

Transcatheter arterial infusion combined with radioactive particles in the treatment of advanced body/tail pancreatic cancer: a retrospective cohort study

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Abstract

Background

Patients with advanced body/tail pancreatic cancer have poor quality of life and low overall survival rate. In recent years, interventional diagnosis and treatment of advanced pancreatic cancer have become increasingly widespread. This retrospective cohort study investigated the efficacy of routine intravenous chemotherapy (the control group), transcatheter arterial infusion (TAI) chemotherapy, and TAI combined with radioactive particles as therapeutic methods for advanced body/tail cancer pancreatic by assessing the short-term and overall survival rates.

Methods

We screened our prospective database for patients with advanced body/tail pancreatic cancer, which tumor deemed unresectable and no other confirmed malignant tumors, patients were assigned into three groups according to their treatment. Analyses with regard to the clinical responses, the 6, 12, and 18-month survival rates and overall survival rates were performed.

Results

The median survival time was 6 months in the control group, 10 months in the TAI group and 13 months in the TAI combined group. The Kaplan–Meier estimates of the OS among the three groups, indicating that there is significant difference among three groups ($P=0.000$). The clinical remission rates were 17.5% in the control group, 41.5% in the TAI group, and 48.0% in the TAI combined group. Covariates analyzed showed that different treatment methods and times affected the results significantly ($P=0.002$).

Conclusions

In the treatment of advanced body/tail pancreatic cancer, TAI and TAI combined with radioactive particles significantly improved the clinical outcomes in patients compared with routine intravenous chemotherapy.

Background

The incidence of pancreatic cancer (PC) has increased considerably over recent decades throughout the world [1]. Pancreatic carcinoma is asymptomatic in the early stages, so patients are often diagnosed with an advanced stage of the disease (TMN stages III and IV [2]), which in the majority of cases is deemed inoperable [3]. Chemotherapeutic regimens and chemoradiotherapy are commonly administered in an attempt to slow disease progression; however, these strategies are often ineffective [4],[5]. Molecular

targeting and stem cell therapy offer alternative treatment strategies; however, these methods are difficult to apply widely in clinic due to technical and economic constraints.

Regional intra-arterial chemotherapy has also been proposed as a potential treatment option for pancreatic carcinoma [1]. Chen and colleagues employed transcatheter arterial infusion chemotherapy (TAI) involving gemcitabine (GEM) and oxaliplatin (OXA) in the treatment of unresectable pancreatic cancer and found it to be well tolerated and highly effective [6]. It has been suggested that if pancreatic cancer initially diagnosed as unresectable can be controlled and disease progression slowed by effective therapy, surgical resection may become an option, thereby potentially increasing long-term survival [7]. The aim of therapy in the case of this malignancy could therefore be localized control and containment to enable surgery.

The implantation of radioactive particles combined with chemotherapy or radiotherapy is another technique that has been reported to be effective for the local control of pancreatic cancer [8], [9]. ^{125}I particles are the most commonly used radioactive particles for this type of cancer therapy because their long half-life and short radiation distance mean that high doses can be targeted specifically to the tumor, thereby not damaging the surrounding tissue [10]. A study by Yu and colleagues showed that when chemoradiotherapy combined with ^{125}I implantation was used to treat advanced pancreatic cancer, a higher local control rate and a better quality of life were recorded in patients compared with the use of chemoradiotherapy alone [11].

In this study, we compared a range of treatments for advanced body/tail pancreatic cancer involving intravascular interventional therapy and TAI combined with particle therapy in terms of the short-term and overall survival rates. Our findings highlight the potential of these novel treatment strategies to significantly improve the survival of patients with advanced pancreatic cancer.

Methods

Patients

In total, 360 patients with locally advanced body/tail pancreatic cancer were reviewed in 8 centers, in which 237 patients diagnosed met the inclusion criterion. Diagnoses were confirmed by histological examination and either clinical or radiological findings. The inclusion criteria for the study were as follows: (1) pathologically or radiologically-diagnosed pancreatic cancer in the body/tail ; (2) tumor deemed unresectable due to the advanced stage of the disease as determined by TNM staging according to AJCC [2], which included stage \geq A and beyond; (3) No other confirmed malignant tumors. The exclusion criteria were as follows: (1) patients with mental disorders or with severe cardiopulmonary dysfunction or advanced cachexia, (2) Multiple metastases throughout the body, (3) insufficient coagulation (platelets $<30 \times 10^9/\text{L}$).

Classification

Patients were assigned to three groups according to their treatment: group A, routine intravenous chemotherapy; group B, transcatheter arterial infusion (TAI) chemotherapy; group C, TAI combined with radioactive particles as therapeutic.

