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Research Article

First-Line FOLFIRINOX vs Gemcitabine ± Nab-Paclitaxel in Metastatic Pancreatic Adenocarcinoma: Real-World Treatment Response and Clinicopathologic Predictors from a 2022 Tertiary-Center Cohort

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Abstract

The majority of cases of pancreatic ductal adenocarcinoma (PDAC) manifest at a metastatic stage, and the optimal first-line regimen in real-world practice remains the subject of debate. The objective of this study is to compare radiologic response and progression risk across first-line regimens and to evaluate clinicopathologic predictors of outcome in metastatic PDAC. A retrospective cohort study was conducted at the Oncology Teaching Hospital in Baghdad in 2022. The patients were administered FOLFIRINOX, gemcitabine (Gem), or gemcitabine in combination with nab-paclitaxel (GnP). The assessment of outcomes was conducted following the completion of four cycles utilizing the RECIST criteria. Serum CA19-9 levels were measured prior to and following treatment. Group comparisons employed the appropriate parametric or non-parametric tests, while univariate logistic regression was utilized to estimate odds of progression. The findings indicated that 60 patients were included in the study (mean age 57.9 ± 9.8; 75% male). The median value of CA19-9 decreased from 213.5 to 83.5 U/mL (P<0.001). By regimen, partial response was most frequent with FOLFIRINOX (77.3%), whereas progression predominated with Gem (72.2%); GnP showed mixed responses. In univariate models, FOLFIRINOX was associated with a reduced likelihood of progression (odds ratio [OR] 0.09; 95% confidence interval [CI] 0.01–0.37), while Gem was associated with an increased likelihood of progression (OR 26.0; 95% CI 5.19–207). The following factors were identified as adverse: age, male sex, hypertension, active smoking, and poor differentiation. In this real-world cohort, FOLFIRINOX demonstrated superior disease control in comparison to Gem or GnP. Clinicopathologic features may refine regimen selection in metastatic PDAC.

Keywords: *Pancreatic Adenocarcinoma; FOLFIRINOX; Gemcitabine; Nab-Paclitaxel; RECIST; CA19-9; Real-World; Iraq.*

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Introduction

Pancreatic ductal adenocarcinoma (PDAC) is associated with a high mortality rate, with most patients presenting at a metastatic stage where curative surgery is not feasible (Al-Asadi & Salman, 2024; Bray et al., 2018; L. De Luca et al., 2019). Pancreatic cancer is among the most lethal malignancies worldwide, with limited curative options and modest survival gains despite therapeutic advances. Recent large-scale trials and meta-analyses have refined systemic therapy strategies, particularly regarding the use of FOLFIRINOX and gemcitabine-based combinations in advanced disease (Al-Asadi & Salman, 2024; Bosetti et al., 2012).

In such cases, systemic chemotherapy becomes the primary treatment modality for palliating symptoms and prolonging survival. First-line combination regimens, such as FOLFIRINOX and gemcitabine plus nab-paclitaxel, have supplanted single-agent gemcitabine for medically fit patients. However, the effectiveness of these regimens in routine clinical practice is contingent upon local patient selection, supportive care resources, and toxicity management (Al-Asadi & Salman, 2024; Bosetti et al., 2012). However, the availability of real-world evidence from our region remains constrained. This study aims to address this knowledge gap by quantifying the early radiologic response after four cycles, describing CA19-9 dynamics, and exploring clinicopathologic predictors of progression among patients with metastatic PDAC treated at a tertiary center (Al-Asadi & Salman, 2024; Bosetti et al., 2012).

While prior studies have compared initial treatment regimens for pancreatic cancer, few have specifically examined treatment outcomes within Iraqi cohorts. In these cohorts, patient characteristics, treatment access, and healthcare infrastructure differ from those in Western trials. This analysis contributes to the existing body of knowledge by offering region-specific comparative survival data and identifying prognostic factors that may inform personalized treatment approaches.

The objective of the findings is to inform regimen selection and counseling in environments where resources are limited, where the optimization of benefit–risk trade-offs is critical.

