Frequency, Severity, and Risk Factors for Acute Pancreatitis After Percutaneous Transhepatic Biliary Stent Placement Across the Papilla of Vater

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Received: 10 February 2017
Accepted: 23 June 2017
Published online: 6 July 2017

Abstract

Purpose: To clarify the frequency, severity, and risk factors of acute pancreatitis after percutaneous biliary stent placement across the papilla of Vater for malignant biliary obstruction.

Materials & Methods: This retrospective study included 95 patients who underwent percutaneous biliary metallic stent placement (64 [67.4%] bare stents and 31 [32.6%] covered stents) across the papilla of Vater for malignant biliary obstruction between January 2010 and December 2012. The incidence of acute pancreatitis (Atlanta classification of acute pancreatitis) and its severity (Common Terminology Criteria for Adverse Events, version 4) were reviewed. Additionally, the characteristics of the patients and biliary stents, as well as the computed tomography findings of the pancreas were evaluated.

Results: Grade 3 acute pancreatitis was observed in 23 patients (24.2%); acute pancreatitis of grade 4 or higher was not observed. The incidence of acute pancreatitis was lower in patients with atrophic pancreas than in those with non-atrophic pancreas (7.5% vs. 36.4%, $p = 0.004$). It was also lower in patients with main pancreatic duct (MPD) obstruction than in those without MPD obstruction (12.5% vs. 36.2%, $p = 0.026$). There was no difference in the incidence of acute pancreatitis between bare and covered stents.

Conclusion: Percutaneous biliary stent placement across the papilla of Vater for malignant biliary stricture caused acute pancreatitis requiring medication in 24.2% of patients. Atrophy of the pancreas and presence of a dilated MPD may be associated with a decreased risk of acute pancreatitis.

Level of Evidence: Level 4, Case Series.

Keywords: Acute pancreatitis, interventional radiology, malignant biliary obstruction, percutaneous biliary stent placement, self-expandable metal stent

Introduction

Endoscopic or percutaneous biliary interventions, such as endoscopic retrograde biliary drainage and percutaneous transhepatic biliary drainage (PTBD), have been used in patients with obstructive jaundice caused by choledocholith or malignant biliary tract obstruction [1-3]. In patients with malignant biliary tract obstruction who are not candidates for surgical resection, chemotherapy, radiation therapy, or other treatments are generally adopted. Additionally, biliary stent placement is indicated for patients who are not candidates for surgical interventions in order to avoid the use of an external tube. Biliary stents can be placed endoscopically or percutaneously [4-10, 3, 11]. A metallic stent is another option, with its patency being superior to that of tube stents owing to its large lumen diameter. Among metallic stents, bare stents and covered stents are available. Theoretically, covered stents can prevent tumor in-growth, and long-term patency is expected with these stents; however, their use is still controversial [12-14].

For middle or lower biliary obstruction, the stent is generally placed across the papilla of Vater. However, acute pancreatitis can occur in 0.8–25.0% of patients, following biliary stent placement across the papilla of Vater, owing to blockage of pancreatic juice flow by the stent [5, 8, 12-14]. The frequency, severity, and risk factors of acute pancreatitis after percutaneous metallic biliary stent placement across the papilla of Vater have not been sufficiently reported [4, 9, 11]. Therefore, the present study aimed to clarify the frequency, severity, and risk factors of acute pancreatitis following percutaneous biliary metallic stent placement across the papilla of Vater for malignant biliary obstruction.

Materials and Methods

Patients

This retrospective study was approved by the institutional review board of our hospital. The study included 95 patients who underwent initial biliary stent placement across the papilla of Vater for malignant biliary stricture between January 2010 and December 2012. The patient characteristics are summarized in Table 1. Of the 95 patients, 58 were men and 37 were women. The median age of the patients was 66 years (range, 38–89 years). The primary tumor was pancreatic cancer in 32 patients, gastric cancer in 29 patients, gallbladder cancer in 6 patients, colon cancer in 5 patients, bile duct cancer in 4 patients, and others in 19 patients. During the study period, all biliary interventions were performed percutaneously by interventional radiologists; no patient underwent endoscopic biliary stent placement in our institution. All the biliary stents used were metallic stents, which were placed percutaneously via the PTBD route by experienced interventional radiologists. Locations of

stents were determined based on demonstration of strictures on fluoroscopic images (figure 1). Stents were placed to cover strictures completely (figure 2). The choice of biliary stents depended on each interventional radiologist. Written informed consent was obtained from each patient before biliary stent placement. The characteristics of the stents are summarized in Table 2. The diameters of the stents placed across the papilla of Vater were 10 mm in 71 patients (74.7%), 8 mm in 23 patients (24.2%), and 6 mm in 1 patient (1.1%). Of the 95 stents used, 64 (67.4%) were bare stents and 31 (32.6%) were covered stents. The Zilver stent (Cook Medical, Bloomington, IN) was most frequently used (47 stents, 49.5%), followed by the Viabil stent (W.L. Gore & Associates, Phoenix, AZ) (19 stents, 20.2%). In 56 (58.9%) cases, balloon dilatation was performed before stent placement for severe stricture (30 cases) or after stent placement for insufficient stent dilatation (26 cases). Medical charts and medical images were reviewed to evaluate the incidence of acute pancreatitis and its severity. The characteristics of the patients and biliary stents, and the computed tomography (CT) findings of the pancreas were also evaluated.

