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Original Article

# Clinical Profile and Outcomes of Pancreatic Adenocarcinoma Patients Treated with Systemic Therapy

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## ABSTRACT

**Introduction:** Pancreatic cancer encompasses a diverse group of malignant tumors that arise within the pancreas, the vast majority of which are of epithelial origin.
**AIM:** To study the clinical profile and outcomes in recurrent or metastatic pancreatic adenocarcinoma patients treated with systemic therapy at GCRI.
**Methodology:** This prospective observational study was conducted in the Department of Medical Oncology at Gujarat Cancer and Research Institute from February 2023 to May 2025.
**Result:** In present study adenocarcinoma was more common in elderly males, with the pancreatic head being the primary site and de novo metastasis constituting the majority of cases. Nab-paclitaxel plus gemcitabine was the used first-line regimen, with partial response observed in 40% of patients and median progression-free survival and overall survival of 4 months and 7 months, respectively. elevated baseline CA 19-9 levels were associated with poorer overall survival, indicating its prognostic significance in metastatic pancreatic adenocarcinoma.
**Conclusion:** Systemic therapy in recurrent or metastatic pancreatic adenocarcinoma provided modest clinical benefit with acceptable toxicity, with nab-paclitaxel plus gemcitabine being the most commonly utilized regimen. Elevated baseline CA 19-9 levels were associated with poorer survival outcomes, suggesting its role as an important prognostic marker in metastatic pancreatic cancer.

***Keywords****: Pancreatic adenocarcinoma, CA 19-9 levels,Systemic therapy.*

## INTRODUCTION

Pancreatic cancer encompasses a diverse group of malignant tumors that arise within the pancreas, the vast majority of which are of epithelial origin. The most prevalent form is pancreatic ductal adenocarcinoma, representing about 85% of all cases.[1] Less common pancreatic neoplasms include serous cystadenomas , mucinous cystic neoplasms , intraductal papillary mucinous neoplasms, acinar cell carcinomas, pancreatoblastomas , pancreatic neuroendocrine tumors, and solid-pseudopapillary neoplasms.[2] Although each of these rarer tumor types constitutes only a small percentage of pancreatic neoplasms, their recognition is critical. The classification of pancreatic neoplasms is primarily based on two key features: their gross appearance and their cellular differentiation. Grossly, these tumors may present as solid, cystic, or intraductal masses. On a microscopic level, they are further categorized according to the type of cell they resemble—such as ductal, acinar, or endocrine differentiation. In children and adolescents, the most frequently occurring pancreatic tumors are pancreatoblastoma and solid pseudopapillary tumors[3] Pancreatic cancers occurring in children and adolescents have different histologic characteristics compared to the ductal adenocarcinoma that is most commonly diagnosed in adults.

Patients with pancreatic adenocarcinoma commonly present with painless jaundice in approximately 50% of cases. Weight loss is a very frequent symptom, occurring in about 90% of patients,[4] while abdominal pain is reported in around 75%. Other symptoms include weakness, pruritus (itching) caused by bile salt deposition in the skin, loss of appetite (anorexia), a palpable, non-tender, distended gallbladder (Courvoisier's sign), pale or clay-colored stools, and dark-colored urine. In some cases, patients may initially present with recurrent deep vein thrombosis (DVT) due to a hypercoagulable state, which lead clinicians to investigate for an underlying malignancy[5]. Pancreatic cancer is 12th most common malignancy accounting for 2.6% of all cancers. In 2022, approximately 510,992 new cases of pancreatic cancer were reported globally, corresponding to an age-standardized incidence rate of 4.7 per 100,000 individuals.[6.] Country with maximum incidence were china and India has one of the lowest pancreatic cancer incidence rates 0.96per 100,000 according to globocon 2022.age standardized mortality rates global 4.5 per 100,000 population with highest in Europe and lowest in south east Asia[7].

