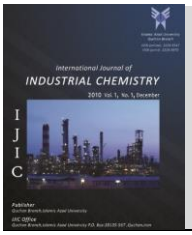

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Evaluation of the efficacy and safety of FOLFIRINOX or albumin-bound paclitaxel in combination with S-1 in patients with pancreatic cancer

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Abstract

To investigate the clinical efficacy and safety of FOLFIRINOX or albumin-bound paclitaxel (Abraxane) combined with S-1 after radical pancreatic cancer surgery. A total of 133 patients who underwent adjuvant chemotherapy with the FOLFIRINOX (60 cases) or Abraxane combined with S-1 (73 cases) after radical resection pancreatic cancer were screened. According to the follow-up data, recurrence and metastasis, chemotherapy adverse reactions (nausea, vomiting, loss of appetite, leukopenia, thrombocytopenia, anemia, neurotoxicity, diarrhea), survival rate (OS), progression-free survival (PFS) and other indicators were collected to evaluate the efficacy and safety of the two chemotherapy regimens. There was significant difference of metastatic tumor site between both groups (P<0.001). The cases of DCR in the Abraxane + S-1 group were higher compared to the FOLFIRINOX group (P<0.001). The occurrence of adverse events was significantly lower in Abraxane + S-1 group during I-II AE compared with the FOLFIRINOX group. However, there was no significant difference in the AE during III-IV between two groups (P>0.05). The OS (HR=1.872, P=0.005) and PFS (HR=1.931, P=0.003) in Abraxane + S-1 group were significantly higher than those in the FOLFIRINOX group. Adjuvant chemotherapy with Abraxane combined with S-1 regimen in patients with pancreatic cancer resection prolonged OS and PFS, improved DCR, with the overall adverse reactions safe and manageable compared with the FOLFIRINOX regimen.

KEYWORDS: FOLFIRINOX; albumin-bound paclitaxel; S-1; pancreatic cancer

1. Introduction

Pancreatic cancer is one of the deadliest digestive system tumors worldwide [1]. The latest China Cancer Center survey report shows that pancreatic cancer in China is 6.92/100,000, ranking 10th in the incidence of malignant tumors, and the mortality rate is 6.16/100,000 [2, 3]. The incidence of pancreatic cancer is increasing worldwide, and the 5-year survival rate is meager, which is a severe threat to human health [4]. Pancreatic cancer is insidious, and its clinical manifestations are not obvious and are primarily non-specific until the advanced stage. Currently, the main treatment options for pancreatic cancer include surgery, chemotherapy, radiotherapy, and targeted therapy [5]. Surgery is currently considered the only possible treatment to cure pancreatic cancer. However, the clinical symptoms of pancreatic cancer are not obvious, and early diagnosis is difficult, leading to the fact that only 15-20% of pancreatic cancer patients have the chance of radical surgery at the time of diagnosis [6]. Pancreatic cancer chemotherapy strategies include postoperative adjuvant chemotherapy, neoadjuvant chemotherapy, and palliative chemotherapy [7]. The first-line adjuvant chemotherapy regimens in China include folinic acid, fluorouracil, irinotecan, oxaliplatin (FOLFIRNOX) regimen, gemcitabine (GEM) regimen, GEM combined with capecitabine regimen, and Tegafur Gimeracil Oteracil Potassium Capsule single agent (S-1) regimen [8-10].

Overall, adjuvant therapy has made significant progress in conducting high-quality, multicenter randomized controlled trials and is now the standard of care after pancreatic cancer resection [11]. Regimens such as FOLFIRINOX and S-1 monotherapy have shown significant advantages in prolonging the survival of patients after pancreatic cancer resection [12, 13]. However, the role of combination of FOLFIRINOX and S-1 in patients after radical pancreatic cancer surgery is unclear. In addition, the combination of albumin-bound paclitaxel (Abraxane) and S-1 has been widely used in the chemotherapy of various cancers, such as advanced gastric adenocarcinoma [14] and gastric cancer [15], and achieved better efficacy and lower toxicity. Therefore, the present study aimed to investigate the clinical efficacy and safety of FOLFIRINOX or albumin-bound paclitaxel (Abraxane) combined with S-1 after radical pancreatic cancer surgery.