Characteristics of the pancreas

With regard to the imaging characteristics of the pancreas, the degrees of pancreatic atrophy and dilation of the main pancreatic duct (MPD) before biliary stent placement were evaluated using CT images obtained by a CT scanner with 80-raw detectors (Aquilion Prime, Toshiba, Tochigi, Japan) (slice thickness: 5 mm) before stent placement. Median duration between CT examination and biliary stent placement was 6 days (range; 0-67). CT images were evaluated by two experienced radiologists independently. To assess the amount of pancreatic parenchyma, we measured the anteroposterior (AP) diameter of the pancreas (figure 3). In a previous study, the mean AP diameter of the pancreatic body was 14.3 mm (range, 7–27 mm), with atrophic changes progressing with age [15]. Furthermore, when the thickness of the pancreatic parenchyma in the pancreatic body was less than 10 mm, it was considered as pancreatic atrophy (figure 4) [16, 15]. The thickness of the pancreatic body was measured at the left margin of the superior mesenteric vein (SMV) for reproducibility. In the present study, pancreatic atrophy was confirmed when the AP diameter of the pancreatic body was less than 10 mm.

To assess for MPD dilation, the diameter of the MPD in the pancreatic body was measured. Generally, an MPD diameter of less than 3 mm is considered normal [17, 18]. Hence, in our study, dilation of the MPD was confirmed when its diameter was over 4 mm (figure 4).

The incidence of acute pancreatitis, its severity, and serum amylase levels before and after stent placement were also evaluated retrospectively.

Acute pancreatitis

Acute pancreatitis was diagnosed according to the Atlanta classification of acute pancreatitis [19]. The diagnostic criteria were abdominal pain, elevation of the serum amylase level, and imaging findings consistent with acute pancreatitis (figure 5). Patients who fulfilled 2 or more criteria were diagnosed with acute pancreatitis [19]. The severity of acute pancreatitis was evaluated according to the Common Terminology Criteria for Adverse Events (CTCAE), version 4[20]. Grade 3 or higher acute pancreatitis, i.e., acute pancreatitis requiring medical treatment, was regarded as clinically severe acute pancreatitis in this study. The serum amylase elevation rate was calculated using the serum amylase levels within 7 days before and after stent placement.

Statistical analysis

The relationships between acute pancreatitis after biliary stent placement with pancreatic atrophy, obstruction of the MPD, stent diameter, and balloon dilatation were evaluated using the chi-square test. Changes in the serum amylase levels before and after biliary stent placement were evaluated using the *t*-test. All statistical analyses were performed using the SPSS software, version 20 (IBM Corp., Armonk, NY). A p-value of <0.05 was considered statistically significant.

Results

In percutaneous biliary stent placement, technical success was achieved in all patients. Among the 95 patients, 40 (42.1%) had atrophy of the pancreas and 48 (50.5%) had obstruction of the MPD before biliary stent placement. The mean serum amylase levels (normal value; 44 - 132 U/L) before biliary stent placement in patients with atrophic and non-atrophic pancreas were 132.7 ± 212.3 U/L (mean ± standard deviation) and 189.9 ± 231.1 U/L, respectively ($p = 0.246$); in patients with and without MPD obstruction, the levels were 197.0 ± 263.2 U/L and 135.0 ± 175.1 U/L, respectively ($p = 0.203$) (Table 3).

Acute pancreatitis after biliary stent placement

Overall, grade 3 acute pancreatitis occurred in 23 (24.2%) patients, while grade 2 acute pancreatitis occurred in 15 (15.8%) patients after biliary stent placement. Acute pancreatitis of grade 4 or higher was not observed. Diagnosis of acute pancreatitis was made one day following biliary stent placement in all cases with acute pancreatitis. In 3 patients, acute pancreatitis could not be assessed owing to lack of data in the medical chart.

Pancreatitis was managed with medication in all patients; no patient underwent biliary stent removal.

