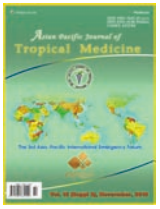

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Survival analysis of 198 patients with pancreatic cancer in Hainan, China: A multi-institution prospective study

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ABSTRACT

Objective: To explore the survival status and prognostic factors of patients with pancreatic cancer in Hainan.

Methods: Clinical data of patients who were diagnosed as pancreatic cancer and visited the First and Second Affiliated Hospital of Hainan Medical University and Haikou People's Hospital from 2013 to 2017 were collected based on electronic medical records. Basic information was collected by a self-designed questionnaire. Data about admission examinations including blood routine examination, blood biochemistry tests, tumour markers tests, imaging examination and other clinical tests were also collected. The date of follow-up via telephone was 30 June 2018. The survival rate was analyzed by the Kaplan–Meier method and the log-rank test. Univariate and multivariate analyses were performed with COX regression model.

Results: A total of 198 patients were included in the study. Kaplan–Meier results showed that the overall survival (OS) in 6 months and 1, 2, 3 and 5 years was 47.4%, 26.8%, 16.4%, 13.2%, and 8.7%, respectively. The median OS was 5.8 months. Log-rank test analysis found that there were significant differences in OS among patients with different age, surgery status, distant metastasis or absolute number of neutrophils, percentage of neutrophils, absolute number of lymphocytes, neutrophil-to-lymphocyte ratio (NLR), CA199 and carcino-embryonic antigen (P<0.1). COX multivariate analysis showed that age, surgical presence, presence or absence of distant metastasis and NLR were significantly associated OS (P<0.05).

Conclusions: Older age, higher NLR and liver or lung metastasis are independent risk factors, while surgical treatment is an independent protective factor for patients with pancreatic cancer.

1. Introduction

The mortality rate of pancreatic cancer is similar to the incidence rate, and its morbidity and mortality are still rising. Pancreatic cancer is currently the fourth leading cause of cancer death worldwide and is expected to rise to the second by 2030[1,2]. It is becoming one of the biggest public health problems threatening human health. Due to its special anatomical location and a hidden and high degree of malignancy, most patients with pancreatic cancer

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lost the chance of surgery due to the time of discovery. Therefore, tertiary prevention is important to prolong the survival time of patients with pancreatic cancer. Studies have shown that multiple factors (age, tumour factors, gender, surgery, past history, cancer typing, metastasis, *etc*.) may affect the survival rate[3-7]. Analysis of survival status and influencing factors in patients with pancreatic cancer in tropical areas of Hainan is scarce. This study analyzed the survival status and influencing factors of patients with pancreatic cancer in three hospitals in Haikou City, Hainan Province from 2013 to 2017 based on electronic medical records and follow-up, aiming to provide a theoretical basis for measures to improve the survival outcome of patients of pancreatic cancer.

2. Materials and methods

2.1. Methods

This study is based on the clinical data from electronic medical records. The survival status of patients was prospectively followed up by telephone. The Ethics committee of the First Affiliated Hospital of Hainan Medical University approved this study based on the protocol described in the Methods section (NO. 2015020). This study was a prospective study and the flow diagram is shown in Figure 1.

2.2. Objects

We obtained oral informed consent from all participants. Electronic medical record data were collected from the First and Second Affiliated Hospital of Hainan Medical University and Haikou People's Hospital from January 2013 to December 2017. Patients who were diagnosed by clinical or pathological and related imaging and had complete medical records, follow-up information and endpoint status were included. The end-point event was death from pancreatic cancer. Patients without clinical data, non-first-time cases, patients with suspected ampullary tumours, and patients with other malignant tumours or severe diseases were excluded.

2.3. Data collection

Basic information was collected by a self-designed questionnaire. Data about admission examinations including blood routine examination, blood biochemistry tests, tumour markers tests, imaging

