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Original Article

Quality of life and survival of patients with malignant bile duct obstruction following different ERCP based treatments

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Abstract: Objective: This study aimed to investigate quality of life and survival of patients with malignant bile duct obstruction after different endoscopic retrograde cholangiopancreatography (ERCP)-based treatments. Methods: A total of 41 patients with malignant bile duct obstruction were treated by ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion, or ERCP combined with radiotherapy/chemotherapy. Results: The risk factors of quality of life in malignant obstructive jaundice patients included bilirubin, CA199, CEA, ALP and γ-GT. TBIL of ≥ 100 μmol/L, CA19-9 of ≥ 200 U/ml, ALP of ≥ 200 U/ml and γ-GT of ≥ 200 U/ml predicted a poor quality of life duration hospitalization. After ERCP, the score of role emotional (RE) significantly increased in ERCP combined with radiotherapy/chemotherapy group. The survival curve showed the median survival time was 10.2 months. The median survival time following ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion and ERCP combined with radiotherapy/chemotherapy was 8.2 months, 8.2 months and 18.3 months, respectively. The median survival time in patients aged < 60 years, with bilirubin of < 100 μmol/L, CA199 of < 200 U/ml, ALP of < 200 U/L, or GGT of < 200 U/L had a longer survival time and higher survival rate. Conclusion: ERCP combined with radiotherapy/chemotherapy may be more effective in improving quality of life and prolonging survival time.

Keywords: Bile duct obstruction, malignant, ERCP, radiotherapy, chemotherapy

Introduction

Obstructive jaundice is a symptom of malignant bile duct obstruction. Malignancies causing bile duct obstruction [1] include hepatocellular carcinoma, cholangiocarcinoma, gallbladder carcinoma [2], pancreatic cancer, ampullary carcinoma [3] and metastatic tumors with consecutive compression of the common bile duct [4]. Patients with malignant biliary obstruction usually present fever, abdominal pain, dyspepsia and jaundice [5]. The diagnosis of malignancy is often dependent on the measurement of tumor markers. High blood AFP is common in hepatocellular carcinoma, while high blood CEA or CA19-9 is associated with malignant pancreaticobiliary disease [6]. Jaundice is a main symptom of malignant bile duct obstruction, and increased jaundice may lead to severe itching. Treatments of malignant obstructive jaundice include surgical intervention, minimally invasive treatment, chemotherapy, and radiotherapy [7]. For patients with advanced cancer and malignant obstructive jaundice, palliative treatment is preferred to attenuate jaundice and improve the quality of life. Minimally invasive treatments include endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic cholangial drainage (PTCD) [8]. ERCP [9], PTCD [10], chemotherapy, and radiotherapy are regarded the options for the palliative treatment of malignant bile duct obstruction [11]. In this study, palliative treatments (ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion, and ERCP with chemotherapy/radiotherapy) were performed for malignant bile duct obstruction in a total of 41 patients with malignant bile duct obstruction and the clinical characteristics, contributing factors, treatment outcome, quality of life, and survival time were investigated in these patients.

Table 1. Baseline characteristics of treated patients

Characteristic	Classification	Number	Percentage (%)
Sex	Male	21	51.2%
	Female	20	48.8%
Age (years)	< 60	11	26.8%
	≥ 60	30	73.2%
Disease	Cholangiocarcinoma	12	29.3%
	Gallbladdercancer	3	7.3%
	Pancreatic cancer	10	24.4%
	Liver cancer	6	14.6%
	Other metastatic carcinoma	10	24.4%
Total bilirubin (TBIL)	< 100 μmol/L	15	36.6%
	≥ 100 μmol/L	26	63.4%
CA199	< 200 U/ml	20	48.8%
	≥ 200 U/ml	21	51.2%
CEA	< 10 μg/L	34	82.9%
	≥ 10 μg/L	7	17.1%
ALP	< 200 U/L	16	39.0%
	≥ 200 U/L	25	61.0%
GGT	< 200 U/L	19	46.3%
	≥ 200 U/L	22	53.7%
Treatment	ERCP with nasal biliary drainage	10	24.4%
	ERCP with endoscopic stent insertion	23	56.1%
	ERCP with radiotherapy/chemotherapy	8	19.5%

Patients and methods

Patients

A total of 41 patients with malignant bile duct obstruction were included in the present study and received palliative treatments between January 2009 and January 2013. The inclusion criteria were as follows: 1) Patients were clinically diagnosed with hilar cholangiocarcinoma, gallbladder carcinoma, cholangiocarcinoma, pancreatic cancer or ampullary carcinoma. 2) The bile duct obstruction was diagnosed mainly by ultrasonography, computed tomography (CT), or magnetic resonance cholangiopancreatography (MRCP). 3) Informed consent was obtained from each patient. Exclusion criteria: 1) Patients had a history of mental illness or serious heart/lung disease. 2) Patients had a language barrier or were unable to cooperate with the questionnaire survey. 3) Patients had been involved in other studies.

Quality of life

The quality of life was assessed with the short form-36 (SF-36) which includes 8 domains: physical function (PF), role-physical (RP), body pain (BP), general health (GH), vitality (VT), social function (SF), role emotional (RE) and mental health (MH) [12, 13]. This questionnaire can be used to evaluate the economic, physical, and psychosocial burden of malignant bile duct obstruction patients. However, the SF-36 health questionnaire alone does not comprehensively evaluate patients with malignant bile duct obstruction. Studies have shown that the specificity module of the QLQ-C30 questionnaire may reflect the specific symptoms of malignant obstructive jaundice [14, 15]. The specificity module of QLQ-C30 is also known as QLQ-MOJ11, and includes five domains: jaundice (JA), digestion (DI), itching (IT), weight loss (LW), and fever (FE). Therefore, the SF-36 combined with QLQ-MOJ11 was employed to comprehensively evaluate the quality of life of patients.

