

## Original Research Article

# Post treatment outcome and quality of life in patients with inoperable advanced gastric carcinoma

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## ABSTRACT

**Background:** The outcome of treatment for advanced gastric carcinoma can vary depending on a number of factors, including the stage and aggressiveness of the cancer, the patient's overall health, and their response to treatment. In general, the prognosis is poor, with a median overall survival of less than one year. Quality of life (QOL) is an important consideration for patients with advanced gastric carcinoma, as they may experience a range of symptoms such as pain, fatigue, and difficulty eating. This study aimed to evaluate the post-treatment outcomes and QOL in patients with inoperable advanced gastric carcinoma after treatment with cisplatin-capecitabine and with oxaliplatin-capecitabine.

**Methods:** This Quasi-experimental study was conducted at the department of oncology, Bangabandhu Sheikh Mujib medical university, Dhaka, Bangladesh. The study duration was 1 year, from February 2021 to March 2022. During this period, a total of 64 cases of advanced gastric cancer were divided in two equal groups, arm A who had received cisplatin capecitabine, and arm B who received oxaliplatin capecitabine.

**Result:** The mean age at diagnosis was 55.85 and 56.76 respectively. The majority of the patients, 43.8% in arm A and 50% in arm B, ranged in age from 61 to 70. The gender distribution was similar, 78% and 69% of patients in arm A and B respectively were male. Both groups had the majority of patients receiving an ECOG performance rating of 2, with 68.8% in arm A and 59.4% in arm B, and the liver being the most common metastatic site for 56.3% in arm A and 50.0% in arm B. The most frequent risk factor was *Helicobacter pylori* infection, observed in 68.8% of arm A and 78.1% of arm B. The most common primary tumor site was the antrum, with 50% and 53.1% patients in arm A and B respectively had the primary tumor in the antrum of the stomach.

**Conclusions:** In inoperable advanced gastric cancer, the cisplatin-capecitabine regimen is equally effective as oxaliplatin-capecitabine in terms of disease outcome. Furthermore, the cisplatin-capecitabine regimen is less costly than the combination of oxaliplatin-capecitabine, and provides almost similar QOL. As a result, the cisplatin-capecitabine regimen could be utilized as an alternate choice in patients who are unable to afford an oxaliplatin-based regimen.

**Keywords:** Carcinoma, Gastric, Capecitabine, Oxaliplatin, Cisplatin

## INTRODUCTION

Cancer is the leading cause of death in many countries of the world, and globally is among the top 5 causes of death.<sup>1</sup> Among the different types of cancer, gastric cancer remains as one of the more prevalent and deadly types of cancer, being the 4<sup>th</sup> most common cancer among men and the 7<sup>th</sup> most common cancer among women.<sup>2,3</sup> Gastric cancer has extremely high mortality, as the 5-year survival rate is <40%, and just in 2020, almost a million deaths were observed worldwide.<sup>4,5</sup> Stomach adenocarcinoma is referred to as "gastric cancer." Adenocarcinoma makes up about 95% of all cases of stomach cancer.<sup>6</sup> Inoperable advanced gastric cancer (AGC) is a stage of the disease in which the tumor is too large or has spread too widely for surgical resection to be a viable treatment option. In these cases, the goal of treatment is to manage symptoms, improve QOL, and prolong survival as much as possible. In recent years, there has been a growing focus on understanding the post-treatment outcomes and QOL in patients with IAGC. Researchers have studied various aspects of QOL, including physical symptoms, emotional well-being, social functioning, and overall survival. Studies have observed that while chemotherapy improved overall survival in patients with IAGC, it also led to significant declines in QOL.<sup>7,8</sup> Patients reported significant reductions in physical functioning, emotional well-being, and social functioning in such studies. Cisplatin-capecitabine and oxaliplatin-capecitabine are two widely used chemotherapy regimens in the treatment of IAGC, yet the post-treatment outcomes and QOL in patients treated with these regimens have not been fully evaluated.<sup>9</sup> Research on the post-treatment outcomes and QOL of patients treated with these regimens is limited, but a recent study found that the combination of oxaliplatin-capecitabine was associated with better QOL outcomes compared to patients treated with cisplatin and capecitabine.<sup>10</sup> The study also reported that the combination of oxaliplatin and capecitabine was associated with better survival outcomes compared to cisplatin and capecitabine.<sup>10</sup> It is important to note, however, that these studies have limitations and more research is needed to confirm these findings and understand the impact of these regimens on post-treatment outcomes and QOL. Furthermore, factors such as individual patient characteristics, comorbidities, and overall health status play a crucial role in determining the most appropriate treatment approach and monitoring treatment outcomes and QOL. So, the present study was conducted with the aim of observing and comparing the post-operative QOL among inoperable advanced gastric carcinoma patients, after treatment with both of the mentioned methods.

### Objective

Objectives were to observe the response status of patients of advanced gastric carcinoma after treatment with cisplatin-capecitabine vs with oxaliplatin capecitabine, to

observe the post-operative QOL among patients of advanced gastric carcinoma after treatment with cisplatin-capecitabine vs with oxaliplatin capecitabine.