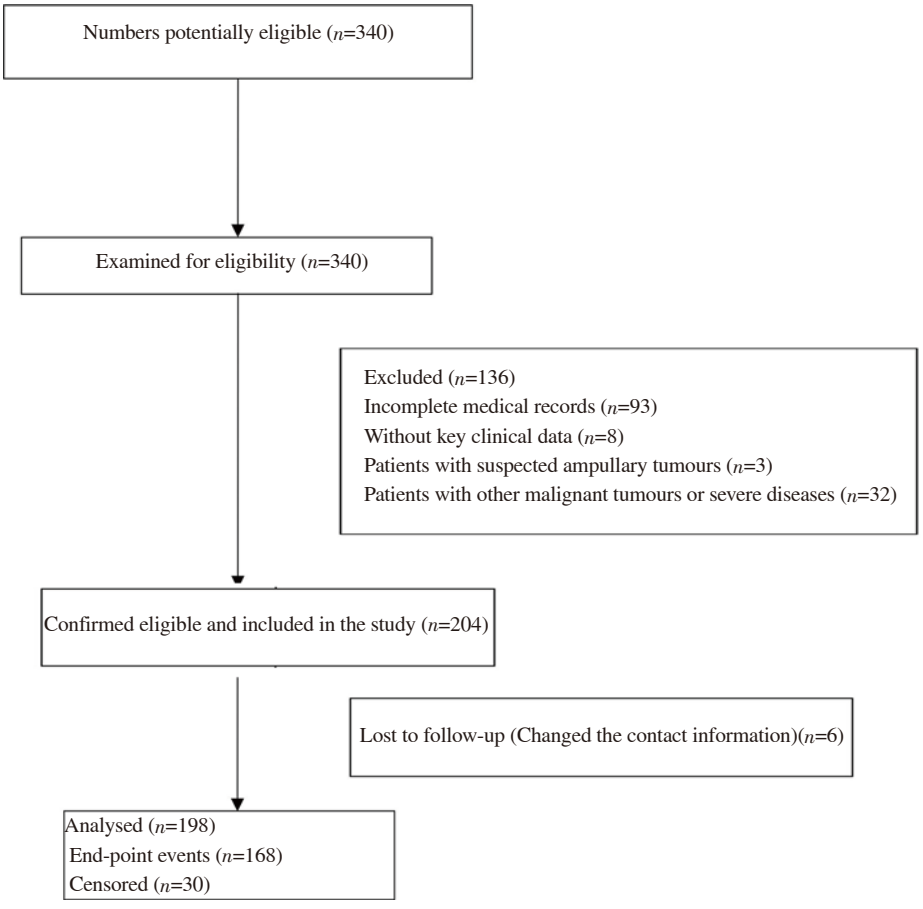

Figure 1. The study flowchart.

examination and other clinical tests were collected. The survival status of patients was confirmed *via* telephone (if death, record the time of death). The survival time was calculated from the time of the first-time diagnosis to 30 June 2018.

2.4. Construction of death risk scoring tool of pancreatic cancer

A multivariate COX regression model was constructed. The significative regression coefficient β and mean value were calculated. Each significative affecting factor was classified and the appropriate reference value W_{ij} for each group was selected (W_{ij}= 0 when binary status is "NO"; or the intermediate value in the selected group as the reference value). The basic risk reference value W_{iREF} for each factor was confirmed (Binary variable: W_{iREF}= 0; the multi-categorical variable: W_{iREF}= the corresponding W_{ij}). The distance D between the grouping of each factor and the base risk reference value was calculated as follows: $D= \beta_i*(W_{ij} - W_{iREF})$. The constant B value for 1 point in the score tool was set. B should be the smallest absolute value ($\beta_i \times$group spacing) among all the influencing factors. $Points_{ij}$ was calculated as follows: $Points_{ij}=D/B$[8,9].

Table 1. Survival rate and median overall survival of patients with pancreatic cancer.

