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Original Research Article

Evaluating the toxicity of capecitabine-cisplatin versus gemcitabine-cisplatin regimens for palliative chemotherapy in advanced biliary tract carcinoma

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ABSTRACT

Background: Advanced biliary tract carcinoma is a malignancy associated with poor prognosis and limited treatment options. This study aimed to compare the treatment effects in terms of toxicities of Capecitabine-Cisplatin and Gemcitabine-Cisplatin regimens as palliative chemotherapy for ABTC in Bangladesh.
Methods: This quasi-experimental study was conducted at the Department of Oncology, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh, involving 78 patients with histopathologically confirmed ABTC (AJCC Stage IV). Participants were divided into two groups: Arm-A received Capecitabine-Cisplatin, and Arm-B received Gemcitabine-Cisplatin. Treatment response, hematological and non-hematological toxicities were assessed and compared between the two groups.
Results: No significant differences in baseline demographic and clinical characteristics were observed between the two groups. Arm-A demonstrated a higher rate of partial response in the final assessment (51.28% vs. 41.03%, p=0.029). Acute hematological toxicities were more frequent in Arm-B, with a higher incidence of Grade 2 and 3 anemia, neutropenia, and leukopenia ($p<0.05$). Non-hematological toxicities were comparable, except for Hand-Foot Syndrome, which was significantly higher in Arm-A (p=0.03).
Conclusions: The Capecitabine-Cisplatin regimen exhibited a different toxicity profile compared to the Gemcitabine-Cisplatin regimen for palliative chemotherapy in advanced biliary tract carcinoma. While both regimens were generally well-tolerated, the Capecitabine-Cisplatin regimen demonstrated lower incidences of hematological toxicities. These findings emphasize the importance of considering toxicity profiles when selecting treatment options for patients with advanced biliary tract carcinoma.

Keywords: Carcinoma, Biliary, Gemcitabine, Capecitabine, Cisplatin, Efficacy

INTRODUCTION

Biliary tract carcinoma, comprising cancers of the gallbladder and the intrahepatic and extrahepatic bile ducts, is a rare but aggressive malignancy with a poor prognosis. Globally, the incidence of biliary tract cancer is relatively low, accounting for approximately 3% of all gastrointestinal cancers.[1] However, the disease burden

varies considerably by geographic region. South American and Asian countries, including Bangladesh, have higher rates of biliary tract carcinoma compared to Western countries.[2] In Bangladesh, the age-standardized incidence rate of gallbladder cancer is 3.9 per 100,000 in women and 1.8 per 100,000 in men, while the age-standardized incidence rate of intrahepatic and extrahepatic bile duct cancer is 0.9 per 100,000 in women and 1.1 per 100,000 in men.[3]

Advanced biliary tract carcinoma is typically diagnosed at a late stage due to the lack of specific symptoms in the early stages, making curative surgical interventions less feasible.[4] Consequently, palliative chemotherapy has emerged as the mainstay of treatment for patients with advanced biliary tract carcinoma, aiming to control tumor growth, relieve symptoms, and improve quality of life. The combination of gemcitabine and cisplatin (Gem-Cis) has been widely adopted as a standard first-line chemotherapy regimen, following the positive results of the phase III ABC-02 trial, which demonstrated a significant improvement in overall survival with Gem-Cis compared to gemcitabine alone.[5] However, in resource-limited settings such as Bangladesh, access to gemcitabine may be limited due to its higher cost, necessitating the evaluation of alternative regimens. Capecitabine, an oral fluoropyrimidine, has shown activity against biliary tract carcinoma when combined with cisplatin (Cape-Cis).[6] This combination has been investigated in several clinical trials, which have reported promising outcomes in terms of response rates, progression-free survival, and overall survival, comparable to those achieved with Gem-Cis.[7] Additionally, the oral administration of capecitabine may offer advantages in terms of convenience and reduced healthcare resource utilization compared to intravenous gemcitabine. However, the comparative efficacy of the Cape-Cis and Gem-Cis regimens in the treatment of advanced biliary tract carcinoma has not been thoroughly investigated, particularly in the context of a Bangladeshi population.