Palliative treatment

In this study, patients received ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion or ERCP with chemotherapy or radiotherapy. ERCP was performed using a therapeutic duodenoscope. A guidewire was advanced proximal to the stricture, and a biliary sphincterotomy was performed at the discretion of the endoscopist. The location of the biliary obstruction was determined by ERCP. When the biliary obstruction was located in the common bile duct and hepatic duct, nasal biliary drainage and endoscopic stent insertion were conducted. In some patients, biliary drainage followed by radiotherapy/chemotherapy was performed.

Statistical analysis

Any discrepancy in questionnaire survey was resolved by discussion until consensus was reached. Data are expressed as mean ± stan-

Table 2. Baseline quality of life in different groups

Domain	ERCP with nasalbiliary drainage	ERCP with endoscopicstent insertion	ERCP with radiotherapy or chemotherapy	Statistic	P
SF-36 questionnaire					
PF	28.50±10.29	38.48±11.72	40.00±12.82	3.066	0.058
RP	5.00±10.54	6.52±15.48	9.38±18.60	0.190	0.828
BP	42.30±6.31	39.91±6.56	46.38±9.81	2.416	0.103
GH	37.50±3.54	37.39±7.96	39.38±8.63	0.230	0.795
VT	25.50±7.25	27.39±10.86	25.00±5.35	0.269	0.766
SF	46.30±11.94	47.35±11.27	47.00±11.12	0.029	0.971
RE	26.60±26.37	33.30±26.72	46.00±30.72	1.137	0.332
MH	26.00±4.32	27.83±8.22	25.00±5.95	0.564	0.574
QLQ-MOJ11 questionnaire					
JA	69.80±20.12	64.48±23.79	66.50±20.97	0.197	0.822
ID	52.00±13.22	54.17±13.39	52.75±10.24	0.112	0.895
IT	41.70±30.69	42.65±30.01	41.75±28.31	0.005	0.995
LW	16.60±23.57	24.57±28.84	54.38±35.44	4.220	0.022
FE	50.10±45.17	39.13±26.10	37.50±27.99	0.757	0.685*

Note: *Nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

Table 3. Baseline quality of life in patients with different serum bilirubin concentration

Domain	< 100 μmol/L	≥ 100 μmol/L	Statistic	P
SF-36 questionare				
PF	40.00±11.65	34.23±12.22	2.191	0.147
RP	13.33±18.58	2.88±10.79	5.908	0.015*
BP	38.27±7.64	43.77±6.71	5.779	0.021
GH	39.33±7.04	36.92±7.22	1.079	0.305
VT	27.67±10.33	25.77±8.45	0.407	0.527
SF	52.60±10.87	43.81±10.12	6.803	0.013
RE	46.67±21.35	26.92±28.43	5.441	0.025
MH	26.67±7.95	26.92±6.55	0.012	0.912
QLQ-MOJ11 questionare				
JA	45.53±24.47	78.08±6.02	14.355	0.000*
ID	51.80±11.20	54.27±13.38	0.363	0.550
IT	17.80±29.87	56.35±17.07	13.359	0.000*
LW	22.20±32.57	32.04±30.62	0.938	0.339
FE	35.53±32.14	44.92±31.33	0.839	0.365

Note: *The nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

dard deviation (SD) and comparisons were performed with one way analysis of variance analysis among groups. Survival time was expressed inmonths as a median. Cumulative survival was estimated using Kaplan-Meier method. The QOL score was compared with one way analysis of varianceamonggroupsatdifferent intervals. If heterogeneity of variance was present, the nonparametric Kruskal-Wallis H test was used. A value of $P < 0.05$ was considered statistically significant. Statistical analysis was performed with SPSS version 17.0.

Results

Patients' characteristics

Between January 2009 and January 2013, 45 patients with malignant obstructive jaundice received ERCP dominant palliative treatments in our department and 4 patients were excluded due to technical failure. Finally, 41 patients met the inclusion criteria and completed the questionnaire survey with SF-36 and QLQ-MOJ11 at baseline. At 6 months after ERCP based treatments, the quality of life was evaluated again in surviving patients. Patients were followed up until January 2013 and the survival rate was calculated. The baseline characteristics and contributing factors (such as bilirubin, CA199, CEA, ALP, GGT and treatments) were evaluated, and the life quality at baseline and after ERCP based treatment and survival was compared among groups.

A total of 41 patients were followed for 4 years. Clinical characteristics such as sex, age, disease, multiple treatments, and biomedical parameters (such as total bilirubin and CA199, CEA, ALP and GGT) were recorded. Diseases in these patients included cholangiocarcinoma, gallbladder cancer, pancreatic cancer, liver cancer, and other metastatic carcinomas. Multiple treatment included ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion, and ERCP combined with radiotherapy or chemotherapy. The baseline characteristics are shown in **Table 1**.