## METHODS

This Quasi-experimental study was conducted at the department of oncology, Bangabandhu Sheikh Mujib medical university, Dhaka, Bangladesh. The study duration was 1 year, from February 2021 to March 2022. During this period, a total of 64 patients with inoperable advanced gastric carcinoma attending the department of clinical oncology, BSMMU, following the inclusion and exclusion criteria were selected for the study. The selected patients were divided in two equal groups of 32 patients each, "arm A" and "arm B". Arm A patients got injection Cisplatin (80 mg/m<sup>2</sup> IV on day 1) plus oral capecitabine (1000 mg/m<sup>2</sup> twice a day on days 1-14) every 3 weeks for 6 cycles. Arm B patients got injection oxaliplatin (130 mg/m<sup>2</sup> IV on day 1) plus oral capecitabine (1000 mg/m<sup>2</sup> twice a day on days 1-14) every 3 weeks for 6 cycles. Before inclusion of the patients in the study, informed written consent was obtained from each participant, and ethical approval regarding the study was also obtained from the ethical review committee of the institution. Patient's refusal to continue in this study and occurrence of unacceptable toxicity necessitating major modification of treatment were grounds for discontinuation of the study for that particular patient. Patients' quality of life was measured using the ECOG performance status scale. A structured data collection form was used as the research instrument, and all collected data was analyzed using SPSS software. A p value of less than 0.05 was considered significant when comparing the results of the two arms using the Chi-square test.

### Inclusion criteria

Patients ≤70 years of age, histo-pathologically proven inoperable advanced gastric adenocarcinoma, stage IV adenocarcinoma only, patients who had given consent to participate in the study were included in the study.

### Exclusion criteria

Patients <18 years of age, patients with A structured data collection form was used as the research instrument >2, patients with a history of chemotherapy, radiotherapy or surgery, pregnant or lactating women, unable to answer the criteria question and exclude those affected with other chronic diseases were excluded.

## RESULTS

In arm A and arm B, the patients' mean ages at diagnosis were 55.85 and 56.76, respectively. The majority of the patients ranged in age from 61 to 70. Arm A had 78% male patients, compared to arm B's 69% male patients, in terms of gender. In both arms, the majority of patients

received an ECOG performance rating of 2. (68.8% in arm A and 59.4% in arm B). The liver was the most common metastatic site in both arms (56.3% in arm A and 50% in arm B). The pyloric antrum was the most frequent site of initial tumors. The most frequent risk factor in both arms was *Helicobacter pylori* infection (68.8% in arm A and 78.1% in arm B).

**Table 1: Distribution of the participants by basic characteristics.**

Characteristics	Arm A, (n=32) (%)	Arm B, (n=32) (%)
<b>Age groups (years)</b>		
18-30	02 (06.3)	01 (03.1)
31-40	03 (09.4)	02 (06.3)
41-50	06 (18.7)	05 (15.6)
51-60	07 (21.9)	08 (25)
61-70	14 (43.8)	16 (50)
<b>Sex</b>		
Male	25 (78)	22 (69)
Female	07 (22)	10 (31)
<b>Site of metastasis</b>		
Lung	04 (12.5)	03 (09.4)
Liver	18 (56.3)	16 (50)
Peritoneum	11 (34.4)	13 (40.6)
Ovary	03 (09.4)	02 (06.3)
<b>ECOG performance</b>		
0	03 (09.4)	05 (15.6)
1	07 (21.9)	08 (25)
2	22 (68.8)	19 (59.4)
<b>Site of primary tumor</b>		
Fundus	06 (18.7)	04 (12.5)
Antrum	16 (50)	17 (53.1)
Body	10 (31.3)	11 (34.4)
<b>Risk factors</b>		
<i>H. pylori</i>	22 (68.8)	25 (78.1)
Smoking	10 (31.3)	13 (40.6)
Type A blood	13 (40.6)	11 (34.4)

**Table 2: Distribution of participants by pre-treatment disease characteristics.**

Disease characteristics	Arm A, (n=32) (%)	Arm B, (n=32) (%)
<b>Site of metastasis</b>		
Lung	04 (12.5)	03 (9.4)
Liver	18 (56.3)	16 (50)
Peritoneum	11 (34.4)	13 (40.6)
Ovary	03 (9.4)	02 (6.3)
<b>Site of primary tumor</b>		
Fundus	06 (18.7)	04 (12.5)
Antrum	16 (50)	17 (53.1)
Body	10 (31.3)	11 (34.4)
<b>ECOG performance</b>		
0	03 (9.4)	05 (15.6)
1	07 (21.9)	08 (25)
2	22 (68.8)	19 (59.4)

In terms of pre-operative disease characteristics, the most common metastatic site was liver in both arms (56.3% in arm A and 50% in arm B). The most common primary tumor site is the antrum. 50% and 53.1% patients from arm A and B respectively had the primary tumor in the antrum of the stomach. Most of the patients in both arms belong to ECOG performance status 2(68.8% in arm A and 59.4% in arm B). The second most common is ECOG performance status 1. Only 9.4% patients in arm A and 15.6% patients in arm B were in ECOG performance status 0.

