Major and minor complications of the pancreas after transcatheter arterial embolization using n-butyl-2-cyanoacrylate for acute bleeding from pancreatic arteries

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- Original article -

Abstract

Purpose: To investigate the major and minor complications of the pancreas after transcatheter arterial embolization (TAE) using n-butyl-2-cyanoacrylate (NBCA) for bleeding from pancreatic arteries.

Materials and methods: Thirty-three patients who underwent TAE using NBCA for acute bleeding from pancreatic arteries and their parent arteries followed by contrast-enhanced computed tomography (CE-CT) were evaluated retrospectively. Complications and risk factors were assessed using the Mann-Whitney U test or Fisher's exact test for the univariate analysis. Patients' characteristic, embolized artery, procedure details, and clinical outcomes were examined as possible risk factors.

Results: TAE was performed successfully in all patients. Minor pancreatic complications occurred in 10 patients (30%), including acute mild pancreatitis (n=4) and focal lack of pancreatic parenchymal enhancement on CE-CT without pancreatitis (n=6). No cases of major pancreatic complications, such as moderate/severe pancreatitis, were reported. Embolized artery was the only significant risk factor. The rate of complications per embolized artery was 15%

(three out of 20 patients) in the arteries of the pancreatic head and 54% (seven out of 13 patients) in the arteries of the pancreatic body and tail (p=0.025).

Conclusion: TAE using NBCA for acute bleeding from pancreatic arteries is efficacious and safe. Mild pancreatic complications were observed more frequently in case of embolization of the pancreatic body and tail region than the pancreatic head.

Keywords: Transcatheter arterial embolization, N-butyl-2-cyanoacrylate, Pancreas, Pancreatitis, Pancreatic infarction

Introduction

Acute hemorrhage after pancreatic surgery or pancreatitis sometimes causes massive bleeding, with high mortality rates in the 25–50% range [1]. However, surgical intervention for acute hemorrhage, including ligation of the target vessel, is usually difficult due to postoperative adhesions and inflammatory changes [2, 3].

Transcatheter arterial embolization (TAE) has been widely used with a high success rate as an effective management method for acute bleeding from pancreatic arteries [4-9]. As a minimally invasive and highly successful method, TAE is the first-line hemostatic procedure for acute bleeding after pancreatic surgery or pancreatitis [2, 10]. Contrastingly, in the case of bleeding in the pancreatic region with small and tortuous blood vessels, it is difficult to isolation using a metallic coil, and embolization using a gelatin sponge has the problem of recanalization of the embolized blood vessel due to abundant anastomosis [9]. In such cases, n-butyl-2-cyanoacrylate (NBCA), a liquid permanent embolization substance approved by the United States Food and Drug Administration for cerebral arteriovenous malformations, is sometimes

chosen as the embolic material. The efficacy of embolization using NBCA for bleeding in the pancreatic region has been reported with a high success rate [3, 7, 11].

In contrast, with embolization using NBCA for pancreas, there are concerns about pancreatic complications such as pancreatitis [12], although a few retrospective studies showed that TAE with NBCA for the pancreas was a safe treatment with no serious complications [7, 13]. Mild pancreatitis or serum amylase elevation sometimes occurred after TAE clinically and an animal experiment showed that selective TAE with NBCA in the pancreas caused localized ischemic necrosis without clinically significant pancreatitis [14]. We estimate these minor complications can lead to serious ones, and a detailed examination is required to help make the procedure safer.

This study aimed to investigate the major and minor complications of the pancreas after TAE using NBCA for acute bleeding from pancreatic arteries and identify the risk factors of pancreatic complications after embolization.

Materials and Methods

Ethical statement

This retrospective study was approved by the Institutional Review Board and the requirement for informed consent was waived. All study procedures were conducted in accordance with the institutional ethical standards and the 1964 Helsinki Declaration and its later amendments.

Patient characteristics

Overall, 38 patients who underwent TAE using NBCA for acute bleeding from pancreatic arteries and their parent arteries between September 2007 and July 2020 were enrolled in this study. In order to assess pancreatic complications correctly, five patients who did not undergo contrast-enhanced computed tomography (CE-CT) after embolization were excluded. Consequently, 33 patients were included in this study, including 27 male and six female patients (age range, 16–85 years; median age, 65 years).