2. Materials and Methods

2.1. Patient enrollment

A total of 133 patients who attended Jiangsu Cancer Hospital from August 2019 to October 2022 underwent adjuvant chemotherapy with the FOLFIRINOX (60 cases) or Abraxane combined with S-1 (73 cases) after radical resection pancreatic cancer were screened. The basic information of patients such as gender, age, primary tumor site and metastatic tumor site. The present study was approved by the Ethics Committee of Jiangsu Cancer Hospital and informed consent was obtained from each participant.

Inclusion criteria: (1) radical resection and pathologically confirmed pancreatic cancer; (2) age between 18 and 75 years; (3) good postoperative recovery with no serious postoperative complications. Predicted survival was more than 3 months; (4) the completed course of chemotherapy ≥3 courses; (5) not received neoadjuvant chemotherapy, radiotherapy, or immunotherapy prior to surgery.

Exclusion criteria: (1) combined significant organ insufficiency; (2) presence of chemotherapy-related contraindications; (3) total follow-up time less than 6 months; (4) patients with palliative resection of pancreatic cancer.

2.2. Treatment regimen

Laparoscopic pancreaticoduodenectomy was performed for pancreatic head and neck cancer, and laparoscopic distal pancreatectomy was performed for carcinoma of the tail of the pancreas. The patients who recovered well after surgery without severe postoperative complications were randomly assigned to the FOLFIRINOX regimen group, and Abraxane combined with S-1 regimen group for regular adjuvant chemotherapy within 1-2 months after surgery.

Abraxane combined with S-1 regimen group: 40-60 mg S-1 (Tegafur Gimeracil Oteracil Potassium Capsule, Qilu Pharmaceutical Co., LTD., Specification: 20 mg/capsule) was taken orally, once a day, and 125 mg/m2 nab-paclitaxel (Shi Yao Group Euyi Pharmaceutical Co., LTD., Specification: 100 mg/tablet) was given intravenously on day 1 and day 8. The regimen was administered every 3 weeks, and lasted for 6 cycles.
FOLFIRINOX regimen group: oxaliplatin (Jiangsu Hengrui Pharmaceutical Co., LTD., Specification: 50 mg/piece) 85 mg/m2, irinotecan (Jiangsu Hengrui Pharmaceutical Co., LTD., Specification: 40 mg/piece) 180 mg/m2, folinic acid (Chifeng Mengxin Pharmaceutical Co., LTD., Specification: 15 mg/tablet) 400 mg/m2 and 5-FU (Shanxi Yabao Pharmaceutical Group Co., LTD., 0.25 g/piece) 400 mg/m2 was intravenously on day 1, followed by 2400 mg/m2 continuous intravenous infusion for 46 h. The regimen was administered every 2 weeks, and lasted for 6 cycles.

2.3. Efficacy evaluation index

The efficacy of this study relied on imaging which included computed tomography (CT) and magnetic resonance imaging (MRI) assessment, and follow-up time was defined as the time from the date of surgery to the patient's death or follow-up cutoff. Overall survival (OS) was defined as the time from radical surgical treatment to the patient's last follow-up or death; Progression-free survival (PFS) was defined as the time between radical surgical treatment and the onset of tumor progression or death (from any cause). Objective response rate (ORR) was defined as tumor volume reduction of more than 30%; Disease control rate (DCR) was defined as no further growth of tumor volume after the use of drugs; Complete remission (CR) was defined as the disappearance of tumor on imaging for more than one month; Partial remission (PR) was defined as 50% reduction in the product of the largest diameter and the largest vertical diameter of the tumor and no increase in other lesions for more than one month; Stable disease (SD) referred to stable disease (no more than 50% reduction in the product of the largest diameter and the largest vertical diameter of the tumor and no increase in size); Progressive disease (PD) referred to tumor maximum diameter and maximum vertical diameter multiplied by more than 25% increase, lasting more than one month.

