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Original Article

Efficacy and Safety of Paclitaxel Plus Ramucirumab as Second–Line Therapy in Advanced Gastric Cancer: A Retro–Prospective Single–Centre Study

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Abstract

Background: Advanced gastric cancer (AGC) has limited treatment options beyond first–line therapy. The combination of paclitaxel and ramucirumab is an approved second–line regimen. This study evaluates the real–world efficacy and safety of this combination in Indian patients.

Aim: To assess the effectiveness and tolerability of paclitaxel plus ramucirumab in advanced gastric/gastroesophageal junction adenocarcinoma in a real–world setting.

Materials and Methods: This retro–prospective study included 85 patients with AGC treated between January 2020 and December 2024 at a tertiary cancer centre in North India. Patients received paclitaxel 80 mg/m² on days 1, 8, and 15, and ramucirumab 8 mg/kg on days 1 and 15 of a 28–day cycle. The primary endpoint was progression–free survival (PFS); secondary endpoints included overall survival (OS), objective response rate (ORR), disease control rate (DCR), and safety.

Results: The median age was 58 years; 71% were male. ECOG PS 0–1 was present in 70%. Prior gastrectomy was reported in 36%. Median PFS was 5.1 months, and OS was 9.3 months. ORR was 27%, and DCR was 66%. Common grade 3/4 adverse events included neutropenia (19%), neuropathy (13%), and hypertension (9%).

Conclusion: Paclitaxel plus ramucirumab is effective and well–tolerated as second–line treatment in Indian AGC patients. Outcomes mirror global data and support its continued use in resource–limited settings.

Keywords: Gastric cancer, ramucirumab, paclitaxel, second–line therapy, Indian population, real–world data.

Introduction

Gastric cancer ranks among the top five most common cancers worldwide and remains a leading cause of cancer mortality.[1] In India, although less frequent than in East Asia, it constitutes a major gastrointestinal malignancy, particularly in the northeastern and southern states.[2,3] Late diagnosis due to vague symptoms contributes to poor outcomes.

First–line treatment typically comprises fluoropyrimidine and platinum–based chemotherapy, with trastuzumab added in HER2–positive cases.[4] Nonetheless, most patients progress, underscoring the need for effective second–line options.[5]

Ramucirumab, a monoclonal antibody targeting VEGFR–2, inhibits angiogenesis and has shown efficacy alone (REGARD trial)[6] and in combination with paclitaxel (RAINBOW trial)[7] for second–line treatment of AGC. However, Indian data on its real–world use remain limited.[8]

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This retro–prospective study assesses outcomes with paclitaxel plus ramucirumab in Indian patients at a tertiary cancer centre.

Materials and Methods

This was a retro–prospective cohort study conducted at the Department of Medical Oncology, Rajiv Gandhi Cancer Institute, Delhi, encompassing patients treated between January 2020 and December 2024. Patients included were those with histologically confirmed metastatic or unresectable gastric or gastroesophageal junction adenocarcinoma who had experienced disease progression following first–line chemotherapy with a fluoropyrimidine and platinum–based regimen. Eligible patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 and adequate hematologic, renal, and hepatic function. Patients were excluded if they had received prior VEGF or VEGFR inhibitors, had active central nervous system metastases, uncontrolled hypertension, or ongoing bleeding disorders.

All patients received intravenous paclitaxel at a dose of 80 mg/m² on days 1, 8, and 15, along with ramucirumab at 8 mg/kg on days 1 and 15 of each 28–day cycle. Treatment continued until disease progression, intolerable toxicity, or patient/physician decision to discontinue. Tumor response assessments were performed using the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1, and imaging studies were conducted every 8 weeks. Toxicities were graded according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

Statistical analyses were conducted using the Kaplan–Meier method to estimate progression–free survival (PFS) and overall survival (OS). Prognostic factors were evaluated using Cox proportional hazards regression models. All statistical tests were two–sided, and a p–value less than 0.05 was considered statistically significant.

Results

Of the 85 patients included, the median age was 58 years (range 32–76), with a male predominance (71%). Most patients (70%) had an ECOG performance status of 0–1, and 36% had previously undergone gastrectomy. Liver metastases were observed in 45%, while 30% had peritoneal involvement. HER2 positivity was identified in 19% of patients. All patients received first–line therapy with a fluoropyrimidine and platinum–based regimen, with trastuzumab included in HER2–positive cases. Baseline characteristics are detailed in Table 1.