The detailed characteristics of all patients are shown in **Table 1**. The most common underlying cause was pancreatitis (n =11), followed by duodenal bleeding (n = 8), post-pancreatic surgery (n = 7), ruptured aneurysms (n = 5), and others (n = 2). Five patients (15%)

had a shock index (heart rate/systolic blood pressure) greater than 1.0. Ten patients (30%) had blood transfusions of more than 10 red blood cell units.

Embolization procedure

Under local anesthesia, a 4- or 5-French (F) sheath was introduced into the left or right common femoral artery. Angiography was performed using a 4- or 5-F J curve catheter from the celiac and superior mesenteric arteries to identify the source of bleeding. A microcatheter (1.7–2.1 F) was introduced coaxially into the parent catheter, and the tip of the microcatheter was placed as close as possible to the bleeding site. If the bleeding site could be exceeded with the catheter, we tried isolation with only metallic coils (these cases were excluded from this study). If this could not be done, we performed embolization with NBCA (Histoacryl, B. Braun, Melsungen, Germany) (**Fig.1**). NBCA was mixed with iodized oil (Lipiodol, Andre Guerbet, Aulnay-Sous-Bois, France) at ratios varying from 1:1 to 1:9, depending on the distance between the tip of the microcatheter and the target lesion or the length of the bleeding segment. The NBCA mixture was injected using a 1- or 3-mL syringe guided under fluoroscopic monitoring. If the catheter could not be inserted to the bleeding artery, prior distal coil embolization of the parent artery (or main branch) of the bleeding artery

was performed to reduce end-organ damage and/or to avoid non-targeted embolization (**Fig.2**). Digital subtraction angiography was performed to confirm the cessation of bleeding. When cessation of bleeding was not achieved, additional TAE was performed. The procedure was completed after confirming successful occlusion of the target blood vessel on angiography, and this was defined as a technical success of TAE.

Definition of embolized arteries

Pancreatic arteries were defined as the superior/inferior pancreaticoduodenal artery (PDA), dorsal pancreatic artery, transverse pancreatic artery, greater pancreatic artery, and caudate pancreatic arteries [15]. The parent arteries of the pancreatic arteries were defined as the splenic artery (SPA), gastroduodenal artery (GDA), common hepatic artery (CHA), and superior mesenteric artery (SMA). Cases of bleeding from the GDA stump hemorrhage after pancreaticoduodenectomy were not included in this study because the GDA stump does not supply blood to the pancreas. These arteries were divided into two categories based on the area of its blood supply: the pancreatic arteries of the pancreatic head (PA-H) for the superior/inferior PDA, their parent arteries such as the GDA, and the prepancreatic or

retropancreatic arcade between the PDA and dorsal pancreatic artery, and the pancreatic arteries of the pancreatic body-tail (PA-BT) for other pancreatic arteries or the SPA [15].

Post-procedural CE-CT scanning

Post-procedural CE-CT was performed to confirm the cessation of bleeding and to assess pancreatic complications using a 96- (SOMATOM Force; Siemens Healthcare, Forchheim, Germany), 64- (Aquilion ONE or 64; Canon Medical Systems, Otawara, Japan), or 16-channel multidetector-row CT scanner (Brilliance-16; Philips Medical Systems, Best, Netherlands). An unenhanced whole abdominal CT scan was obtained in the transverse section. Dual-phasic abdominal CE-CT was performed 30–45 and 100–120 s after intravenous administration of the contrast material with 5 and 0.5–1.0 mm slice thickness. Iodinated non-ionic contrast material was injected at a dose of 510 mgI/kg body weight with a fixed injection duration of 30 s.

Evaluation factors

Data of clinical symptoms and laboratory tests were collected from medical records. Two interventional radiologists with 17 and 12 years of experience independently reviewed the

angiographic and post-procedural CE-CT findings. We discussed and reached a consensus on the bleeding vessel, the details of the embolization procedure, and postoperative CT findings. Patient characteristics, procedure details, embolized arteries, pancreatic and other complications, and outcomes were evaluated.