**AIM**

To study the clinical profile and outcomes in recurrent or metastatic pancreatic adenocarcinoma patients treated with systemic therapy at GCRI

**METHODOLOGY**

This prospective observational study was conducted in the Department of Medical Oncology at Gujarat Cancer and Research Institute from February 2023 to May 2025. A total of 56 patients with a histopathological diagnosis of metastatic or recurrent pancreatic adenocarcinoma who fulfilled the inclusion criteria were enrolled in the study. The study was initiated after obtaining approval from the Institutional Review Committee (IRC). Patients were included if they were aged 18 years or above and had confirmed metastatic or recurrent pancreatic adenocarcinoma based on radiological imaging and histopathological examination. Patients younger than 18 years of age and those with other histological subtypes, including neuroendocrine tumor/carcinoma, small cell carcinoma, mixed neuroendocrine-non-neuroendocrine neoplasm (MiNEN), lymphoma, and sarcoma, were excluded from the study.

**RESULT**

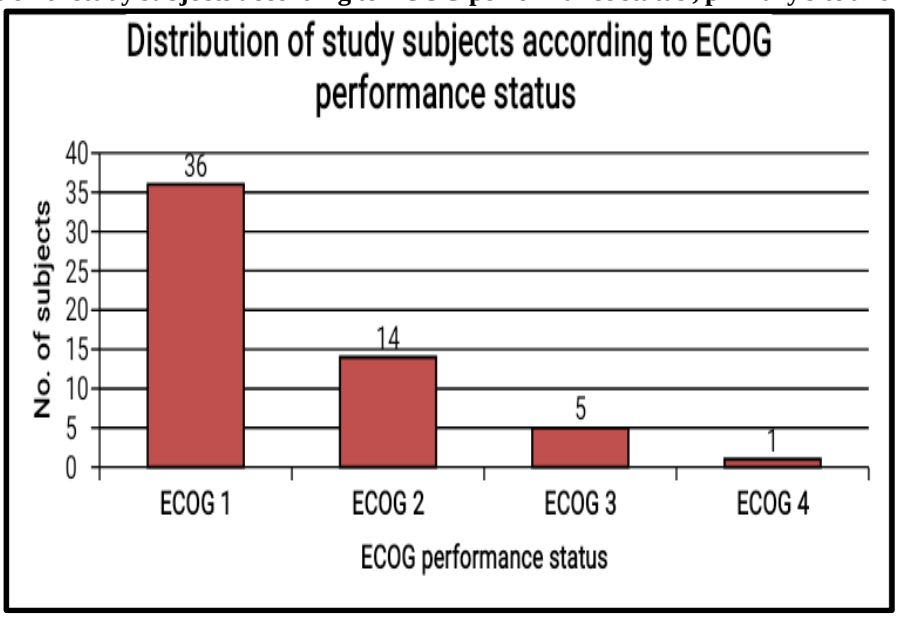
**Table 1: Baseline characteristics of study subjects**

