JBUON 2020; 25(2): 1056-1062
ISSN: 1107-0625, online ISSN: 2241-6293 • www.jbuon.com
Email: editorial_office@jbuon.com

ORIGINAL ARTICLE

Effect of PTCD-based biliary stent placement combined with ^{125}I particle intracavitary irradiation in treating pancreatic head cancer

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Summary

Purpose: *To explore the efficacy and safety of percutaneous transhepatic cholangial drainage (PTCD)-based biliary stent placement combined with iodine-125 (^{125}I) particle intracavitary irradiation versus palliative internal biliary-intestinal drainage in the treatment of pancreatic head cancer-induced obstructive jaundice.*

Methods: *The clinical data of 110 patients with pancreatic head cancer, who were admitted to and treated in our hospital from July 2013 to July 2016 were registered. Among them, 55 patients underwent PTCD-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation (^{125}I group), while the other 55 patients received palliative internal biliary-intestinal drainage (Surgery group). The jaundice index, and liver function parameters before and after treatment, duration of stent patency, tumor growth and incidence of adverse reactions were compared between the two groups of patients, and the patient overall survival (OS) time was followed up and recorded.*

Results: *The two therapies both effectively alleviated jaundice and improved liver function in patients. There were no statistically significant differences in the preoperative liver function parameters albumin (ALB), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL) and direct bilirubin (DBIL) between the two groups of patients, and the liver function was significantly improved at each period of time after operation, showing a statistically significant difference. At 3 months after operation, ^{125}I group had substantially lower levels of ALT, AST, TBIL and DBIL, but a prominently higher level of ALB than Surgery group. The complications of patients mainly included pancreatitis, recurrent biliary infections and stent blockage, which were resolved after symptomatic treatments. After operation, the maximum diameter of tumors was enlarged in both groups, and the tumor size in Surgery group and ^{125}I group was increased from 3 months after operation to 6 months after operation, with a more obvious increase in Surgery group. The total clinical benefit rate (CBR) was 61.8% (34) and 54.5% (30), and the mean survival time of patients was 13.4±4.9 months and 12.7±4.6 months in ^{125}I group and Surgery group, respectively. Moreover, the OS in ^{125}I group was notably superior to that in Surgery group.*

Conclusion: *PTCD-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation can effectively relieve jaundice, improve liver function, repress tumor growth, prolong survival and produce tolerable adverse reactions in the patients with pancreatic head cancer who lose the opportunity for surgery or are intolerant to surgery.*

Key words: *biliary stent, ^{125}I particles, pancreatic head cancer, efficacy*

Introduction

Pancreatic head cancer is an extremely highly malignant gastrointestinal malignancy, and due to the insidious onset, is usually detected in advanced stage making it difficult to be radically resected via

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Received: 08/01/2020; Accepted: 02/02/2020

surgery, with the 5-year survival rate of only 7% or so [1-3]. The patients with advanced pancreatic head cancer tend to present progressively aggravated jaundice that can cause multi-system pathological changes, with the main manifestations being liver and kidney function impairment, decline in gastrointestinal barrier function and immune function and severe malnutrition. Most patients will die in a short time if no efficacious treatment measures are taken promptly [4-6]. The release of biliary obstruction is of great significance for the patients with pancreatic head cancer who lose the opportunity for surgical reaction of tumors.

In iodine-125 (^{125}I) particle radiotherapy, encapsulated radioactive ^{125}I particles are implanted (or placed) into the human tumor tissues or the surroundings through an applicator or surgery to make the tumor tissues exposed to long-term and low-dose radiation, thereby achieving the target of radiotherapy. Its advantages are minimal invasiveness, persistent and effective irradiation, high target dose, and easy protection [7,8]. Therefore, the present study retrospectively analyzed the clinical efficacy and safety of percutaneous transhepatic cholangial drainage (PTCD)-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation versus palliative internal biliary-intestinal drainage in the treatment of pancreatic head cancer, hoping to provide a novel clinical treatment mode.