Routine intravenous chemotherapy

For the control group, concurrent chemotherapy was performed. This involved the intravenous administration of GEM 800-1000 mg/m², no less than 30 min, once a week for 2 weeks, breaking for 1 week, and starting for another course of treatment, totally four courses.

Transcatheter arterial infusion (TAI) chemotherapy

For the TAI treatment group, a 5-Fr arterial sheath was placed in the right femoral artery under local anesthesia and the celiac trunk was selected by 5-Fr RH catheter under digital subtraction angiography (DSA). Then, a combination of GEM 800–1000 mg/m², was injected via the RH catheter for 2 h at 1/2 dosage, and so was the 5-fluorouracil (FU) 500 mg/m² but for 20 h.

Radioactive I¹²⁵ particle implantation

Patients in the TAI combined treatment group received arterial infusion combined with ablation or radioactive particles. For radioactive I¹²⁵ particle implantation in the TAI combined treatment group, patients first underwent CT (uMI-510 PET-CT, United Imaging, Shanghai, China), and the images were entered into a treatment plan system (TPS, Astro Tech Ltd, Beijing, China). The gross tumor volume (GTV) was confirmed by analysis of the scans by a medical specialist, and 0.5–1.0 cm was added to the boundary of the GTV to include the periphery of the tumor. Then, implantation of I¹²⁵ radiological particles (radioactivity, 0.55–0.75 mCi; dose, 120–140Gy; dose rate, 0.05–0.10Gy h⁻¹; half-life, 59.6 days; effective radius, 1.72 cm; Zhibo Bio-Tech Ltd, Beijing, China) was performed at the periphery of the tumors. The radioactive dose was evaluated 1 week after implantation, and a D90 (the dose to 90% of the volume) of 60–140 Gy was expected. If the actual dose was lower than this, implantation could be repeated.

Therapeutic effect

Changes in imaging and OS, as well as 6, 12, 18 -month survival rates, were used as indicators of efficacy of the treatment. The treatment response was evaluated 4–6 weeks after each treatment using the modified Response Evaluation Criteria in Solid Tumors (mRECIST).

A complete response (CR) was defined as disappearance of any intratumoral arterial enhancement in all lesions; a partial response (PR) was defined as a 30% decrease in the sum of the diameters of viable (contrast enhancement in the arterial phase) lesions; progressive disease (PD) was defined as an increase of 20% in the sum of the diameters of viable lesions; and stable disease (SD) was defined as any case that did not qualify as either PR or PD. The two largest foci were selected among the multifocal

lesions for measurement. CR and PR were considered as valid. OS refers to the time starting at initial interventional therapy until death or final follow-up (December 2015).

Follow-up

Follow-up of the patients was conducted from January, 2009, to December, 2015, to assess patient survival. Of the 237 patients enrolled in the study, 9 cases were lost at follow-up, constituting a loss rate of 3.80%.

Statistical analysis

Data were analyzed using the SPSS[®] version 16.0 software. OS, 6, 12, 18 -month survival rates in the three groups were compared by analysis of variance (ANOVA). OS rates were also estimated by the Kaplan–Meier method, and survival differences were analyzed by the log-rank test. $P < 0.05$ was considered statistically significant.

Results

The baseline characteristics of these patients are presented in Table 1. The study group comprised 134 male and 103 female patients, with an average age of 65.89 ± 11.64 years (range: 30–90 years). The control group ($n = 80$) who received routine intravenous chemotherapy, The TAI group ($n = 82$) who received arterial infusion, and the TAI combined group ($n = 75$) who received arterial infusion combined with radioactive particle implantation.

Table 1
Patients' baseline characteristics

Variables	Control group n = 80	TAI group n = 82	TAI combined group n = 75	P value
Gender				0.090
Male	53 (66.25%)	41 (50%)	40 (53.33%)	
Female	27 (33.75%)	41 (50%)	35 (46.67%)	
Age (years)	66.31 ± 11.76	68.11 ± 13.08	66.84 ± 13.17	0.167
TNM stage				0.679
T3N1M0	10 (12.5%)	9 (10.96%)	7 (9.3%)	
T3N1M1	62 (87.5%)	73 (89.2%)	68 (90.67%)	
Tumor size				0.202
< 3.0	1 (1.25%)	0 (0%)	0 (0%)	
3.0–5.0	2 (2.5%)	0 (0%)	0 (0%)	
> 5.0	77 (96.25%)	82 (100%)	75 (100%)	
Metastasis				0.685
Yes	75 (93.75%)	74 (90.24%)	68 (90.67%)	
No	5 (6.25%)	8 (9.76%)	7 (9.3%)	
Ascites				0.337
Yes	6 (7.5%)	2 (2.4%)	4 (5.3%)	
No	74 (92.5%)	80 (97.6%)	71 (94.7%)	
Jaundice				0.000
Yes	14 (17.5%)	42 (51.2%)	8 (10.7%)	
No	66 (82.5%)	40 (48.8%)	67 (89.3%)	
Child-Pugh class				0.000
A	0 (0%)	0 (0%)	0 (0%)	
B	16 (20.0%)	19 (23.2%)	40 (53.3%)	
C	64 (80.0%)	63 (76.8%)	35 (46.7%)	
CA 19 - 9				0.131
CA 19 - 9, carbohydrate antigen 19 - 9.				