Changes in the serum amylase levels and incidence of grade 3 acute pancreatitis after biliary stent placement in patients with or without obstruction of the MPD and atrophy of the pancreas are summarized in Table 3. The incidence of grade 3 acute pancreatitis and the serum amylase elevation rate were significantly lower in patients with atrophic pancreas than in those with non-atrophic pancreas (7.5% vs. 36.4%, $p = 0.004$, and 2.2 fold vs. 11.0 fold, $p = 0.001$, respectively). Additionally, the incidence of grade 3 acute pancreatitis and the serum amylase elevation rate were significantly lower in patients with MPD obstruction than in those without MPD obstruction (12.5% vs. 36.2%, $p = 0.026$, and 2.2 fold vs. 12.2 fold, $p < 0.001$, respectively). There was no difference in the incidence of grade 3 acute pancreatitis between the patient groups that received bare and covered stents (28.1% vs. 16.1%, $p = 0.438$). The incidence of grade 3 acute pancreatitis was 19.7% (14/71) in the group that received stents with a diameter of 10 mm, compared to 37.5% (9/24) in the group that received stents with a diameter of 8 mm or less. There was no statistical difference between these two groups ($p=0.149$). There was also no relation in the incidence of grade 3 acute pancreatitis with the presence or absence of balloon dilatation (17.9% [10/56] vs. 33.3% [13/39], $p=0.094$).

Discussion

In the present study, grade 3 acute pancreatitis was observed in 24.2% of the patients in whom biliary stents were placed across the papilla of Vater percutaneously. All the patients were managed well with conservative treatment, and severe acute pancreatitis of grade 4 or higher were not noted. In biliary stent placement for patients with malignant biliary stricture invading the inferior bile duct, the stent can only be placed across the papilla of Vater, and the distal end of the stent should be in the duodenum. Previous studies have suggested that acute pancreatitis occurs in 0.8–25.0% of patients who have undergone endoscopic or percutaneous biliary stent placement across the papilla of Vater [5, 6, 8, 7, 11]. Additionally, a previous study revealed that the incidence of acute pancreatitis was lower in patients with suprapapillary biliary stent placement (4.1%) than in those with transpapillary (across the papilla Vater) biliary stent placement (25.0%) [11].

The risk factors of acute pancreatitis after percutaneous biliary stent placement have not been reported enough. Studies on endoscopic biliary stent placement have shown that accidental injection of contrast medium into the pancreatic duct, high axial force of the stent, non-pancreatic cancer, and age >40 years were risk factors of acute pancreatitis after endoscopic biliary stent placement [5, 8]. Endoscopic sphincterotomy has been reported to be a promising method for decreasing the occurrence of acute pancreatitis after biliary stent placement [6]; however,

this is still controversial [5, 7, 8].

In the present study, the incidence of acute pancreatitis after biliary stent placement was lower in patients who had atrophic pancreatic parenchyma than in those who did not have atrophic pancreatic parenchyma. The blockage of the pancreatic duct might not influence the atrophic pancreatic parenchyma owing to the low exocrine function. Previous studies on pancreatic surgery have suggested that the risk of a pancreatic fistula after pancreaticoduodenectomy is higher in patients with normal pancreas (soft pancreas) than in those with fibrotic pancreas (hard pancreas) [21-23]. This difference in the pancreas results from differences in the numbers of residual exocrine cells. A large number of exocrine cells correlates with severe acute pancreatitis after biliary stent placement [5]. Additionally, patients with existing pancreatic duct obstruction are considered to have outflow obstruction of pancreatic juice before biliary stent placement; therefore, the stent might not have a strong influence on outflow blockage, and it might reduce the incidence of acute pancreatitis [5]. Patients with atrophic pancreatic parenchyma and pancreatic duct dilation had less elevation of the serum amylase level, and this might have resulted from the mechanism described above. According to these results, a biliary stent should be placed in the suprapapillary position in patients with abundant pancreatic parenchyma or a patent MPD, as long as it is possible to avoid acute pancreatitis [11].

A covered stent can prevent tumor growth into the stent, and theoretically, long-term stent patency is expected with this stent. There was no difference in the incidence of acute pancreatitis between bare and covered stents in this study, and this finding was consistent with the results of previous studies [5, 12, 14, 11]. Hence, covered stent placement may be preferable for malignant lower biliary stricture; however, there is controversy regarding the patency of covered and bare stents [14, 13, 12]. A previous study suggested that stent placement with high axial force can increase the risk of acute pancreatitis [5]. In the present study, no relationships were noted between the characteristics of the stent and the incidence of acute pancreatitis after biliary stent placement across the papilla of Vater. However, there was bias (e.g., operator's preference) in the choice of stents. Therefore, the study could not appropriately evaluate the relationships.

The present study has several limitations. First, it was retrospective in nature. Therefore, the reliability of the evaluated data might be low. Another limitation is the grading of acute pancreatitis. The indication of medication for acute pancreatitis in each patient was decided by the physician. Therefore, the indication of medication might be biased, and this might have influenced the CTCAE grading for acute pancreatitis. Additionally, the anteroposterior diameter of the pancreatic body was measured at the left margin of the SMV to evaluate the diameter of the pancreas. However, it does not always represent the thickness of the entire pancreas because

differences are present among the head, body, and tail of the pancreas. Therefore, if the thickness is measured at the pancreatic tail, the result might differ from that in the present study.