Table 4. Baseline quality of life in patients with different serum CA199 concentration

Domain	< 200 U/ml	≥ 200 U/ml	Statistic	P
SF-36 questionare				
PF	36.75±12.49	35.95±12.21	0.043	0.837
RP	7.5±14.28	5.95±15.62	0.109	0.743
BP	39.40±7.33	44.00±7.05	4.196	0.047
GH	36.75±7.83	38.81±6.50	0.844	0.364
VT	24.25±6.93	28.57±10.51	2.391	0.130
SF	46.95±10.69	47.10±11.79	0.002	0.967
RE	35.05±29.72	33.29±25.95	0.041	0.840
MH	25.20±5.37	28.38±8.09	2.178	0.148
QLQ-MOJ11 questionare				
JA	64.05±24.51	68.19±19.72	0.357	0.554
ID	51.55±11.89	55.10±13.19	0.815	0.372
IT	39.15±31.16	45.19±27.47	0.435	0.514
LW	25.00±32.29	31.71±30.78	0.465	0.499
FE	45.00±31.24	38.14±32.25	0.477	0.494

Notes: Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

Table 5. Baseline quality of life in patients with different serum CEA concentrations

Domain	Less than 10 ug/L	Greater than or equal to 10 ug/L	Statistic	P
PF	36.18±11.87	37.14±14.68	0.036	0.851
RP	7.35±15.73	3.57±9.45	0.372	0.545
BP	41.00±7.47	45.43±6.80	2.097	0.156
GH	37.21±7.41	40.71±5.35	1.407	0.243
VT	26.76±9.60	25.00±6.45	0.214	0.646
SF	47.85±10.44	43.00±14.26	1.107	0.299
RE	34.29±26.71	33.43±33.50	0.006	0.941
MH	26.94±7.32	26.29±5.59	0.050	0.825
JA	66.82±22.36	63.00±21.51	0.172	0.681
ID	54.26±13.06	49.00±9.11	1.024	0.318
IT	43.59±29.85	35.71±26.30	0.418	0.522
LW	28.41±31.99	28.57±30.12	0.000	0.990
FE	45.15±29.61	23.71±37.06	2.798	0.102

Notes: Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

Contributing factors and quality of life at baseline

In this study, patients were divided into three groups according to treatments: ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion, and ERCP with radiotherapy/chemotherapy. Patients completed the SF-36 and QLQ-MOJ11 at baseline. The baseline data of life quality in the different treatment groups were collected and analyzed using SPSS version 17.0 software (**Table 2**). Results showed the quality of life assessed with SF-36 was comparable among there groups. The score of weight loss (IW) assessed with QLQ-MOJ11 significantly increased in the ERCP with radiotherapy/chemotherapy group: the body weight of patients decreased, which may be associated with the advanced tumor stage.

Patients were divided into two groups according to serum bilirubin concentration: < 100 μmol/L and ≥ 100 μmol/L. According to the assessment with SF-36, the scores for RP, RE and SF significantly increased in patients of < 100 μmol/L group, indicating that these patients had better RP, RE, and SF. The score for BP significantly increased in patients of ≥ 100 μmol/L group, indicating that these patients are less sensitive to body pain. According to the assessment with QLQ-MOJ11, the scores for jaundice and itching significantly increased in patients of ≥ 100 μmol/L group, indicating that these patients show increased jaundice and itching (**Table 3**).

Patients were divided into two groups according to serum CA199 concentration: < 200 U/ml and ≥ 200 U/ml. According to the assessment with SF-36 and QLQ-MOJ11, the scores for BP significantly increased in patients of ≥ 200 U/ml group, indicating that these patients are less sensitive to body pain. There were no significant differences in the scores for other domains in these patients (**Table 4**).

Patients were divided into two groups according to serum CEA concentration: < 10 μg/L and ≥ 10 μg/L. On the basis of assessment with the SF-36 and QLQ-MOJ11, no significant differences were observed in the domains among groups (**Table 5**).

Patients were divided into two groups according to serum ALP concentration: < 200 U/L and ≥ 200 U/L. On the basis of assessment with the

Table 6. Baseline quality of life in patients with different serum ALP

Domain	< 200 U/L	≥ 200 U/L	Statistic	P
PF	39.38±13.15	34.40±11.39	1.649	0.207
RP	12.50±18.26	3.00±10.99	5.041	0.025*
BP	38.38±7.39	43.92±6.81	6.057	0.018
GH	40.31±7.18	36.20±6.81	3.409	0.072
VT	29.38±10.47	24.60±7.76	2.808	0.102
SF	52.44±8.21	43.56±11.49	5.615	0.018*
RE	41.69±26.01	29.32±27.87	2.021	0.163
MH	28.25±7.93	25.92±6.34	1.083	0.304
JA	48.38±25.91	77.56±6.42	10.308	0.001*
ID	51.38±13.69	54.64±11.86	0.656	0.423
IT	25.00±33.30	53.28±19.87	7.034	0.008*
LW	16.63±24.37	36.00±33.32	4.017	0.052
FE	45.81±27.05	38.72±34.38	0.487	0.490

Notes: *The nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

Table 7. The influence of different GGT levels on baseline quality of life

Domain	< 200 U/L	≥ 200 U/L	Statistic	P
PF	37.37±11.06	35.45±11.64	0.246	0.622
RP	10.53±17.31	3.41±11.69	3.034	0.082*
BP	40.47±7.77	42.86±7.19	1.045	0.313
GH	39.47±6.64	36.36±7.43	1.968	0.169
VT	27.63±10.32	25.45±8.00	0.577	0.452
SF	51.42±8.21	43.23±12.06	4.260	0.039*
RE	38.63±27.98	30.27±27.15	0.939	0.338
MH	28.42±6.91	25.45±6.93	1.871	0.179
JA	56.05±26.89	74.91±11.39	3.103	0.078*
ID	51.47±12.71	55.00±12.45	0.802	0.376
IT	34.16±34.83	49.23±21.56	1.861	0.173*
LW	22.74±25.02	33.36±35.72	1.179	0.284
FE	47.37±30.20	36.41±32.51	1.237	0.273

Notes: *Nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

SF-36, the scores for RP and SF significantly increased in patients of < 200 U/L group, indicating that these patients have better RP and SF, but the score for BP significantly increased in patients of ≥ 200 U/L group, indicating that these patients are less sensitive to body pain. On the basis of assessment with the QLQ-MOJ11, the scores for jaundice and itching significantly increased in patients of ≥ 200 U/L group, indicating that these patients are vulnerable to jaundice and itching (**Table 6**).