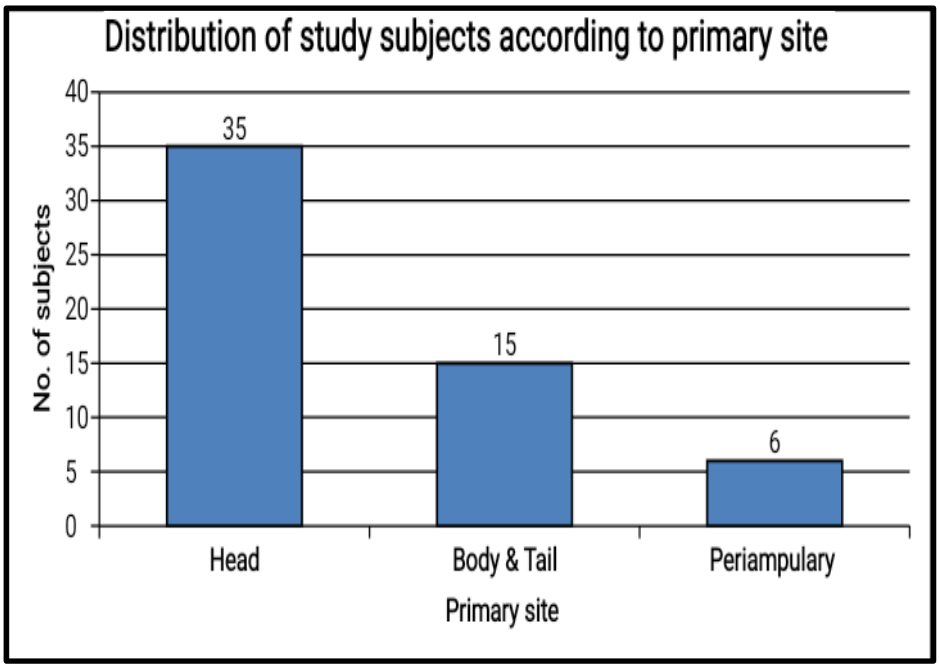
| **Characteristics** | | Number | Percentage |
|---|---|---|---|
| **Age in years** | **40-49 years** | 10 | 17.9 |
| | **50-59 years** | 19 | 33.9 |
| | **60-69 years** | 23 | 41.1 |
| | **70-79 years** | 4 | 7.1 |
| **Gender** | **Female** | 24 | 42.9 |
| | **Male** | 32 | 57.1 |
| **Comorbidities** | **Diabetes** | 15 | 26.8 |
| | **Hypertension** | 16 | 28.6 |
| | **CAD** | 2 | 3.6 |
| | **Hypothyroidism** | 1 | 1.8 |
| | **No comorbidity** | 25 | 44.6 |
| **Addiction** | **Smoking** | 14 | 25 |
| | **Alcohol** | 12 | 21.4 |
| | **No addiction** | 40 | 71.4 |

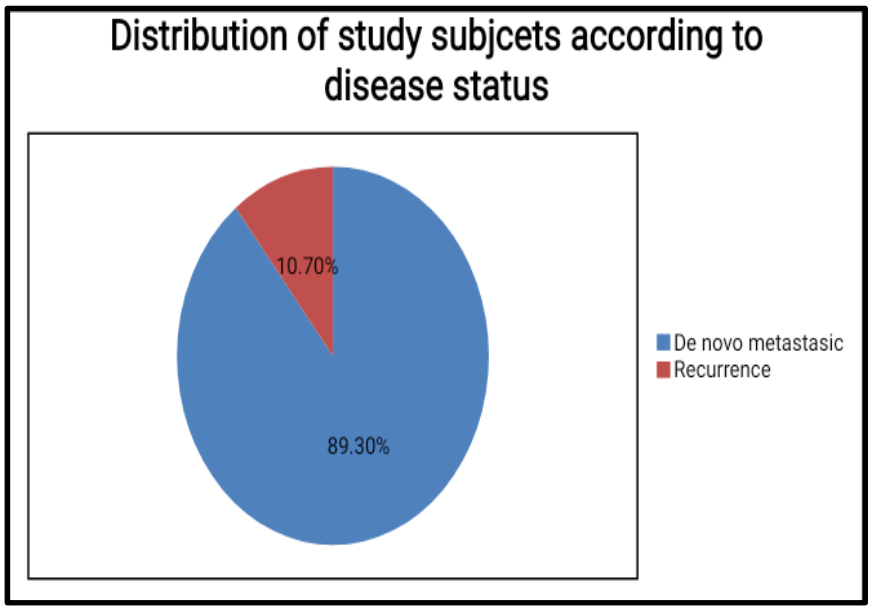
| | | | |
|---|---|---|---|
| **Clinical presentation** | **Nausea / Vomiting** | 29 | 51.8 |
| | **Jaundice** | 12 | 21.4 |
| | **Abdominal pain** | 11 | 19.6 |
| | **Weight loss** | 7 | 12.5 |

The study included 56 patients with recurrent or metastatic pancreatic adenocarcinoma, with a mean age of 58.38 years and majority are males (57.1%). Most patients' common comorbidities included hypertension (28.6%) and diabetes mellitus (26.8%), while 44.6% had no associated comorbidities.Smoking and alcohol consumption were reported in 25% and 21.4% of patients, respectively, whereas 71.4% had no addiction history. Nausea and vomiting was the most common presenting symptom (51.8%), followed by jaundice (21.4%), abdominal pain (19.6%), and weight loss (12.5%).