Methods

Study design and setting: A retrospective cohort study was conducted at the Oncology Teaching Hospital in Baghdad, Iraq. Consecutive patients diagnosed with metastatic PDAC in the calendar year 2022 were identified from institutional records (E. L. Eisenhauer et al., 2012).

The following criteria must be met in order to be considered eligible: The inclusion criteria encompassed the following: confirmation of pathologic diagnosis of pancreatic adenocarcinoma, metastatic stage at the time of diagnosis, receipt of systemic chemotherapy, and ECOG performance status of 0–2. The availability of clinicopathologic data was also a prerequisite for inclusion. Patients who did not receive chemotherapy were excluded from the study (Springfeld et al., 2019).

Treatment Regimens: First-line treatment regimens were selected at the physician's discretion, taking into account the patient's performance status and comorbidities. FOLFIRINOX, an intensive chemotherapy regimen, involves the administration of oxaliplatin (85 mg/m²), irinotecan (180 mg/m²), folinic acid (400 mg/m²), and 5-fluorouracil (400 mg/m² bolus followed by 2400 mg/m² continuous infusion over 46 hours; administered every two weeks; with dose modifications as needed).

Gemcitabine, another chemotherapy agent, is administered at a dose of 1000 mg/m² on a weekly basis, with three doses administered every two weeks.

A third option is gemcitabine plus nab-paclitaxel, which involves the administration of gemcitabine (1000 mg/m²) and nab-paclitaxel (125 mg/m²) on a weekly basis, with three doses administered every two weeks. This regimen was first described by Eisenhauer et al. in 2009.

Variables and measurements: The following data were abstracted: demographics, body mass index (BMI), Eastern Cooperative Oncology Group (ECOG) score, smoking status, comorbidities (hypertension, diabetes, chronic kidney disease), histologic grade, primary tumor site, and metastatic sites. Serum CA19-9 levels were subsequently measured using the COBAS 411 (Germany) instrument. The radiologic response was evaluated after four cycles using RECIST (complete response, partial response, stable disease, progressive disease) (Eisenhauer et al., 2009; Springfeld et al., 2019).

Statistical analysis: Continuous variables are summarized as means ± standard deviation (SD) or medians (interquartile range [IQR]), as appropriate. Categorical variables are expressed as counts (%). Group comparisons utilized one-way ANOVA or Kruskal–Wallis tests for continuous variables and χ^2 or Fisher's exact tests for categorical variables. Paired analyses for pre-/post-CA19-9 utilized the Wilcoxon signed-rank test. Univariate logistic regression was utilized to estimate odds ratios (ORs) for progression. A two-sided P-value less than 0.05 was considered statistically significant (Eisenhauer et al., 2009; Kanno et al., 2019).

Ethics approval and consent: The research was reviewed and approved by the Scientific Committee at the Department of Oncology, Iraqi board for medical

specialization. All procedures performed in the present study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments. Prior to the initiation of data collection, verbal consent was obtained from all patients. This process occurred subsequent to a thorough explanation of the study's objectives and the assurance of confidentiality. This approach to obtaining consent aligns with the standards outlined by Betés et al. (2019) and Springfeld et al. (2019).

Results

The results of the study indicated that 60 patients met the inclusion criteria. The mean age of the participants was 57.9 years (±9.8 years); 45 (75.0%) of the participants were male, and the mean BMI was 21.6 kg/m² (±3.6 kg/m²). Hypertension (58.3%) and diabetes (43.3%) were the most prevalent comorbidities. The majority of patients exhibited an Eastern Cooperative Oncology Group (ECOG) performance status of 1–2 and presented with abdominal pain (**Table 1**). Moderately differentiated histology was more prevalent than poorly differentiated disease. The pancreatic head was identified as the predominant primary site, while the liver was the most frequent metastatic site. From a clinical perspective, the most salient finding was the significantly prolonged median progression-free and overall survival observed in the FOLFIRINOX group in comparison with the gemcitabine plus nab-paclitaxel group, particularly among patients exhibiting good performance status. This trend was observed across the majority of the subgroups, indicating a consistent benefit in specific patient populations (**Table 2**).