Influencing factors	Survival rate (%)					mOS (months)	χ^2	*P*
	0.5 year	1 year	2 years	3 years	⩾5 years			
Age (years)						5.8	27.572	<0.001
30— (*n*=4)	75.0	50.0	25.0	25.0	25.0	14.4		
40— (*n*=18)	77.8	53.8	46.2	46.2	36.9	24.1		
50— (*n*=36)	63.9	38.5	12.8	9.6	9.6	7.7		
60— (*n*=51)	49.0	25.6	14.2	8.5	4.3	5.8		
70— (*n*=61)	39.3	17.8	14.2	14.2	7.1	4.8		
80— (*n*=28)	18.5	11.1	5.6	5.6	0.0	3.2		
Surgery						5.8	18.703	<0.001
Yes (*n*=32)	84.4	67.9	39.7	29.7	29.7	16.9		
No (*n*=166)	40.4	19.0	11.9	10.0	4.7	5.0		
Distant metastasis						5.8	13.490	<0.001
No (*n*=94)	58.4	36.0	23.9	20.7	14.2	7.4		
Yes (*n*=104)	37.5	17.2	9.7	6.4	3.2	4.5		
Percentage of neutrophils						5.9		<0.001
Normal (*n*=127)	56.6	31.6	22.3	17.1	11.4	6.9		
Abnormal (*n*=63)	31.7	17.5	7.9	5.3	5.3	3.3		
Absolute number of neutrophils						5.9	4.815	0.028
Normal (*n*=141)	51.7	29.9	20.1	15.3	10.5	6.4		
Abnormal (*n*=49)	38.8	18.4	0.7	0.7	0.7	4.4		
Absolute number of lymphocytes						5.9	3.515	0.061
Normal (*n*=167)	50.2	27.6	17.3	14.4	10.5	6.2		
Abnormal (*n*=23)	30.4	16.3	10.9	10.9	10.9	3.2		
NLR						5.9	8.411	0.004
<2.43 (*n*=72)	59.7	35.1	26.7	21.8	15.6	6.9		
⩾2.43 (n=118)	41.4	21.8	11.4	7.1	5.3	4.8		
CA199 (U/mL)						5.7	3.795	0.051
<37 (*n*=48)	56.2	32.7	27.3	23.4	23.4	7.6		
⩾37 (*n*=124)	43.4	25.4	14.1	10.7	4.0	5.3		
CEA (μg/L)						5.9	5.652	0.017
<5 (*n*=74)	55.4	34.3	23.8	23.8	12.3	6.9		
⩾5 (*n*=103)	42.6	21.1	12.2	6.3	6.3	5.3		

mOS: median overall survival; NLR: neutrophil-to-lymphocyte ratio; CEA: carcino-embryonic antigen.

Table 2. COX regression analysis of risk factors of survival status.

Items*	Univariate analysis			Multivariate analysis		
	Regression coefficients (β)	*P*	HR (95%*CI*)	Regression coefficients (β)	*P*	HR (95%*CI*)
Surgery or not	-1.017	<0.001	0.362 (0.223–0.586)	-0.620	0.019	0.538 (0.321–0.902)
NLR	0.085	<0.001	1.088 (1.046–1.132)	0.065	0.002	1.067 (1.023–1.112)
Liver or lung metastasis	0.567	<0.001	1.763 (1.296–2.400)	0.397	0.020	1.487 (1.066–2.075)
Age	0.031	<0.001	1.031 (1.018–1.044)	0.023	0.001	1.024 (1.010–1.037)
Absolute number of neutrophils	0.077	<0.001	1.080 (1.037–1.126)	-	-	-
Percentage of neutrophils	0.027	<0.001	1.028 (1.013–1.043)	-	-	-
Absolute number of lymphocytes	-0.457	<0.001	0.633 (0.476–0.841)	-	-	-
Percentage of lymphocytes	-0.033	<0.001	0.968 (0.951–0.985)	-	-	-

HR: Hazard ratio. *: Surgery or not: Yes=1, No=0; NLR: <2.43=0, ⩾2.43=1; Liver or lung metastasis: Yes=1, No=0; Age: 30–39=1, 40–49=2, 50–59=3, 60–69=4, 70–79=5, 80–90=6; Absolute number of neutrophils: 2×10^9/L– 7×10^9/L=0, >7×10^9/L or <2×10^9/L=1; Percentage of neutrophils: 50%–70%=0, >70% or <50%=1; Absolute number of lymphocytes: 0.8×10^9/L– 4×10^9/L=0, >4×10^9/L or <0.8×10^9/L=1; Percentage of lymphocytes (20%–40%=0, >40% or <20%=1.

2.5. Statistical methods

Data were analyzed by SPSS 19.0 software. Survival rate was analyzed by the Kaplan–Meier method and the log-rank test was used to compare the survival rates between groups. Multivariate analysis was performed by COX regression model. $P<0.1$ was considered as a statistically significant difference, along with test level $\alpha = 0.1$ for Kaplan–Meier analysis. $P<0.05$ was considered as a statistically significant difference, as well as test level $\alpha = 0.05$ for COX regression analysis.

2.6. Quality control

Data were collected according to the unified requirements of the inclusion criteria. After the double-extraction and input of data, invalid data were eliminated according to the exclusion criteria. Data verification was carried out at the data entry stage and after the input, extreme values, outliers, and inconsistent logic were verified.