Characteristic	Value
Median age	58 years
Male sex	71%
ECOG PS 0–1	70%
Prior gastrectomy	36%
Liver metastases	45%
Peritoneal metastases	30%
HER2–positive	19%
1st–line chemotherapy	100%

Table 1. Baseline Characteristics of Study Population (N=85)

The objective response rate (ORR) was 27%, which included 2% complete responses and 25% partial responses. An additional 39% of patients had stable disease, yielding a disease control rate (DCR) of 66%. The median progression–free survival (PFS) was 5.1 months (95% CI: 4.3–5.9), and the median overall survival (OS) was 9.3 months (95% CI: 8.1–10.5), as illustrated in Figure 1 and Figure 2, respectively. Detailed efficacy outcomes are shown in Table 2.

Outcome	Result
Median PFS	5.1 months (95% CI: 4.3–5.9)
Median OS	9.3 months (95% CI: 8.1–10.5)
ORR	27% (CR 2%, PR 25%)
DCR	66% (includes SD: 39%)

Table 2. Efficacy Outcomes

Subgroup analysis demonstrated that patients with ECOG performance status 0–1 had a median OS of 10.1 months compared to 6.2 months for those with ECOG 2. Similarly, patients who had undergone prior gastrectomy experienced better survival outcomes, with a median OS of 10.5 months versus 7.5 months in those without prior surgery.

The treatment regimen was generally well tolerated. The most frequent grade 3 or 4 adverse events included neutropenia (19%), neuropathy (13%), and hypertension (9%). Fatigue (≥ grade 3) occurred in 6% of patients, while proteinuria and gastrointestinal perforation were less common (2% and 1%, respectively). There were no treatment–related deaths reported. Table 3 summarizes the toxicity profile.

Discussion

Our study presents real–world evidence supporting the clinical efficacy and safety of the paclitaxel plus ramucirumab regimen in Indian patients with advanced gastric cancer (AGC) who progressed after first–line

Adverse Event	Incidence (%)
Neutropenia	19%
Neuropathy	13%
Hypertension	9%
Fatigue (≥ grade 3)	6%
Proteinuria	2%
GI perforation	1%

Table 3. Grade 3/4 Adverse Events

therapy. The results are consistent with those reported in pivotal phase III trials such as RAINBOW and REGARD, validating the applicability of these regimens across diverse populations and practice settings.[7]

The observed median progression–free survival (PFS) of 5.1 months and median overall survival (OS) of 9.3 months in our cohort are in close agreement with the RAINBOW trial, which reported a median PFS of 4.4 months and OS of 9.6 months for patients treated with paclitaxel plus ramucirumab.[7] Similarly, the objective response rate (ORR) of 27% and disease control rate (DCR) of 66% in

