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Original Research Article

PREOPERATIVE CHEMO-RADIOTHERAPY WITH CAPECITABINE ALONE VERSUS CAPECITABINE PLUS OXALIPLATIN IN LOCALLY ADVANCED RECTAL CANCERS – IMPACT ON ACHIEVING A COMPLETE PATHOLOGICAL RESPONSE

Maddikunta Sandeep Reddy[1], V Naresh Kumar[2], B Shilpa[3], Gooty Sai Heeresh Reddy[4], Bestha Sangeetha[5], Endluri Prudhvi Raj[6]

[1]Assistant Professor, Department of Surgical Oncology, State cancer institute, Kurnool Medical College, Kurnool, India.
[2]Associate Professor, Department of Surgical Oncology, State cancer institute, Kurnool Medical College, Kurnool, India.
[3]Assistant professor, Department of Radio-diagnosis, Santhiram Medical College and General Hospital, Nandyal, India.
[4]Resident, Department of General Surgery, State cancer institute, Kurnool Medical College, Kurnool, India.
[5]Resident, Department of General Surgery, State cancer institute, Kurnool Medical College, Kurnool, India.
[6]Resident, Department of General Surgery, State cancer institute, Kurnool Medical College, Kurnool, India

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Corresponding Author:
Dr. Maddikunta Sandeep Reddy,
Email: sandeepreddy55@gmail.com

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ABSTRACT

Background: Locally advanced rectal cancer (LARC) is commonly managed with neoadjuvant chemo-radiotherapy (NACRT) aimed at tumour downstaging, increasing the likelihood of R0 resection, and improving sphincter preservation. Capecitabine is widely used as a radiosensitizer in this setting. However, the potential benefit of adding Oxaliplatin to standard NACRT in improving pathological complete response (pCR) rates remains controversial, especially considering the associated toxicity burden. **Aim:** To compare the efficacy and safety of standard NACRT with Capecitabine alone versus NACRT with Capecitabine plus Oxaliplatin in achieving complete pathological response in patients with LARC. **Materials and Methods:** This retrospective observational study was conducted at the Department of Surgical Oncology, State Cancer Institute, Kurnool Medical College, Kurnool, over a one-year period from February 2024 to February 2025. A total of 70 patients with LARC meeting eligibility criteria were included. Patients were divided into two groups: one receiving NACRT with Capecitabine alone (Cap arm, n=32) and the other receiving NACRT with Capecitabine plus Oxaliplatin (Capox arm, n=38). Baseline characteristics, pathological complete response rates, R0 resection rates, sphincter preservation rates, and treatment-related toxicity were compared between the groups. **Result:** The two groups were comparable in terms of baseline characteristics including age, gender, performance status, tumour location, and disease staging. Pathological complete response was achieved in 21.88% of patients in the Cap arm and 18.52% in the Capox arm, with no statistically significant difference (p=0.794). R0 resection rates were similar between groups (90.62% Cap arm vs. 92.10% Capox arm, p=0.81), as were sphincter preservation rates (62.50% Cap arm vs. 65.78% Capox arm, p=0.76). Hematological toxicity was significantly higher in the Capox arm (36.84%) compared to the Cap arm (15.62%, p=0.04), and neuropathy was observed exclusively in the Capox arm (28.94%, p<0.001). **Conclusion:** The addition of Oxaliplatin to standard NACRT with Capecitabine does not significantly improve pathological complete response, R0 resection, or sphincter preservation rates in patients with LARC. However, it significantly increases toxicity, particularly hematological complications and neuropathy. Routine use of Oxaliplatin in NACRT should be reserved for carefully selected high-risk patients.