3. Results

3.1. General information

A total of 198 patients met the criteria, including 113 male cases and 85 female cases, aged from 30-90 years. As showed in Table 1, the overall median survival time was 5.8 months. The overall survival rates in 0.5, 1, 2, 3 and 5 years were 47.4%, 26.8%, 16.4%, 13.2% and 8.7%, respectively.

Table 3. Parameters of COX regression model.

Risk factors	Mean	β	W_{ij}	W_{iREF}	D	B	$Points_{ij}$
Age (years)	66.170	0.023				0.230	
30— (*n*=4)			34.500		-0.230		-1.000
40— (*n*=18)			44.500	44.500	0.000		0.000
50— (*n*=36)			54.500		0.230		1.000
60— (*n*=51)			64.500		0.460		2.000
70— (*n*=61)			74.500		0.690		3.000
80— (*n*=28)			85.000		0.930		4.000
Surgery	0.160	-0.620					
Yes (*n*=32)			1.000		-0.620		-3.000
No (*n*=166)			0.000	0.000	0.000		0.000
NLR	4.280	0.065					
<2.43 (*n*=72)			0.000	0.000	0.000		0.000
⩾2.43 (*n*=118)			1.000		0.065		1.000
Distant metastasis	0.630	0.397					
No (*n*=73)			0.000	0.000	0.000		0.000
Yes (*n*=125)			1.000		0.397		2.000

NLR: neutrophil-to-lymphocyte ratio.

Table 4. Corresponding table of risk estimation and point.

Point total	Estimate of risk
-4	0.111
-3	0.138
-2	0.172
-1	0.209
0	0.256
1	0.311
2	0.374
3	0.445
4	0.524
5	0.607
6	0.691
7	0.772

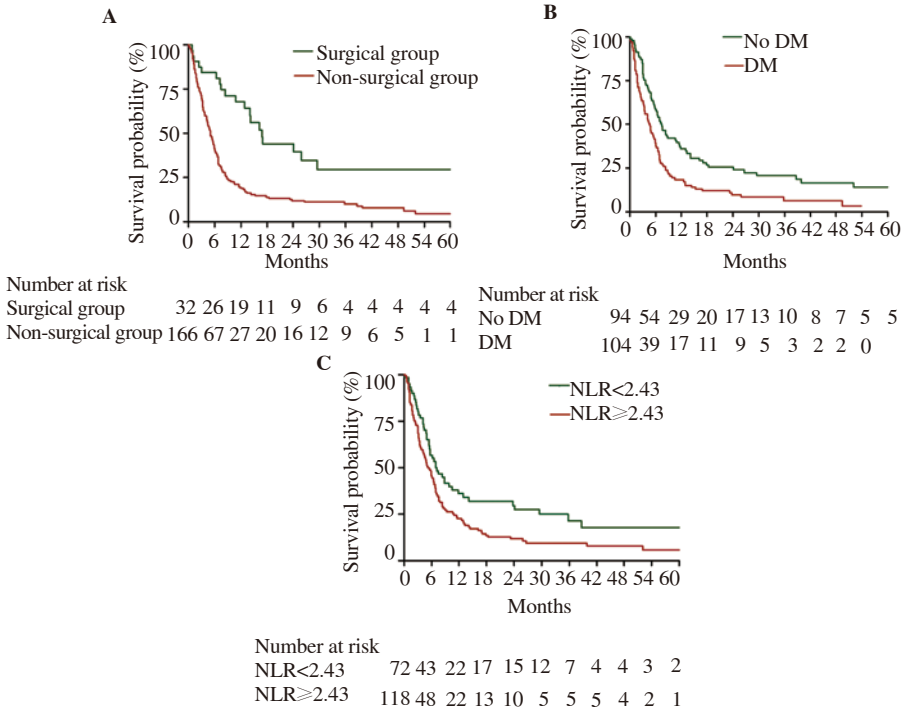

Figure 2. Comparison of median overall survival among patients with different surgical status (A), metastasis status (B) and NLR: neutrophil-to-lymphocyte ratio (C). DM: distant metastasis.

3.2. Median survival analysis

Log-rank test analysis results indicated that there were differences in the survival rates among patients with different age, surgery status, distant metastasis, percentage of neutrophils, absolute number of neutrophils, absolute number of lymphocytes, neutrophil-to-lymphocyte ratio (NLR), CA199 and carcino-embryonic antigen (P<0.1) (Table 1). The survival curves of subgroups for surgery, distant metastasis and NLR variables are shown in Figure 2. However, there were no significant differences in the overall median survival time among patients with different gender, tumour location, blood glucose, globulin, albumin, haemoglobin, alanine transaminase (ALT), aspartate aminotransferase (AST), osmolality and lymphocyte percentage variables (P>0.1) (Supplementary Table 1).

