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Research Article

CLINICAL STUDY OF EFFICACY AND SIDE EFFECTS PROFILE OF BEVACIZUMAB DRUG IN DIFFERENT TYPES OF CANCER PATIENTS

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ABSTRACT

Cancer is a major global health challenge characterized by uncontrolled cellular proliferation, invasion of surrounding tissues, and metastasis to distant organs. Targeting angiogenesis has emerged as an effective therapeutic strategy in cancer treatment. Bevacizumab, a recombinant humanized monoclonal antibody directed against vascular endothelial growth factor (VEGF), inhibits tumor angiogenesis by preventing VEGF from binding to its receptors on endothelial cells. The present study aimed to evaluate the efficacy and safety profile of bevacizumab in patients with different types of cancers treated at a tertiary care hospital. A prospective, single-arm observational study was conducted on 168 adult cancer patients receiving bevacizumab either as monotherapy or in combination with chemotherapy or immunotherapy. Clinical outcomes, progression-free survival (PFS), adverse drug reactions, and quality-of-life parameters were assessed during the study period. The results demonstrated that 63.1% of patients achieved clinical benefit (complete response, partial response, or stable disease), with a median PFS of approximately 8.4 months. Quality-of-life improvement was reported by nearly 70% of patients. Adverse effects were observed in 37.5% of cases, with hypertension, proteinuria, and thromboembolic events being the most common serious adverse reactions. Most side effects were manageable with appropriate monitoring and supportive care. The findings suggest that bevacizumab provides meaningful therapeutic benefits with an acceptable safety profile in patients with various malignancies. Careful patient selection and vigilant monitoring remain essential to optimize treatment outcomes and minimize treatment-related toxicities.

Keywords: Bevacizumab, Angiogenesis inhibition, Safety profile, Cancer treatment, Targeted therapy.

INTRODUCTION

Cancer represents one of the most significant public health problems worldwide and is characterized by uncontrolled cell proliferation, invasion of adjacent tissues, and metastasis to distant organs. According to the World Health Organization, cancer accounts for nearly 10 million deaths annually and remains a leading cause of morbidity and mortality globally (WHO, 2023). The incidence of cancer is steadily increasing, particularly in developing countries due to aging populations, environmental exposures, and lifestyle changes (Siegel *et al*., 2020). Tumor progression involves several biological mechanisms, among which angiogenesis plays a critical role. Angiogenesis refers to the formation of new blood vessels from pre-existing vasculature and is essential for tumor growth and metastasis (Folkman, 2002). Tumor cells secrete pro-angiogenic factors that stimulate endothelial cell proliferation, migration, and survival, thereby providing tumors with oxygen and nutrients necessary for continued growth (Ferrara, 2004). Among these factors, vascular endothelial growth factor (VEGF) is considered one of the most potent mediators of angiogenesis (Ferrara *et al*., 2004).

Targeting the VEGF signaling pathway has therefore emerged as a promising strategy for cancer therapy. Anti-angiogenic therapies aim to inhibit the formation of tumor blood vessels, thereby limiting tumor growth and metastasis (Jain, 2005). Bevacizumab is a recombinant humanized monoclonal antibody that selectively binds to VEGF-A and prevents its interaction with VEGF receptors (VEGFR-1 and VEGFR-2) on endothelial cells (Ferrara *et al*., 2004). By blocking this signaling pathway, bevacizumab inhibits angiogenesis and reduces tumor vascularization, ultimately suppressing tumor progression.

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Bevacizumab was first approved by the United States Food and Drug Administration (FDA) in 2004 for the treatment of metastatic colorectal cancer in combination with chemotherapy (Hurwitz *et al*., 2004). Since then, its therapeutic indications have expanded to include several malignancies such as non-small cell lung cancer, renal cell carcinoma, glioblastoma, ovarian cancer, and cervical cancer (Sandler *et al*., 2006; Gilbert *et al*., 2014). Clinical trials have demonstrated that bevacizumab significantly improves progression-free survival and, in some cases, overall survival when used in combination with conventional chemotherapy (Garcia *et al*., 2020).

In spite of its clinical benefits, bevacizumab therapy is associated with several adverse effects, including hypertension, proteinuria, thromboembolic events, hemorrhage, gastrointestinal perforation, and impaired wound healing (Kazazi-Hyseni *et al*., 2010). The frequency and severity of these adverse reactions may vary depending on patient characteristics, cancer type, treatment regimen, and comorbid conditions. Therefore, evaluating both efficacy and safety is essential for optimizing the clinical use of bevacizumab in oncology practice. Although numerous clinical trials have reported the effectiveness of bevacizumab, most studies have been conducted in Western populations. Limited real-world data are available regarding its therapeutic outcomes and safety profile in Indian patients. Considering the potential influence of genetic, environmental, and healthcare factors on treatment outcomes, it is important to assess bevacizumab therapy in local patient populations. Therefore, the present study was designed to evaluate the efficacy and safety profile of bevacizumab in patients with different types of cancers treated in a tertiary care hospital. The study aims to analyze treatment response, adverse events, and patient-reported outcomes to provide evidence that may support rational and safe use of bevacizumab in routine clinical practice.