The diagnosis of acute pancreatitis was defined based on the revised Atlanta classification of acute pancreatitis. Diagnosis of acute pancreatitis requires two of the following three features: abdominal pain consistent with acute pancreatitis, serum lipase activity (or amylase activity) at least three times greater than the upper limit of normal, and characteristic findings of acute pancreatitis on CE-CT [16, 17]. CT diagnosis and severity classification of pancreatitis were assessed based on the modified CT severity index **(Table 2)** [18]; however, focal lack of pancreatic parenchymal enhancement in the embolized area on CE-CT in patients who did not meet the diagnostic criteria for acute pancreatitis was considered to be a different finding rather than pancreatic necrosis with pancreatitis. In the case of pancreatitis before TAE, the diagnosis of worsening pancreatitis was defined as the increased severity of modified CT severity index. Mild pancreatitis and focal lack of pancreatic parenchymal enhancement on CE-CT without pancreatitis were defined as minor pancreatic complications, while moderate/severe

pancreatitis and focal lack of pancreatic parenchymal enhancement on CE-CT that required additional therapy, such as necrosectomy, were defined as major pancreatic complications.

Non-pancreatic complications were categorized as major or minor according to the guidelines of the Society of Interventional Radiology (SIR) Standards of Practice Committee [19].

Statistical analysis

Univariate analyses were performed to determine the risk factors associated with pancreatic complications after TAE with NBCA. Patients' characteristic, embolized artery, procedure details, and clinical outcomes were assessed as candidate of the risk factor. Continuous variables were analyzed using the Mann-Whitney U test, and qualitative variables were analyzed using Fisher's exact test. P-values < 0.05 were considered statistically significant. All statistical analyses were performed using EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of the R commander designed to add statistical functions that are frequently used in biostatistics [20].

Results

Embolized artery and embolization procedure

A total of 37 bleeding vessels were detected in 33 patients (**Table 3**). Of these 33 patients, 29 (88%) had active bleeding from a single vessel, whereas patients (12%) had active bleeding from multiple vessels. TAE was technically successful in all patients. The PA-H was embolized in 20 patients (61%) and the PA-BT in 13 patients (39%). No patient required both PA-H and PA-BT embolization. There were 6 patients who received TAE of the parent artery of pancreatic arteries (embolization of the GDA or SPA) **(Table 3)**. NBCA was used as the sole embolic material in 27 arteries (73%), whereas NBCA was used in combination with microcoils in 10 arteries (27%). Mixed concentrations of NBCA to Lipiodol ranged from 10% to 50% (mean, 27.3%) and were used at 20–33% in most cases.

Complications after TAE

The mean serum amylase level before the procedure was 151.5 ± 142.3 IU/L (normal range, 65–185 IU/L). The most increased mean level within 1 week after the procedure was

279.0 ± 438.4 IU/L. There was no statistically significant difference in the mean serum amylase level before and after the procedure (p=0.087).

Follow-up CE-CT was performed in 33 patients 2–72 days (median = 7 days) after embolization. Pancreatic complications occurred in 10 patients (30%). All were minor, including acute mild pancreatitis (n = 4) and focal lack of pancreatic parenchymal enhancement on CE-CT without pancreatitis (n = 6). All patients with pancreatitis as a complication of TAE did not require any additional invasive treatment and recovered with conservative treatment only. Of the six patients with focal lack of pancreatic parenchymal enhancement on CE-CT without pancreatitis, four patients showed no change in amylase levels before and after embolization, whereas the remaining two patients had slightly elevated amylase levels without apparent clinical symptom (mean, 162.5 vs. 328.5 U/L). There were no cases of major pancreatic complications. Although small splenic infarctions as a result of non-targeted embolization were observed in 7/33 cases (21%), no major non-pancreatic complications occurred.

Clinical outcomes

Primary hemostasis was achieved in all cases; however, re-bleeding after TAE occurred in seven (21%) cases. None of the embolized arteries were recanalized, and re-bleeding occurred from another artery. Additional embolization was performed and hemostasis was achieved. The mean length of hospital stay was 78.9 ± 71.4 days, and prolongation of hospitalization was not required for the treatment of TAE complications. Four patients died during their hospital stay as a result of other underlying conditions, including renal dysfunction (day 22), pancreatic cancer (day 44), sepsis (day 66), and massive cerebral hemorrhage (day 180). The remaining 29 patients were alive at discharge, and no procedure-related deaths were reported.