Patients were divided into two groups according to serum GGT concentration: < 200 U/L and ≥ 200 U/L. According to the assessment with the SF-36, the score for SF significantly increased in patients of < 200 U/L group, indicating that these patients have a better social function. There were no significant differences in the scores for other domains among groups (**Table 7**).

Influence of different treatments on the quality of life

The quality of life was evaluated before and after ERCP based treatments with SF-36 and QLQ-MOJ11. The score for RE using the SF-36 significantly increased in ERCP with radiotherapy/chemotherapy group, indicating that these patients have a better emotion and an optimistic attitude towards life (**Table 8**).

At six-month after ERCP based treatments, only 31 patients survived and received the evaluation of quality of life with the SF-36 and QLQ-MOJ11. No significant differences were observed in the scores for the domains measured among three groups (**Table 9**).

Survival analysis

The survival curve of patients with malignant bile duct obstruction is shown in **Figure 1**. According to the survival curve, the median survival time was 10.2 months after ERCP based treatments in patients with malignant bile duct obstruction.

The survival curves of patients in different groups are shown in **Figure 2**. As shown in **Figure 2**, the median survival time in patients of ERCP with nasal biliary drainage group, ERCP with endoscopic stent insertion group, and ERCP with radiotherapy/chemotherapy group was 8.2 months, 8.2 months and 18. 3 months, respectively. Statistical analysis showed the median survival time in ERCP with radiothera-

Table 8. Influence of different treatments on the quality of life

Field	ERCP with nasalbiliary drainage	ERCP with endoscopicstent insertion	ERCP with radiotherapy/ chemotherapy	Statistic	P
PF	42.50±26.17	46.52±21.71	60.00±7.07	3.713	0.156*
RP	30.00±38.73	29.35±34.26	40.63±35.20	0.314	0.732
BP	54.80±13.30	55.83±13.75	64.00±12.69	1.301	0.284
GH	43.00±14.94	48.48±12.19	48.75±9.54	0.749	0.480
VT	35.50±22.79	41.96±18.39	45.63±8.63	0.238	0.888*
SF	58.80±27.63	62.65±23.21	72.00±11.12	0.791	0.461
RE	54.40±42.22	53.70±35.96	91.75±15.28	7.613	0.022*
MH	37.60±18.30	42.61±15.61	42.50±6.02	0.413	0.665
JA	51.10±16.89	42.39±17.92	37.63±14.63	1.505	0.235
ID	53.40±8.73	44.35±12.38	47.25±10.24	2.265	0.118
IT	28.20±20.83	28.91±20.23	25.00±21.82	0.107	0.899
LW	9.90±15.94	21.61±25.80	37.38±21.54	3.162	0.054
FE	36.70±36.78	30.22±17.18	29.00±21.40	0.158	0.924*

Notes: *Nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

Table 9. Quality of life at six months after ERCP based treatments

Field	ERCP with nasalbiliary drainage	ERCP with endoscopicstent insertion	ERCP with radiotherapy/ chemotherapy	Statistic	P
PF	66.43±23.40	50.88±25.57	55.71±28.35	0.904	0.416
RP	71.43±26.73	54.41±35.61	71.43±36.60	0.954	0.397
BP	72.29±4.54	58.53±18.71	67.71±14.90	3.827	0.418*
GH	52.86±15.77	47.65±14.91	50.71±14.27	0.330	0.722
VT	55.00±14.72	51.47±21.34	53.57±24.10	0.079	0.924
SF	78.86±9.55	64.12±21.62	73.43±26.58	1.385	0.267
RE	85.71±26.30	64.88±34.31	76.14±41.84	0.960	0.395
MH	54.86±7.90	48.24±20.12	49.71±21.15	0.321	0.728
JA	30.71±6.05	27.29±10.84	37.00±19.69	1.495	0.474*
ID	51.00±9.11	47.71±10.57	51.00±9.11	0.419	0.662
IT	12.00±12.57	10.88±11.69	19.00±20.17	0.842	0.442
LW	14.14±17.64	31.12±21.93	33.00±0.00	2.462	0.104
FE	18.86±17.64	17.53±20.75	23.71±25.23	0.213	0.810

Note: *Nonparametric Kruskal-Wallis H test was used. Abbreviations: PF: Physical function, RP: Role-physical, BP: Body pain, GH: General health, VT: Vitality, SF: Social function, RE: Role emotional, MH: Mental health, JA: Jaundice, DI: Digestion, IT: Itching, LW: Weight loss, FE: Fever.

py/chemotherapy was longer than in other two groups indicating that ERCP followed by chemotherapy/radiotherapy can prolong the survival time of patients with malignant bile duct obstruction.