Conclusion

Percutaneous biliary metallic stent placement across the papilla of Vater for malignant biliary stricture led to acute pancreatitis requiring medication in 24.2% of patients. Atrophy of the pancreas and presence of a dilated pancreatic duct might decrease the risk of acute pancreatitis after percutaneous biliary stent placement.

Conflict of interest

The authors declare that they have no conflict of interest.

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Fig 1. Cholangiography before stent placement.

Cholangiography demonstrated complete obstruction in the inferior bile duct (arrow)

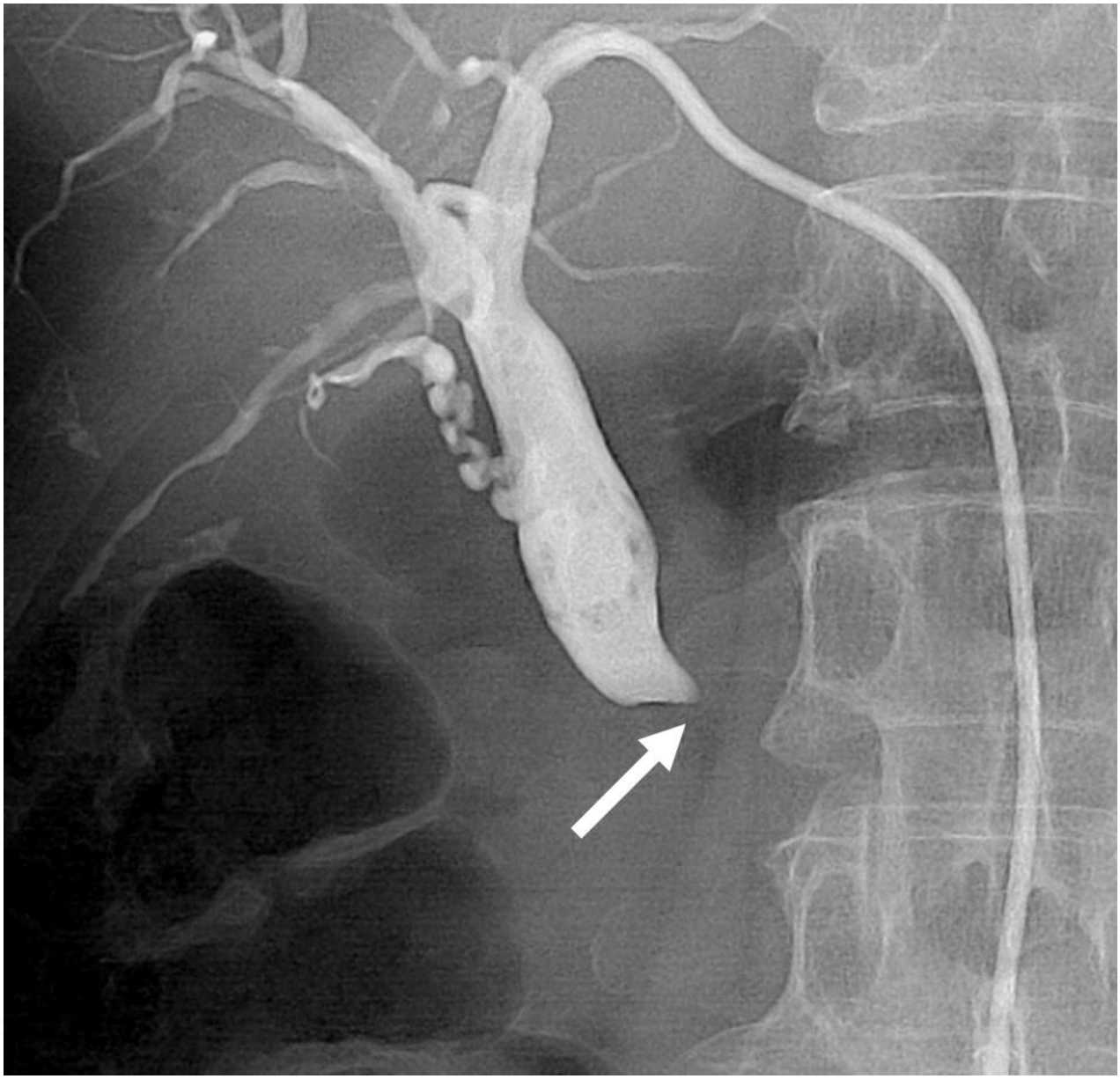

Fig 2. Cholangiography after stent placemen.