Variables	Control group	TAI group	TAI combined group	P value
	n = 80	n = 82	n = 75	
Normal	12 (15.0%)	20 (23.4%)	21 (28.0%)	
Unusual	68 (85.0%)	62 (75.6%)	54 (72.0%)	
CA 19 – 9, carbohydrate antigen 19 – 9.				

Comparison of the OS times among the three groups

The median survival time were 6.54 ± 0.63 months in the control group, 10.12 ± 0.80 months in the TAI group, and 13.62 ± 0.98 months in the TAI combined group. Figure 1 illustrates the Kaplan–Meier estimates of the OS times among the three groups, indicating that TAI treatment and TAI combined with radioactive particles therapy significantly prolongs survival times in patients with advanced body/tail pancreatic cancer compared with routine intravenous chemotherapy. The data indicate that, on average, this therapeutic combination can extend the survival times of patients with advanced pancreatic cancer by 3 months compared with TAI alone.

Comparison of the overall response to therapy among the three groups

The patients in each of the groups were evaluated for their response to therapy. As shown in Table 2, the overall control rates (CR + PR) were improved in the TAI (41.5%) and TAI combined (48.0%) treatment groups compared with the control group (17.5%). Furthermore, the rates of stable and progressive disease were decreased in the two treatment groups (32.9% and 25.6% for the TAI group, and 28.0% and 24.0% for the TAI combined group, respectively) compared with the control group (47.5% and 35.0%, respectively).

Table 2
Overall response to therapy in the three groups of patients

Response, n (%)	Control group	TAI group	TAI combined group	Total	P value
	n = 80	n = 82	n = 75	n = 237	
CR + PR, n (%)	14 (17.5%)	34 (41.5%)	36 (48.0%)	84 (35.4%)	0.000
SD, n (%)	38 (47.5%)	27 (32.9%)	21 (28.0%)	86 (36.3%)	
PD, n (%)	28 (35.0%)	21 (25.6%)	18 (24.0%)	67 (28.3%)	
CR, complete remission; PR, partial remission; SD, stable disease; PD, progressive disease.					

To investigate the response to therapy on an individual level, one cases were analyzed in greater depth. Figure 2 provides representative CT images for one particular case studies diagnosed with advanced body/tail pancreatic cancer who received TAI combined with radioactive particles therapy. A 78-year-old man diagnosed with advanced body/tail pancreatic cancer who had previously been treated with a high-intensity ultrasonic focusing knife. The cancer was located in the pancreatic body (Fig. 2A, indicated by

an arrow). After arterial infusion combined with radioactive particles therapy, a partial response was achieved (Fig. 2B, indicated by an arrow). Positive responses to therapy were therefore achieved in the case.

Comparison of the 6, 12, and 18-month survival rates among the three groups

The 6, 12, and 18-month survival rates were found to be significantly improved in the TAI group (71.95%, 17.07%, and 7.32%) and the TAI combined group (80%, 53.33%, and 20%) compared with the control group (37.5%, 11.25%, and 3.75%, respectively) (Table 3). Taken together, our results provide evidence that TAI, and TAI combined with radioactive particles therapy, can significantly improve the survival of patients with advanced body/tail pancreatic cancer compared with routine intravenous chemotherapy.