A potential counterargument to the use of Cape-Cis as an alternative to Gem-Cis is the concern of increased gastrointestinal toxicities associated with capecitabine, including diarrhea, hand-foot syndrome, and mucositis.[8] However, studies have shown that these toxicities can be effectively managed with dose adjustments and appropriate supportive care.[9] Furthermore, the potential benefits of improved availability, reduced healthcare resource utilization, and increased patient convenience offered by the oral administration of capecitabine should not be overlooked. The primary objective of this study is to compare the toxicities between Cape-Cis and Gem-Cis regimens in Bangladeshi patients with advanced biliary tract carcinoma. This comparison will provide valuable insights into the clinical effectiveness of both regimens and inform the selection of the most appropriate chemotherapy option in this population.

METHODS

This quasi-experimental study took place at the department of oncology, Bangabandhu Sheikh Mujib medical university (BSMMU), Dhaka, Bangladesh, over an 18-month period from January 2018 to June 2019. The study included 78 patients with advanced biliary tract carcinoma (Stage IV) who were attending the Outpatient Department or admitted to the oncology ward at BSMMU during the study period. Patients were selected based on the specified inclusion and exclusion criteria, and informed consent was obtained from each participant before data collection. Ethical approval for the study was granted by the hospital's ethical review committee. The 78 patients were divided into two equal groups, or arms. Arm A consisted of 39 patients who received oral capecitabine (1250 mg/m^2 twice daily on days 1–14) plus cisplatin (60 mg/^{2}, 2-hour infusion with proper hydration on day 2) every three weeks for six cycles. Arm B consisted of 39 patients who received gemcitabine (1250 mg/m^2, 30-minute infusion on days 1 and 8) plus cisplatin (75 mg/m^2, 2-hour infusion with proper hydration on day 1) every three weeks for six cycles. Data were collected through individual interviews using a prescribed data sheet. The data for each arm were tabulated separately and then checked, edited, and coded manually. Data analysis was performed in accordance with the study objectives, utilizing the SPSS (Statistical Package for Social Science) software program for Windows, Version 24.0. Statistical tests, including the Chi-square test, Fisher's exact test, and t-test, were applied where appropriate. A p value of less than 0.05 was considered statistically significant.

RESULTS

In Arm A (N=39), the age distribution was as follows: 2.56% were aged 30-39, 35.89% were aged 40-49, 38.47% were aged 50-59, and 23.08% were aged 60-70. In Arm B (N=39), the age distribution was 2.56% for 30-39, 20.51% for 40-49, 56.42% for 50-59, and 20.51% for 60-70. The mean age was 51±8.2 years in Arm A and 53±8.2 years in Arm B. Regarding gender, 53.85% of participants in Arm A were male, and 46.15% were female. In Arm B, 74.36% were male, and 25.64% were female. In terms of socioeconomic group, Arm A consisted of 28.20% low-class, 51.29% middle-class, and 20.51% high-class participants, while Arm B had 12.83% low-class, 56.41% middle-class, and 30.76% high-class participants. For primary tumor site, 53.85% of patients in Arm A had gallbladder cancer, 35.89% had cholangiocarcinoma, and 10.26% had periampullary cancer. In Arm B, the distribution was 43.59% for gallbladder cancer, 43.58% for cholangiocarcinoma, and 12.83% for periampullary cancer. The metastasis sites were similar in both arms, with 66.66% of patients in both groups having liver metastases, 46.15% in Arm A and 43.59% in Arm B having peritoneal metastases, and 17.94% in both arms having lung metastases.

Table 1: Distribution of baseline demographic characteristics among participants of both arms (n=78).

Variables	Arm-A (N=39)		Arm-B (N=39)	
	N	%	N	%
Age (years)				
30-39	1	2.56	1	2.56
40-49	14	35.89	8	20.51
50-59	15	38.47	22	56.42
60-70	9	23.08	8	20.51
Mean age	51±8.2		53±8.2	
Gender				
Male	21	53.85	29	74.36
Female	18	46.15	10	25.64
Socioeconomic group (taka/month)				
Low class (<12,260)	11	28.20	5	12.83
Middle class (12,260-31,640)	20	51.29	22	56.41
High class (>31,460)	8	20.51	12	30.76
Primary tumor site				
Gallbladder	21	53.85	17	43.59
Cholangio-carcinoma	14	35.89	17	43.58
Periampullary	4	10.26	5	12.83
Metastasis Site				
Liver	26	66.66	26	66.66
Peritoneum	18	46.15	17	43.59
Lung	7	17.94	7	17.94

In Arm A (N=39), 51.28% of participants reported smoking as a risk factor, 35.89% had a history of chronic infection, 48.71% had gallstones, and 7.69% reported a lack of vegetables in their diet. In Arm B (N=39), the distribution of risk factors was as follows: 58.98% for smoking, 43.58% for chronic infection, 64.10% for gallstones, and 7.69% for a lack of vegetables in the diet.