A metallic bare stent (10 mm in diameter and 40 mm in length) was placed to cover the obstruction completely

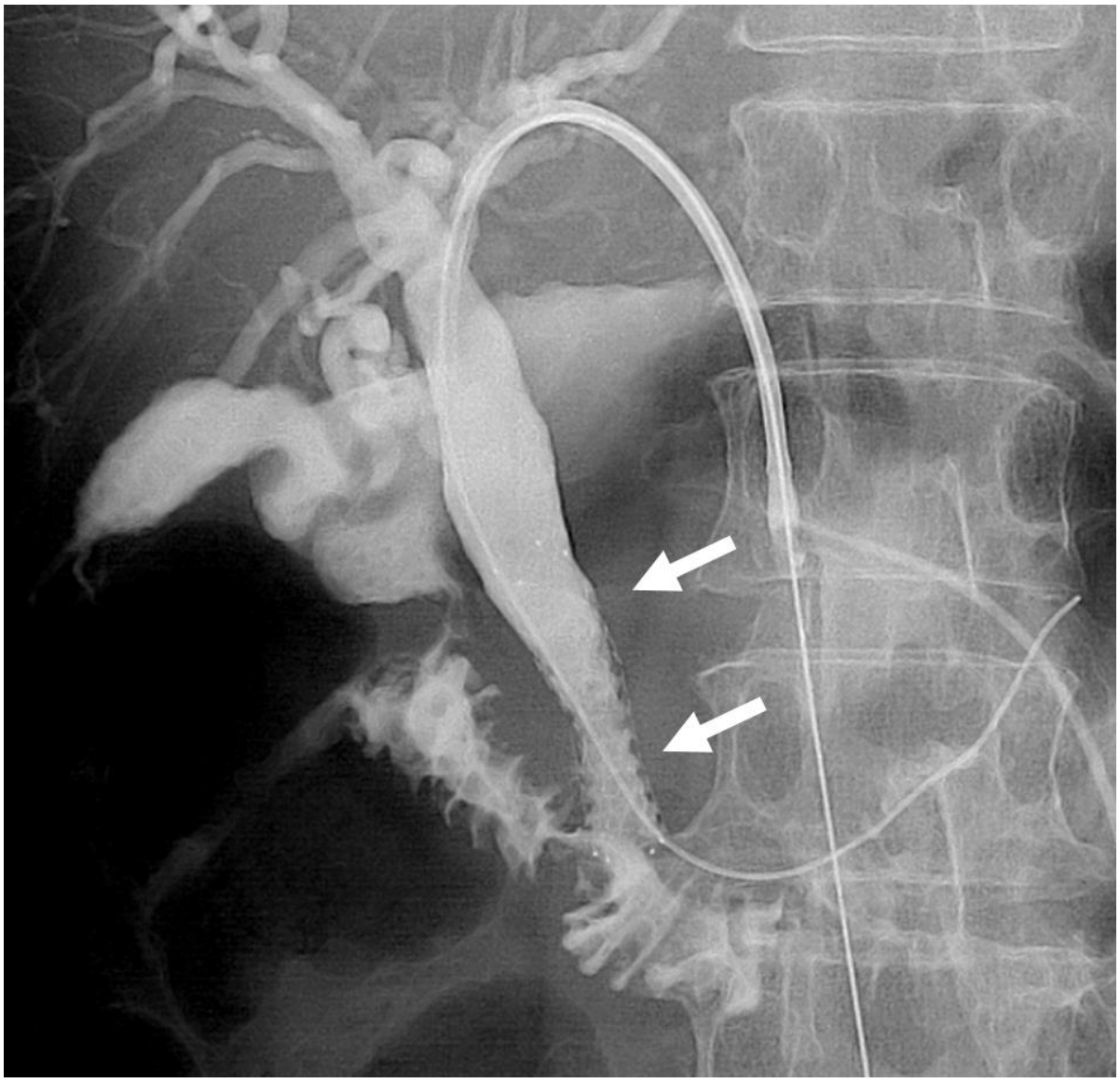

Fig 3. CT image of a normal pancreas.

The anteroposterior diameter of the pancreatic body was 18 mm (double arrow). The main pancreatic duct was not dilated.

