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Original Article

Comparison of Efficacy and Safety between CAPOX and FOLFOX6 in Metastatic Colorectal Carcinoma

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ABSTRACT

Objective: To compare the efficacy and safety of CAPOX versus FOLFOX6 in patients with metastatic colorectal carcinoma in terms of disease progression, mortality, and treatment-related toxicities.

Methodology: This randomized controlled trial was conducted at the Department of Oncology, Jinnah Hospital, Lahore, from September 2025 to February 2026, following ethical approval from the institutional review board. Patients aged 20 to 80 years with metastatic colorectal carcinoma planned for postoperative chemotherapy were recruited using a non-probability consecutive sampling technique after obtaining informed written consent. A total of 248 patients were screened, of whom 216 eligible patients were randomized to either CAPOX or FOLFOX6 treatment groups. During follow-up, 15 patients in the CAPOX group and 22 patients in the FOLFOX6 group were lost to follow-up; therefore, the final analysis was performed on 179 patients, including 93 in the CAPOX group and 86 in the FOLFOX6 group. Outcomes included disease progression, dose reduction, hepatotoxicity, diarrhea, neuropathy, treatment discontinuation, and mortality. Data was analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.

Results: Baseline demographic and clinical characteristics were comparable between the two groups ($p > 0.05$). Disease progression occurred in 25(26.9%) patients in the CAPOX group and 32(37.2%) patients in the FOLFOX6 group [odd ratio (OR) 0.62, 95% confidence interval (CI):0.33-1.17; $p=0.138$]. Neuropathy was significantly less frequent in the CAPOX group compared with the FOLFOX6 group (24.7% vs. 47.7%; $p=0.001$). Hepatotoxicity was less frequent in the CAPOX group than in the FOLFOX6 group (5.4% vs. 14.0%); however, this difference did not reach statistical significance ($p=0.051$). Mortality, dose reduction, treatment discontinuation, and diarrhea did not differ significantly between the groups ($p > 0.05$).

Conclusion: In patients with metastatic colorectal carcinoma, CAPOX was associated with a significantly lower frequency of neuropathy compared with FOLFOX6. CAPOX and FOLFOX6 treatment groups showed no statistically significant difference in disease progression, mortality, dose reduction, hepatotoxicity, diarrhea, and treatment discontinuation.

Keywords: *Colorectal Neoplasms. Neoplasm metastasis. Capecitabine. Oxaliplatin.*

INTRODUCTION

Colorectal cancer remains a major contributor to the global cancer burden, with substantial mortality despite advances in prevention, early detection, and systemic therapy. About 904,019 deaths and approximately 1,926,425 new colorectal cancer cases were documented worldwide in 2022.[1] Regional differences in incidence and outcomes persist, reflecting differences in risk factor profiles, screening uptake, stage at presentation, and access to hospital care.[2] Metastatic colorectal cancer is associated with a markedly poorer prognosis than localized disease. At the time of initial diagnosis nearly one fifth of patients usually present with metastatic disease and a further one fourth develop distant spread after treatment of earlier stage disease.[3] Current population level data show low long term survival in distant stage disease. An effective treatment regimen is needed that patients can easily tolerate and continue for the full course.[4] For patients with metastatic colorectal cancer, systemic therapy remains the primary treatment modality. The regimen selection guided by performance status, tumor biology, prior treatment exposure, and primary tumor location.[5] The commonly used chemotherapeutic regimes are 5-fluorouracil with leucovorin & oxaliplatin (FOLFOX6) and capecitabine with oxaliplatin (CAPOX). The CAPOX regimen offers oral fluoropyrimidine and avoids continuous 5-fluorouracil infusion, but FOLFOX6 needs central venous access for prolonged infusion with implications for catheter related complications and service delivery constraints.[6] Comparative evidence has demonstrated distinct toxicity profiles between CAPOX and FOLFOX6 regimens, with variations in the incidence of neutropenia, diarrhea, and peripheral neuropathy. These differences directly influence dose intensity, treatment modifications, and discontinuation rates, ultimately impacting overall treatment outcomes.[5] A study conducted at a cancer center in Pakistan reported that CAPOX based therapy was generally well tolerated, with diarrhea and peripheral neuropathy being the most frequently observed toxicities.[6]