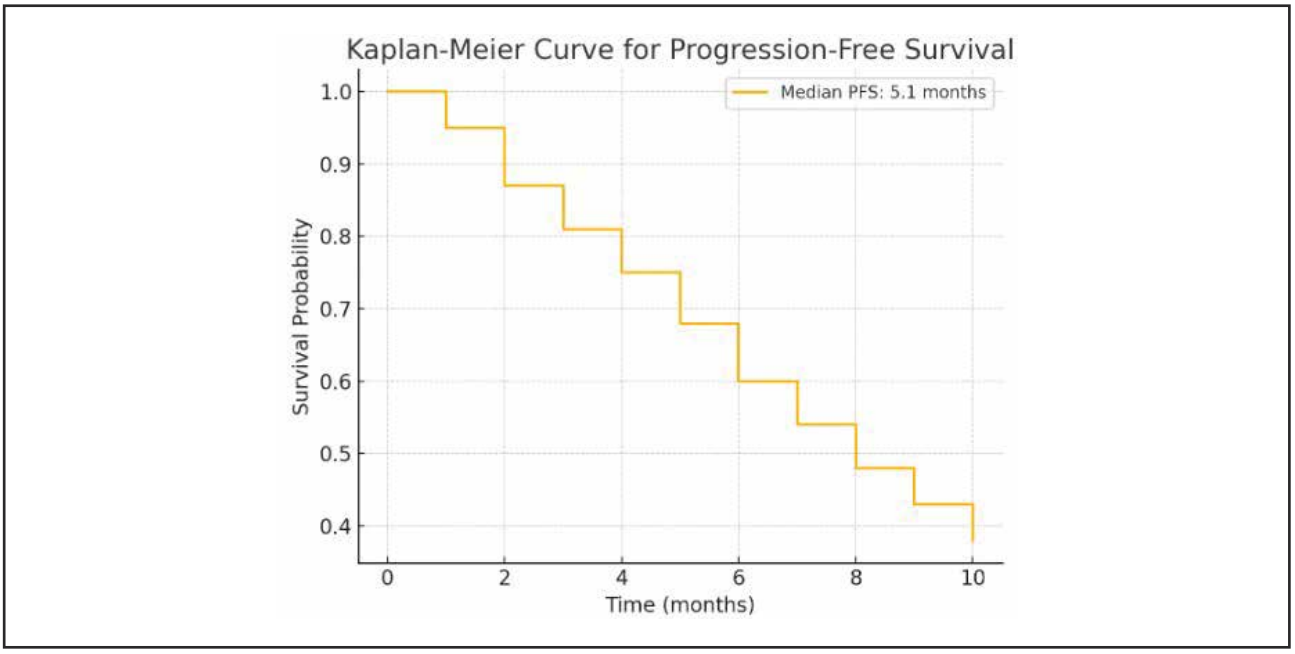


Figure 1. Kaplan–Meier curve showing progression–free survival (PFS) for the study cohort. Median PFS was 5.1 months (95% CI: 4.3–5.9).

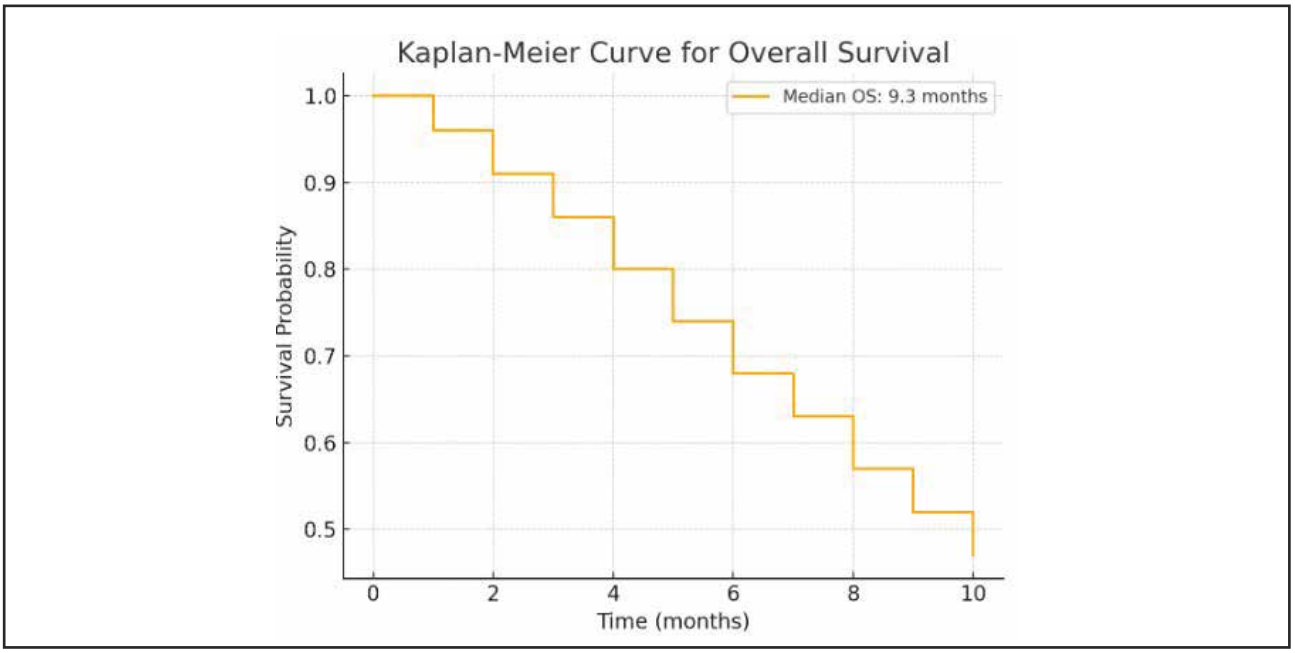


Figure 2. Kaplan–Meier curve depicting overall survival (OS) for the study population. Median OS was 9.3 months (95% CI: 8.1–10.5).

our study align with RAINBOW's ORR of 28% and DCR of 80%, reflecting the consistency of outcomes in both clinical trial and real–world settings.

