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Survival Outcomes of Systemic Therapy in Advanced and Metastatic Pancreatic Adenocarcinoma: A Single-Center Retrospective Study

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Abstract

Background: Pancreatic Ductal Adenocarcinoma (PDAC) remains one of the most lethal malignancies, with limited treatment options yielding poor outcomes. This study aimed to evaluate the real-world clinical characteristics, treatment patterns, and outcomes of patients with locally advanced unresectable and de-novo metastatic PDAC in single center Saudi Arabia, providing regional data to compare with international benchmarks.

Methods: This is a retrospective, single center study involving 36 patients diagnosed with unresectable locally advanced or de-novo metastatic PDAC between January 2021 and January 2026.

Results: The median age at diagnosis was 60 years, FOLFIRINOX was the most common first-line treatment (55.1%), followed by gemcitabine plus nab-paclitaxel (15.1%). The median PFS for first-line treatment was 6 months. The median OS was 12 months for the entire cohort. higher median of overall survival duration among cases of pancreatic tumor who did not do dose reduction, perform surgery, had a good response and received maintenance treatment respectively (p=0.018, 0.006, 0.027, and 0.029). Independent prognostic factors for PFS and OS included performance status, first-line regimen.

Conclusions: This real-world study confirms that clinical outcomes for locally advanced unresectable and metastatic PDAC in Saudi Arabia are consistent with international data, with FOLFIRINOX showing superior outcomes over gemcitabine-based regimens. However, both treatments reflect the persistent poor prognosis of PDAC.

Keywords: Adenocarcinoma; FOLFIRINOX; Gemcitabine; Nab-paclitaxel; Pancreatic cancer; Survival.

Introduction & Background

Pancreatic Ductal Adenocarcinoma (PDAC) remains one of the most lethal malignancies worldwide, typically characterized by late-stage diagnosis and poor long-term prognosis [1]. For the vast majority of patients presenting with locally advanced or distant metastatic disease, systemic chemotherapy serves as the cornerstone of palliative management [2].

For over a decade, the standard first-line treatment paradigms for advanced pancreatic cancer have been anchored by two multi-agent regimens:

- **FOLFIRINOX** (in fusional 5- fluorouracil, leucovorin, irinotecan, and oxaliplatin), which demonstrated a significant survival advantage over gemcitabine monotherapy in the milestone **PRODIGE** trial (median OS: 11.1 vs. 6.8 months) [1].

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- Gemcitabine plus Nab-Paclitaxel (GNP), established by the MPACT trial, showing a median OS of 8.5 months compared to 6.7 months with gemcitabine alone [2].

While clinical trials provide strict efficacy data, real-world populations often include elderly patients or those with multiple comorbidities who face varied drug toxicities and require frequent dose modifications [3,4]. Furthermore, Single-Agent Gemcitabine remains an ongoing fallback strategy for patients presenting with suboptimal performance status [3,5].

Methods

This is a single center retrospective observational study to evaluate patient characteristic, treatment trends, and clinical outcome for LA (locally advanced) unresectable and de-novo metastatic PDAC. Medical records of patients diagnosed PDAC treated in single center was retrospectively reviewed. Patients who were 18-years of age or older and diagnosed from January 1st, 2021, to January 1st, 2026, with LA unresectable or de-novo metastatic PDAC with no prior pancreatic surgery and received palliative first-line systemic therapy were included.

Results

Among pancreatic tumor cases included in the study the mean age was (60.02±7.06) years. 63.9% of them were males versus 36.1% of them were females. As regards stage of tumor 41.7% of cases had a Locally advanced stage, but 58.3% had a metastatic stage. 77.8% had grade 1 performance on presentation versus 22.2% with grade 2. All cases received 1st line of treatment, 50% of them go to 2nd line of treatment, 11.2% of cases go through 3rd line of treatment. as regards laboratory investigation the median CA19-9 level was (389) ranged between 7, and 10000 (Table 1).

Table 1: Description of demographic and clinical characteristic among cases with pancreatic tumor.