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In resource limited settings, differences in oncology infrastructure, supportive care, and toxicity monitoring may further influence treatment selection and outcomes. A study from Pakistan reported real world chemotherapy utilization patterns in metastatic colorectal cancer, with FOLFOX being the most commonly used regimen (38.3%), followed by CAPOX (19.9%); and the survival rate was significantly lower in patients who did not receive chemotherapy, which emphasizes the importance of systemic therapy.[7] However, direct comparative evidence between CAPOX and FOLFOX6 in the local setting remains limited. Therefore, this study was conducted to compare disease progression and treatment related toxicities between CAPOX and FOLFOX6 in patients with metastatic colorectal carcinoma, aiming to identify the regimen that offers an optimal balance between efficacy and tolerability in routine clinical practice.

METHODOLOGY

This randomized controlled trial registered at ClinicalTrials.gov (NCT07334587, 31-12-2025) was performed at the Department of Oncology, Jinnah Hospital, Lahore, from September 2025 to February 2026 after taking ethical approval from the institutional review board (Letter No. ERB193/2/29-08-2025/AIMC/JHL, 29-08-2025). OpenEpi software was used to calculate the sample size of 216 patients (108 per group) with 95% confidence level, 80% power, and taken peripheral neuropathy rates of 31.3% in the FOLFOX4 group and 14.3% in the CAPOX group.[8,9] Out of 248 screened patients, 216 patients were eligible & randomized, while 15 cases in the CAPOX and 22 cases in the FOLFOX6 group were lost to follow up. Therefore, the final analysis was performed on 179 patients (93 in the CAPOX group and 86 in the FOLFOX6 group). Participant flow was presented in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines (Figure 1).

Adult patients with metastatic colorectal carcinoma presenting to the outpatient oncology department for postoperative systemic chemotherapy were screened and recruited by means of a non-probability consecutive sampling method. Informed written consent was acquired from the patients. Patients aged 20 to 80 years of either sex were eligible if they had histologically confirmed stage IV metastatic colorectal carcinoma and were planned to receive postoperative chemotherapy. Exclusion criteria included non-metastatic disease at diagnosis, the presence of another active malignancy, prior adjuvant chemotherapy received at another center, documented preexisting neurological disorders, and participation in another interventional trial.

Patients fulfilling the eligibility criteria were assigned in equal ratio either to CAPOX or FOLFOX6 group utilizing a computerized randomization protocol. Treatment assigned to each groups was concealed through opaque, serially labelled, tamper proof envelops, which were unsealed after patient enrolment. Blinding of both the patients and the treating physicians was not possible due to differences in drug administration route, dosing schedule, and infusion duration between the two regimens.

Baseline data was recorded on a standardized proforma before allocation. The proforma included information regarding age, gender, body mass index (BMI), smoking status, duration of disease, primary tumor site, stage, Eastern Cooperative Oncology Group (ECOG) performance status, diabetes mellitus, hypertension, anemia, family history of cancer, interval between surgery and chemotherapy, and total number of involved lymph nodes. Prechemotherapy clinical assessment and routine laboratory investigations were performed according to departmental protocol to document baseline hematologic and hepatic status and to confirm fitness for systemic therapy. In the CAPOX group, intravenous oxaliplatin 130 mg/m² was given on first day with 1000 mg/m² oral capecitabine every 12 hours on days 1 to 14, repeated every 3 weeks for 6-8 cycles. In the FOLFOX6 group, intravenous oxaliplatin 85 mg/m² and leucovorin 400 mg/m² were given on first day, followed by bolus 5-fluorouracil and 46 hour continuous infusion 5-fluorouracil 2400 mg/m², repeated every 2 weeks for 12 cycles. All injectable chemotherapy drugs were prescribed by the consultant medical oncologist and administered in the oncology daycare chemotherapy unit by trained oncology nursing staff experienced in cytotoxic drug administration, under the supervision of the oncology registrar and consultant medical oncologist. Standard supportive care was provided, and before each cycle, patients underwent clinical assessment and laboratory monitoring to evaluate treatment tolerance. Dose reductions, treatment delays or discontinuation were implemented when clinically indicated based on toxicity, and outcomes were recorded at the end of treatment.