Methods

General information

The data of eligible patients admitted to and treated in our hospital from July 2013 to July 2016 were analyzed. All the enrolled patients were definitely diagnosed preoperatively through abdominal color Doppler ultrasonography, plain and contrast-enhanced computed tomography (CT) scans of the upper abdomen, magnetic resonance cholangiopancreatography and puncture biopsy. Indication for stenting in ^{125}I group: Patients refusing or unsuitable for radical surgery suffering from pancreatic head cancer-induced malignant obstructive jaundice. Indication for surgery in Surgery group: Patients underwent palliative biliary-intestinal drainage since the tumors could not be radically resected via surgery based on preoperative diagnosis, or intraoperative verification. Exclusion criteria: Patients who were unable to tolerate surgery or interventions due to severe organ dysfunction, those with severe coagulation dysfunction, those with definite extensive metastasis in systemic organs, or those who could not undergo biliary stent implantation for severe biliary obstruction. The present study enrolled 55 patients with pancreatic head cancer who underwent PTCD-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation and had follow-up information, and 55 pancreatic head cancer patients undergoing palliative internal biliary-intestinal drainage in the same period. Among them, there were 72 males and 38 females, aged 53.0-85.0 years (mean 63.6±10.4). The difference in the pre-treatment baseline information between two groups of patients was not statistically significant (p>0.05) (Table 1). The present study was approved by the Ethics Committee of Jining No.1 People's Hospital, and all the subjects followed the Declaration of Helsinki, were informed of this study, and signed the informed consent.

Treatment methods

Stenting in ^{125}I group: After admission and signed informed consent, the patients completed relevant examinations, were informed of treatment schemes, and ultrasound-guided PTCD was performed in those who had no obvious surgical contraindications based on the examination results. At 5-7 days after PTCD, PTCD-based biliary metallic stent placement and ^{125}I particle placement were performed under DSA. First, the obstruction was located via intraoperative angiography, and the length and diameter of the obstructive bile duct were measured. Then, an appropriate metallic stent was implanted by a pusher. Subsequently, a guidewire was

Table 1. Baseline characteristics of the studied patients

Parameters	*^{125}I group (n=55) n (%)*	*Surgery group (n=55) n (%)*	*p value*
Age (years)	64.6±10.3	62.2±10.5	0.322
Gender (Male/ Female)	38/17	34/21	0.548
Clinical TNM staging			0.543
III	35 (36.6)	39 (40.8)	
IV	20 (54.9)	16 (53.5)	
Tumor diameter (cm)	4.6±2.2	4.4±2.0	0.619
KPS score			0.552
80-90	18 (55.9)	22 (50)	
70-80	37 (44.1)	33 (50)	

TNM: tumor, node, metastasis; KPS: Karnofsky performance status

inserted into the bile duct via the PTCD tube, and the single-bend angiography catheter was replaced with a sheath tube. Meanwhile, with the direction adjusted, the guidewire passed through the narrow part to the distal end and reached the duodenum ultimately. Following the withdrawal of angiography catheter, a proper metallic stent was selected, and placed across the narrow obstructive segment using a conveyor along the guidewire under fluoroscopic guidance, and the selected stent was released when it was confirmed to be able to completely or partially exceed the narrow segment. If favorable metallic stent expansion or balloon-assisted expansion was angiographically observed in the operation, ^{125}I particle placement was performed concurrently or electively if not. With a P-shaped tube as the applicator of ^{125}I particles, their distribution in the tube was designed according to the length of the obstructive segment. Number of particles to be implanted into tumors = (tumor length + width + height)/3×5/activity of each particle. First, ^{125}I particles were separated using sterilized medical plastic tubes at an interval of 0.6-1.0 cm, with the end blocked. Then, the P-shaped tube containing ^{125}I particles was placed into the planned site for stent intracavitary irradiation, and a drainage bag was connected outside of the lateral cavity after the peripheral cavity was fixed.