Variables	Number (n=36)	
	Mean±SD	Median (Range)
Age (years)	60.02±7.06	62(42-71)
Sex	**No.**	**%**
Male	23	63.9%
Female	13	36.1%
Performance status on presentation		
Performance 1	28	77.8%
Performance 2	8	22.2%
Stage of tumor		
Locally advanced	15	41.7%
Metastatic	21	58.3%
Lines of treatments		
1st line	36	100%
2nd line	18	50%
3rd line	4	11.2%
Base line investigations		
CA 19-9	2547.5±3678.8	389(7-10000)

The 1st line treatment implemented to 77.8% of cases received FOLFORINOX treatment, followed by 8.3% of them received Gemcitabine -nap-paclitaxel treatment. After treatment the median CA19-9 was (201) with range between and median PFS was 6 months ranged between (3-36). 61.1% of them showed side effects 33.3% of them had vomiting, 19.4% fatigue, and 8.3% diarrhea. The median duration between diagnosis and starting 1st line treatment was (59 days) and the median duration between starting treatment and progression was (167 days) after 1st line treatment (Table 2).

Table 2: Description of cases assessment at 1st line treatment among cases with pancreatic tumor.

Variables	Number (n=36)	
	No.	%
1st line of treatment		
FOLFORINOX	28	77.8%
Gemcitabine Capecitabine	2	5.6%
Gemcitabine -nap-paclitaxel	3	8.3%
Gemcitabine	1	2.8%
XElOX	1	2.8%
Paclitaxel Carboplatin	1	2.8%
Side effects		
Vomiting	12	33.3%
Diarrhea	3	8.3%
Fatigue	7	19.4%
Duration between	**Mean±SD**	**Median (Range)**
Diagnosis and start treatment	57.3±33.9	59(0-122)
Treatment starting to progression	223.3±173.5	167(31-730)
Laboratory investigation	**Mean±SD**	**Median (Range)**
CA 19-9	3187.3±8177.4	201(0-45689)
PFS1	8.75±9.03	6(3-36)

One half of cases (received) the 2nd line treatment (50%), 50% of them received (Gemcitabine Capecitabine) treatment, and 22.2% for each (Gemcitabine -nap-paclitaxel, and Gemcitabine) treatment. 5.6% of them treated with Gemcitabine Cisplatine. After treatment the median CA19-9 was (48) with and median PFS was 3 months ranged between (1-25). 27.8% of them showed side effects 11.1% had vomiting, and fatigue versus 5.6% had diarrhea. The median duration between starting 2nd line treatment and progression was (75.5 days) (Table 3).

Few cases proceeded to the 3rd line treatment (11.1%). 75% of them treated with Gemcitabine -nap-paclitaxel. After treatment the median PFS ranged between (0 and 4 months) with median duration from starting treatment to progression (122 days) (Table 4).

The median overall survival of cases studied was 12 months ranged between 5 and 50 months. With 66.7% of cases had dose reduction, 33.3% showed neutropenia, with 13.9% had neutropenic fever.41.7% of cases had a delayed cycle, 11.1% of them received SBRT radiotherapy versus 5.6% were on concurrent chemo-radiotherapy. 25% of cases were underwent surgery, 83.3% of them showed partially response but 11.1% had progression for disease. 8.3% of them received maintenance treatment and 47.2% were survived after treatment course versus 52.8% were non survived (Table 5).

Table 3: Description of cases assessment at 2nd line treatment among cases with pancreatic tumor.

Variables	Number (n=18)	
	No.	%
2nd line of treatment		
Gemzar Capecitabine	9	50%
Gemcitabine -nap-paclitaxel	4	22.2%
Gemcitabine	4	22.2%
Gemcitabine Cisplatin	1	5.6%
Laboratory investigation	**Mean±SD**	**Median(Range)**
CA 19-9	1719.08±3906.3	48(0-19828)
PFS1	5.5±5.9	3(1-25)
Duration between		
Treatment starting to progression	79.3±60.8	75.5(0-184)
Side effects		
Vomiting	2	11.1%
Diarrhea	1	5.6%
Fatigue	2	11.1%

Table 4: Description of cases assessment at 3rd, 4th, and 5th lines of treatment among study group.

Variables	Number (n=4)	
	No.	%
3rd line of treatment	**(n=4)**	
FOLFORINOX	1	25%
Gemcitabine -nap-paclitaxel	3	75%
Duration to progression	122.3±50.2	122(61-184)
	Mean±SD	**Median(Range)**
PFS	0.91±1.6	0(0-4)

Among pancreatic tumor cases there was a statistically significant decrease in PFS level after 2nd and 3rd line treatment (p0.006), on the other hands no change in CA19-9 at different follow up (p=0.36) (Table 6).