All patients were followed-up for 6 months. During this period, patients were followed at regular intervals corresponding to each chemotherapy cycle, i.e., every 3 weeks in the CAPOX group and every 2 weeks in the FOLFOX6 group, from treatment initiation until completion of therapy or disease

progression, whichever occurred earlier. Additional unscheduled visits were arranged as needed for toxicity assessment or clinical deterioration.

The primary outcome variable was disease progression. Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 was used to evaluate the disease progression.[10] Progression was determined as at least a 20% increase in the sum of diameters of target lesions compared with the smallest sum recorded during the study, with an absolute increase of at least 5 mm, or the appearance of one or more new lesions. The secondary outcome variables were treatment related toxicities, including dose reduction, hepatotoxicity, diarrhea, peripheral neuropathy, treatment discontinuation, and mortality. The grading of these variables was done in agreement with the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0.[11] All outcomes were recorded in a predesigned data collection proforma as binary variables (yes or no).

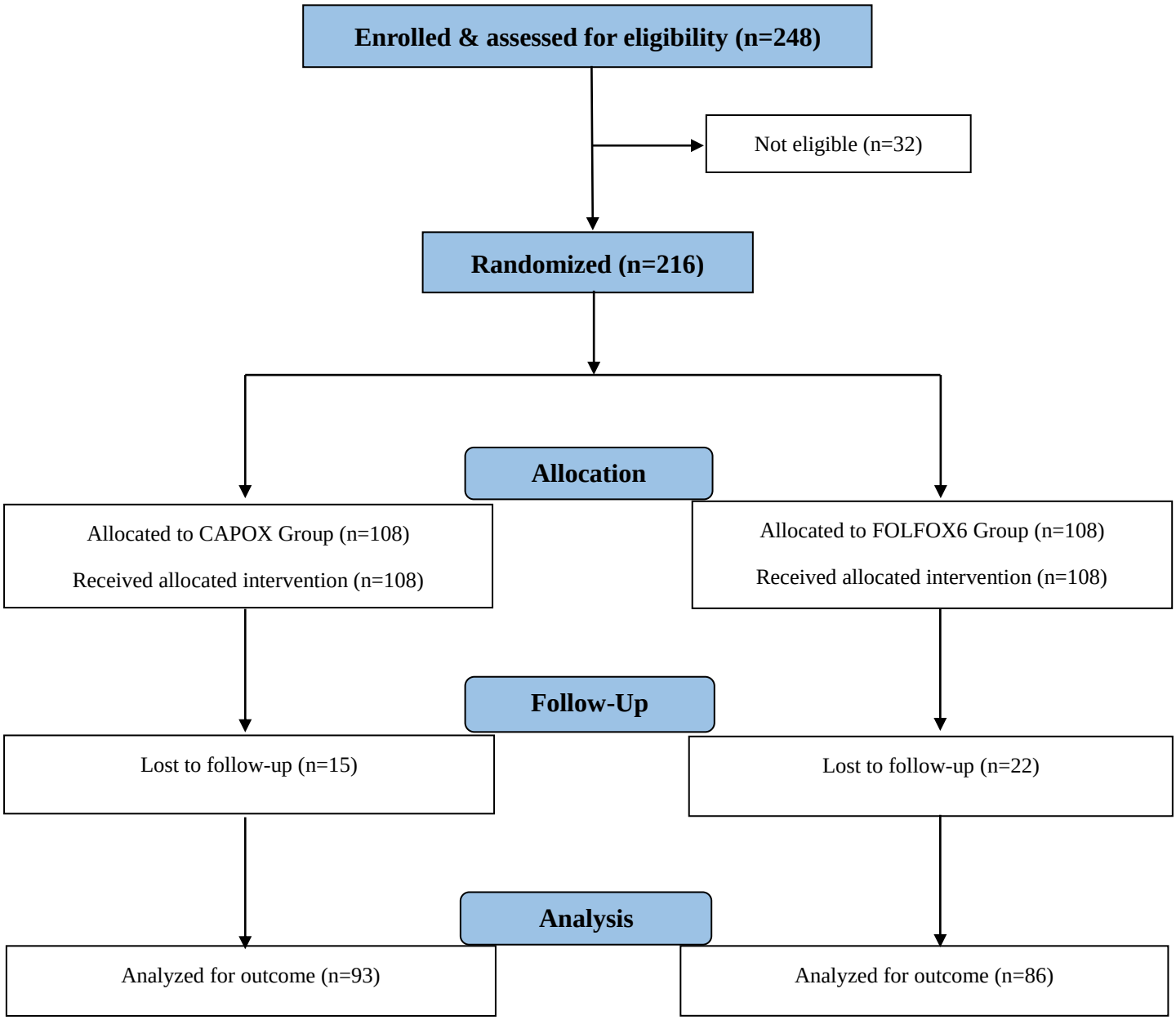

Figure 1: Flow Chart according to CONSORT Guidelines

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) version 26 was employed for entry and analysis of data. Mean & standard deviation was computed for continuous variables. Categorical data were reported as frequency and percentage. The independent samples t-test was applied for comparisons of continuous variables between groups and the categorical variables were compared using the Chi-square test. For each binary outcome, odds ratios (OR) with 95% confidence intervals (CI) were reported. A p-value <0.05 was taken as significant.

RESULTS