Table 3
Comparisons of the 6, 12, and 18-month survival rates among the three groups

Time (months)		Control group	TAI group	TAI combined group	P value
		Cases, n (%)	Cases, n (%)	Cases, n (%)	
6	Survival	30 (37.5%)	59 (71.95%)	60 (80%)	0.000
	Death	50 (62.5%)	23 (28.05%)	15 (20%)	
12	Survival	9 (11.25%)	14 (17.07%)	40 (53.33%)	0.000
	Death	71 (88.75%)	68 (82.93%)	35 (46.67%)	
18	Survival	3 (3.75%)	6 (7.32%)	15 (20%)	0.002
	Death	77 (96.25%)	76 (92.68%)	60 (80%)	

Discussion

Previous studies have shown that ¹²⁵I particle implantation is a feasible and safe procedure for unresectable pancreatic cancer [12]; however, a large-scale study to assess the long-term effects of this combination treatment on patient survival has been lacking. Here, we report a retrospective cohort study investigating the curative effects of TAI chemotherapy with or without radioactive particle implantation in patients with unresectable advanced body/tail pancreatic cancer. The survival was positively affected as demonstrated by the 12-month survival rate (53.33% vs. 11.25% for the combined treatment vs. control groups) and median survival times (13.62 ± 0.98 months vs. 6.54 ± 0.63 months for the combined treatment vs. control groups).

In a previous study, Hong and colleagues assessed the clinical effectiveness and safety of continuous TAI of GEM and FU versus systemic venous chemotherapy in patients with advanced pancreatic carcinoma [13]. In our study, TAI chemotherapy involved a combination of GEM 800–1000 mg/m², and 5-FU 500 mg/m²; RFA at a temperature of 85–100; and a dosage of 120–140 Gy of ¹²⁵I particles was used for implantation. Several previous studies have also reported improved clinical outcomes in patients with advanced pancreatic cancer after receiving ¹²⁵I particle implantation combined with chemotherapy or radiotherapy in various combinations at a range of dosages [9],[11], [14],[15],[16]. For example, Yu and colleagues performed ¹²⁵I particle implantation at a lower dose (88.71 Gy) combined with chemotherapy (GEM, 1000 mg/m²) and radiotherapy (30.62 Gy) and obtained a local control rate of 73.33%, a 12-month survival rate of 72.0%, and a median overall survival time of 14 months in advanced pancreatic cancer patients [11]. There is therefore accumulating evidence for the value of combining different treatment modalities to control unresectable pancreatic malignancies to extend the life expectancy of patients.

The combined therapeutic use of TAI with radioactive particle implantation has been more widely documented for hepatocellular carcinoma (HCC) [17],[18],[19],[20]. In recent years, the ¹²⁵I particle implantation therapy has gradually been applied clinically and has achieved certain therapeutic effects. A study by Dai F and colleagues showed that the ¹²⁵I particle implantation therapy significantly inhibited the local growth of advanced NSCLC [21]. And a study by Sun and colleagues demonstrated that the combination of transcatheter arterial chemoembolization with endovascular implantation of ¹²⁵I particles was effective at increasing the survival rates in HCC patients with portal vein tumor thrombosis compared with transcatheter arterial chemoembolization treatment alone [20]. Consistently, it was found in our study that the TAI combination therapy significantly improved clinical outcome of patients with unresectable pancreatic cancer.

Conclusions

the implantation of ¹²⁵I particles into tumors combined with TAI chemotherapy results in an improved response rate and prolonged survival in patients with unresectable advanced body/tail pancreatic cancer compared with standard intravenous chemotherapy. This offers a promising therapeutic strategy with which to extend the lifespan of patients with this type of malignancy.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Shanghai Tenth People's Hospital, Tongji University. Written informed consent and permissions for the possibility of utilizing their clinical data anonymously were obtained from all subjects.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

SH, CC, and YY: Substantial contributions to acquisition of data, analysis and interpretation of data, drafting the article, performed the statistical analyses, revising it critically for important intellectual content. JC, LY, HX, JL, WW, and YL: Substantial contributions to acquisition of data, analysis and interpretation of data, and performed the statistical analyses. LW, SZ, FL, WW, JJ, HL, SY, JL, and JH: Substantial contributions to acquisition of data, analysis and interpretation of data. RL, ML, and XZ: Substantial contributions to study conception and design, analysis and interpretation of data. All authors involved in revising it critically for important intellectual content, read and approved the final manuscript.