Table 6: Description of outcomes among cases with pancreatic tumor.

Variables	parameter		p-value
	Median	(Range)	
CA 19-9			
Base line	389	0-10000	0.36
After 1st line	201	0-45689	
After 2nd line	48	0-19828	
PFS			
After 1st line	6	3-36	**0.006***
After 2nd line	3	1-25	
After 3rd line	0	0-4	

Table 5: Description of outcomes among cases with pancreatic tumor.

Variables	Number (n=36)	
	Mean±SD	Median(Range)
Overall survival (m)	15.8±11.3	12(5-50)
Dose reduction	**No.**	**%**
No	12	33.3%
Yes	24	66.7%
Neutropenia		
No	24	66.7%
Yes	12	33.3%
Neutropenic fever		
No	31	86.1%
Yes	5	13.9%
Delay of cycle		
No	21	58.3%
Yes	15	41.7%
Radiotherapy		
No	30	83.3%
Concurrent chemoradiotherapy	2	5.6%
SBRT	4	11.1%
Surgery		
No	27	75%
Yes	9	25%
Response		
Partial	30	83.3%
Complete	2	5.6%
Disease progression	4	11.1%
Maintenance treatment		
No	33	91.7%
Yes	3	8.3%
Survival rate		
Non-survived	19	52.8%
Survived	17	47.2%

The table illustrated that there was a statistically significant higher median overall survival among cases with ECOG performance status 1 compared with ECOG 2 and cases with locally advanced stage (p0.019, and 0.005) compared with metastatic stage. On the other hand, there was no statistically significant difference in overall survival p-value >0.05 (between men and women) (Table 7, Figure 1).

The overall survival duration showed a statistically significant positive correlation with each of PFS level after 1st and 2nd lines treatment variables (Table 10). Which indicated an increase in PFS level will associate with increase in overall survival duration among cases. Longer duration from start treatment to progression after 1st lint treatment were associated with longer duration of overall survival (p0.001). On the other hand, there was no statistically significant correlation with p-value >0.05 between overall survival duration and other variables (Figure 2).

Table 7: Comparison of overall survival duration in different clinical data among cases with pancreatic tumor.

Variables	Overall survival (m)		p-value
	Median	Range	
Sex			
Male	10	6-40	0.97
Female	12	5-50	
Performance status on presentation			
Performance 1	14	5-50	**0.019***
Performance 2	8	5-26	
Stage of tumor			
Locally advanced	17	6-50	**0.005***
Metastatic	9	5-25	

Table 8: Comparison of overall survival duration in different clinical outcomes among cases with pancreatic tumor.

Variables	Overall survival (m)		p-value
	Median	(Range)	
Dose reduction			
No	20	6-50	**0.018***
Yes	9	5-40	
Neutropenia			
No	13	6-50	0.104
Yes	9.5	5-26	
Neutropenic fever			
No	12	5-50	0.66
Yes	12	6-25	
Delay of cycle			
No	14	5-50	0.65
Yes	12	5-40	
Radiotherapy			
No	9.5	5-50	
Concurrent chemo-radiotherapy	37	34-40	0.10
SBRT	13	12-14	
Surgery			
No	9	5-40	**0.006***
Yes	20	9-50	
Response			
Partial	12	5-50	**0.027***
Complete	7	5-17	
Disease progression	40	40-40	
Maintenance treatment			
No	10	5-40	**0.029***
Yes	25	20-50	
Survival rate			
Non-survived	12	5-26	1
Survived	9	5-50	

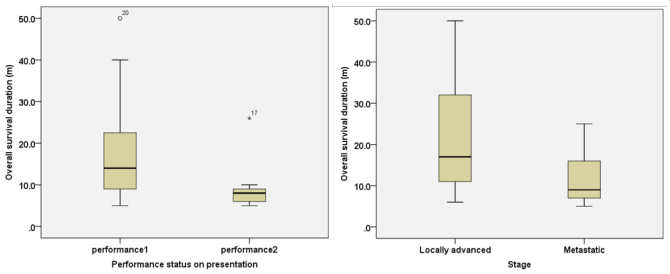


Figure 1: The table illustrated that there was a statistically significant higher median of overall survival duration among cases of pancreatic tumor who did not do dose reduction, perform surgery, had a good response and received maintenance treatment respectively (p=0.018, 0.006, 0.027, and 0.029).