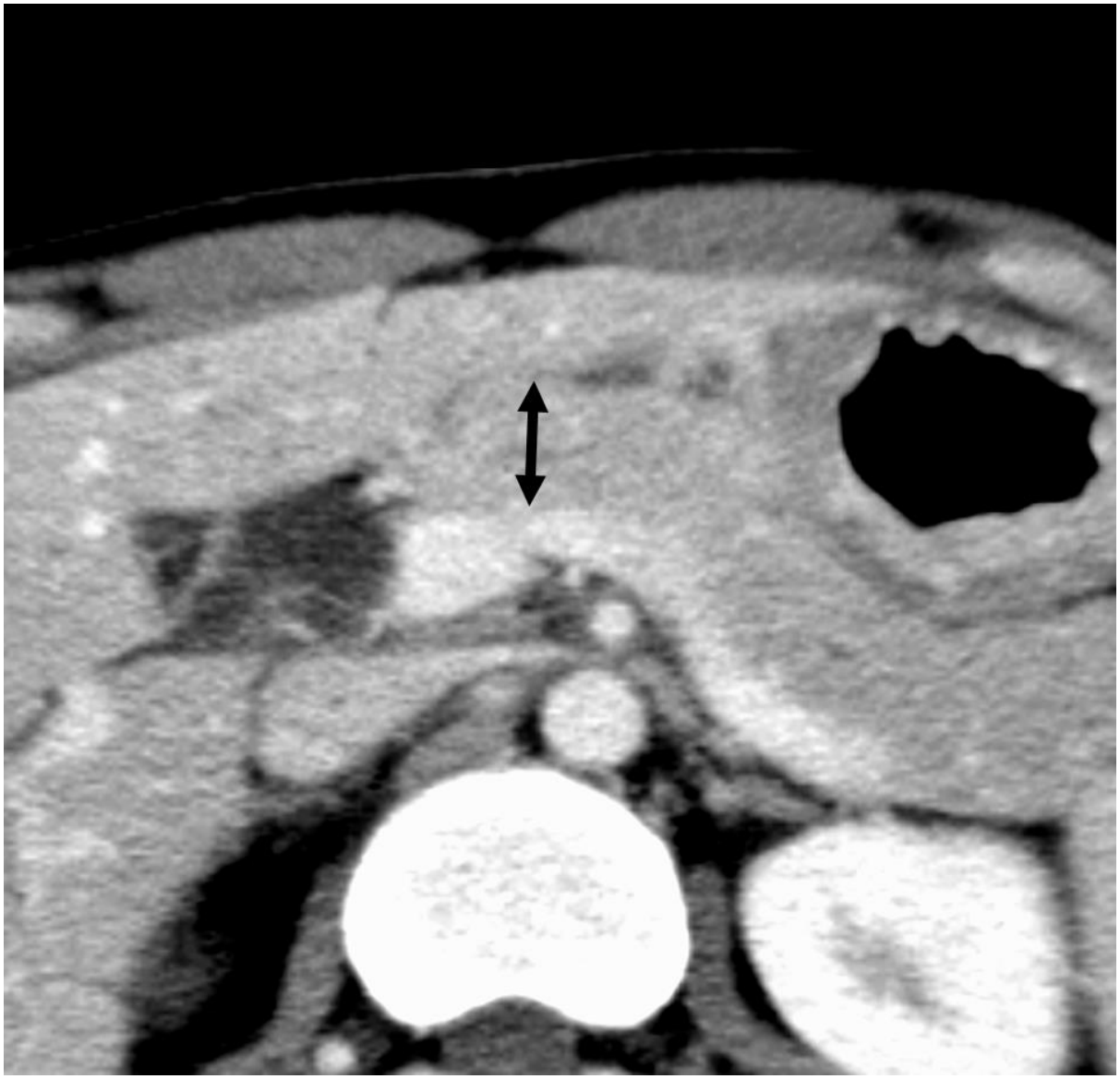

Fig 4. CT image of an atrophic pancreas with dilatation of the main pancreatic duct.

On this contrast-enhanced CT before stent placement, thickness of the pancreatic body was 6.9 mm since the thickness of the ventral pancreatic parenchyma was 3.1 mm (white arrow) and dorsal pancreatic parenchyma was 3.8 mm (black arrow). The diameter of the main pancreatic duct in the pancreatic body was 7.6 mm.