Palliative surgery in Surgery group: After admission, the patients were subjected to relevant examinations, were introduced to treatment schemes, and signed the informed consent. When the examination results confirmed no obvious contraindications to surgery, palliative internal drainage, namely cholecystectomy + internal biliary-intestinal Roux-en-Y drainage was carried out, and there were 4 cases of concurrent lymph node biopsy and 3 cases of concurrent tumor biopsy and retroperitoneal lymph node biopsy.

Observation indicators

At 1 week before operation, and 1 and 3 months after operation, all the patients were examined by plain and contract-enhanced CT scans of the upper and middle abdomen, while the changes in the maximum diameter of tumors were recorded.

Moreover, at 1 week, 1 month and 3 months after operation, routine blood test, routine serum biochemistry and tumor markers CEA and CA19-9 were performed for review, and the changes in the levels of liver function parameters serum albumin (ALB), alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBIL) and direct bilirubin (DBIL).

At 1 month after treatment, CT was conducted again to determine the distribution of particles, observe the patency of stent and verify the displacement and detachment of ^{125}I particles. When the ^{125}I particles had no therapeutic effect (6 months later), they were replaced to continue intracavitary irradiation, or the P-shaped tube was removed, according to the willingness of patients. The removed P-shaped tubes and particles were disposed by the Nuclear Medicine Department of our hospital in a centralized manner.

Clinical benefit response: The comprehensive evaluation criteria for the three indicators pain [visual analog scale (VAS), physical status (KPS scale) and weight change were as follows: (1) Based on physical status improved by ≥20 points, analgesic dose decreased by ≥50%, and weight increased by ≥7%, the improvement in one indicator and stability in another one indicator, or improvement in any two indicators for longer than 4 weeks was considered as response, no changes in any two indicators as stability, and worsening in any indicator as no response. (2) Stable analgesic dose and physical status and non-body fluid retention-induced weight gain by ≥7% for more than 4 weeks were defined as response, and stable weight or weigh loss as no response [9].

The incidence of postoperative adverse reactions in patients was observed and recorded, and the patient survival was followed up and recorded.

Statistics

In the present study SPSS 22.0 software (IBM, Armonk, NY, USA) was used for statistical analyses. Measurement data were presented as mean ± standard deviation, and inter-group comparisons were made using pairwise t-test. The arithmetic data were compared using x^2 test or Fisher's exact test. T-test was conducted for intra-group matching data on serum liver function parameters and tumor markers, while the intergroup comparisons were made via two-way analysis of variance (ANOVA). The incidence of adverse reactions was compared as one-way ordinal ranked data using the Mann-Whitney U test. The survival curves were plotted using the Kaplan-Meier method and log-rank test was used to detect intergroup differences. $P<0.05$ suggested statistically significant differences.

Results

Surgical conditions and liver function recovery

The ^{125}I particle placement was successfully performed in 48 patients concurrently, and in 7 patients at 1 week postoperatively in ^{125}I group, and the palliative surgery was also successful in the 55 patients in Surgery group with no surgery-related deaths. After operation, the jaundice gradually vanished, and pruritus and other symptoms were gradually resolved and disappeared. The mean duration of stent patency was 8.9±5.0 months. Before operation, there were no statistically significant differences in the liver function parameters ALB, ALT, AST, TBIL and DBIL between the two groups of patients ($p>0.05$), and the liver function was obviously improved at each period of time after operation, showing a statistically significant difference ($p<0.05$). The differences in all the liver function parameters at 7 days and 1 month after operation between the two groups were not statistically significant, and at 3 months after operation ^{125}I group had substantially lower levels of ALT, AST, TBIL and DBIL, but a prominently higher level of ALB than the Surgery group ($p<0.05$) (Table 2).