3.3. Analysis of factors affecting survival rate

Single-factor analysis of COX regression showed that age, surgery, distant metastasis, NLR, absolute number of neutrophils, percentage of neutrophils, absolute number of lymphocytes and percentage of lymphocytes were prognostic factors affecting the survival rate of pancreatic cancer patients. Multivariate analysis of COX regression showed that age, surgical status, distant metastasis and NLR were the prognostic factors of patients with pancreatic cancer (P<0.05) (Table 2).

3.4. Prediction of risk probability of pancreatic cancer

According to the formula:

$$\sum_{i=1}^{p}\beta_i\bar{\chi}_i \approx \text{Mean or Proportion} \times \beta_i,\quad \sum_{i=1}^{p}\beta_i\chi_i \approx \beta_i \times W_{iREF} + \beta_i \times \text{Point},$$

$$\hat{p} = S_{0(t)}^{\exp\left(\sum_{i=1}^{p}\beta_i\chi_i - \sum_{i=1}^{p}\beta_i\bar{\chi}_i\right)}$$

the risk probability value corresponding to each score in this study is shown in Tables 3 and 4.

4. Discussion

Pancreatic cancer has a high malignancy and an insidious onset. Its diagnosis and treatment are extremely difficult, and the mortality rate is high. The influence of age on the survival time of pancreatic cancer is still controversial. Literature indicated that half year and one-year survival rate were lower in the pancreatic cancer patients aged less than 60 years[10]. Zhu *et al.* believed that the survival of patients depended on the age of onset[6]. Wang *et al.* showed that patients aged 60 to 65 years old were at higher risk[11]. The incidence rate of pancreatic cancer was low before the age of 30 and gradually increased after the age of 30, which was similar to the results of this study. We found a significant correlation between age and the survival time (P<0.001). Age was stratified every 10 years in this study. Median survival was shorter in the older age group than in the younger age group, suggesting that the older the age, the shorter the survival rate. This could be because older patient was often in poorer physical fitness and was often in the advanced stage of cancer, with less opportunities for surgery and a poorer prognosis.

It was reported that surgical treatment was an independent factor affecting the survival of pancreatic cancer patient[12]. The surgical resection rate of pancreatic cancer is low, with 15% for patients with pancreatic head cancer, and 10% for patients with pancreatic cancer and pancreatic tail cancer. According to the epidemiological survey of pancreatic cancer in 8 provinces and cities in China over the past 10 years, the median survival time after radical surgery was 17.11 months, and the 1, 3 and 5-year survival rates were 54.36%, 13.47% and 8.47%, respectively, which were higher than those without surgery[13]. Literature showed that patients with palliative care had a shorter survival time than patients with surgery[5]. This is consistent with the results of this study. The data in our study showed that the survival time of the surgical treatment group was longer than that of the non-surgical treatment group (P<0.05). The reason may be that most patients with feasible surgical treatment are diagnosed in the early or middle stage of pancreatic cancer and have no distant metastasis. Besides, all clinical examinations are also in line with surgical indications. Surgical treatment can control the patient's condition to a certain extent, inhibit the rapid growth of cancer cells, increase the life expectancy of patients and improve the quality of life. However, most patients are often misdiagnosed as gastrointestinal or hepatobiliary diseases before diagnosis, and then miss the opportunity of surgical resection. Therefore, early detection and radical surgery as early as possible are important for improving the prognosis of pancreatic cancer.

It reported that the 5-year survival rate of patients with advanced organ metastases was about 8%, and the average survival time was 6 months[1]. The distant metastasis in this study included liver, lung, bone, lymphatic metastasis and even multiple organ metastasis, of which liver metastasis and lymphatic metastasis accounted for the largest proportion. The liver is the most visible and best metastatic site for pancreatic cancer[14]. The results showed that patients with liver or lung metastases had a shorter median survival time than patients without liver or lung metastasis. Liver or lung metastasis was independent risk factors. The poor prognosis of patients with liver or lung metastasis is mainly due to the fact that the liver and lung have more important function among the organs. If they are violated, the degree of deterioration of disease will be aggravated, thus affecting the prognosis of the patient. Besides, the number of metastatic organs has a certain impact on the prognosis. The higher the number of metastatic organs, the shorter the median survival time

of the patient. Lymph node metastasis is an important marker for the clinical stage of pancreatic cancer, and its metastasis is considered to be one of the important factors affecting the survival of patients with pancreatic cancer. If lymphatic metastasis occurs, it usually involves multiple sets of lymph nodes[15], promoting spread of cancer cells widely and aggravating the patient's condition. However, our study showed that lymph node metastasis had no significant correlation with the prognosis and survival rate of patients, which may be due to individual differences in population and errors caused by selection bias.