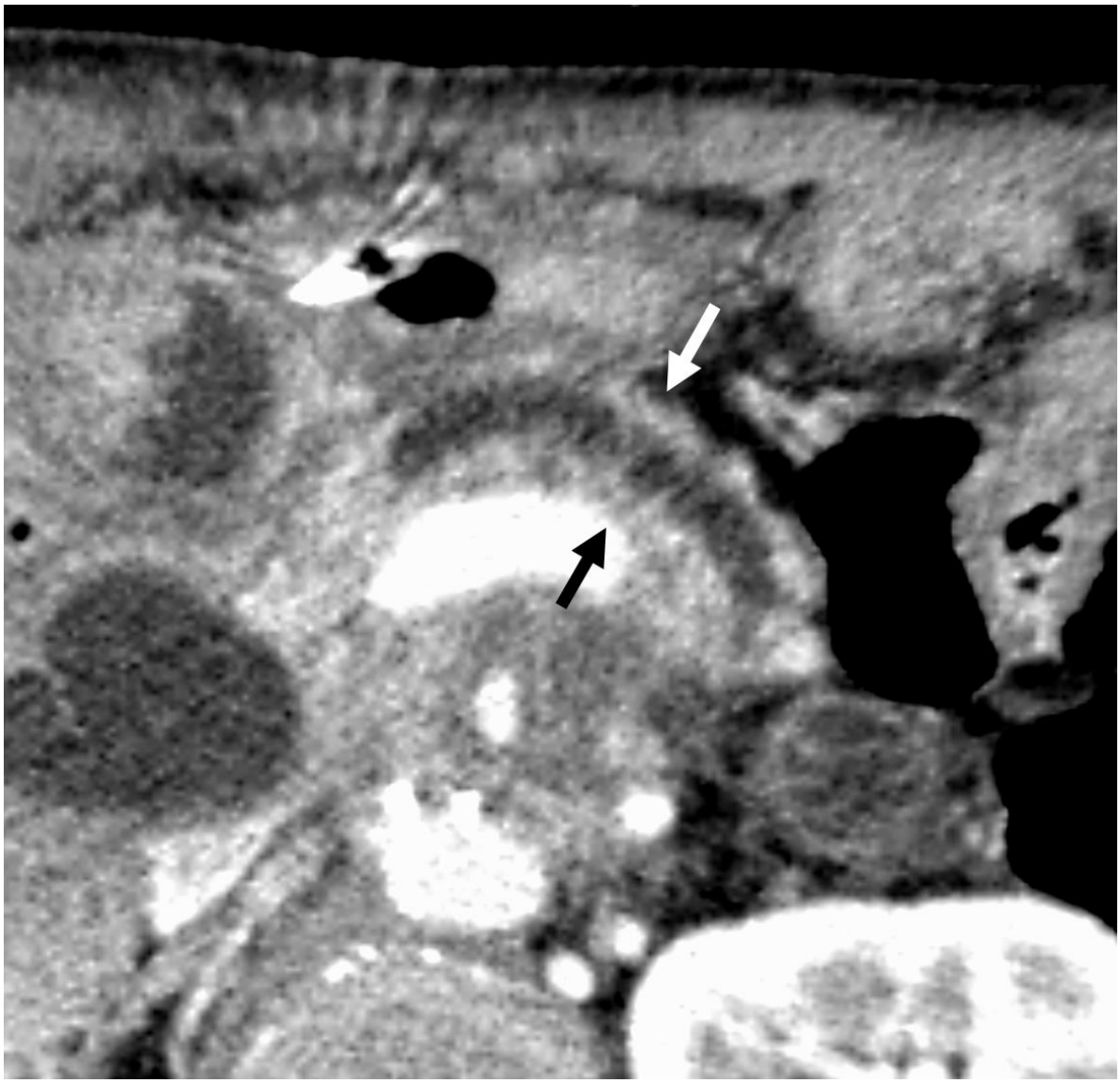

Fig 5. CT image of acute pancreatitis following stent placement (obtained one day after biliary stent placement). Contrast-enhanced CT of the patient who had abdominal pain and elevation of serum amylase level (1,557 U/L) after biliary stent placement demonstrated fluid infiltration around the pancreas (arrows). Enhancement of the pancreatic parenchyma was preserved. An imaging diagnosis of acute pancreatitis was made.