Table 2. Comparison of liver function indices of patients in the two studied groups (mean±SD)

	^{125}I group (n=55)	*Surgery group (n=55)*	*p value*
Alb (g/L)			
Pretreatment	32.2±3.0	31.9±2.8	0.589
7 days posttreatment	32.5±3.5	32.1±3.4	0.345
1 month posttreatment	36.6±3.9	35.8±3.7	0.172
3 months posttreatment	39.3±3.6	37.5±3.8	0.012
ALT (U/L)			
Pretreatment	172.6±66.5	164.7±71.8	0.551
7 days posttreatment	70.9±18.1	73.2±18.9	0.516
1 month posttreatment	48.7±16.4	51.1±17.7	0.462
3 months posttreatment	35.6±19.4	49.1±18.3	0.001
AST (U/L)			
Pretreatment	188.6±76.5	196.5±71.5	0.577
7 days posttreatment	73.9±24.4	78.9±28.7	0.420
1 month posttreatment	60.0±22.7	66.5±20.7	0.321
3 months posttreatment	39.6±19.2	58.5±19.9	0.001
TBIL (μmol/L)			
Pretreatment	272.6±80.4	260.6±86.8	0.454
7 days posttreatment	108.6±59.9	100.6±61.6	0.308
1 month posttreatment	39.6±16.5	46.6±14.4	0.139
3 months posttreatment	22.1±10.5	33.4±11.3	0.001
DBIL (μmol/L)			
Pretreatment	217.1±71.0	202.6±80.8	0.489
7 days posttreatment	89.7±51.5	82.2±55.3	0.228
1 month posttreatment	23.3±13.3	28.4±10.0	0.190
3 months posttreatment	11.9±8.8	19.1±9.6	0.001

Alb: albumin, ALT: alanine transaminase, AST: aspartate aminotransferase, TBIL: total bilirubin, DBIL: direct bilirubin

Postoperative complications and treatments

After operation, ^{125}I group had 8 cases of pancreatitis that was treated with administration of somatostatin and correction of electrolyte imbalance for 4-7 days; 2 cases of acute cholangitis that was alleviated after drainage by opening PTCD tube and administration of antibiotics for 2-5 days; 2 cases of complicated abdominal hemorrhage and 1 case of complicated gastroparesis. Besides, the long-term complications of patients in ^{125}I group mainly included recurrent biliary infections and stent blockage. At the end of the present study, in ^{125}I group, 23 (41.8%) patients suffered from recurrent biliary infections, which were improved after anti-infective and choleretic treatments, while 14 patients had stent blockage, of whom 11 patients were complicated with duodenal obstruction and died within 3 months after recurrent jaundice.

In the Surgery group, there were 3 patients with incision infection treated through cleaning, dressing change and a second suture of incision, 4 patients with pancreatic symptoms, 4 patients with abdominal hemorrhage and 3 patients with gastroparesis, who recovered after continuous gastrointestinal decompression, administration of gastrointestinal stimulants and nutrition support, and 1 patient with bilioenteric anastomotic leakage treated with puncture drainage, and symptomatic and supportive treatment (Table 3).

Comparisons of short-term efficacy and clinical benefit rate (CBR)

Before operation, the difference in the maximum diameter of tumors between ^{125}I group and the Surgery groups was not statistically significant (32.2±5.3 mm *vs.* 31.8±4.6 mm, p=0.673). After operation, the maximum diameter of tumors enlarged in both groups, and the tumor size in the Surgery group and ^{125}I group increased from 36.0±5.5 mm *vs.* 33.6±5.7 mm at 3 months after operation to 42.9±6.4 mm *vs.* 37.3±6.1 mm at 6 months after operation, with a more obvious increase in Surgery group, and the differences between the two groups were statistically significant (p=0.027, p<0.001).