The mean age was 59.64±7.40 years in the CAPOX group versus 58.59±7.42 years in the FOLFOX6 group (p=0.346). Mean duration of cancer was 7.85±4.17 months versus 8.46±4.48 months (p=0.351). Similarly, BMI was comparable between CAPOX and FOLFOX6 groups (24.70±3.01 kg/m² versus 25.19±3.61 kg/m²) (p=0.316). The interval from surgery to chemotherapy was also comparable between groups (34.19±14.33 days versus 32.65±13.03 days, p=0.453). Mean number of involved lymph nodes was 4.19±1.83 in the CAPOX group and 4.37±1.86 in the FOLFOX6 group (p=0.518). Both groups were also comparable in terms of demographic and clinical characteristics of the study subjects (Table 1).

Disease progression was observed in 25(26.9%) cases in the CAPOX group and 32(37.2%) cases in the FOLFOX6 group. The progression was numerically lower in the CAPOX group but not statistically significant (p=0.138). Hepatotoxicity was less frequent in the CAPOX group than in the FOLFOX6 group (5.4% vs. 14.0%). This difference was also not statistically significant (p=0.051). Neuropathy was significantly less in the CAPOX group as compared to FOLFOX6 group (24.7% vs. 47.7%) (p=0.001). Both groups were comparable in terms of mortality, dose reduction, treatment discontinuation, and diarrhea (p >0.05) (Table 2).

Table 1: Comparison of Demographic and Clinical Characteristics of Patients in Treatment Groups (n=179)

Demographic and Clinical Characteristics of Patients		CAPOX Group (n=93)	FOLFOX6 Group (n=86)	p-value
		Frequency & Percentage		
Gender	**Male**	55(59.1%)	51(59.3%)	0.982
	Female	38(40.9%)	35(40.7%)	
Primary Tumor Location	**Right Colon**	36(38.7%)	37(43.0%)	0.557
	Left Colon	57(61.3%)	49(57.0%)	
Stage	**IVA**	36(38.7%)	35(40.7%)	0.815
	IVB	42(45.2%)	35(40.7%)	
	IVC	15(16.1%)	16(18.6%)	
ECOG Performance Status	**0**	58(62.4%)	53(61.6%)	0.961
	1	30(32.3%)	29(33.7%)	
	≥2	5(5.3%)	4(4.7%)	
Smoking	**Yes**	29(31.2%)	26(30.2%)	0.890
	No	64(68.8%)	60(69.8%)	
Diabetes Mellitus	**Yes**	23(24.7%)	26(30.2%)	0.410
	No	70(75.3%)	60(69.8%)	
Hypertension	**Yes**	35(37.6%)	33(38.4%)	0.919
	No	58(62.4%)	53(61.6%)	
Anemia	**Yes**	23(24.7%)	24(27.9%)	0.630
	No	70(75.3%)	62(72.1%)	
Family History of Colorectal Cancer	**Yes**	12(12.9%)	12(14.0%)	0.837
	No	81(87.1%)	74(86.0%)	