INTRODUCTION

Rectal cancer is a significant global health burden and represents a major subtype of colorectal malignancies. Its management has evolved considerably over the years, particularly in the context of locally advanced rectal cancer (LARC), where achieving local control and reducing distant metastasis remain crucial goals. The introduction of neoadjuvant chemoradiotherapy (NACRT) has played a pivotal role in improving outcomes for these patients by facilitating tumour downstaging, increasing the likelihood of R0 resection, and enhancing sphincter preservation rates. Despite these advances, there remains an ongoing debate regarding the optimal chemotherapeutic regimen to be used concurrently with radiotherapy. Capecitabine, an oral fluoropyrimidine, has become a widely accepted radiosensitizer in the preoperative setting due to its favourable toxicity profile and ease of administration. It effectively mimics continuous infusion 5-fluorouracil (5-FU), offering similar efficacy with better patient convenience. The use of Capecitabine as a single-agent NACRT backbone has yielded encouraging results in terms of tumour response and resectability. However, to further enhance pathological complete response (pCR) rates and long-term survival, several trials have explored the addition of oxaliplatin, a platinum-based chemotherapeutic agent with proven efficacy in colorectal cancer. The rationale behind incorporating oxaliplatin into NACRT regimens stems from its demonstrated synergistic activity with fluoropyrimidines and its potential to increase tumour cell radiosensitivity. Preclinical studies suggested that oxaliplatin may contribute to enhanced local tumour control when combined with capecitabine and radiation therapy. This hypothesis led to the initiation of multiple clinical trials aimed at determining whether the addition of oxaliplatin to standard preoperative chemoradiotherapy could improve key clinical outcomes such as pCR, sphincter preservation, and disease-free survival. Initial studies evaluating this combination produced mixed results. Some trials reported marginal improvements in pCR rates with the addition of oxaliplatin, whereas others showed no statistically significant benefit. Despite the potential theoretical advantages, concerns quickly emerged regarding the increased toxicity profile associated with oxaliplatin, particularly its hematologic side effects and the risk of peripheral neuropathy. These toxicities not only affect patient quality of life but may also compromise treatment compliance and delay definitive surgical management. Achieving a pathological complete response following NACRT is an important prognostic marker, as it has been associated with improved long-term outcomes, including overall survival and local control. However, enhancing pCR rates should not come at the expense of significantly higher toxicity. The challenge in LARC management has therefore been to strike the appropriate balance between treatment efficacy and tolerability. While increasing the intensity of chemotherapy regimens may seem promising, the potential trade-off in terms of patient safety and postoperative recovery cannot be overlooked. Several large-scale studies have attempted to clarify this issue by directly comparing NACRT with capecitabine alone versus NACRT with capecitabine plus oxaliplatin. Some of these studies suggested no significant difference in tumour response or surgical outcomes, while consistently reporting higher rates of treatment-related adverse effects in patients receiving oxaliplatin.[1] Furthermore, retrospective analyses and meta-analyses have echoed similar concerns, emphasizing that the marginal potential benefit of adding oxaliplatin does not convincingly outweigh the risks associated with its toxicity.[2] These studies underscore the importance of individualized patient selection and careful consideration of the potential benefit-to-risk ratio when intensifying preoperative regimens. The global incidence of colorectal cancer, including rectal cancer, continues to rise, particularly in developing countries where lifestyle changes, dietary patterns, and aging populations contribute to the increasing disease burden.[3] In this context, optimizing treatment strategies to achieve better tumour control while maintaining patient safety is a priority. The goal remains to provide curative treatment with the least possible morbidity, maximizing the chance for sphincter preservation and improved quality of life. As colorectal cancer statistics continue to show alarming trends worldwide,[4] including significant prevalence rates in rapidly urbanizing regions,[5] the need for clear, evidence-based treatment guidelines becomes increasingly urgent. The results of prior clinical trials and real-world studies have highlighted the potential of capecitabine-based NACRT as an effective, safe, and patient-friendly treatment approach. Yet, whether the addition of oxaliplatin provides any tangible advantage beyond this standard regimen remains a contentious issue.[6] Recent propensity-matched analyses and randomized controlled trials have reinforced these findings, concluding that although oxaliplatin may have a theoretical role in enhancing tumour response, its clinical benefit in terms of pCR and long-term survival remains debatable[7]. The ongoing question is whether escalating preoperative therapy with oxaliplatin is justified in the routine management of LARC, or whether it should be reserved for specific high-risk patient populations who may derive more substantial benefit from intensified regimens. In light of these controversies, this study aims to further explore the impact of adding oxaliplatin to standard capecitabine-based NACRT in patients with LARC. By comparing pathological response rates, surgical outcomes, and toxicity profiles between these two approaches, this investigation seeks to contribute to the growing body of evidence that informs treatment decisions in this challenging clinical setting. The

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primary objective is to determine whether the addition of oxaliplatin offers a meaningful advantage over capecitabine monotherapy in achieving a complete pathological response, without disproportionately increasing the risk of treatment-related complications.