The clinical benefit was evaluated in all the patients, and the two groups had 24 and 20 cases

Table 3. Comparison of adverse reactions of patients in the two studied groups

Parameters	*^{125}I group (n=55) n (%)*	*Surgery group (n=55) n (%)*	*p value*
Incision infection	1 (1.8)	3 (5.5)	0.618
Pancreatitis	8 (14.5)	4 (7.3)	0.360
Bile duct infection	23 (41.8)	10 (18.2)	0.012
Stent obstruction	14 (25.5)	0 (0)	0.001
Duodenal obstruction	11 (20.0)	9 (16.4)	0.805
Gastroparesis	1 (1.8)	3 (5.5)	0.618
Intra-abdominal hemorrhage	2 (3.6)	4 (7.3)	0.679
Pancreatic fistula	2 (3.6)	2 (3.6)	1.000
Bilioenteric anastomotic fistula	0 (0)	1 (1.8)	0.856

Table 4. Comparison of serum CA19-9 and CEA level of patients in the two studied groups (mean±SD)

	^{125}I group (n=55)	*Surgery group (n=55)*	*p value*
CA19-9 level (U/mL)			
Pretreatment	606.6±59.5	619.7±61.8	0.260
7 days posttreatment	523.9±76.1	550.2±87.0	0.094
1 month posttreatment	386.7±64.4	562.1±66.7	0.001
3 months posttreatment	355.6±57.4	559.1±54.3	0.001
CEA level (U/mL)			
Pretreatment	40.4±5.5	39.6±6.1	0.472
7 days posttreatment	31.9±4.0	32.8±4.1	0.246
1 month posttreatment	22.1±4.7	26.6±4.4	0.001
3 months posttreatment	23.3±3.4	27.7±3.3	0.001

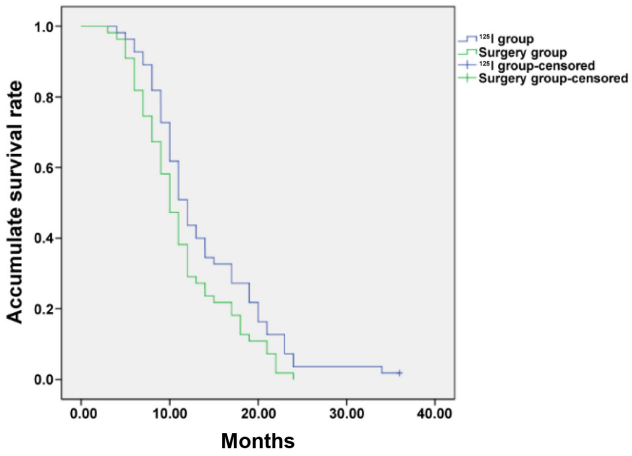

Figure 1. Kaplan-Meier survival curves of patients in ^{125}I group and surgery group. The overall survival rate of patients in ^{125}I group was significantly higher than that of surgery group (p=0.034).

of decreases by more than 50% in both the dose of analgesic drugs and the pain intensity VAS score, respectively, 19 and 17 cases of obvious improvement in physical status, respectively, and 10 and 17 cases of 7% and above weight gain, respectively, and the above conditions lasted for longer than 4 weeks. The total CBR was 61.8% (n=34) and 54.5% (n=30) in the two groups, respectively.

Comparisons of CA19-9 and CEA levels before and after treatment

There were no statistically significant differences in serum CA19-9 and CEA levels between the two groups before operation (p>0.05). At 7 days after operation, the levels of serum CA19-9 and CEA declined substantially in the two groups, but the differences between the two groups were not statistically significant (p>0.05), while at 1 and 3 months after operation, their levels in ^{125}I group were notably lower than those in the Surgery group (p<0.001) (Table 4).

Patient survival based on follow-up results

All the 110 patients completed the 3-36-month follow-up until July 2019. The mean survival time of patients was 13.4±4.9 months in ^{125}I group and 12.7±4.6 months in the Surgery group. Up to the end of follow-up, only 1 patient was still alive in ^{125}I group, with no patient alive in the Surgery group. Additionally, there were 39 and 42 deaths of advanced metastatic malignancy and systemic

organ failure, 7 and 5 deaths of duodenal obstruction-induced inability to eat, 5 and 6 deaths of gastrointestinal hemorrhage, and 3 and 2 deaths of cardiac arrest in the two groups, respectively. The patient survival curves were plotted using the Kaplan-Meier method and log-rank test was used to detect intergroup differences. As shown in Figure 1, the OS in ^{125}I group was considerably superior to that in the Surgery group (p=0.034).