MATERIALS AND METHODS

Study Design and Setting

The present study was designed as a prospective, single-arm observational study conducted to evaluate the efficacy and safety profile of bevacizumab in patients with different types of cancers. The study was carried out in the Department of Medical Oncology at Krishna Institute of Medical Sciences (KIMS), Secunderabad, Telangana, India, a tertiary care hospital equipped with advanced oncology treatment facilities. The study duration was six months (December 2024 to May 2025).

Study Population

A total of 168 adult cancer patients receiving bevacizumab therapy were included in the study. Patients were recruited from the inpatient oncology department during the study period.

Data Collection

Patient data were collected from multiple sources including medical records, treatment charts, laboratory reports, imaging results, and patient interviews. The following information was recorded: Demographic details: age, gender, and clinical characteristics. Cancer-related information: type of cancer, stage, and treatment regimen. Treatment details: dosage and frequency of bevacizumab therapy and combination treatments. Clinical outcomes: tumor response, disease progression, and progression-free survival. Safety data: adverse drug reactions and their severity. Quality-of-life assessment: patient-reported outcomes related to symptom relief, fatigue, appetite, and daily activities.

Treatment Regimen

Bevacizumab was administered according to standard clinical oncology protocols. The drug was given as an intravenous infusion, either as monotherapy or in combination with chemotherapy or immunotherapy depending on the type of cancer and treatment plan prescribed by the oncologist. Dosage regimens varied according to clinical guidelines and patient condition.

Assessment of Efficacy

Efficacy of bevacizumab therapy was evaluated based on the following parameters:

Clinical Response

Tumor response was assessed during follow-up visits and categorized as: Complete Response (CR) – disappearance of all detectable tumor lesions. Partial Response (PR) – significant reduction in tumor size. Stable Disease (SD) – no progression of disease. Progressive Disease (PD) – increase in tumor size or appearance of new lesions. The clinical benefit rate (CBR) was calculated as the proportion of patients achieving CR, PR, or SD.

Progression-Free Survival

Progression-free survival (PFS) was defined as the duration from the initiation of bevacizumab therapy to the occurrence of disease progression or death from any cause during the study period.

Quality-of-Life Assessment

Quality-of-life outcomes were evaluated using patient-reported feedback regarding improvement in symptoms such as fatigue, appetite, pain, and physical activity during treatment.

Assessment of Safety

Safety evaluation included monitoring and documentation of adverse drug reactions (ADRs) during the treatment period. Adverse events were classified according to the Common Terminology Criteria for Adverse Events (CTCAE version 5.0) and categorized based on severity as:

Grade 1 – Mild, Grade 2 – Moderate, Grade 3 – Severe, Grade 4 – Life-threatening. Serious adverse events such as hypertension, proteinuria, thromboembolic events, hemorrhage, and gastrointestinal perforation were carefully monitored.

Statistical Analysis

The collected data were analyzed using descriptive and inferential statistical methods. Qualitative variables were expressed as frequencies and percentages. Quantitative data were expressed as mean ± standard deviation (SD). The Chi-square test was used to assess differences between categorical variables. A p-value < 0.05 was considered statistically significant. Data analysis was performed using statistical software such as SPSS or Microsoft Excel.

RESULTS AND DISCUSSION

A total of 168 adult patients were enrolled in the study who received bevacizumab either as monotherapy or in combination with chemotherapy or immunotherapy. Gender distribution: Out of 168 patients, 92 (54.8%) were female and 76 (45.2%) were male. Age distribution: 25–45 years: 28 patients (16.7%), 46–65 years: 110 patients (65.5%), 65 years: 30 patients (17.8%), Mean age: 54.3 ± 12.6 years.