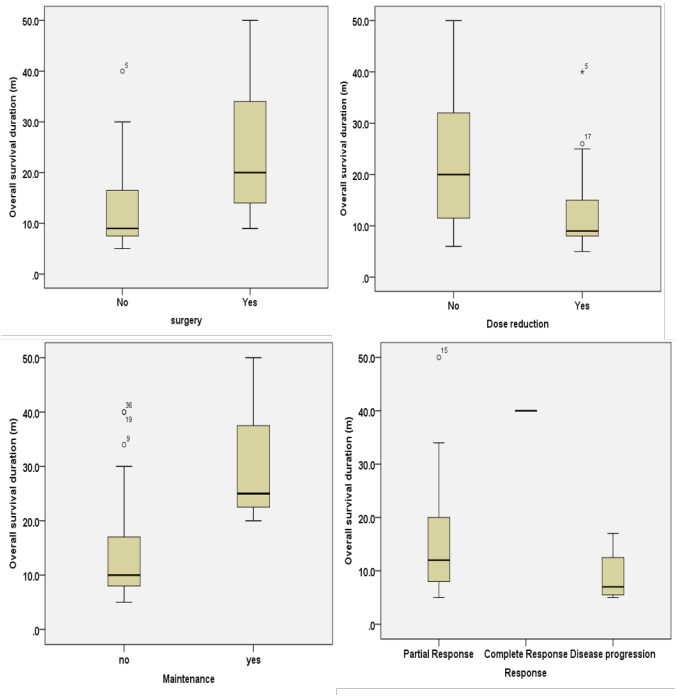


Figure 2: Cases who had no delay in cycle showed a statistically significant higher percentage of surviving rate (79.5% versus 23.5% among cases with delayed cycle (p=0.049). on the other hands there was no significant association between other clinical data and survival rate among pancreatic tumor cases (p>0.05) (Table 9).

Kaplan -Meier test illustrated that exactly 50% of the patients in this treatment group survived longer than 30 months with 95% Confidence Interval (CI): 16.08 to 43.92 months (Table 11). This indicates that if this treatment were given to the wider population, we are 95% confident the true median survival would fall between roughly 16 and 44 months.as regards mean survival duration it was 26.96 months ranged between 20.56 and 33.36 months (Figure 3).

Table 9: Comparison of clinical outcomes as regards survival outcomes among cases with pancreatic tumor.

Variables	Not Survived (n=19)		Survived (n=17)		p-value
	No	%	No.	%	
Dose reduction					
No	5	26.3%	**7**	41.2%	0.48
Yes	14	73.7%	10	58.8%	
Delay of cycle					
No	8	42.1%	13	76.5%	**0.049***
Yes	11	57.9%	4	23.5%	
Radiotherapy					
No	18	94.7%	14	82.4%	0.30
Chemo-radiotherapy	0	0%	2	11.8%	
SBRT	1	5.3%	1	5.9%	
Surgery					
No	16	84.2%	11	64.7%	0.26
Yes	3	15.8%	6	35.3%	
Response					
Partial	15	78.9%	**15**	88.2%	0.06
Complete	0	0%	2	11.8%	
Disease progression	4	21.1%	0	0%	
Maintenance TTT					
No	17	89.5%	**16**	94.1%	0.1
Yes	2	10.5%	1	5.9%	

Table 10: Correlation between overall survival duration with clinical and laboratory data among cases.

Variables	Overall survival duration	
	r	P-value
Age (years)	0.17	0.33
CA 19-9 at baseline	0.12	0.47
CA19-9 after 1st line treatment	-0.04	0.83
PFS after 1st line treatment	**0.77**	**0.001***
PFS after 2nd line treatment	**0.76**	**0.001***
Duration between Diagnosis and start treatment (m)	**0.52**	**0.001***
Duration between starting Treatment by 1st line to prognosis (m)	**0.77**	**0.001***
Duration between starting Treatment by 2nd line to prognosis (m)	-0.13	0.60

Table 11: Kaplan -Meier test overall surviving duration among study group.