2.4. Safety evaluation index

Adverse reactions during chemotherapy, according to the National Cancer Institute Common Toxicity Classification Criteria Version 4.0 (CTCAE 4.0), common adverse reactions include nausea, vomiting, reduced appetite, leukopenia, thrombocytopenia, anaemia, neurotoxicity and diarrhea. When patients experience chemotherapy-related adverse severe reactions, symptomatic supportive therapy and adjuvant chemotherapy may be appropriately delayed for 1-2 weeks depending on treatment recovery.

2.5. Follow-up visit

After the completion of chemotherapy, follow-ups were conducted every 2-3 months by a combination of telephone and outpatient follow-ups. The items to be reviewed include chest CT scan, whole abdomen enhanced CT or whole abdomen enhanced MRI and tumor markers including carbohydrate antigen 19-9 (CA19-9), carbohydrate antigen 12-5 (CA12-5), carcinoembryonic antigen (CEA), and positron emission tomography/computed tomography (PET/CT) if necessary.

2.6. Statistical analysis

SPSS 22.0 software was applied for data analysis, and the Shapiro-Wilk test was used to determine whether the measurement data conformed to a normal distribution. Normally distributed measurement data were expressed as mean ± standard deviation, and t-test was used for two measures that obeyed normal distribution with equal variance, otherwise Mann-Whitney U test was used. The c2 test was used for comparison between groups for numerical data, and Kaplan-Meier survival analysis was used for comparison of PFS and DS in the two groups. The difference was statistically significant at $P<0.05$.

3. Results

3.1 Basic information of enrolled pancreatic cancer patients

As shown in Table 1, there were no significant differences in gender, age, and primary tumor site between two groups (P>0.05). However, as for the metastatic tumor site, in the FOLFIRINOX group, there were 27 liver metastases, 5 abdominal metastases, and 28 multiple metastases; in the Abraxane + S-1 group, there were 34 liver metastases, 27 abdominal metastases, and 12 multiple metastases. There was significant difference of metastatic tumor site between both groups (P<0.001).

Table 1. Clininopathological information of all enrolled patients

Clinicopathological index	FOLFIRINOX (n = 60)	Abraxane + S-1 (n = 73)	P value
Gender			0.206
Male	33	48	
Female	27	25	
Age			0.316
≤62	34	35	
>62	26	38	
Primary tumor site			0.910
Head and neck of pancreas	29	36	
Pancreatic body caudal	31	37	
Metastatic tumor site			<0.001
hepatic metastasis	27	34	
peritoneum metastasis	5	27	
Multiple metastasis	28	12	

3.2. The comparison of clinical efficacy of two groups

The clinical efficacy of the two groups was analyzed in Table 2. As shown, in the FOLFIRINOX group, the PR cases were 9, SD cases were 29, PD cases were 22, ORR was 15.00%, and DCR was 63.33%. In the Abraxane + S-1 group, PR cases were 21, SD cases were 45, PD cases were 7, ORR was 28.77%, and DCR was 90.41%. Collectively, the cases of DCR in the Abraxane + S-1 group were higher compared to the FOLFIRINOX group (P<0.001).

Table 2. Clinical efficacy of all enrolled patients

Clinical efficacy	FOLFIRINOX (n = 60)	Abraxane + S-1 (n = 73)	P value
PR	9	21	
SD	29	45	
PD	22	7	
ORR (CR + PR)	9 (15.00%)	21 (28.77%)	0.059
DCR (PR + SD)	38 (63.33%)	66 (90.41%)	<0.001

*Note: PR: partial remission. SD: stable disease. PD: progressive disease. ORR: objective response rate. CR: complete remission. DCR: disease control rate.