**Figure 1,2,3: Distribution of study subjects according to ECOG performance status , primary site and disease status**






The majority of patients had a good performance status at presentation, with 64.3% having an ECOG performance status of 1, while ECOG PS 2, 3, and 4 were observed in 25%, 8.9%, and 1.8% of patients, respectively. The pancreatic head was the most common primary tumor site (62.5%), followed by the body and tail (26.8%) and periampullary region (10.7%).Most patients in the study presented with de novo metastatic disease (89.3%), whereas only 10.7% had recurrent disease.

**Table 2: Distribution of study subjects according to CA19-9 levels**

| CA19-9 levels | Number of patients | Out of 56(%) |
|---|---|---|
| **Normal** | 20 | 35.71 |
| **Elevated** | 36 | 64.29 |

In this study, serum CA 19-9 levels were elevated in the majority of patients, with 36 out of 56 (64.29%) showing raised CA 19-9 values. In contrast, 20 patients (35.71%) had normal CA 19-9 levels. Among the 56 patients evaluated for CA19-9 levels, the mean value was 2807 U/ml. AND the median value was 1090U/ml. The range extended from as low as 6.9 U/ml to values exceeding 10,000U/ml,

**Table 3: Distribution of study subjects according to type of first line chemotherapy**

| CHEMOTHERAPY | Number of patients | Percentage (out of 50) |
|---|---|---|
| **NAB PACLITAXEL + GEMCITABINE** | 32 | 57.1 |
| **GEMCITABINE + ERLOTINIB** | 8 | 14.3 |
| **MODIFIED FOLFIRINOX** | 5 | 8.9 |
| **SA GEMCITABINE** | 5 | 8.9 |
| **BEST SUPPORTIVE CARE** | 6 | 10.8 |

Most commonly administered first-line treatment regimen was Nab-paclitaxel plus gemcitabine, administered to 32 out of 56 patients (57.1%). Gemcitabine with erlotinib was used in 8 patients (14.3%), while modified folfirinox and single-agent gemcitabine (SA Gemcitabine) were each administered to 5 patients (8.9%). Best supportive care was provided to 6 patients (10.7%) who were not considered as candidates for systemic therapy due to poor performance status or co-morbidities

**Table 4: Distribution of study subjects according to type of 2nd line chemotherapy**

| CHEMOTHERAPY | Number of patients | Percentage (out of 50) |
|---|---|---|
| **CAPOX** | 36 | 72 |
| **CAPECITABINE** | 9 | 18 |
| **NAB PACLITAXEL + GEMCITABINE** | 5 | 10 |

Second line chemotherapy was received by 50 patients among them CAPOX (capecitabine + oxaliplatin), was administered to 36 patients (70%). Capecitabine monotherapy was given to 9 patients (18%), while nab-paclitaxel plus gemcitabine was used in 5 patients (10%)

**Table 5: Distribution of study subjects according to severe adverse effect Grade 3/4**

| Severe Adverse effect | Number of patients | Percentage (out of 50) |
|---|---|---|
| **Diarrhoea** | 4 | 8 |
| **Fatigue** | 9 | 18 |
| **Infection** | 1 | 2 |
| **Peripheral neuropathy** | 2 | 4 |
| **Neutropenia** | 13 | 26 |

In the study population, adverse events related to treatment were observed with varying frequencies. Neutropenia was the most common, affecting 13 out of 56 patients (26%), followed by fatigue, reported in 9 patients (18%). Diarrhoea was noted in 4 patients (8%), while peripheral neuropathy occurred in 2 patients (4%). Infection was the least frequent adverse event, seen in only 1 patient (2%)

**Table 6: Distribution of study subjects according to response to first line chemotherapy**

| Response | Number of patients | Percentage (out of 50) |
|---|---|---|
| **Complete response** | 0 | 0 |
| **Partial response** | 20 | 40 |
| **Stable disease** | 14 | 28 |
| **Progressive disease** | 16 | 32 |

Radiological response using contrast enhanced CT scan or PET scan was assessed every 3 months of systemic therapy. the following table describes the response to first 3 months of first line systemic therapy .The treatment outcomes among the 50 patients evaluated in the study revealed varying degrees of response. A complete response was not observed in any patient. While partial response was noted in 20 patients (40%), Stable disease was seen in 14 patients (28%),while progressive disease was observed in 16 patients (32%).