MATERIALS AND METHODS

The present study is a one-year retrospective observational analysis conducted in the Department of Surgical Oncology, State Cancer Institute, Kurnool Medical College, Kurnool. The study was carried out over a period of one year, from February 2024 to February 2025, and included a total of 70 patients undergoing treatment for locally advanced rectal cancer (LARC). The primary objective was to assess and compare the pathological response to neoadjuvant chemo-radiotherapy (NACRT) using Capecitabine alone versus Capecitabine in combination with Oxaliplatin, with a focus on the rates of complete pathological response.

All patients included in the study were diagnosed with adenocarcinoma of the rectum, with the tumour located within 12 centimeters from the anal verge or accessible by digital rectal examination. Eligible patients had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 and were clinically staged as T3/T4 and/or N-positive with no evidence of distant metastasis (M0) based on radiological and clinical evaluation.

Patients were excluded from the study if they presented with synchronous distant metastases, multicentric disease, a history of previous pelvic malignancy, or if they had undergone prior systemic chemotherapy or pelvic radiotherapy.

This study aimed to provide insight into whether the addition of Oxaliplatin to standard NACRT with Capecitabine offers any significant advantage in achieving complete pathological response in patients with locally advanced rectal cancer.

RESULTS

Table 1: Distribution of Patients by Treatment Groups

The study included a total of 70 patients diagnosed with locally advanced rectal cancer (LARC). These patients were divided into two treatment groups. The first group, comprising 32 patients (45.71%), received neoadjuvant chemo-radiotherapy (NACRT) with Capecitabine alone, referred to as the Cap arm. The second group included 38 patients (54.29%) who received NACRT with Capecitabine combined with Oxaliplatin, referred to as the Capox arm. The slightly higher number of patients in the Capox group was incidental and does not indicate any selection bias, as patients were grouped based on institutional treatment protocols during the study period.

Table 2: Baseline Characteristics of the Study Population

The baseline characteristics of both groups were comparable, indicating that the groups were well-balanced and thus suitable for direct comparison. The mean age of patients was 54.2 ± 8.1 years in the Cap arm and 53.7 ± 7.9 years in the Capox arm, with no statistically significant difference (p=0.78). In terms of gender distribution, 68.75% of the Cap arm and 65.79% of the Capox arm were male (p=0.82), suggesting no significant gender bias between groups.

Performance status, measured by ECOG score, showed that 84.37% of patients in the Cap arm and 86.84% in the Capox arm had an ECOG status of 0-1, indicating good general health status across both groups (p=0.73). The tumour's anatomical distance from the anal verge was within 8 cm in 59.37% of the Cap arm and 57.89% of the Capox arm (p=0.88), reflecting similar tumour locations. Regarding tumour staging, cT4 disease was present in 43.75% of the Cap arm and 44.74% of the Capox arm (p=0.92). Additionally, clinically node-positive disease (cN+) was seen in 71.87% of the Cap arm and 73.68% of the Capox arm (p=0.85). None of these differences were statistically significant, confirming comparable baseline disease severity in both groups.

Table 3: Pathological Complete Response (pCR) Rates

The primary endpoint of the study was to assess the pathological complete response (pCR) after NACRT. In the Cap arm, 7 out of 32 patients (21.88%) achieved pCR, whereas in the Capox arm, 7 out of 38 patients (18.52%) achieved pCR. The difference between the two groups was not statistically significant (p=0.794). The majority of patients in both groups had residual disease upon surgical evaluation, with 78.12% in the Cap arm and 81.48% in the Capox arm showing persistent tumour presence. These results suggest that the addition of Oxaliplatin to Capecitabine-based NACRT did not confer a significant advantage in achieving complete tumour regression.

Table 4: R0 Resection and Sphincter Preservation Rates

R0 resection, defined as complete tumour removal with negative margins, was achieved in 90.62% of patients in the Cap arm and 92.10% of patients in the Capox arm, with no statistically significant difference between groups (p=0.81). Sphincter preservation, an important functional outcome for patients, was achieved in 62.50% of patients in the Cap arm and 65.78% in the Capox arm (p=0.76). These results indicate that the addition of Oxaliplatin did not improve surgical outcomes in terms of complete resection or preservation of the anal sphincter.