3.3. Incidence of adverse events (AEs) in two groups

After treatment, the incidence of adverse events in the two groups was recorded in Table 3. In the FOLFIRINOX group, during I-II AE, nausea cases were 49, vomiting cases were 31, reduced appetite cases were 57, leukopenia cases were 47, thrombocytopenia cases were 8, anaemia cases were 12, neurotoxicity cases were 15, and diarrhea cases were 7; during III-IV AE, nausea cases were 11, vomiting cases were 4, reduced appetite cases were 3, leukopenia cases were 2, thrombocytopenia case was 1, neurotoxicity case

was 1 and diarrhea case was 1. As for the Abraxane + S-1 group, during I-II AE, nausea cases were 45, vomiting cases were 5, reduced appetite cases were 32, leukopenia cases were 64, thrombocytopenia cases were 11, anaemia cases were 13, neurotoxicity cases were 68 and diarrhea cases were 6; during III-IV AE, nausea cases were 2, vomiting cases were 1, reduced appetite cases were 5, leukopenia cases were 9, thrombocytopenia case was 1, anaemia cases were 2 and neurotoxicity cases were 5. Taken together, the occurrence of adverse events was significantly lower in Abraxane + S-1 group during I-II AE compared with the FOLFIRINOX group. However, there was no significant difference in the AE during III-IV between two groups (P>0.05).

Table 3. Incidence of adverse events (AEs) of all enrolled patients

Adverse events	FOLFIRINOX (n = 60)		Abraxane + S-1 (n = 73)	
	I-II AE	III-IV AE	I-II AE	III-IV AE
Nausea	49 (81.67%)	11 (18.33%)	45 (61.64%)	2 (2.74%)
Vomiting	31 (51.67%)	4 (6.67%)	5 (6.85%)	1 (1.37%)
Reduced appetite	57 (95.00%)	3 (5.00%)	32 (43.84%)	5 (6.85%)
Leukopenia	47 (78.33%)	2 (3.33%)	64 (87.67%)	9 (12.33%)
Thrombocytopenia	8 (13.33%)	1 (1.67%)	11 (15.07%)	1 (1.37%)
Anaemia	12 (20.00%)	0	13 (17.81%)	2 (2.74%)
Neurotoxicity	15 (85.00%)	1 (1.67%)	68 (93.15%)	5 (6.85%)
Diarrhea	7 (11.67%)	1 (1.67%)	6 (8.22%)	0

*Note: AE: adverse events.

3.4. The prognosis in two groups

As demonstrated in Figure 1, the OS was significantly higher in Abraxane + S-1 group in contrast with the FOLFIRINOX group (HR=1.872, P=0.005). Moreover, Figure 2 depicted that the progression-free survival (PFS) was better in Abraxane + S-1 group in relation to the FOLFIRINOX group (HR=1.931, P=0.003). Corporately, Abraxane + S-1 group patients had a more favorable prognosis than the FOLFIRINOX group.

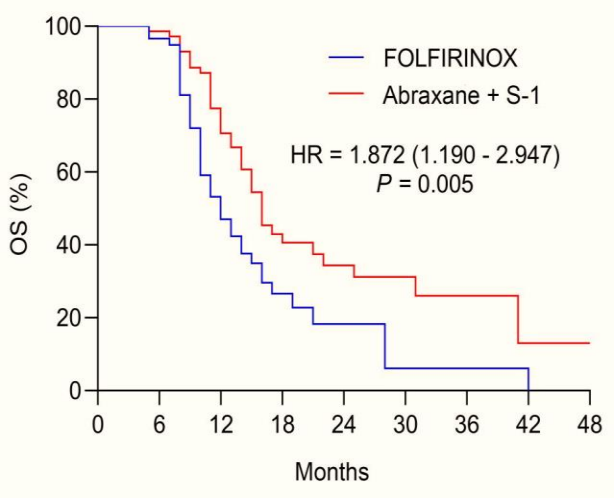

Figure 1. The OS rate of pancreatic cancer patients. OS: overall survival. HR: hazard ratio.