**Table 7: Progression free survival (PFS) among study subjects (in months)**

| First line systemic therapy | Median PFS (months) | 95% CI |
|---|---|---|
| **GEMCITABINE + ERLOTINIB (N=8)** | 3 | 1.89 – 4.11 |
| **MODIFIED FOLFIRINOX (N=5)** | 7 | 2.71 – 11.29 |
| **NAB PACLITAXEL +GEMCITABINE (N=32)** | 6 | 5.52 – 6.48 |
| **SA GEMCITABINE (N=5)** | 4 | 2.83 – 5.17 |
| **Overall (N=56)** | 4 | 2.78 – 5.22 |
| **P value** | **<0.001 (S)** | |

The median progression-free survival (PFS) varied significantly across different treatment regimens. Patients treated with modified FOLFIRINOX had the longest median PFS of 7 months, followed by nab-paclitaxel plus gemcitabine with a median PFS of 6 months. Those who received single-agent gemcitabine had a median PFS of 4 months, while the gemcitabine plus erlotinib group had the shortest median PFS of 3 months. The overall median PFS for the study population was 4 months.

**Table 8: Overall survival (OS) among study subjects in relation to CA19-9 level**

| CA19-9 level | Median overall survival(in months) | 95% CI |
|---|---|---|
| **Normal** | 9.0 | 8.16 – 9.84 |
| **Elevated** | 5.0 | 3.53 – 6.47 |
| **P value** | **<0.001 (S)** | |

The overall survival (OS) analysis based on CA19-9 levels demonstrated a significant difference in outcomes. Patients with normal CA19-9 levels had a median overall survival of 9.0 months (95% CI: 8.16–9.84), whereas those with elevated CA19-levels had a median overall survival of 5.0 months (95% CI: 3.53–6.47). The p-value<0.001 indicates that this difference is statistically significant, highlighting elevated CA19-9 as a strong negative prognostic marker in recurrent/metastatic pancreatic adenocarcinoma

**DISCUSSION**

In an Indian study conducted by Ramaswamy et al.[8], the median age was 56 years (range: 23–79 years). The results of our study are in concordance with the findings of the above study. In another study by Sirohi et al.[9], similar findings were observed, with 42.6% of patients being female and 57.4% male. The findings in these studies are consistent with those of the present study.

In the present study, diabetes was present in 15 patients (26.8%), hypertension in 16 patients (28.6%), and the proportion of patients with comorbidities were 55.4%.In the study conducted by Ramaswamy et al.[8], diabetes mellitus was present in 72 patients (47.1%), and hypertension in 44 patients (28.8%). Similarly, in the study by Sirohi et al.[9], comorbidities were present in 38 patients (37.6%). Comparable results were also found in our study.

In the present study, habituation smoking was reported in 14 patients (25%), while alcohol consumption was noted in 12 patients (21.4%). In contrast, the study by Amit et al.[10] showed a higher prevalence of substance abuse, with 124 patients (61.1%) reporting smoking and 113 patients (55.7%) reporting alcohol consumption.

In the present study, the most common presentation was nausea and vomiting,reported in 29 patients (51.8%), followed by jaundice in 12 patients(21.4%) and abdominal pain in 11 patients(19.6%).The study conducted by Amit et al.[10] showed that the most common clinical presentation of pancreatic cancer was nausea and vomiting, present in 99 patients(48.8%), followed by jaundice in 65 patients (32%) and abdominal pain in 39 patients(19.2%) .

In the study conducted by Kunal et al.[11] 270 patients (76.5%) had ECOG PS<1. The results of these studies are in concordance with the findings of the present study.

In our study, cancer in the head of the pancreas was present in 35 patients (62.5%).which is in line with the above said studies. Similar results were observed in the study by Kunal et al.[11] where the head of the pancreas was the most common primary site in 157 patients (44.4%), followed by the body and tail in 98 patients (27.8%).