The survival curves of patients in different age groups are shown **Figure 3**. As shown in **Figure 3**, the median survival time was 32 months for patients of < 60 years and 8 months for patients of ≥ 60 years. The median survival time in ≥ 60 years group was shorter than in < 60 years group.

The survival curves of patients with different diseases are shown **Figure 4**. As shown in **Figure 4**, the median survival time of patients with cholangiocarcinoma, gallbladder cancer, pancreatic cancer, liver cancer and other metastatic carcinomas was 8.5 months, 19.0 months, 5.5 months, 15.6 months and 18.5 months, respectively. The median survival time of patients with pancreatic cancer and cholangiocarcinoma was shorter than that of patients with other diseases.

The survival curves of patients with different serum bilirubin concentration are shown **Figure 5**. As shown in **Figure 5**, the median survival time was 16 months for patients with serum bilirubin concentration of < 100 μmol/L and 8.2 months for those with serum bilirubin concentration of ≥ 100 μmol/L. The median survival time in < 100 μmol/L group was longer than in ≥ 100 μmol/L group, indicating that elevated serum bilirubin may influence the survival time of patients with malignant bile duct obstruction: the higher the serum bilirubin, the shorter the survival time is.

The survival curves of patients with different serum CEA concentrations are shown **Figure 6**. As shown in **Figure 6**, the median survival time was 10.2 months for patients with serum CEA concentration of < 10 μg/L and 7.3 months for patients with serum CEA concentration of ≥ 10 μg/L. The median survival time in < 10 μg/L group was longer than in ≥ 10 μg/L group indicating that the elevated serum CEA may influence the

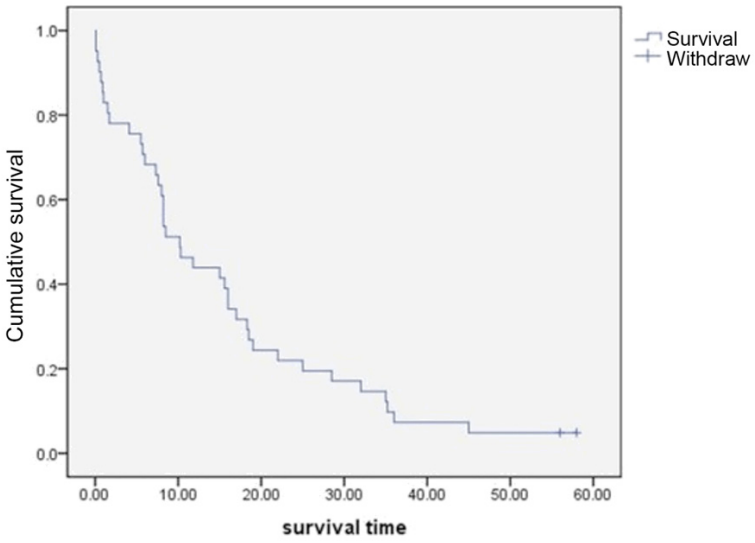

Figure 1. The survival curve of patients with malignant bile duct obstruction.

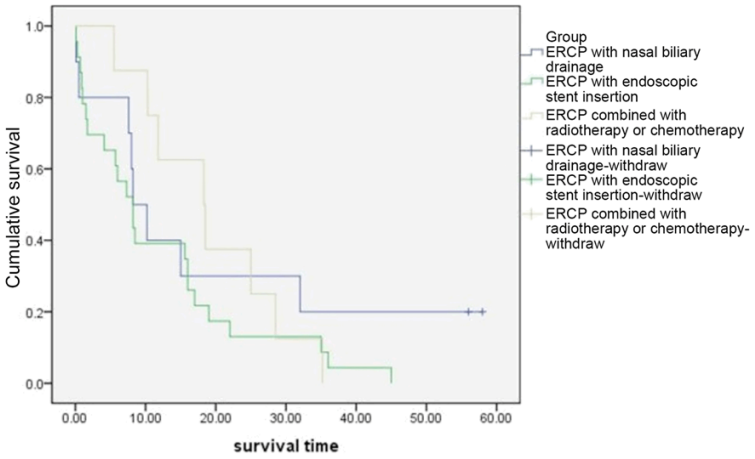

Figure 2. The survival curves of patients in different groups.

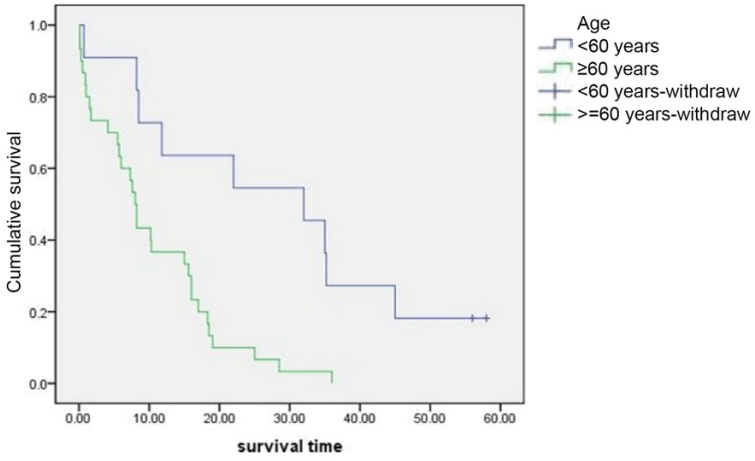

Figure 3. The survival curves of patients in different age groups.

survival time of patients with malignant bile duct obstruction: the higher the serum CEA, the shorter the survival time is.