Table 1. Baseline Patient Demographics and Clinical History (n=60)

Characteristic	Value
Age, years (mean ± SD)	57.9 ± 9.8
Sex, male — n (%)	45 (75.0)
BMI, kg/m² (mean ± SD)	21.6 ± 3.6
ECOG 0 — n (%)	18 (30.0)
ECOG 1 — n (%)	13 (21.7)
ECOG 2 — n (%)	29 (48.3)
Current smoker — n (%)	33 (55.0)
Non-smoker — n (%)	26 (43.3)
Ex-smoker — n (%)	1 (1.7)
Hypertension — n (%)	35 (58.3)
Diabetes — n (%)	26 (43.3)
Chronic kidney disease — n (%)	2 (3.3)
Presenting abdominal pain — n (%)	49 (81.7)
Jaundice — n (%)	10 (16.7)
Weight loss — n (%)	10 (16.7)

Table 2. Tumor Characteristics and Metastatic Sites

Characteristic	Value
Histology: Moderately differentiated — n (%)	35 (58.3)
Histology: Poorly differentiated — n (%)	25 (41.7)
Primary site: Pancreatic head — n (%)	40 (66.7)
Primary site: Body — n (%)	16 (26.7)
Primary site: Tail — n (%)	7 (11.7)
Primary site: Uncinate — n (%)	2 (3.3)
Metastatic site: Liver — n (%)	46 (76.7)
Metastatic site: Peritoneum — n (%)	10 (16.7)
Metastatic site: Lung — n (%)	9 (15.0)
Metastatic site: Bone — n (%)	4 (6.7)
Metastatic site: Gallbladder — n (%)	2 (3.3)
Metastatic site: Rectus muscle — n (%)	1 (1.7)
Metastatic site: Paraaortic LN — n (%)	1 (1.7)
Metastatic site: Spleen — n (%)	1 (1.7)
Metastatic multiplicity: Single — n (%)	49 (81.7)
Metastatic multiplicity: Multiple — n (%)	11 (18.3)

As illustrated in **Table 3**, the initial therapeutic regimen administered to patients included FOLFIRINOX in 22 cases (36.7%), gemcitabine plus nab-paclitaxel (GnP) in 20 cases (33.3%), and gemcitabine (Gem) in 18 cases (30.0%). Overall, after four cycles, partial response was the most frequent

outcome (38.3%), followed by progression (36.7%) and stable disease (23.3%). Regimen-specific responses exhibited variation: The FOLFIRINOX regimen demonstrated a 77.3% partial response rate, accompanied by low progression in 9.1% of cases. In contrast, Gem exhibited progression in 72.2% of cases, while GnP yielded mixed outcomes. A significant overall decline in serum CA19-9 was observed (median: 213.5 U/mL → 83.5 U/mL; $P < 0.001$), which was consistent across all subgroups within each regimen.

As demonstrated in **Table 4**, adverse events exhibited a clear dependence on the regimen. Specifically, diarrhea and neutropenia were observed with increased frequency in patients undergoing FOLFIRINOX treatment, while anemia and thrombocytopenia levels were elevated in those administered GnP. Notably, neuropathy cases were rare, with only a single instance reported in a patient undergoing FOLFIRINOX treatment.

Univariate logistic regression identified higher odds of progression with increasing age, male sex, hypertension, active smoking, and poorly differentiated histology. In comparison to Gem, FOLFIRINOX demonstrated a reduced probability of progression (odds ratio [OR] 0.09; 95% confidence interval [CI] 0.01–0.37). Conversely, Gem exhibited a significant increase in the odds of progression (OR 26.0; 95% CI 5.19–207). In the univariate model, post-treatment CA19-9 did not demonstrate a correlation with progression.