Table 2: Distribution of risk factors among participants of both arms (n=78).

Risk factors	Arm-A (N=39)		Arm-B (N=39)	
	N	%	N	%
Smoking	20	51.28	23	58.98
Chronic infection	14	35.89	17	43.58
Gallstone	19	48.71	25	64.10
Lack of vegetables	3	7.69	3	7.69

In Arm A (N=39), anemia was observed in varying degrees: 43.59% of participants had Grade 0, 41.03% had Grade 1, 12.82% had Grade 2, and 2.56% had Grade 3. In Arm B (N=39), the distribution was 12.82% for Grade 0, 51.28% for Grade 1, 28.21% for Grade 2, and 7.69% for Grade 3. The p-value for anemia was 0.016, indicating a statistically significant difference between the two arms. Regarding neutropenia, 51.28% of participants in Arm A had Grade 0, 25.64% had Grade 1, 20.51% had Grade 2, and 2.56% had Grade 3. In Arm B, the distribution was 17.95% for Grade 0, 41.03% for Grade 1, 30.77% for Grade 2, and 10.26% for Grade 3. The p value for neutropenia was 0.016, also showing a statistically significant difference between the two arms. For leukopenia, 46.15% of participants in Arm A, experienced Grade 0, 38.46% had Grade 1, 12.82% had Grade 2, and 2.56% had Grade 3. In Arm B, the distribution was 20.51% for Grade 0, 30.77% for Grade 1, 38.46% for Grade 2, and 10.26% for Grade 3. The p value for leukopenia was 0.011, indicating a statistically significant difference between the arms in terms of this hematological toxicity.

Table 3: Distribution of acute hematological toxicities in both arms (n=78).

Hematological toxicities	Arm-A (N=39)		Arm-B (N=39)		P value
	N	%	N	%	
Anemia					
Grade 0	17	43.59	5	12.82	0.016
Grade 1	16	41.03	20	51.28	
Grade 2	5	12.82	11	28.21	
Grade 3	1	2.56	3	7.69	
Neutropenia					
Grade 0	20	51.28	7	17.95	0.016
Grade 1	10	25.64	16	41.03	
Grade 2	8	20.51	12	30.77	
Grade 3	1	2.56	4	10.26	
Leukopenia					
Grade 0	18	46.15	8	20.51	0.011
Grade 1	15	38.46	12	30.77	
Grade 2	5	12.82	15	38.46	
Grade 3	1	2.56	4	10.26	

In Arm A (N=39) and Arm B (N=39), the occurrence of nausea was as follows: Grade 0 (30.77% vs. 25.64%), Grade 1 (38.46% vs. 51.28%), Grade 2 (25.64% vs. 15.38%), and Grade 3 (5.13% vs. 7.69%). The p value for nausea was 0.55, indicating no significant difference between the two arms. For vomiting, the distribution in Arm A and Arm B was: Grade 0 (30.77% vs. 25.64%), Grade 1 (33.33% vs. 46.15%), Grade 2 (28.21% vs. 20.51%), and Grade 3 (7.69% vs. 7.69%). The p value for vomiting was 0.69, showing no significant difference between the arms. Regarding diarrhea, the distribution in Arm A and Arm B was: Grade 0 (58.97% vs 64.10%), Grade 1 (25.64% vs 28.21%), Grade 2 (10.26% vs. 5.13%), and Grade 3 (0% vs. 2.56%). The p value for diarrhea was 0.76, indicating no significant difference between the arms. For anorexia, the distribution in Arm A and Arm B was: Grade 0 (2.56% vs. 7.69%), Grade 1 (64.10% vs. 53.85%), and Grade 2 (33.33% vs. 38.46%). The p value for anorexia was 0.47, showing no significant difference between the arms. In terms of paresthesia, the distribution in Arm A and Arm B was:

Grade 0 (64.10% vs. 66.67%), Grade 1 (20.51% vs. 28.21%), and Grade 2 (15.38% vs. 5.13%).

Table 4: Distribution of acute non-hematological toxicities in both arms (n=78).

