale has shown high sensitivity (0.87) and specificity (0.90) in cancer populations [27].

#### 2.4.5. Social Support

The Medical Outcomes Study Social Support Survey, validated across diverse populations [28], was used to assess emotional/informational and tangible support. The scale demonstrated strong internal consistency (Cronbach's  $\alpha = 0.91$ ) [29].

#### 2.4.6. Treatment Response

RECIST version 1.1 criteria were employed to evaluate treatment response, following international oncology guidelines [30]. Measurements were performed using standardized imaging techniques at baseline and every three cycles, with established inter-observer agreement rates [31].

#### 2.4.7. Adverse Event Documentation

Adverse events were documented using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, following standardized oncology protocols [32]. Events were categorized by organ system and severity grade according to established guidelines [33].

# 2.5. Study Duration and follow-up

Patients were followed up for a minimum period of six months or until completion of planned chemotherapy cycles, following standard oncology practice guidelines [34]. Regular assessments were conducted at baseline, during each chemotherapy cycle, and at the end of treatment, adhering to established monitoring protocols [35, 36].

#### 2.6. Statistical Analysis

Data analysis was performed using SPSS version 26.0. Statistical methods were selected based on current biostatistical recommendations [37]. Chi-square tests were used to analyze associations between risk factors and treatment outcomes, with a significance level of p<0.05. Multivariate logistic regression analysis was performed to identify independent predictors of treatment outcomes [38].

#### 3. Results

## 3.1. Demographic Characteristics

Among the 150 participants enrolled in the study, the mean age was 50.57±12.62 years. Female participants constituted 66.7% (n=100) of the study population, while males represented 33.3% (n=50). Demographic analysis revealed that 82% (n=123) were married, and 56.7% (n=85) had no formal education [40]. Employment status indicated that 54% (n=81) were homemakers, followed by 38% (n=57) in full-time employment.

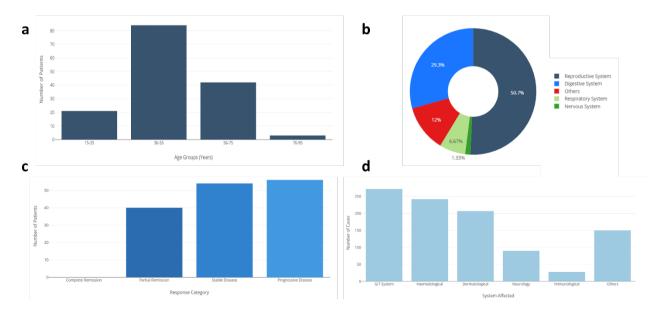


Figure 1. Results of a. Age Distribution b. Distribution of cancer types c. Treatment response according to RECIST criteria d. Distribution of adverse effects

## 3.2. Cancer Distribution and Classification

Reproductive system malignancies emerged as the predominant cancer type, affecting 50.66% (n=76) of participants, with breast cancer accounting for 33.3% (n=50) of all cases. Digestive system malignancies were the second most common, representing 29.3% (n=44) of cases. Respiratory system cancers constituted 6.7% (n=10), while nervous system malignancies were observed in 1.3% (n=2) of cases [41].

# 3.3. Physical Functioning

The Barthel Index evaluation revealed that 62% (n=93) of patients maintained complete independence in daily activities. Slight dependence was observed in 8.7% (n=13), moderate dependence in 26% (n=39), and severe dependence in 3.3% (n=5) of patients. No patients demonstrated total dependence [42].

Table 1. Daily Activities of Chemotherapy Patients Based on Barthel Index

S.No Scoring Female Male Total 1. 100-Independence 63 30 93 2. 8 5 13

91-99-Slight Dependence 25 39 3. 61-90-Moderate Dependence 14 21-60-Severe Dependence 4. 3 2 5 5. 0-20-Total Dependence 0 0 0 99 51 150 6. Total

## 3.4. Comorbidity

Analysis using the Cumulative Illness Rating Scale identified hypertension as the most prevalent comorbidity, affecting 12.7% (n=19) of patients, with 89.5% (n=17) of these patients on antihypertensive medication. Surgical history was documented in 9.3% (n=14) of patients, while head and neck conditions affected 14.7% (n=22) [43].

Table 2. Co-Morbidities of Cancer Patients based on Cumulative Illness Rating Scale (CIRS)

S.No	Co-Morbidities	Female	Male	Total
1.	Hypertension	1	1	2
2.	Hypertension with Medication	12	5	17
3.	Diabetes Mellitus	0	1	1
4.	Diabetes Mellitus with Medication	2	0	2
5.	Surgery	13	1	14
6.	Head and Neck	7	15	22
7.	Liver Disease/Jaundice/Gall Stones	2	1	3

# 3.5. Psychological Status

HADS assessment revealed that 83.3% (n=125) of patients exhibited normal anxiety levels, while 14% (n=21) showed abnormal anxiety scores. Depression assessment indicated normal levels in 80% (n=120) of patients, with 16% (n=24) showing abnormal depression scores [44].