Discussion

Relieving biliary obstruction has a very important implication for the patients with advanced pancreatic head cancer who have lost the opportunity for surgical resection of tumors. For the patients with pancreatic head cancer, effective biliary drainage can theoretically mitigate the symptoms quickly, and improve the jaundice-induced heart, brain, liver and kidney function impairment, further raising the patient quality of life and prolonging their survival [10]. According to literature reports, the mean survival time is 6-9 months in patients with malignant obstructive jaundice after palliative drainage [11-13].

The common clinical release methods for pancreatic head cancer-induced obstructive jaundice are external and internal drainage. Compared with the external drainage, internal biliary drainage accords more with the normal physiological structure of the human body, and the enterohepatic circulation, metabolism and the immune function in organisms can gradually recover to normal, with an obviously decreased infection rate [14]. Internal Roux-en-Y drainage is a frequently used procedure for palliative internal biliary-intestinal drainage, with exact efficacy. In the present study, 55 patients had substantial improvements in the liver function parameters at 7 days, and 1 and 3 months after palliative surgery, and fewer postoperative complications. However, the maximum diameter of tumors was remarkably increased at 3 and 6 months after operation due to lack of inhibitory effect on tumors. Since laparotomy-assisted internal biliary drainage is likely to cause intraoperative hemorrhage, with long operation time and large traumas, the patients recover slowly after operation [15]. Moreover, it is difficult to successfully complete such a drainage procedure in older patients who cannot tolerate surgery, and those with postoperative recurrent metastasis and advanced pancreatic head cancer-induced malignant obstructive jaundice.

In comparison with palliative internal biliary-intestinal drainage, percutaneous biliary metallic stent implantation has advantages such as small traumas, absence of absolute contraindications to surgery and repeatable operation, so it is a preferable option for treating pancreatic head cancer accompanied by obstructive jaundice. However, different degrees of stenosis or obstruction will appear in the internal metallic stents with the increase in tumor volume [16]. If applicable, biliary metallic stent placement can be supplemented by radiochemotherapy, immunotherapy and necessary psychotherapy to prolong the survival time of patients and improve their quality of life. Some authors have reported that biliary stenting combined with ^{125}I particle intracavitary irradiation can extend the duration of stent patency and the survival of patients compared with biliary stent placement alone, but there is a scarcity of multi-center large-scale reports [17,18]. ^{125}I particle radiotherapy refers to the treatment in which encapsulated radioactive ^{125}I particles are implanted (or placed) into the human tumor tissues or the surrounding through an applicator or surgery to make the tumor tissues expose to long-term and low-dose radiation, thereby achieving the target of radiotherapy. ^{125}I particle irradiation has been demonstrated to be able to effectively inhibit tumor growth and prolong the duration of stent patency [19,20]. The results of the present study indicate that the two surgical procedures can effectively lower serum bilirubin level, mitigate symptoms and improve liver function.

Based on the results of this study, as with palliative internal biliary-intestinal drainage, PTCD-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation also effectively relieved biliary obstruction and improved liver function, without increasing surgical complications in the patients with comparable age, ALT, TBIL and ALB. With the inhibitory effect of ^{125}I particle irradiation, the postoperative tumor volume was increased more slowly and the survival time of patients was longer in ^{125}I group than those in the Surgery group.

The present study has some limitations. For example, the sample size was not large enough and follow-up contents were less comprehensive. Therefore, large-sample prospective multi-center randomized controlled trials need designing more rigorously and scientifically to corroborate the preliminary exploration results of this study in the future, so as to provide references for the choice of treatment schemes for such patients.

Conclusions

PTCD-based biliary metallic stent placement combined with ^{125}I particle intracavitary irradiation can effectively relieve jaundice, improve liver function, repress tumor growth, prolong survival

and produce tolerable adverse reactions in patients with pancreatic head cancer who have lost the opportunity for surgery or are intolerance of surgery.

Conflict of interests

The authors declare no conflict of interests.

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