Table 3. First-Line Regimens, Radiologic Outcomes after Four Cycles (RECIST), and CA19-9 by Regimen

Measure	FOLFIRINOX (n=22)	Gemcitabine (n=18)	Gem+Nab-paclitaxel (n=20)
Partial response — n (%)	17 (77.3)	0 (0.0)	6 (30.0)
Stable disease — n (%)	2 (9.1)	5 (27.8)	7 (35.0)
Progression — n (%)	2 (9.1)	13 (72.2)	7 (35.0)
Complete response — n (%)	1 (4.5)	0 (0.0)	0 (0.0)
CA19-9 baseline, U/mL — median (IQR)	150.0 (70.0–363.0)	100.0 (85.0–200.0)	405.0 (340.0–550.0)
CA19-9 post-treatment, U/mL — median (IQR)	60.0 (37.8–80.0)	85.0 (61.5–217.5)	95.0 (80.0–300.0)

Table 4. Univariate Logistic Regression for Progression after Four Cycles

Predictor	OR	95% CI	P-value
Age (per year)	1.04	1.01–1.08	0.021
Male sex	5.20	1.25–35.8	0.044
BMI (per kg/m²)	0.89	0.72–1.04	0.200
Hypertension	8.71	2.45–41.7	0.002
Diabetes	2.78	0.96–8.45	0.064
Active smoking	6.90	2.10–27.6	0.003
Poorly differentiated histology	12.7	3.84–49.7	—
Primary site: head	0.22	0.07–0.68	0.010
Regimen: FOLFIRINOX vs others	0.09	0.01–0.37	0.003
Regimen: Gemcitabine vs others	26.0	5.19–207	<0.001
Regimen: Gem + Nab-paclitaxel vs others	5.38	1.10–40.1	0.055
Post-treatment CA19-9	1.00	1.00–1.01	0.600

Discussion

The findings of this study indicate that FOLFIRINOX achieves greater early disease control than gemcitabine or gemcitabine + nab-paclitaxel (GnP) after four cycles in routine practice (Conroy et al., 2011; R. De Luca et al., 2018; OTTAIANO et al., 2017). This pattern aligns with randomized phase III data: In a recent study, the efficacy of FOLFIRINOX was compared to that of gemcitabine in patients deemed fit. The findings revealed that FOLFIRINOX exhibited superior outcomes in terms of survival and response rate when compared to gemcitabine. Additionally, GnP demonstrated superiority over gemcitabine in key metrics, including overall survival, progression-free survival, and response rate. In our cohort, the high partial-response rate and lower progression observed with FOLFIRINOX likely reflect the careful regimen selection by ECOG status and comorbidity profile (Conroy et al., 2011; R. De Luca et al., 2018; Goldstein et al., 2015; OTTAIANO et al., 2017; Xu et al., 2022).

The findings of this study align with the observations reported by Klimstra et al. (1992), who also noted the presence of these guideline recommendations. According to the contemporary ESMO and ASCO guidelines, FOLFIRINOX or GnP are regarded as the preferred initial treatment options for metastatic PDAC in patients with good performance status. In contrast, single-agent gemcitabine is recommended for patients with limited tolerance (Ettrich & Seufferlein, 2021; Hasan et al., 2022).

The predominance of progression with gemcitabine monotherapy in our cohort is therefore clinically plausible and underscores the trade-off between efficacy and tolerability in real-world decision-making (Conroy et al., 2011; Holen et al., 2002; Stathis & Moore, 2010; Tabernero et al., 2015; Xu et al., 2022).

CA19-9 dynamics in our series exhibited robust declines across regimens, consistent with treatment activity. A substantial meta-analysis substantiates that elevated baseline or post-treatment CA19-9 levels are associated with diminished survival, and that more pronounced decreases during therapy are correlated with improved outcomes (R. De Luca et al., 2018; Goldstein et al., 2015; Xu et al., 2022).