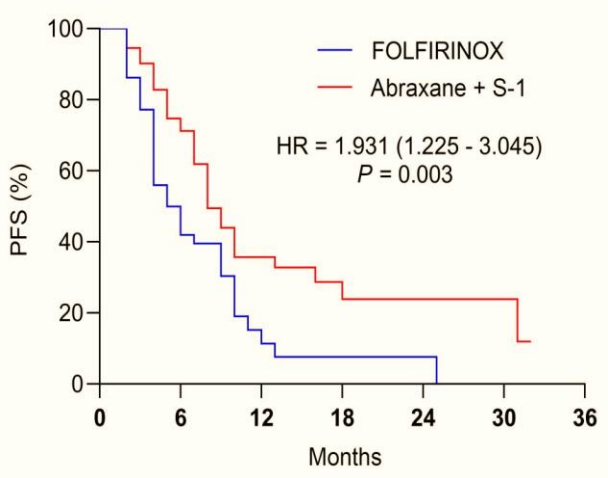

Figure 2. The PFS rate of pancreatic cancer patients. PFS: progression-free survival. HR: hazard ratio.

4. Discussion

Pancreatic cancer is characterized by a high recurrence rate, mortality rate, and inferior prognosis. Early surgical resection is currently the only way to cure pancreatic cancer. However, surgery alone cannot make patients survive for a long time, and the median survival after surgery is about 8-10 months [16, 17]. Years of randomized controlled trials have proved that adjuvant chemotherapy is an essential part of pancreatic cancer treatment, which significantly prolongs the survival cycle of patients and is currently the standard of care for patients after surgery. However, the optimal adjuvant chemotherapy regimen is not known. Tegafur Gimeracil Oteracil Potassium Capsule is a popular antineoplastic drug in recent years, based on tegafur, which can be administered orally [18]. The compound dosage formulation is a third-generation fluorouracil derivative with good absorbability and high bioavailability [19]. As a third-generation fluorouracil derivative, it consists of tegafur, gimeprazine, and octreotide [20]. Tegafur can be converted to 5-Fu in the body, Gimeracil can inhibit the catabolism of 5-Fu, and Oteracil can inhibit the phosphorylation of fluorouracil and reduce the gastrointestinal toxic side effects [21]. Since its introduction, the FOLFIRINOX regimen has produced remarkable clinical results due to its multidrug combination, which has dramatically improved survival time in progressive pancreatic cancer [22]. However, the efficacy is matched by severe chemotherapeutic side effects, making it intolerable for patients in poor physical condition [23]. There is evidence at home and abroad that patients with standard doses of FOLFIRINOX have more adverse reactions [24]. The current clinical use of the FOLFIRINOX regimen is mostly a modified version of mFOLFIRINOX, which aims to reduce adverse effects in patients without reducing the efficacy of chemotherapy by reducing the dose of some drugs [25, 26].

Albumin-bound paclitaxel is formed by nanoparticles of albumin and paclitaxel, and its antitumor effects are mainly performed by blocking critical interphase and mitotic processes [27, 28]. Compared with conventional paclitaxel drugs, it alleviates the severe allergic reactions caused by co-solvents, while increasing the concentration of the drug in tumor cells, improving the efficacy and reducing the toxic reactions [29-31]. Our investigation found that in the FOLFIRINOX group, DCR, OS, and PFS were significantly lower than those in the Abraxane combined with S-1 group, while the incidence of adverse reactions was higher than that in the Abraxane combined with S-1 group. Consistently, a previous study has proven that S-1 plus Abraxane is an efficient and safe regimen as first-line treatment for patients with advanced gastric cancer [32]. Of note, Masaya Suenaga et al have pointed that S-1 and nab-paclitaxel have a synergetic effect in preclinical studies with good tolerability, and may play a role in pancreatic cancer tumor angiogenesis [33].

5. Conclusion

In conclusion, our study demonstrates that the application of Abraxane combined with S-1 in post-pancreatic cancer resection patients can effectively control disease, prolong the OS and PFS of patients, and with high safety, which is worthy for clinical promotion.

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