Table 3. Anxiety and Depression of Chemotherapy Patients

S. No	Hospital Anxiety and Depression Scale	Female	Male	Total
1.	Anxiety			
2.	Normal	83	42	125
3.	Borderline abnormal	1	3	4
4.	Abnormal	15	6	21
5.	Depression			
6.	Normal	80	40	120
7.	Borderline Abnormal	3	3	6
8.	Abnormal	16	8	24

## 3.6. Social Support

The Medical Social Support Survey revealed that 86.7% (n=130) of patients received high levels of social support (81.20% on the scale). Only 5.3% (n=8) reported low social support levels (40.62% on the scale), indicating strong family and community support systems [45].

Table 4. Emotional & Tangible Support to Chemotherapy Patients

S.No	Medical Social Support Survey Scale	Female	Male	Total
1.	100.00%	2	0	2
2.	81.20%	85	45	130
3.	79.60%	0	1	1
4.	64.00%	2	2	4
5.	62.23%	2	0	2
6.	57.81%	0	2	2
7.	40.62%	6	2	8
8.	29.68%	1	0	1

#### 3.7. Adverse Events

Gastrointestinal complications emerged as the most frequent adverse events (27.5%, n=272 events), followed by hematological complications (24.5%, n=242 events) and dermatological manifestations (21%, n=207 events). Cardiovascular complications were least common, accounting for 0.8% (n=8) of all documented adverse events [46].

Table 5. Adverse Drug Reactions Based on Organ System

S.No	Adverse Effects	Female	Male	Total
1.	Haematological System	158	84	242
2.	GIT System	123	149	272
3.	Dermatological System	159	48	207
4.	Neurology	56	34	90
5.	Cardiovascular System	5	3	8
6.	Immunological System	19	9	28
7.	Otis	12	6	18
8.	Ophthalmology	9	5	14
9.	Others	67	43	110

# 3.8. Treatment Response

RECIST criteria evaluation revealed progressive disease in 37.3% (n=56) of patients, stable disease in 35.4% (n=54), and partial remission in 26.7% (n=40) of patients (shown in Figure 1d). No complete remission cases were documented during the study period [47].

## 3.9. Statistical analysis

Significant correlations were identified between treatment outcomes and several risk factors. Age served as the most significant factor ( $\chi^2$ =14.2241, p=0.027231), suggesting that treatment effectiveness varies meaningfully across different age groups. Physical functioning, as measured by the Barthel Index, also demonstrated a strong association with treatment outcomes ( $\chi^2$ =17.472, p=0.007694), indicating that patients' baseline functional status plays a crucial role in their response to therapy. [48]

Particularly strong associations were found with comorbidities ( $\chi^2$ =41.6832, p<0.00001), showing how the presence of additional medical conditions significantly influences treatment effectiveness. Mental health factors proved equally important, with both anxiety ( $\chi^2$ =24.2136, p=0.000072) and depression ( $\chi^2$ =27.4174, p=0.000016) showing robust correlations with treatment outcomes. The strongest statistical relationship was observed with adverse reactions ( $\chi^2$ =418.5113, p<0.00001), emphasizing how side effects substantially impact treatment success. Interestingly, the level of social support was the only examined factor that showed no significant association with treatment outcomes ( $\chi^2$ =0.9409, p=0.918619). These unexpected results indicate that while emotional and practical support may enhance patient comfort, it may not directly influence the biological effectiveness of chemotherapy treatment

## 4. Conclusion

The study results show that successful chemotherapy management requires consideration of physical functioning, comorbidities, and psychological well-being. The strong association identified between treatment outcomes and various patient factors highlight the importance of individualized treatment approaches and comprehensive pre-treatment assessments. These results provide valuable insights for developing targeted interventions and support systems to optimize chemotherapy outcomes in diverse patient populations.

# Compliance with ethical standards

## Conflict of interest statement

The authors declare that they have no conflicts of interest regarding the publication of this manuscript. None of the authors have any financial or personal relationships with other people or organizations that could inappropriately influence their work.

## Statement of ethical approval

This study was conducted after obtaining approval from the Institutional Ethics Committee of Koringa College Hospital (IEC/KCP/2024/001). The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

## Statement of informed consent

Written informed consent was obtained from all individual participants included in the study prior to their enrollment. The consent covered participation in the study, data collection, and publication of findings while maintaining participant confidentiality.

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