	Estimate	SE	95% Confidence Interval	
			Lower Bound	Upper Bound
Mean	26.96	3.26	20.56	33.36
Median	30	7.11	16.08	43.92

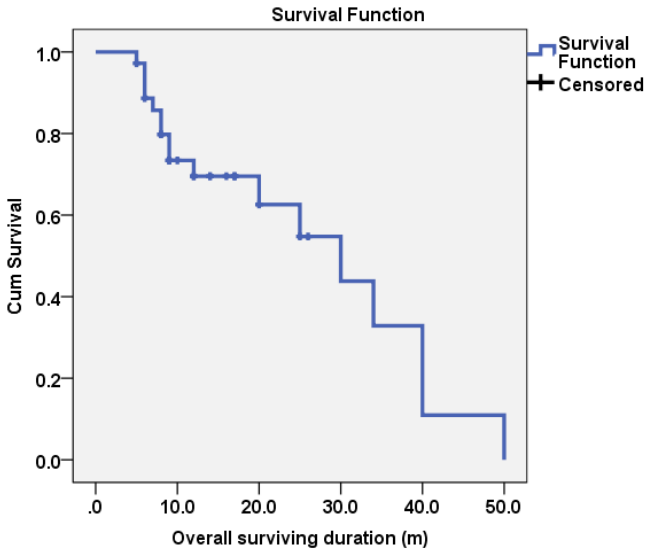


Figure 3: Graph.

Statistical analysis

- Data analysis performed using the Statistical Package of Social Science (SPSS) software version 26 in windows 11 (SPSS Inc., Chicago, IL, USA).
- Simple descriptive analysis in the form of numbers and percentages of qualitative data, and arithmetic means as central tendency measurement, standard deviations as a measure of dispersion of quantitative parametric data. median and range for non-parametric quantitative data.
- Quantitative data included in the study first tested for normality by One-Sample Kolmogorov-Smirnov test in each study group then inferential statistic tests selected.
- The Kruskal Wallis test used to compare non parametric quantitative data between more than two independent groups.
- The Mann-Whitney test used to compare non parametric quantitative data between two independent groups.
- Wilcoxon tests used in comparing non parametric quantitative data between two groups of dependent data
- Chi square test used to compare between two of more than two qualitative groups.
- Bivariate Spearman's correlation test to test the association between quantitative non parametric variables
- Kaplan -Meier test for survival analysis.
- The P-value< 0.05 was considered as statistically significant

Discussion

Our study serves to characterize patients' characteristics, treatment trends, and outcomes of locally advanced unresectable and metastatic PDAC in our center and compare our treatment outcome with available literature. Data concerning this disease is scarce in our region that makes this study of importance.

The median age at diagnosis in our population was 60 years that is younger than reports from western populations and comparable to reports from Asia and North Africa with exception of Japan [7-16]. This can be explained by the relatively younger population in these countries in contrary to western population PDAC has a male predominance, and [7,8,13,14,16,17].

World outcomes of cancer treatment against prospective Randomized Control Trials (RCTs) can help as a benchmark to identify gaps to deliver best practice, figure current clinical challenges, and optimize the use of available treatments [18]. Outcomes of treated advance PDAC for the whole group in our study was comparable to reports from other parts of the World [16,19,20].

Majority of world retrospective reports comparing the efficacy of FOLFIRINOX with gemcitabine -nap paclitaxel as a first line have resulted in better overall response rate, and longer Progression Free Survival (PFS), and Overall Survival (OS) in favor of FOLFIRINOX [12,14,17,19-22]. On the other hand, Prospective studies comparing the efficacy of FOLFIRINOX with gemcitabine -nap paclitaxel as a first-line are scarce with one trial from Japan (JCOG1611, GENERATE) that failed to show superiority of FOLFIRINOX over gemcitabine -nap paclitaxel, in contrast it resulted in numerically longer OS in gemcitabine -nap paclitaxel arm and was terminated for futility [23]. Recently, the NAPOLI 3 trail compared NALIRIFOX vs. gemcitabine -nap paclitaxel in the first-line setting of patients with metastatic Pancreatic Duct Adenocarcinoma (PDAC). The trial showed superiority of NALIRIFOX over gemcitabine -nap paclitaxel with median OS of 11·1 months vs. 9·2 months (HR 0·83; 95% CI 0·70–0·99; p=0·036), adding another option to the first-line treatment landscape [24].