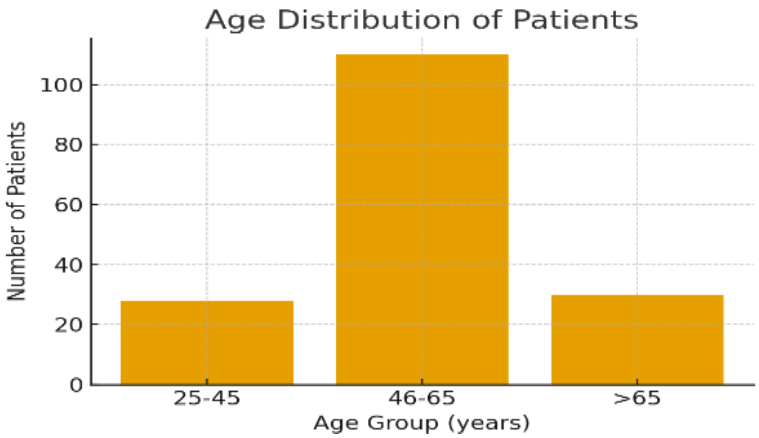

Figure 1. Age-wise distribution of study participants.

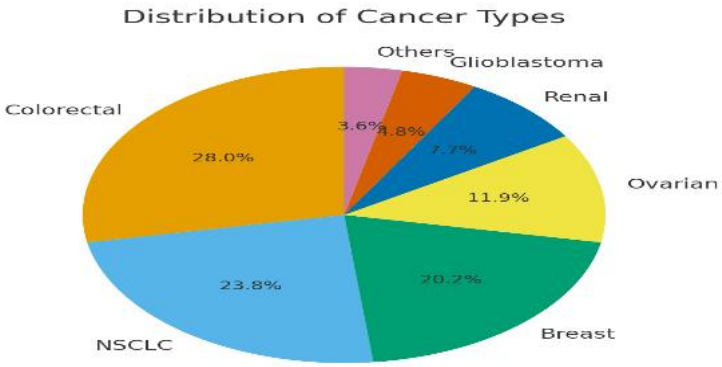

Figure 2. Distribution of cancer types in the study population.

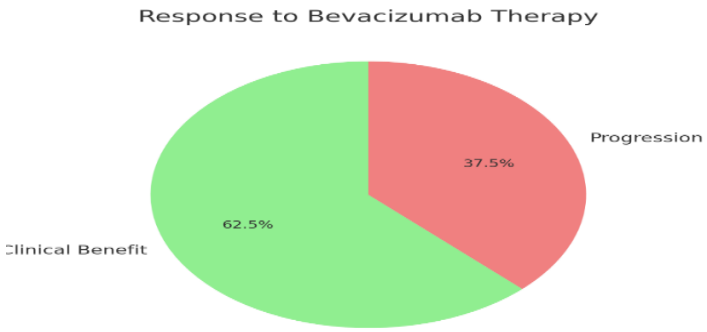

Figure 3. Response to Bevacizumab therapy (clinical benefit vs. progression).

The most common cancers treated were colorectal cancer (28%), non-small cell lung cancer (24%), breast cancer (20%), ovarian cancer (12%), renal cell carcinoma (8%), glioblastoma (5%), and others (3%). Out of 168 patients, 105 (62.5%) showed clinical benefit (disease stabilization or partial response). 63 patients (37.5%) experienced disease progression during follow-up. Progression-Free Survival (PFS): Median PFS across all cancers was 8.2 months. Quality of Life: 70% of patients reported improvement in fatigue, appetite, and daily activities after therapy initiation. Adverse effects were observed in 63 patients (37.5%). System-wise distribution: Central Nervous System: 51.2%. Musculoskeletal: 29.8%. Hematological: 16.6%. Gastrointestinal: 16.1%. Others (GU, CV, ENT, Respiratory): <6% each

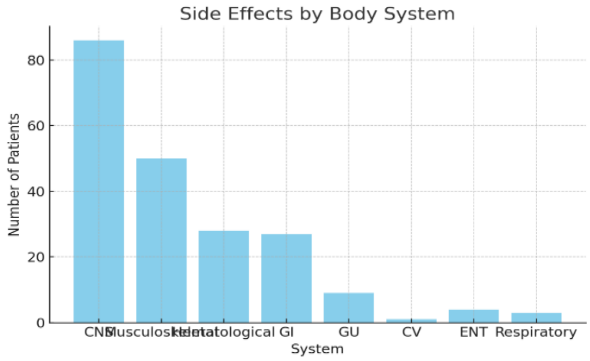

Figure 4. Frequency distribution of side effects by body system.