The survival curves of patients with different serum CA199 concentrations are shown **Figure 7**. As shown in **Figure 7**, the median survival time was 15 months for patients with serum CA199 concentration of < 200 U/ml and 7.6 months for patients with serum CA199 concentration of ≥ 200 U/ml. The median survival time in < 200 U/ml group was longer than in ≥ 200 U/ml group, indicating that the elevated CA199 may influence the survival time of patients with malignant bile duct obstruction: the higher the serum CA199 concentration, the shorter the survival time is.

The survival curves of patients with different serum ALP concentrations are shown **Figure 8**. As shown in **Figure 8**, the median survival time was 8.5 months for patients with serum ALP concentration of < 200 U/L and 10.3 months for patients with serum ALP concentration of ≥ 200 U/L. The median survival time in < 200 U/L group was shorter than in ≥ 200 U/L group. This suggests that the increased serum ALP may influence the survival time of patients with malignant bile duct obstruction: the higher the serum ALP concentration, the shorter the survival time is.

The survival curves of patients with different serum GGT concentrations are shown **Figure 9**. As shown in **Figure 9**, the median survival time was 8.2 months for patients with

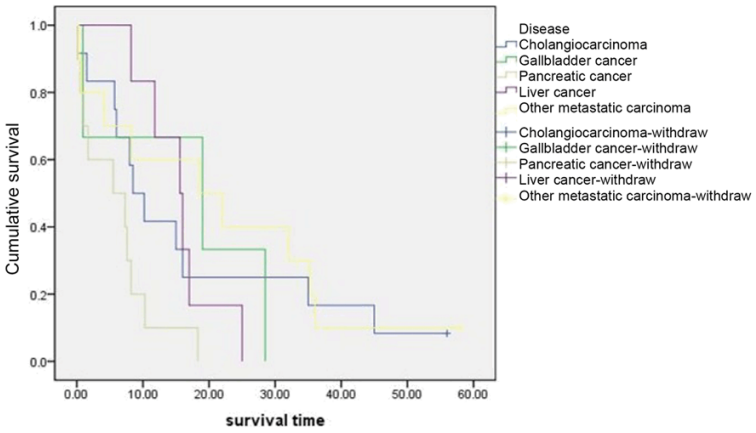

Figure 4. The survival curves of patients with different diseases.

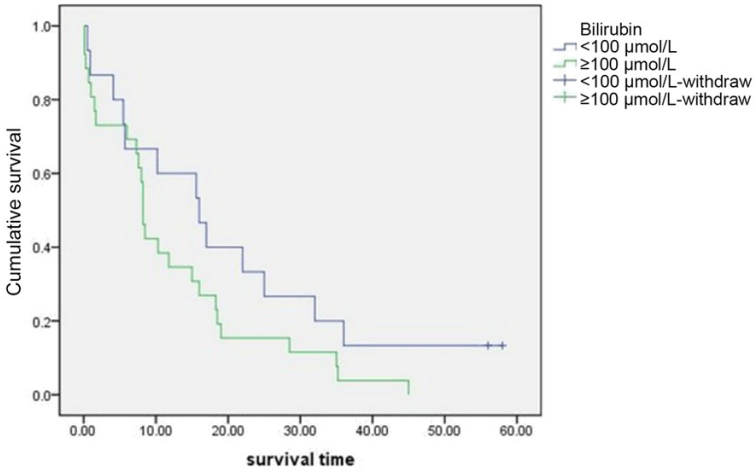

Figure 5. The survival curves of patients with different serum bilirubin concentration.

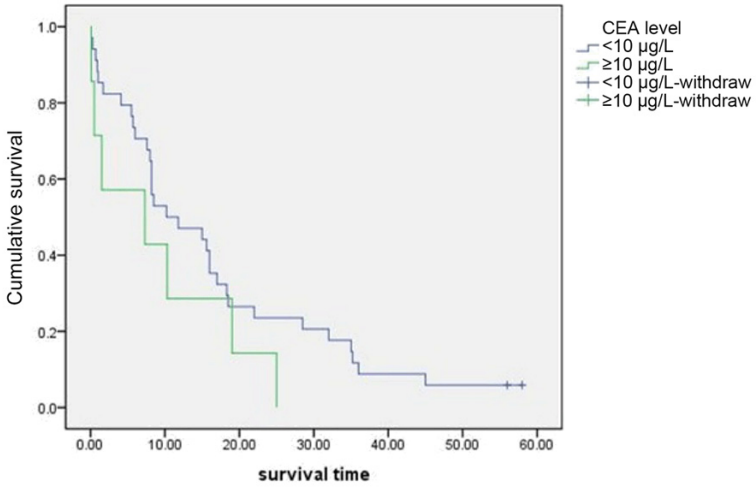

Figure 6. The survival curves of patients with different serum CEA concentrations.

serum GGT concentration of < 200 U/L and 16 months for patients with serum GGT concentration of ≥ 200 U/L. The median survival time in < 200 U/L group was shorter than in ≥ 200 U/L group. This suggests that the increased serum GGT may influence the survival time of patients with malignant bile duct obstruction: the lower the serum GGT concentration, the shorter the survival time is.