The 1st line treatment implemented to 77.8% of cases received FOLFORINOX treatment, followed by 8.3% of them received Gemcitabine -nap-paclitaxel treatment. After treatment the median CA19-9 was (201)), and median PFS was 6 months, ranged between (3-36). 61.1% of them showed side effects 33.3% had vomiting, 19.4% had fatigue, and 8.3% had diarrhea. The median overall survival among cases was 12 months, that was comparable to what was reported in PRODIGE 4/ACCORD 11 trial showing 31.6% ORR, median PFS and OS was 6.4 months, and 11.1 months, respectively [25].

In our study 66.7% of cases had dose reduction, 33.3% showed neutropenia, with 13.9% had neutropenic fever. 41.7% of cases had a delayed cycle, 11.1% of them received SBRT radiotherapy versus 5.6% were on concurrent chemo-radiotherapy. The table illustrated that that there was a statistically significant higher median overall survival duration among cases of pancreatic tumor who did not do dose reduction.

It is noteworthy that dose reduction in FOLFIRINOX regimen does not alter its efficacy as shown in a recent meta-analysis of modified FOLFIRINOX vs. standard FOLFIRINOX in metastatic PDAC [26]. In this meta-analysis the ORR was (33.8% versus 28.2%; p = 0.1) for modified FOLFIRINOX, and standard FOLFIRINOX, respectively. This finding is comparable with the ORR of 31.6% in the PRODIGE 4/ACCORD 11 trial [25,26]. In addition, the rates of neutropenia and febrile neutropenia in the modified FOLFIRINOX group were lower as reported in the PRODIGE 24/ACCORD 24 trial [27].

Variables	Overall survival (m)		p-value
	Median	(Range)	
Dose reduction			
No	20	6-50	**0.018***
Yes	9	5-40	
Neutropenia			
No	13	6-50	0.104
Yes	9.5	5-26	
Neutropenic fever			
No	12	5-50	0.66
Yes	12	6-25	
Delay of cycle			
No	14	5-50	0.65
Yes	12	5-40	

One half of cases were eligible for the 2nd line treatment (50%), 50% of them received (Gemcitabine Capecitabine) treatment, and 22.2% for each (Gemcitabine -nap-paclitaxel, and Gemcitabine) treatment only 5.6% of them treated with Gemcitabine Cisplatin. After treatment the median CA19-9 was [48] and median PFS was 3 months ranged between [1-25]. 27.8% of them showed side effects 11.1% had vomiting, and fatigue versus 5.6% had diarrhea, similar to reported literature [28,10,14]. Most studies in the second line setting have evaluated 5-FU based regimens. Second-line GNP post FOLFIRINOX was studied in single arm phase II trial resulting in median PFS of 5.8 months (95% CI, 4.3-8.7) which is higher than our study with median PFS was 3.8 months [29].

Other reports have highlighted that age and CA 19 - 9 as prognostic factor which we did not appreciate in our analysis [14,15,30]. In our study there was a statistically significant higher median of overall survival duration among cases with locally advanced stage vs metastatic (p 0.005).

Our study reports the outcomes of patients with locally advanced unresectable and metastatic pancreatic ductal adenocarcinoma treated in single center, emphasizing the need for future research in several key areas. Future studies should explore molecular biomarkers to identify genetic alterations that could guide treatment decisions, integrate novel therapeutic agents such as targeted therapies and immunotherapies to improve patient outcomes, and assess patient-reported outcomes to better understand the impact of treatments on quality of life. Additionally, focusing on personalized treatment strategies and long-term follow-up could enhance understanding and management of this aggressive cancer, ultimately aiming to improve survival rates and treatment effectiveness in this patient population.

Our study has several limitations. First, being retrospective, second, the choice of first-line treatment regimen was done by the treating physicians with no clear criteria have been established and possibly influenced by treatment availability. Lastly, some prognostic factors, such as Body Mass Index (BMI), smoking, and molecular testing were not examined due to lack of data.

Conclusions

In conclusion, our study demonstrated that our current practice in single center for treating advance PDAC matches the global standards with similar outcomes observed in the pivotal randomized controlled trials.

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