The REGARD trial, which assessed ramucirumab monotherapy, demonstrated a modest OS benefit of 5.2 months compared to 3.8 months with placebo, establishing its role as a second–line agent.[6] However, its low response rate (3%) highlighted the need for combination strategies, ultimately positioning paclitaxel plus ramucirumab as the preferred second–line approach. Our findings reaffirm this combination's superiority in terms of response and survival benefit.

The subgroup analysis in our study reveals key prognostic indicators, consistent with earlier findings. Patients with ECOG performance status 0–1 had a significantly improved median OS compared to those with ECOG 2, underscoring the influence of functional status on treatment outcomes.[13] Furthermore, patients with a history of prior gastrectomy experienced better outcomes (median OS 10.5 months vs. 7.5 months), which may be attributed to lower tumor burden, improved drug tolerance, or favorable tumor biology.[14]

The safety profile observed in our cohort corroborates global data. Grade 3/4 toxicities such as neutropenia (19%), neuropathy (13%), and hypertension (9%) were within expected ranges and manageable with supportive care and dose adjustments. These findings are consistent with post–marketing surveillance data and real–world experiences in East Asian and Western populations.[8,16] Importantly, no new safety signals emerged, and the incidence of gastrointestinal perforation and proteinuria remained low, reflecting the regimen's favorable risk–benefit balance.[17]

Real–world studies like ours add value by capturing patient heterogeneity, treatment pragmatism, and healthcare system dynamics not always reflected in controlled trials. Our data, derived from a tertiary cancer center in North India, highlight the feasibility of administering this regimen outside of clinical trials, even in resource–constrained environments. In India, where a large proportion of patients pay out–of–pocket for cancer therapy, treatment decisions must account for cost–effectiveness and accessibility. The relatively predictable and manageable toxicity profile of this combination supports its continued use.

While immunotherapy has become an emerging frontier in gastric cancer, with agents like nivolumab and pembrolizumab showing promise in later lines of therapy or biomarker–selected populations, their high cost and limited availability in India currently restrict widespread use.[20] Until broader accessibility is achieved, chemotherapy–based regimens such as paclitaxel and ramucirumab remain critical in the treatment armamentarium.

The strengths of this study include a well–defined cohort, standardized response assessments using RECIST 1.1 criteria, and robust survival analyses. The retro–prospective design enabled comprehensive data capture while maintaining prospective uniformity in treatment and follow–up. Nonetheless, limitations must be acknowledged. These include the single–center design, potential selection bias, absence of biomarker correlation (e.g., VEGF expression, MSI, PD–L1), and limited follow–up beyond the study cut–off.

Future research should focus on prospective, multi–institutional studies evaluating real–world outcomes across diverse Indian populations. Additionally, incorporation of biomarker–driven approaches could optimize patient selection and further personalize therapy. Health economic analyses are also essential to assess cost–benefit ratios, especially with the emergence of biosimilars and evolving insurance landscapes in India.

In conclusion, this study adds to the growing body of evidence validating paclitaxel plus ramucirumab as an effective and safe second–line option in advanced gastric cancer. Its relevance is particularly pronounced in countries like India, where treatment affordability and practicality play pivotal roles in therapeutic decision–making. With favorable survival outcomes and manageable toxicity, this regimen merits continued inclusion in standard–of–care protocols until more accessible, biomarker–guided alternatives become widely available.

Conclusion

Paclitaxel plus ramucirumab is a safe and effective second–line therapy in Indian patients with AGC. Further prospective, multi–center studies are warranted.[19,20]

Conflict of Interest

None declared.

Ethics Approval

Approved by the Institutional Ethics Committee, Rajiv Gandhi Cancer Institute. Patient consent was waived for retrospective data.

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