Discussion

Malignant bile duct obstruction can be caused by a variety of diseases including cholangiocarcinoma, gallbladder cancer, liver cancer, and other metastatic carcinomas. Patients with malignant bile duct obstruction often present several physiological and psychological ramifications, including immune dysfunction, jaundice, pruritus, fever, anorexia, indigestion, weight loss, pessimism, and reduced activity, all of which may adversely impact the quality of life of these patients. As a palliative treatment, decompression may improve the quality of life by relieving jaundice and pruritus [7]. Decompression makes other treatments feasible by decreasing total bilirubin to less than 1.5 times the upper limit of normal, which is necessary for the prevention of toxicity in chemotherapy [16]. ERCP is a technically challenging procedure, with the successful cannulation rate varying between 63% and 98% [17-21]. Therefore, endoscopic biliary drainage has become an effective treatment for malignant bile duct obstruction. In this study, ERCP based pallia-

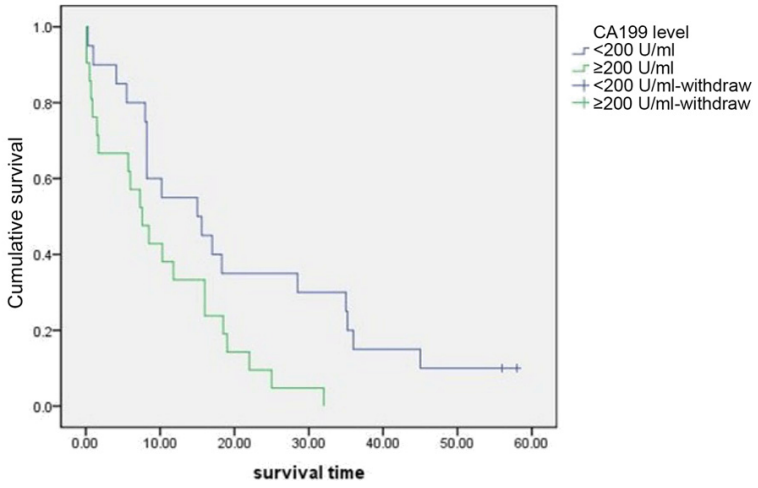

Figure 7. The survival curves of patients with different serum CA199 concentrations.

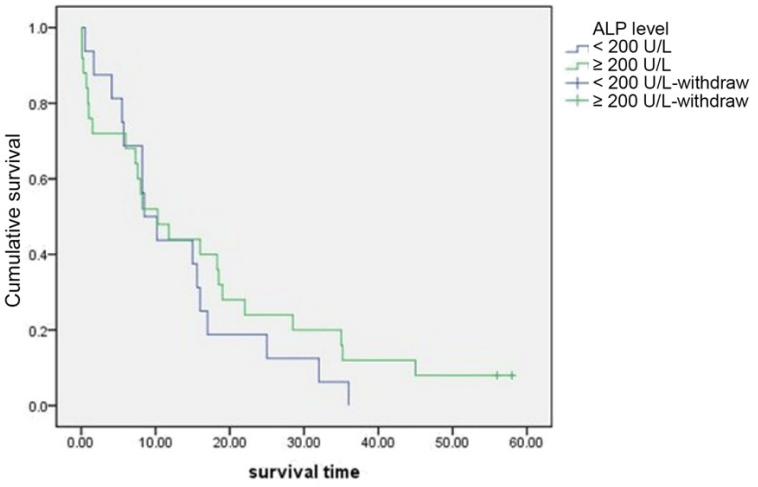

Figure 8. The survival curves of patients with different serum ALP concentrations.

tive treatments were employed to attenuate the clinical symptoms of malignant bile duct obstruction. These treatments were ERCP with nasal biliary drainage, ERCP with endoscopic stent insertion, and ERCP followed by radiotherapy/chemotherapy.

The quality of life is currently an important parameter measuring the efficacy of palliative treatment. It reflects the effect of the disease and that of the treatment on physical, social, family, emotional, and functional well-being. Studies have suggested improvements in different aspects of quality of life after palliative treatments. Abrham et al assess quality of life of patients with the SF-36 at baseline and one month after stent placement [22]. Saluj et al assessed the quality of life according to the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire 30 (EORTC QLQ-C30) in malignant bile duct obstruction patients [23]. Zou et al used both QLQ-C30 and QLQ-MOJ11 to evaluate the quality of life of patients with malignant obstructive jaundice [15]. QLQ-MOJ11 is a specificity module of the QLQ-C30 and includes the specific symptoms of malignant obstructive jaundice, such as jaundice, digestion, itching, weight loss, and fever. In this study, SF-36 was used to assess the quality of life on the basis of PF, RP, BP, GH, VT, SF, RE, and MH and QLQ-MOJ11 to assess the specific symptoms, such as jaundice, digestion, itching, weight loss and fever. Because the radiotherapy/chemotherapy after ERCP usually last for six months, patients were followed up for six months and the quality of life was evaluated again. In addition, patients were followed up until January 2013 for the determination of survival rate.

In three treatment groups, the scores for weight loss significantly increased in ERCP with radiotherapy/chemotherapy group. This may be associated with the cachexia in patients with advanced cancers. In patients with different serum bilirubin concentrations, the scores for jaundice, itching, and body pain significantly increased in those with serum bilirubin concentration of ≥ 100 μmol/L. However, the scores for RP, RE, and SF significantly decreased in patients with high serum bilirubin, indicating that these patients often had jaundice and itching, were less sensitive to body pain, and had inferior RP, bad RE, and weak SF. In patients with different serum CA199 concentrations,