In our study, de novo metastasis was present in 50 patients (89.3%), which is comparable to other studies. In the study by Ramaswamy et al.[8], it was present in 123 patients (80.4%).

In this study, CA 19-9 levels were elevated in the majority of patients, with 36 out of 56 (64.29%) showing raised values. In contrast, 20 patients (35.71%) had normal CA 19-9 levels. Similarly, in the study by Sirohi et al.[9], baseline CA 19-9 was elevated in 49 patients (70%) and normal in 21 patients (30%).

In the study by Ramaswamy et al.[8], gemcitabine plus nab-paclitaxel was the most commonly used regimen in (39.2%) patients, followed by gemcitabine plus erlotinib (16.3%) patients and mFOLFIRINOX (13.7%) patients. Similarly, in our study, nab-paclitaxel plus gemcitabine was the most frequently used regimen (57.1%) patients, followed by gemcitabine plus erlotinib (14.3%) patients.For second line treatment, Ramaswamy et al.[8] reported higher use of capecitabine based regimens (40%) patients and gemcitabine based regimens were used only in (15%) patients . In contrast, in our study, CAPOX was used in 72% patients, capecitabine monotherapy in 18% patients, and nab-paclitaxel plus gemcitabine in 10% patients, indicating a stronger preference for capecitabine based therapies.

The treatment response in the study by Ramaswamy et al[8] was as follows: partial response (31.4%), stable disease (18.3%), and progressive disease (35.3%). In our study Partial response was noted in 20 patients(40%). stable disease in 14 patients (28%),while progressive disease was observed in 16 patients (32%). Although slight differences were noted, the overall response patterns remained consistent across both studies.

In the study conducted by Ramaswamy et al,[8] partial response was observed in 48 patients (31.4%), stable disease in 28 patients (18.3%), progressive disease in 54 patients (35.3%), and response was not evaluable in 23 patients (15%). In the present study, partial response was observed in 20 patients (40%), stable disease in 14 patients (28%), and progressive disease in 16 patients (32%). No cases were categorized as responses not evaluable in the present study.

The most common Grade 3 and 4 toxicity observed in our study was neutropenia (26%), followed by fatigue (18%). Similarly, in the study by Ramaswamy et al.[8], neutropenia (13.3%) and fatigue (18.5%) were the most common severe adverse effects. Other side effects observed in both studies included peripheral neuropathy and infection.

In the present study, the overall median progression-free survival (PFS) was 4 months, while the median overall survival (OS) was 7 months. These findings are comparable to those reported in other Indian studies. However, slightly better outcomes were observed in the study by Kunal et al.[11], where the median OS was 9.6 months and the median PFS was 8.4 months.

In the study by Ben George et al[12], patients with elevated baseline CA 19-9 had a median overall survival of 7.2 months, compared to 8.8 months in those with normal levels. These findings are consistent with our study, where patients with normal CA 19-9 levels had a median overall survival of 9.0 months, whereas those with elevated levels had a median survival of only 5.0 months. Together, these results underscore the prognostic value of CA 19-9 in predicting survival outcomes in patients with metastatic pancreatic cancer.

## CONCLUSION

Metastatic pancreatic adenocarcinoma in the present study was more commonly observed in elderly male patients, with the pancreatic head being the predominant primary site and de novo metastatic disease constituting the majority of cases. Most patients had a good performance status at presentation, and elevated CA 19-9 levels. The clinical profile and demographic characteristics of the our study population were comparable to those reported in other Indian studies.Nab-paclitaxel plus gemcitabine was the most commonly used first-line chemotherapy regimen, while capecitabine-based regimens were commonly used in as the second-line regimen. Partial response and stable disease were achieved ,with neutropenia and fatigue being the most common severe adverse effects. The median progression-free survival and overall survival were 4 months and 7 months, respectively. Elevated baseline CA 19-9 levels were associated with poorer survival outcomes, highlighting its prognostic importance in metastatic pancreatic adenocarcinoma.

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