Table 2: Comparison of Outcomes between CAPOX and FOLFOX6 Treatment Groups

Outcomes		CAPOX Group (n=93)	FOLFOX6 Group (n=86)	Odds Ratio (95% CI)	p value
		Frequency & Percentage			
Disease Progression	**Yes**	25(26.9%)	32(37.2%)	0.62(0.33 to 1.17)	0.138
	No	68(73.1%)	54(62.8%)		
Dose Reduction	**Yes**	22(23.7%)	27(31.4%)	0.68(0.35 to 1.31)	0.246
	No	71(76.3%)	59(68.6%)		
Hepatotoxicity	**Yes**	5(5.4%)	12(14.0%)	0.35(0.12 to 1.04)	0.051
	No	88(94.6%)	74(86.0%)		
Diarrhea	**Yes**	27(29.0%)	18(20.9%)	1.55(0.78 to 3.07)	0.212
	No	66(71.0%)	68(79.1%)		
Neuropathy	**Yes**	23(24.7%)	41(47.7%)	0.36(0.19 to 0.68)	0.001*
	No	70(75.3%)	45(52.3%)		
Treatment Discontinuation	**Yes**	15(16.1%)	21(24.4%)	0.60(0.28 to 1.25)	0.167
	No	78(83.9%)	65(75.6%)		
Mortality	**Yes**	9(9.7%)	14(16.3%)	0.55(0.23 to 1.35)	0.187
	No	84(90.3%)	72(83.7%)		

***Significant p-value*

DISCUSSION

The present study compared the efficacy and safety of CAPOX and FOLFOX6 in metastatic colorectal carcinoma patients. Disease progression was seen in 26.9% of the cases in CAPOX group and 37.2% of the cases in FOLFOX6 group (p=0.138; OR 0.62, 95% CI 0.33-1.17). Mortality rate was also not statistically significant between the two groups. On contrary, Degirmencioglu et al. demonstrated significantly lower progression (27.36% vs. 42.34%; p=0.016) and mortality (16.04% vs. 35.77%; p=0.001) rates in the CAPOX group.[12] A retrospective study involving patients with metastatic colorectal carcinoma reported a disease progression rate of 30.4% (95% CI: 0.19-0.44) with CAPOX treatment, which was identified as the main reason for chemotherapy discontinuation.[9] Rashid et al. showed the progression rate of 23.8% with the CAPOX treatment regimen in patients with metastatic colorectal carcinoma.[13] Another study found no significant difference between CAPEOX and FOLFOX in progression free survival (p=0.23).[14] The variation across studies may reflect differences in disease stage, molecular profiles, and the use of adjuvant versus palliative treatment settings.

In this study, neuropathy was less in the CAPOX group as compared to the FOLFOX6 group (24.7% vs. 47.7%) (p=0.001). In contrast, Degirmencioglu et al. observed no statistical significant difference in the occurrence of neuropathy between both groups (p=0.21).[12] A study observed significantly lower neuropathy rates in patients receiving CAPOX (30%) compared with FOLFOX6 (56%).[15] Kibudde et al. reported peripheral neuropathy in 14.3% of patients treated with oxaliplatin based regimens.[9] In Pakistan, a study reported a high incidence of neuropathy (81.9%) among patients receiving neoadjuvant CAPOX therapy.[6] Kalkan et al. noted significantly lower neuropathy in patients treated with CAPOX for three months (30%) compared with those receiving CAPOX or FOLFOX for six months (54.5%).[16] A study conducted in 2026 pooled data from six trials, also confirmed reduced neuropathy with a three month duration of oxaliplatin based treatment compared with six months (4.2% vs. 13.6%, p <0.001).[17] Yoshino et al. also reported lower rates of peripheral sensory neuropathy in patients receiving shorter duration CAPOX treatment compared with FOLFOX6.[18]