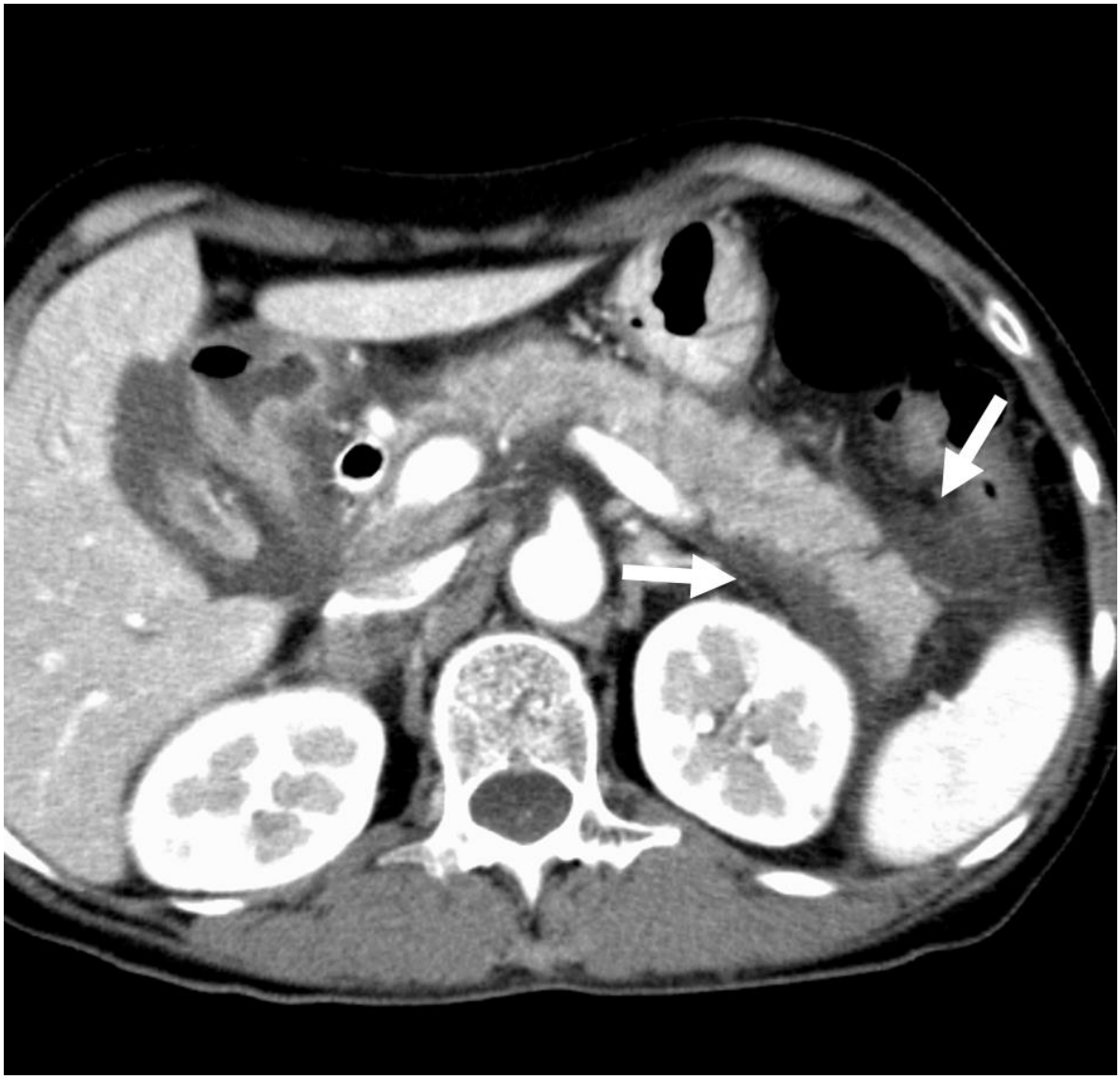

Table 1: Characteristics of patients who underwent percutaneous biliary stent placement across the papilla of Vater

Characteristic	N=95 Value (%)
Sex	
Male	58 (61.1)
Female	37 (38.9)
Age, years (median)	66 (range, 38–89)
Primary disease	
Pancreatic cancer	32 (33.7)
Gastric cancer	29 (30.5)
Gallbladder cancer	6 (6.3)
Colon cancer	5 (5.3)
Bile duct cancer	4 (4.2)
Others	19 (20)
Pancreatic atrophy	
(+)	40 (42.1)
(−)	55 (57.9)
MPD obstruction	
(+)	48 (50.5)
(−)	47 (49.5)
Metallic stent diameter	
10 mm	71 (74.7)
8 mm	23 (24.2)
6 mm	1 (1.1)
Stent type	
Bare	64 (67.4)
Covered	31 (32.6)

*Data are presented as number (percentage) or median (range).

Abbreviations: MPD, main pancreatic duct

Table 2: Characteristics of stents placed percutaneously across the papilla of Vater for malignant biliary obstruction

Stent	Bare/covered	Laser-cut/woven	No. (Total = 95)	%
Zilver	Bare	Laser-cut	47	49.5
Viabil	Covered	Woven	19	20.0
NitiS	Covered	Woven	11	11.6
Epic	Bare	Laser-cut	9	9.5
HANARO	Bare	Woven	5	5.3
HANARO	Covered	Woven	1	1.1
BONA	Covered	Woven	1	1.1
SMART	Bare	Laser-cut	1	1.1
Fluency	Bare	Laser-cut	1	1.1

Table 3: Changes in the serum amylase levels and incidence of grade 3 acute pancreatitis after biliary stent placement

	Preoperative serum amylase (mean ± SD, U/L)	p-value	Postoperative serum amylase (mean ± SD, U/L)	p-value	Serum amylase elevation rate (fold)	p-value	Grade 3 acute pancreatitis (%)	p-value
MPD								
Patent	135.0 ± 175.1	0.203	1100.0 ± 1426.9	0.005	12.2	<0.001	36.2	0.026
Obstructed	197.0 ± 263.2		408.9 ± 704.7		2.2		12.5	
Pancreas								
Non-atrophic	189.9 ± 231.1	0.246	1145.5 ± 1393.3	<0.001	11.0	0.001	36.4	0.004
Atrophic	132.7 ± 212.3		214.1 ± 329.3		2.2		7.5	

*Some laboratory data were not available owing to lack of data in the medical chart. The number of patients whose data were available is presented in the table.

Abbreviations: MPD, main pancreatic duct