Table 5: Toxicity Comparison between Groups

The incidence of adverse events of grade 2 or higher was evaluated to compare treatment-related toxicity. Gastrointestinal toxicity occurred in 25.00% of patients in the Cap arm compared to 39.47% in the Capox arm, though this difference did not reach

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statistical significance (p=0.18). However, hematological toxicity was significantly higher in the Capox arm (36.84%) compared to the Cap arm (15.62%), with a p-value of 0.04, indicating a statistically significant increase in blood-related complications with the addition of Oxaliplatin.

Moreover, neuropathy, a known side effect of Oxaliplatin, was absent in the Cap arm (0.00%) but was observed in 28.94% of patients in the Capox arm, with a highly significant p-value of <0.001. These findings demonstrate that while the addition of Oxaliplatin did not significantly improve oncological outcomes, it did increase treatment-related toxicity, particularly hematological complications and neuropathy.

Table 1: Distribution of Patients by Treatment Groups

Treatment Group	Number of Patients	Percentage (%)
Capecitabine alone (Cap)	32	45.71%
Capecitabine + Oxaliplatin (Capox)	38	54.29%
Total	**70**	**100%**

Table 2: Baseline Characteristics of the Study Population

Characteristic	Cap Arm (n=32)	Capox Arm (n=38)	p-value
Mean Age (years)	54.2 ± 8.1	53.7 ± 7.9	0.78
Gender (Male)	22 (68.75%)	25 (65.79%)	0.82
ECOG 0-1	27 (84.37%)	33 (86.84%)	0.73
Tumour Distance ≤ 8 cm	19 (59.37%)	22 (57.89%)	0.88
cT4 stage	14 (43.75%)	17 (44.74%)	0.92
cN positive	23 (71.87%)	28 (73.68%)	0.85

Table 3: Pathological Complete Response (pCR) Rates

Outcome	Cap Arm (n=32)	Capox Arm (n=38)	p-value
Patients achieving pCR	7 (21.88%)	7 (18.52%)	0.794
Patients with Residual Disease	25 (78.12%)	31 (81.48%)	-

Table 4: R0 Resection and Sphincter Preservation Rates

Surgical Outcome	Cap Arm (n=32)	Capox Arm (n=38)	p-value
R0 Resection Achieved	29 (90.62%)	35 (92.10%)	0.81
Sphincter Preservation Achieved	20 (62.50%)	25 (65.78%)	0.76

Table 5: Toxicity Comparison between Groups

Adverse Events (Grade ≥ 2)	Cap Arm (n=32)	Capox Arm (n=38)	p-value
Gastrointestinal Toxicity	8 (25.00%)	15 (39.47%)	0.18
Hematological Toxicity	5 (15.62%)	14 (36.84%)	0.04*
Neuropathy	0 (0.00%)	11 (28.94%)	<0.001*

DISCUSSION

This retrospective study evaluated the addition of Oxaliplatin to Capecitabine-based neoadjuvant chemoradiotherapy (NACRT) in patients with locally advanced rectal cancer (LARC). The distribution of patients between the Capecitabine (Cap) and Capecitabine plus Oxaliplatin (Capox) arms was nearly balanced, with 32 and 38 patients respectively. Such an even distribution, free from selection bias, reflects institutional treatment patterns similar to those observed by Li et al. (2022),[6] where patients were grouped according to evolving protocols rather than strict randomization, providing real-world insights into treatment efficacy.

Baseline characteristics, including age, gender distribution, ECOG performance status, tumour location, and clinical staging, were comparable between groups. This is consistent with trials such as the German CAO/ARO/AIO-04 by Rödel et al. (2012),[7] and the MOSAIC trial by Andre et al. (2009),[9] where maintaining balanced baseline populations allowed for unbiased comparisons of treatment efficacy. In our study, the mean age was approximately 54 years across both groups, with a male predominance of around 66-69%, and a majority of patients having an ECOG status of 0-1, reflecting good general health. Similar proportions of patients presented with lower rectal tumours and advanced cT4 or cN+ disease, confirming comparable disease severity across both groups.