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Figures

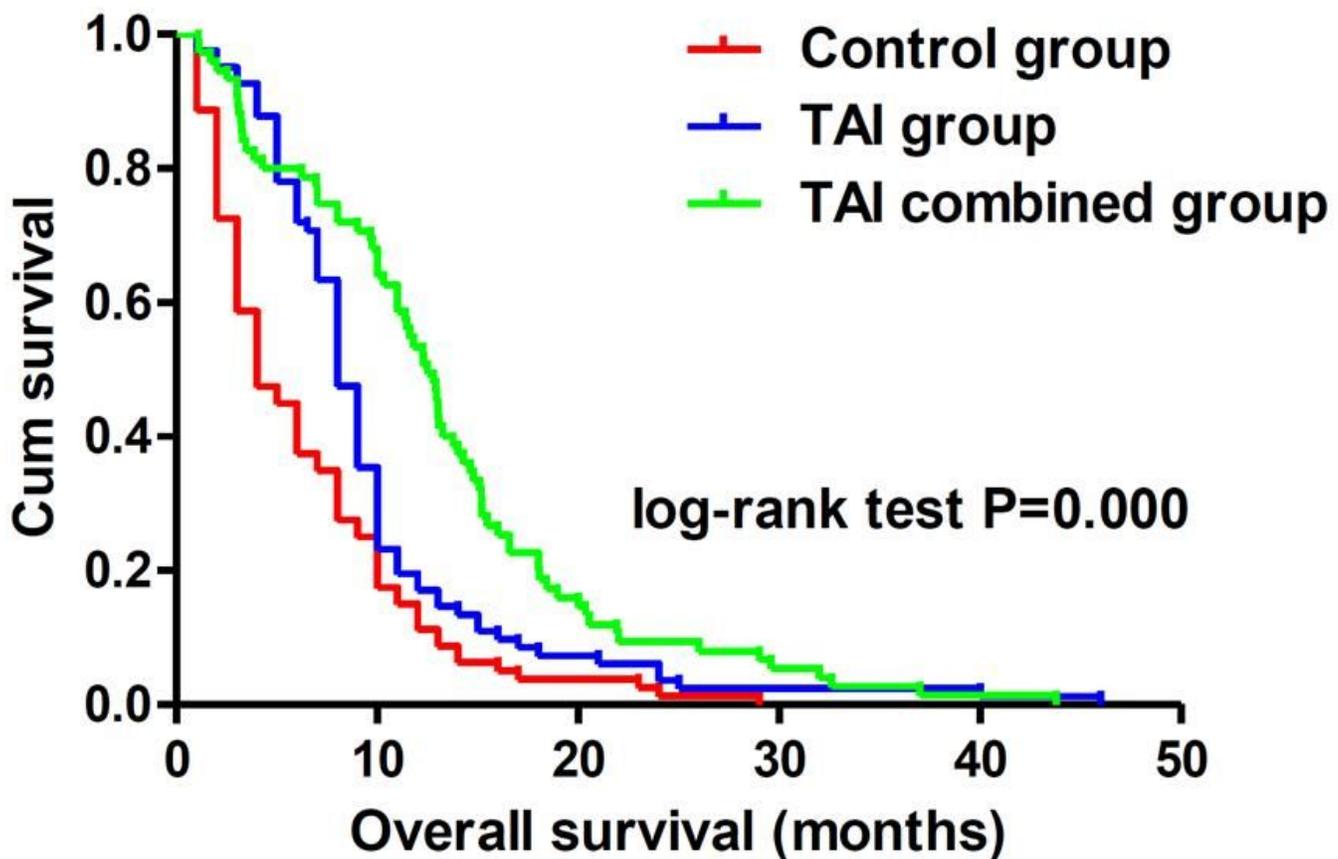


Figure 1

Kaplan–Meier estimates of the overall survival rates among the three groups (control, TAI, and the TAI combined group)

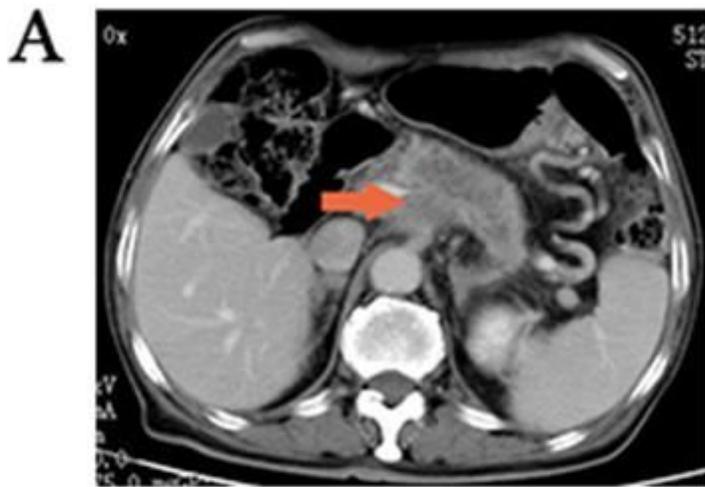


Figure 2

Representative CT images of one case studied treated with arterial infusion combined with radioactive particles therapy A and B: A. The cancer was located in the pancreatic body (arrow). B. After arterial infusion combined with radioactive particles therapy, a partial response was achieved (arrow).