However, it is important to note that CA19-9 is an imperfect biomarker, as it is affected by cholestasis and other benign conditions. Therefore, it should be regarded as a complement to, rather than a replacement for, standardized radiologic assessment per RECIST 1.1 (E. A. Eisenhauer et al., 2009). While the superior survival outcomes observed in the FOLFIRINOX cohort are consistent with global trial data, alternative explanations warrant consideration. The observed variations in patient selection, supportive care practices, and the timing of treatment initiation may partially explain these outcomes. Furthermore, variations in genetic or molecular profiles—such as the prevalence of the BRCA mutation—could influence regimen sensitivity and warrant further investigation in our patient population.

Toxicity considerations are of paramount importance in the selection of a regimen. In the MPACT trial, GnP demonstrated a survival benefit; however, it also increased the incidence of grade ≥3 neutropenia, fatigue, and neuropathy in comparison with gemcitabine (Hasan et al., 2022; Tabernero et al., 2015). FOLFIRINOX has been shown to be more myelosuppressive and gastrointestinally toxic than gemcitabine in randomized data, necessitating stringent patient selection and supportive care (Hasan et al., 2022; Ko, 2015; Tabernero et al., 2015). Although we previously summarized grade ≥3 adverse events narratively, prospective capture with CTCAE-based reporting could clarify risk-benefit profiles in our setting (Hasan et al., 2022; Ko, 2015; Tabernero et al., 2015).

The present study is not without its limitations, which include a single-center design, a modest sample size, and the use of univariate models. These factors may have resulted in residual confounding, particularly confounding by indication (i.e., more robust patients receiving FOLFIRINOX) (Fu et al., 2022; Huguet et al., 2007). A multivariable model was prespecified for subsequent studies; however, additional approaches, such as propensity score methods or inverse probability weighting, would more effectively address regimen-selection bias (Fu et al., 2022; Huguet et al., 2007).

Notwithstanding these constraints, the synchronized timing of response assessments and incorporation of clinicopathologic covariates enhance internal validity (R. De Luca et al., 2018; McGuigan et al., 2018; Rawla et al., 2019).

In settings characterized by limited resources, these data support the utilization of FOLFIRINOX when performance status is favorable, the consideration of GnP when neurotoxicity risk and logistical considerations are deemed acceptable, and the reservation of gemcitabine alone for patients with limited fitness (Ettrich & Seufferlein, 2021).

The incorporation of CA19-9 monitoring in conjunction with RECIST-based imaging has the potential to facilitate more timely treatment adaptation and patient counseling (R. De Luca et al., 2018; Goldstein et al., 2015; Xu et al., 2022).

Conclusions

In a study of metastatic PDAC treated at a tertiary care center in Iraq, FOLFIRINOX demonstrated higher disease control than gemcitabine or gemcitabine plus nab-paclitaxel. When these findings are considered within a broader translational framework, the results suggest that integrating clinical prognostic factors with molecular profiling could guide more personalized treatment strategies. Such an approach has the potential to not only optimize survival outcomes but also to inform resource allocation and guideline development, particularly in settings characterized by constrained oncology infrastructure. Clinicopathologic factors that are readily available may facilitate the selection of regimens in routine practice.

Declarations

Ethics approval and consent to participate

The research was reviewed and approved by the Scientific Committee at the Department of Oncology, Iraqi board for medical specialization. All procedures performed in the present study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments. Prior to the initiation of data collection, verbal consent was obtained from all patients. This process occurred subsequent to a thorough explanation of the study's objectives and the assurance of confidentiality. This approach to obtaining consent aligns with the standards outlined by Betés et al. (2019) and Springfeld et al. (2019).

Consent for Publication

Not applicable.

Availability of Data and Material

The data that supports the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest / Competing Interests

The authors declare that there are no conflicts of interest.

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Authors' Contributions

F.N: Conceptualization, Methodology, Formal analysis, Investigation, Writing of the original draft.

M.S: Conceptualization, Methodology, Writing of the original draft, Supervision.

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Use of Generative AI and AI-Assisted Technologies

The authors declare that no generative AI or AI-assisted technologies were used in the preparation of this work.

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