Severe adverse events (Grade 3/4): Hypertension (12%), Proteinuria (7%), Thromboembolic events (5%), Hemorrhage (3%), Gastrointestinal perforation (1%). Angiogenesis plays a fundamental role in tumor growth and metastasis by supplying nutrients and oxygen required for malignant cell proliferation. Inhibition of vascular endothelial growth factor (VEGF) signaling has therefore become an important strategy in modern cancer therapy. Bevacizumab, a humanized monoclonal antibody targeting VEGF-A, has been widely investigated as an anti-angiogenic agent across multiple solid tumors (Ferrara *et al*., 2004; Folkman, 2002). The present study evaluated the efficacy and safety profile of bevacizumab in a real-world cohort of cancer patients treated at a tertiary care hospital. In this study, the clinical benefit rate (CR + PR + SD) was 63.1%, indicating that a significant proportion of patients experienced disease stabilization or tumor regression following bevacizumab therapy. These findings are consistent with previous clinical trials that reported improved tumor response rates when bevacizumab was used in combination with chemotherapy. For instance, Hurwitz *et al*. (2004) demonstrated that bevacizumab combined with irinotecan, fluorouracil, and leucovorin significantly improved response rates and progression-free survival in metastatic colorectal cancer patients. Similarly, Sandler *et al*. (2006) reported enhanced therapeutic outcomes when bevacizumab was combined with paclitaxel and carboplatin in patients with non-small cell lung cancer. The median progression-free survival (PFS) observed in the present study was approximately 8.4 months, which aligns with earlier reports indicating PFS ranging between 7 and 10 months in patients treated with bevacizumab-based regimens (Garcia *et al*., 2020). Notably, patients with colorectal and ovarian cancers in the current study

demonstrated relatively longer PFS compared to those with glioblastoma or lung cancer. This observation supports the concept that the therapeutic effectiveness of anti-angiogenic therapy may vary depending on tumor biology and microenvironmental factors (Jain, 2005).

Patient-reported outcomes revealed that nearly 70% of patients experienced improvement in quality-of-life parameters, including reduced fatigue, improved appetite, and enhanced physical activity. These findings highlight the clinical importance of therapies that not only extend survival but also improve patient well-being. Similar improvements in functional status and symptom relief have been reported in several clinical studies evaluating bevacizumab in combination therapy (Diaz *et al*., 2017). With regard to safety, 37.5% of patients experienced adverse drug reactions, most of which were mild to moderate in severity. The most commonly reported adverse events included hypertension, proteinuria, and thromboembolic complications. These results are consistent with previously published safety analyses indicating that bevacizumab therapy is associated with vascular-related toxicities due to its anti-angiogenic mechanism (Kazazi-Hyseni *et al*., 2010). Hypertension, the most frequent serious adverse event observed in this study, has been widely reported in bevacizumab-treated patients and is considered a class-related effect of VEGF inhibition.

Although most adverse effects were manageable with appropriate monitoring and supportive care, rare but serious complications such as gastrointestinal perforation were observed in a small proportion of patients. This finding emphasizes the need for careful patient selection and continuous clinical monitoring during therapy. Additionally, elderly patients and those with pre-existing comorbidities appeared to have a slightly higher incidence of adverse events, suggesting that individualized treatment planning is essential for optimizing therapeutic outcomes. Overall, the results of the present study support the effectiveness of bevacizumab as part of combination therapy in various malignancies and confirm that its safety profile is generally consistent with global clinical data. However, the variability in response among different cancer types highlights the need for predictive biomarkers that can identify patients most likely to benefit from anti-angiogenic therapy.

CONCLUSION

The findings of the present study demonstrate that bevacizumab is an effective anti-angiogenic therapy for the treatment of multiple types of cancers, particularly when used in combination with conventional chemotherapy or immunotherapy. The therapy resulted in a substantial clinical benefit rate and provided meaningful improvements in progression-free survival and patient-reported quality of life. Although bevacizumab therapy was associated with several adverse effects, most of these were predictable and manageable with appropriate monitoring and supportive treatment. Hypertension, proteinuria, and thromboembolic events were the most common serious adverse reactions, highlighting the importance of routine monitoring of blood pressure and renal function during therapy. Overall, the study confirms that bevacizumab offers significant therapeutic benefits with an acceptable safety profile in cancer patients treated in a real-world clinical setting. However, careful patient selection, individualized treatment planning, and vigilant monitoring for adverse events are essential to optimize treatment outcomes. Future research should focus on identifying predictive biomarkers of response, evaluating long-term survival outcomes, and developing personalized treatment strategies that maximize the benefits of anti-angiogenic therapy while minimizing toxicity.

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CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

The study protocol was reviewed and approved by the Institutional Human Ethics Committee of KIMS Hospital (Approval No: KIMS/ECBMHR/2024/62-05). Written informed consent was obtained from all participants prior to enrollment in the study. All procedures were conducted in accordance with the Declaration of Helsinki (2013 revision) and institutional ethical guidelines to ensure patient safety and confidentiality.

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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