The current study observed no significant difference (p=0.051) in hepatotoxicity rates between CAPOX (5.4%) and FOLFOX6 (14.0%) treatment groups. Another study noted low hepatotoxicity rates in both groups (2.83% versus 5.11%; p=0.52).[12] The near significant finding in the current analysis, together with results from other studies, suggests that CAPOX may carry a lower hepatotoxic burden.

Regarding diarrhea, no significant difference between CAPOX and FOLFOX6 groups (29.0% vs. 20.9%; p=0.212) was found in this study. McShane and Armstrong reported substantially higher diarrhea with CAPOX (26.9%) as compared to the FOLFOX regimen (2.99%) (p=0.002).[19] A study from Pakistan reported that diarrhea was the most frequently observed toxicity among patients receiving neoadjuvant CAPOX therapy.[6] A meta-analysis by Zhan et al. revealed that the rate of diarrhea was

higher with FOLFOX compared to CAPOX regimens. Although the CAPOX regimen ranked first in terms of safety profile among 29 different regimens, diarrhea was still reported in a study.[20]
Mortality was not significantly (p=0.187) different between the two treatment groups (9.7% vs 16.3%) in our study. Chowdhury et al. reported inferior survival with CAPOX (p <0.001); however, substantial confounding by indication was acknowledged, as patients receiving CAPOX were older and had a higher proportion of stage IV disease.[21] In another study, no significant survival differences were found between regimens.[22] The treatment discontinuation rates in the present study (16.1% versus 24.4%; p=0.167) contrast with McShane and Armstrong, who observed significantly higher discontinuation rates with CAPOX (46.2% vs 10.5%; p <0.001).[19] This inconsistency may reflect differences in patient selection, dose modification, and institutional practices.

CONCLUSION

In patients with metastatic colorectal carcinoma, CAPOX was linked to a significantly reduced frequency of neuropathy in comparison to FOLFOX6. CAPOX and FOLFOX6 treatment groups showed no statistically significant difference in disease progression, mortality, dose reduction, hepatotoxicity, diarrhea, and treatment discontinuation. These findings suggest that both regimens remain clinically usable options, with CAPOX offering a lower neuropathy burden in this study. Regimen selection should be individualized according to toxicity profile, patient preference, treatment adherence, comorbidities, and institutional chemotherapy delivery resources.

LIMITATIONS & RECOMMENDATIONS

This study had several limitations. Firstly, the final analysis included only patients who completed outcome assessment, and those lost to follow-up were excluded; therefore, attrition bias cannot be ruled out. Second, molecular profiling data were unavailable, limiting subgroup analysis. Third, the follow-up duration was relatively short, preventing mature progression free survival and overall survival analyses. Fourth, adverse effects were recorded during routine clinical care, and patient reported symptom burden may not have been fully captured using formal quality of life instruments. Further multicenter randomized trials with larger sample sizes, intention-to-treat analysis, longer follow-up, standardized radiological response assessment, molecular subgroup stratification, and formal quality of life evaluation are recommended.

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Authors' Contributions:
Authors approved the draft and are accountable in ensuring that questions related to accuracy or integrity of the work are duly investigated and resolved.
P.A: Conceived and designed the study, interpreted data, critically revised the manuscript, and approved the final version.
K.B: Contributed to study design, data interpretation, manuscript revision, and approved the final version.
R.N: Conducted literature review, interpreted findings, drafted and revised the manuscript, and approved the final version.
H.A: Contributed to clinical data analysis, manuscript revision, and approved the final version.
H.R: Participated in data collection, data organization, manuscript preparation, and approved the final version.
Z.M: Contributed to clinical data acquisition, clinical discussion refinement, and approved the final version.

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