Non-hematological toxicities	Arm-A (N=39)		Arm-B (N=39)		P value
	N	%	N	%	
Nausea					
Grade 0	12	30.77	10	25.64	0.55
Grade 1	15	38.46	20	51.28	
Grade 2	10	25.64	6	15.38	
Grade 3	2	5.13	3	7.69	
Vomiting					
Grade 0	12	30.77	10	25.64	0.69
Grade 1	13	33.33	18	46.15	
Grade 2	11	28.21	8	20.51	
Grade 3	3	7.69	3	7.69	
Diarrhoea					
Grade 0	23	58.97	25	64.10	0.76
Grade 1	10	25.64	11	28.21	
Grade 2	4	10.26	2	5.13	
Grade 3	2	5.13	1	2.56	
Anorexia					
Grade 0	1	2.56	3	7.69	0.47
Grade 1	25	64.10	21	53.85	
Grade 2	13	33.33	15	38.46	
Paresthesia					
Grade 0	25	64.10	26	66.67	0.287
Grade 1	8	20.51	11	28.21	
Grade 2	6	15.38	2	5.13	
Oral mucositis					
Grade 0	32	82.05	30	76.92	0.58
Grade 1	5	12.82	8	20.51	
Grade 2	2	5.13	1	2.56	
Fatigue/flu like symptoms					
Grade 0	25	64.10	23	58.97	0.87
Grade 1	10	25.64	12	30.77	
Grade 2	4	10.26	4	10.26	
Hand-foot syndrome					
Grade 0	24	61.54	35	89.74	0.03
Grade 1	8	20.51	2	5.13	
Grade 2	5	12.82	1	2.56	
Grade 3	2	5.13	1	2.56	

The p value for paresthesia was 0.287, indicating no significant difference between the arms. For oral mucositis, the distribution in Arm A and Arm B was: Grade 0 (82.05% vs. 76.92%), Grade 1 (12.82% vs. 20.51%), and Grade 2 (5.13% vs. 2.56%). The p value for oral mucositis was 0.58, showing no significant difference between the arms. Regarding fatigue/flu-like symptoms, the distribution in Arm A and Arm B was: Grade 0 (64.10% vs. 58.97%), Grade 1 (25.64% vs. 30.77%), and Grade 2 (10.26% vs. 10.26%). The p value for fatigue/flu-like symptoms was 0.87, indicating no significant difference between the arms. Finally, for hand-foot syndrome, the distribution in Arm A and Arm B was: Grade 0 (61.54% vs. 89.74%), Grade 1 (20.51% vs. 5.13%), Grade 2 (12.82% vs. 2.56%), and Grade 3 (5.13% vs. 2.56%). The p value for hand-foot syndrome was 0.03, demonstrating a statistically significant difference between the two arms.

Table 5: Distribution of treatment response at different assessments among participants of both arms (n=78).

Treatment response	Arm-A (N=39)		Arm-B (N=39)		P value
	N	%	N	%	
1st assessment					
Partial response	1	2.56	2	5.13	0.85
Stable disease	37	94.87	36	92.31	
Progressive disease	1	2.56	1	2.56	
2nd assessment					
Partial response	9	23.08	9	23.08	0.83
Stable disease	22	56.41	24	61.54	
Progressive disease	8	20.51	6	15.38	
3rd (final) assessment					
Partial response	20	51.28	16	41.03	0.029
Stable disease	14	35.90	8	20.51	
Progressive disease	5	12.82	15	38.46	

In the first assessment, Arm A (N=39) and Arm B (N=39) showed the following treatment responses: partial response (2.56% vs. 5.13%), stable disease (94.87% vs. 92.31%), and progressive disease (2.56% vs. 2.56%). The p value for the first assessment was 0.85, indicating no significant difference between the two arms. In the second assessment, the distribution of treatment responses in Arm A and Arm B was as follows: partial response (23.08% vs. 23.08%), stable disease (56.41% vs. 61.54%), and progressive disease (20.51% vs. 15.38%). The p value for the second assessment was 0.83, showing no significant difference between the arms. In the third (final) assessment, the distribution of treatment responses in Arm A and Arm B was: partial response (51.28% vs. 41.03%), stable disease (35.90% vs. 20.51%), and progressive disease (12.82% vs. 38.46%). The p value for the third assessment was 0.029, demonstrating a statistically significant difference between the two arms.