Tumour factor CA19-9 is a mucin in human serum and is a sialylated Lewis blood group antigen. It is currently the most sensitive clinical marker for pancreatic cancer, with a sensitivity of 61% to 86%[16,17]. Studies showed that patients with advanced pancreatic cancer with normal levels of CA19-9 had a higher survival rate than patients with abnormal levels of CA19-9[18]. Kaplan–Meier analysis showed a difference in the survival rate between patients with CA19-9>37 U/mL and CA19-9≤37U/mL, but COX regression analysis showed no correlation between CA19-9 and survival time. *In vitro* experiments by Tazzyman *et al.* showed that neutrophils inhibited a variety of cells (such as lymphocytes, NK cells and T cells, *etc*.), causing tumour cells to "escape" and not be eliminated, and finally causing tumour tissue proliferation (or proliferation)[19]. Neutrophils can also increase the secretion of vascular endothelial growth factor and matrix metalloproteinase, while vascular endothelial growth factor can promote lymph node metastasis in pancreatic cancer, resulting in a shorter survival time[20]. Our study showed that NLR was a simple, rapid and reliable indicator, which was closely related to the survival rate of patients with pancreatic cancer and can provide a reference value for the treatment. The NLR value is determined by both neutrophils and lymphocytes. High NLR indicates that the relative increase of neutrophils and/or the relative decrease of lymphocytes could inhibit the body's immune response to tumour cells, thereby, reducing the body's anti-tumour sensitivity. COX multivariate analysis from this study found that NLR was an independent factor affecting the prognosis of pancreatic cancer patient. Patients with a higher NLR had a poorer prognosis. By selecting significative affecting factors *via* COX multivariate regression, the tool of the risk prediction probability can be developed to directly obtain the death probability value of pancreatic cancer.

In summary, a variety of factors can affect the survival status of patients with pancreatic cancer. Although different conclusions from different studies, most still believe that surgery is the most effective method for the treatment of pancreatic cancer. Age, liver and lung metastasis and NLR may be effective predictors of the prognosis.

Conflicts of interest statement

The authors declare that there are no conflicts of interest.

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Authors' contribution

Z.X.S., H.R.H., Y.J.Z., and Y.Y. were responsible for design, organization, implementation and quality control of the project. Z.K.S. participated in collecting data. Y.M.S. acquired, analyzed, interpreted data and wrote the original manuscript. K.L. and E. C.M. prepared the English version of the original manuscript. Y.J.Z. modified linguistic expression of the manuscript. All authors reviewed and edited the manuscript.

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Supplementary Table 1. Univariate analysis of prognostic factors in patients.

Affecting factors	mOS (months)	χ^2	*P*
Gender		1.094	0.296
Male（*n*=113）	5.0		
Female（*n*=85）	6.6		
Tumor location		0.236	0.889
Head of pancreas （*n*=51）	6.4		
Body of pancreas (*n*=140)	5.7		
Tail of pancreas (*n*=7)	4.5		
Blood glucose		0.028	0.867
Normal（*n*=108）	5.8		
Abnormal（*n*=84）	6.0		
Globulin		0.107	0.743
Normal（*n*=154）	5.9		
Abnormal（*n*=26）	7.2		
Albumin		1.394	0.238
Normal（*n*=35）	6.6		
Abnormal（*n*=120）	5.3		
Haemoglobin		1.608	0.205
Normal（*n*=50）	6.9		
Abnormal（*n*=140）	5.7		
Alanine transaminase ALT)		0.050	0.822
Normal（*n*=91）	6.4		
Abnormal（*n*=77）	6.0		
Aspartate aminotransferase (AST)		1.0	0.317
Normal（*n*=75）	6.6		
Abnormal（*n*=93）	5.9		

Osmolality			0.778	0.378
	Normal（*n*=90）	6.4		
	Abnormal（*n*=98）	5.8		
Lymphocyte percentage			2.161	0.142
	Normal（*n*=86）	6.2		
	Abnormal（*n*=104）	5.0		