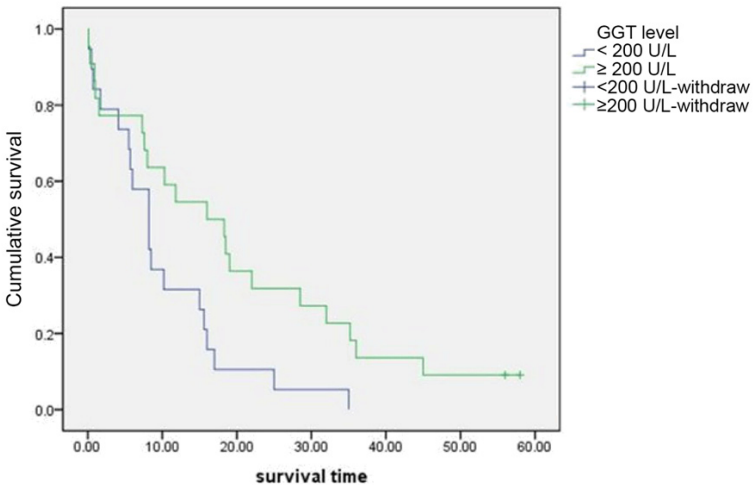

Figure 9. The survival curves of patients with different serum GGT concentrations.

the scores for BP significantly increased in patients with serum CA199 concentration of ≥ 200 U/ml, indicating that these patients were less sensitive to body pain. In patients with different serum CEA concentrations, no significant differences were observed in the scores of domains measured with SF-36 and QLQ-MOJ11. In patients with different serum ALP concentrations, the scores for jaundice and itching significantly increased in patients with serum ALP concentration of ≥ 200 U/L (assessment with QLQ-MOJ11). The scores for RP and SF significantly decreased in patients with high serum ALP concentration, but that for BP significantly increased in those with serum ALP concentration of ≥ 200 U/L. This indicates that patients with serum ALP concentration of ≥ 200 U/L are vulnerable to jaundice and itching and less sensitive to body pain, and have inferior RP, and weak SF. In patients with different serum GGT concentrations, the score for SF significantly decreased in patients with serum GGT concentration of ≥ 200 U/L, indicating that these patients have worse social function.

According to the assessment with the SF-36, the score for RE significantly increased in ERCP with radiotherapy/chemotherapy group after ERCP. This indicates that these patients have a better emotion and an optimistic attitude towards life. There were no significant differences in the scores for domains measured with SF-36 and QLQ-MOJ11 at six months among three groups.

Survival analysis showed the median survival time was 10.2 months in patients with malignant bile duct obstruction after ERCP based treatments. The median survival time in ERCP with nasal biliary drainage group, ERCP with endoscopic stent insertion group, and ERCP with radiotherapy/chemotherapy group was 8.2 months, 8.2 months and 18.3 months, respectively. The median survival time in ERCP with radiotherapy/chemotherapy group was longer than in other two groups, indicating that this treatment may prolong the survival time of patients with malignant bile duct obstruction. Of patients in different age groups, the median survival time was 32 months for patients aged < 60 years, and 8 months for patients aged ≥ 60 years, showing significant difference between them. The median survival time of patients with cholangiocarcinoma, gallbladder cancer, pancreatic cancer, liver cancer, and other metastatic carcinomas was 8.5 months, 19.0 months, 5.5 months, 15.6 months and 18.5 months, respectively. The median survival time of patients with pancreatic cancer and cholangiocarcinoma was shorter than that of patients with other diseases. The median survival time was 16 months for patients with serum bilirubin concentration of < 100 μmol/L, and 8.2 months for those with serum bilirubin concentration of ≥ 100 μmol/L. The median survival time was longer in patients with serum bilirubin concentration of < 100 μmol/L, indicating that high serum bilirubin may influence the survival time of patients with malignant bile duct obstruction. The median survival time was 10.2 months for patients with serum CEA concentration of < 10 μg/L, and 7.3 months for those with serum CEA concentration of ≥ 10 μg/L. The median survival time in patients with serum CEA concentration of < 10 μg/L was longer, indicating that high serum CEA may influence the survival time of patients with malignant bile duct obstruction. The median survival time was 15 months for patients with serum CA199 concentration of < 200 U/ml, and 7.6 months for those with serum CA199 concentration of ≥ 200 U/ml. The median sur-

vival time in patients with serum CA199 concentration of < 200 U/ml was longer, indicating that high serum CA199 may also influence the survival time of patients with malignant bile duct obstruction. The median survival time was 8.5 months for patients with serum ALP concentration of < 200 U/L and 10.3 months for those with serum ALP concentration of ≥ 200 U/L, showing no significant difference between them. This indicates that high serum ALP does not affect the survival time of patients with malignant bile duct obstruction. The median survival time was 8.2 months for patients with serum GGT concentration of < 200 U/L and 16 months for those with serum GGT concentration of ≥ 200 U/L, showing no significant difference between them. This indicates that high serum GGT does not shorten the survival time of patients with malignant bile duct obstruction.

Conclusions

In summary, ERCP followed by radiotherapy/chemotherapy may improve the quality of life and prolong the survival time of patients with malignant bile duct obstruction. Of contributing factors, high serum bilirubin predicts a worse quality of life and a shorter survival time; high serum ALP and GGT may worsen the quality of life, but have no influence on the survival time; high serum CA199 and CEA have no impact on the quality of life, but reduces the survival time. In addition, older patients (≥ 60 years) and those with pancreatic cancer and cholangiocarcinoma have a shorter survival time. In conclusion, ERCP followed by radiotherapy/chemotherapy is more effective than other two treatments in improving the quality of life and prolonging survival time of patients with malignant bile duct obstruction, and the quality of life and survival time are influenced by many factors.

Disclosure of conflict of interest

None.

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