DISCUSSION

In this study, we sought to evaluate and compare the toxicities between the Capecitabine-Cisplatin (Arm A) and Gemcitabine-Cisplatin (Arm B) regimens for palliative chemotherapy in patients with advanced biliary tract carcinoma in Bangladesh. Our findings contribute valuable insights into the comparative outcomes of these two treatment regimens in this challenging clinical setting. Firstly, the baseline demographic characteristics

and risk factors in our study population were generally well-matched between the two arms, with some variations in age distribution, gender, and socioeconomic group composition. This similarity allowed us to make valid comparisons between the treatment groups. Notably, both groups had a high prevalence of gallstones as a risk factor, which is consistent with the established association between gallstone disease and biliary tract carcinoma.[10] In the present study, the primary focus was to compare the toxicity of Capecitabine-Cisplatin and Gemcitabine-Cisplatin regimens as palliative chemotherapy in patients with advanced biliary tract carcinoma (ABTC). The results revealed that hematological toxicities were more frequently observed in patients treated with the Gemcitabine-Cisplatin regimen (Arm-B). Specifically, Grade 2 and 3 anemia, neutropenia, and leukopenia were significantly higher in Arm-B compared to Arm-A ($p<0.05$). These findings are consistent with previous studies that reported higher hematological toxicity rates associated with Gemcitabine-Cisplatin treatment in ABTC patients.[5,11] Conversely, the incidence of Hand-Foot Syndrome, a non-hematological toxicity, was significantly higher in patients treated with Capecitabine-Cisplatin (Arm-A) compared to those receiving Gemcitabine-Cisplatin (Arm-B) ($p=0.03$). This finding is in line with previous reports suggesting that Hand-Foot Syndrome is a common side effect of capecitabine treatment.[12] Other non-hematological toxicities, such as nausea, vomiting, diarrhea, anorexia, paresthesia, oral mucositis, and fatigue/flu-like symptoms, were comparable between the two treatment arms. While the study primarily focused on toxicity, it is worth noting that Arm-A (Capecitabine-Cisplatin) demonstrated a superior tumor response rate compared to Arm-B (Gemcitabine-Cisplatin) (51.28% vs. 41.03%, $p=0.029$). These findings suggest that the Capecitabine-Cisplatin regimen may provide more favorable outcomes in terms of tumor response. A meta-analysis by Lee et al. also reported similar results, showing a higher objective response rate for the Capecitabine-Cisplatin regimen compared to the Gemcitabine-Cisplatin regimen.[13] It is important to note that the UK ABC-02 trial, a pivotal phase III study, demonstrated the efficacy of the Gemcitabine-Cisplatin regimen in the treatment of advanced biliary tract carcinoma.[5] However, our study suggests that the Capecitabine-Cisplatin regimen may offer an alternative treatment option with a better tumor response rate and a distinct toxicity profile, which could be particularly relevant for certain patient populations. In light of our findings, it is essential to explore additional treatment strategies and predictive biomarkers to optimize therapeutic outcomes and minimize adverse effects for patients with advanced biliary tract carcinoma.

Limitations

Our findings should be considered in the context of the study's limitations, such as the single-center design and relatively small sample size. Additionally, future multicenter, randomized controlled trials are needed to confirm and expand upon our results. It is also essential to consider individual patient characteristics when selecting the most appropriate treatment regimen, as personalized approaches may help optimize therapeutic outcomes and minimize adverse effects.

CONCLUSION

In conclusion, the Capecitabine-Cisplatin regimen demonstrated a superior tumor response rate and a lower incidence of hematological toxicities compared to the Gemcitabine-Cisplatin regimen in patients with advanced biliary tract carcinoma in Bangladesh. While the toxicity profiles differed, both regimens were generally well-tolerated. These findings suggest that the Capecitabine-Cisplatin regimen may offer an effective and tolerable treatment option for patients with ABTC. Further studies with larger sample sizes are warranted to confirm these results and inform treatment guidelines, with a focus on balancing treatment efficacy and toxicity.

Recommendations

Based on the findings of this study, we recommend considering the Capecitabine-Cisplatin regimen for treating advanced biliary tract carcinoma in Bangladesh due to its superior tumor response rate and distinct toxicity profile. However, individual patient characteristics and preferences should be taken into account. Future studies with larger sample sizes and diverse populations are needed to validate these findings. Further research should explore novel treatment strategies, and healthcare professionals should be educated on the potential benefits and side effects of the Capecitabine-Cisplatin regimen. Collaborative efforts between researchers, clinicians, and policymakers are essential for promoting evidence-based treatment guidelines to improve patient outcomes and reduce disease burden.

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