The primary endpoint, pathological complete response (pCR), was achieved in 21.88% of patients in the Cap arm and 18.52% in the Capox arm, with no statistically significant difference (p=0.794). These findings align with the study by Li et al. (2022),[6] who reported pCR rates of 21.2% for Capecitabine alone and 19.7% for Capecitabine plus Oxaliplatin, suggesting that the addition of Oxaliplatin does not significantly improve tumour regression. Similarly, Dexin (2015),[9] reported pCR rates of 20.8% and 18.3% in Capecitabine and Capox groups, respectively, supporting the notion that Oxaliplatin offers no consistent advantage in terms of pCR. Interestingly, the German CAO/ARO/AIO-04 trial by Rödel et al. (2012),[7] demonstrated a modest increase in pCR with Oxaliplatin addition (17% versus 13%), but this did not translate into substantial

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clinical benefit across all patient groups. Our findings add to this growing body of evidence, highlighting the limited impact of Oxaliplatin on complete pathological response.

Surgical outcomes, including R0 resection and sphincter preservation rates, are critical indicators of treatment success. In our study, R0 resection was achieved in 90.62% of Cap arm patients and 92.10% of Capox arm patients, with no significant difference (p=0.81). These high resection rates are consistent with international benchmarks reported by Sauer et al. (2004),[10] and van Gijn et al. (2011),[11] where optimized NACRT protocols resulted in R0 resections exceeding 90%. Sphincter preservation rates in our study were 62.50% in the Cap arm and 65.78% in the Capox arm (p=0.76), similar to findings from Frykholm et al. (1993),[12] and Gerard (1994)[13], who emphasized that tumour location and surgical expertise are primary determinants of sphincter preservation rather than chemotherapy intensification. Furthermore, Saif et al. (2008),[14] demonstrated favourable downstaging and sphincter preservation with Capecitabine alone, aligning with our results that did not show additional benefits from Oxaliplatin.

Toxicity outcomes revealed important differences between the groups. Gastrointestinal toxicity of grade 2 or higher occurred in 25.00% of Cap arm patients and 39.47% of Capox arm patients, although this difference was not statistically significant (p=0.18). These findings align with observations by Kim et al. (2007),[15] who reported increased gastrointestinal side effects with Oxaliplatin-based regimens, albeit without significant oncological advantage.

More notably, hematological toxicity of grade 2 or higher was significantly higher in the Capox arm at 36.84%, compared to 15.62% in the Cap arm (p=0.04). This mirrors the results from Yothers et al. (2011),[16] who reported an increased incidence of hematological complications in Oxaliplatin-containing regimens, raising concerns about the added toxicity burden. Moreover, peripheral neuropathy, a hallmark side effect of Oxaliplatin, was absent in the Cap arm but present in 28.94% of Capox arm patients (p<0.001), underscoring the well-established neurotoxicity risk associated with Oxaliplatin as described by Andre et al. (2009),[17] and Dexin (2015).[18]

The overall findings of our study are consistent with several international studies, suggesting that while Oxaliplatin may offer theoretical synergistic benefits when combined with Capecitabine, these benefits do not consistently translate into improved tumour regression, surgical outcomes, or sphincter preservation. Conversely, the addition of Oxaliplatin results in a significant increase in hematological toxicity and neuropathy, which can adversely affect patient quality of life and treatment compliance.

Considering the global burden of colorectal cancer, particularly in regions like China and other parts of Asia as reported by Zheng et al. (2019) and Siegel et al. (2020), the need for effective yet tolerable treatment regimens remains paramount. Our results support the selective use of Oxaliplatin in LARC, suggesting that Capecitabine-based NACRT remains an effective standard of care for many patients, with Oxaliplatin reserved for specific high-risk scenarios where the potential benefits justify the increased toxicity.

CONCLUSION

The addition of Oxaliplatin to standard NACRT does not provide a statistically significant advantage over standard NACRT alone in terms of pathological complete response, sphincter preservation, or R0 resection rates. However, its inclusion is associated with increased toxicity, particularly hematological side effects and neuropathy. Therefore, routine use of Oxaliplatin in NACRT for LARC should be carefully considered and reserved for selected high-risk cases.

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