**Table 3: Treatment responses after the completion of treatment for both arm A and arm B.**

Response	Arm A, (n=32) (%)	Arm B, (n=32) (%)	P value
<b>Partial response (PR)</b>	18 (56.3)	15 (46.9)	0.751
<b>Stable disease (SD)</b>	06 (18.8)	07 (21.9)	
<b>Progressive disease (PD)</b>	08 (25)	10 (31.3)	

In arm A, 18 (56.3%) patients had a partial response (PR), while 15 (46.9%) patients in arm B had a PR. In both groups, stable diseases (SD) were also detected (18.8% in arm A and 21.9% in arm B). There were 8 (25%) cases of progressive disease (PD) in arm A and 10 (31.3%) cases of PD in arm B.

**Table 4: Distribution of post-treatment quality of life among participants.**

ECOG performance status	Arm A, (n=32) (%)	Arm B, (n=32) (%)	P value
<b>ECOG 0</b>	06 (18.8)	08 (25)	0.774
<b>ECOG 1</b>	14 (43.8)	11 (34.4)	
<b>ECOG 2</b>	08 (25)	07 (21.9)	
<b>ECOG 3</b>	04 (12.5)	06 (18.8)	

Among the participants, 08 (25.0%) patients in arm A and 07 (21.9%) patients in arm B had ECOG 2 at post-operative final follow-up. Four (12.5%) patients in arm A and 06 (18.8%) patients in arm B had ECOG 3. These differences were not statistically significant between two groups (p=0.774).

**DISCUSSION**

Systemic chemotherapy is the cornerstone of advanced gastric cancer treatment. A total of 64 patients with histopathologically verified advanced stomach cancer were enrolled in the current study for therapy, and the patients were separated into two equal groups of 32 patients. For the treatment of advanced gastric cancer, arm A patients received cisplatin-capecitabine, while arm B patients received oxaliplatin-capecitabine. In terms of

basic features, it was discovered that very few participants were under the age of 50, with the majority of participants falling between the ages of 61 and 70. (43.8% in arm A and 50% in arm B). Although the underlying cause has yet to be discovered, previous research has found a high prevalence of stomach cancer among the elderly, which is consistent with our findings.<sup>11</sup> The study population had a high male preponderance, with an overall male: female ratio of 1.36:1. This high incidence of stomach cancer cases among men was not unusual, as several studies found it to be more than twice as common as in the female population.<sup>12,13</sup> The current study did not include any patients with an ECOG score of more than 2. Among the existing participants, 68.8% of arm A and 59.4% of arm B were from ECOG scale 2, whereas 21.9% of arm A and 25% of arm B were ECOG scale 1 at the time of admission in the study. The antrum was the predominant tumor location in both arms, with 50% in arm A and 53.1% in arm B. The largest prevalence was seen in terms of body tumor, which was observed in 31.3% of arm A and 34.4% of arm B. Among the visible risk variables, *Helicobacter pylori* infection was found in 68.8% of arm A individuals and 78.1% of arm B participants. Smoking and type A blood were also common among the subjects. Type A blood had a little higher prevalence than smoking among arm A subjects, however the situation was inverted in arm B. Many other research has found that *H. Pylori* infection is a prevalent risk factor for stomach cancer.<sup>14-16</sup> The disease characteristics of the patients did not have much different between the 2 groups, as majority of both groups had metastasis in the liver area, and the primary tumor was in antrum for over half the participants of both arms. Antrum was the most common site of tumor in other studies as well.<sup>17</sup> During the treatment period and after treatment, patients were assessed to see the treatment responses. The final assessment was done after the completion of treatment, at the 12<sup>th</sup> week. In arm A, 18 (56.3%) patients showed partial response (PR) and in arm B, PR was observed in 15 (46.9%) patients. Stable diseases (SD) were also observed in both arms (18.8% in arm A and 21.9% in arm B). There were 08 (25.0%) progressive disease (PD) in arm A and 10 (31.3%) PD in arm B. The difference of treatment response between the two groups was not statistically significant. These findings were similar to and supported by other studies as well.<sup>17</sup> At post-operative final follow-up, the majority of patients in both groups (43.8% in arm A and 34.4% in arm B) had a performance status of ECOG 1, indicating that they were able to carry on all pre-disease performance without restriction. 25% of patients in arm A and 21.9% of patients in arm B had a performance status of ECOG 2, indicating that they were able to carry on only light activity, and unable to carry out any work activities. 12.5% of patients in arm A and 18.8% of patients in arm B had a performance status of ECOG 3, indicating that they were able to carry on only limited self-care and unable to carry out any work activities. This was a

comparatively better outcome compared to some studies with chemotherapy as the treatment method.<sup>18</sup>

### Limitations

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

### CONCLUSION

The present study findings can conclude that cisplatin-capecitabine was as well tolerated as oxaliplatin-capecitabine. Both regimens had a similar safety profile and post-operative quality of life.

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