Risk factors of pancreatic complications

Embolization of the PA-BT was a significant risk factor for pancreatic complications ($p=0.025$) according to the univariate analysis (**Table 4**). Other factors had no effect on pancreatic complications after TAE.

Discussion

The present study revealed that TAE with NBCA for acute bleeding from pancreatic arteries is a safe and effective treatment option with a high rate of hemostasis. In contrast, minor pancreatic complications, in which none were major complications, occurred in approximately 30% of the patients after TAE. Although there are a few reports that TAE with NBCA for the pancreas was a safe treatment with no complications [7, 13], there have been no detailed assessments of minor complications or post-embolization CE-CT findings. In addition, some previous reports included cases of embolization for bleeding from the GDA stump after pancreaticoduodenectomy, which has no blanches to the pancreas, suggesting that ischemic complications of the pancreas may have been underestimated.

In this study, we found a focal lack of pancreatic parenchymal enhancement with a clear boundary of the embolized area without pancreatitis on CE-CT in some cases. Patients with such CT findings did not require specific treatment, although they sometimes had mildly elevated levels of pancreatic enzymes. We believe that this CT finding indicates pancreatic infarction. No studies have confirmed the radiological-pathological correlation of pancreatic infarction after TAE using NBCA in humans; however, this has been demonstrated in previous experiments using swine models [14]. Pancreatic infarction or ischemic necrosis is reported to

be rare because of the rich arterial blood supply of the pancreas along with its numerous vascular anastomoses [21]. Pancreatic infarction is pathologically distinct from acute necrotizing pancreatitis and is mainly caused by disturbance of blood flow due to vasculitis or malignant hypertension. Acute necrotizing pancreatitis is rarely caused by pancreatic infarction [22]. Furthermore, because of its rarity, little is known about pancreatic infarction and its clinical course. However, our study suggests that pancreatic infarction after TAE for pancreatic arteries might be more common than initially thought. However, it should be noted that infarction should not be misdiagnosed as necrotizing pancreatitis. These two conditions can be differentiated by the differences in the degree of local complications and the severity of pancreatitis.

Embolization of the PA-BT was a risk factor for pancreatic complications in our study. Collateral blood vessels of the pancreatic body and tail region are poorly developed compared to the pancreatic head region; the pancreatic body and tail should be more vulnerable to ischemia than the pancreatic head, which has abundant anastomosis between the superior mesenteric artery and the celiac artery [23, 24]. In support of this, all case reports of severe pancreatitis after TAE resulted from non-selective embolization of the pancreatic body and tail

[25-27]. However, all complications were minor, and there were no major complications even after embolization of the pancreatic body and tail in our study. Although it was not clear whether minor complications, such as focal pancreatic infarction, would lead to major ones, selective embolization may have prevented such complications from occurring. In brief, TAE with NBCA for the pancreas should be safe; however, selective embolization, especially at the pancreatic body and tail, is recommended to avoid serious complications.

In general, the re-bleeding rate of embolization with NBCA is low [13, 28]; however, seven out of 33 patients (21%) had re-bleeding in this study. One of the supposed reasons for the higher incidence of re-bleeding is that duodenal ulcers are included in diseases where t the PDA requires embolization. In the case of duodenal ulcer bleeding, selective embolization is preferable for ulcer healing; however, it increases the risk of re-bleeding from another vessel. A previous report showed that re-bleeding occurred in 40% of cases after NBCA embolization for duodenal bleeding [29]; rich collateral blood vessels may be one of the reasons for re-bleeding.

This study had several limitations. First, this study was retrospective in nature, with data from a single institution. Multivariate analysis was required to estimate risk factors, but this could not be performed due to the small number of patients. Although this is the largest study

focusing on the pancreatic complications of TAE with NBCA for pancreatic arteries, further prospective studies with a larger number of patients are required to confirm the results. Second, embolization was performed by multiple interventional radiologists at our institute. The embolization method was similar but not completely the same. Third, all patients underwent CE-CT after the procedure in this study; however, the timing of CE-CT and laboratory tests were not set in stone. Taken together, pancreatic complications might not have been rigorously evaluated. Established protocols of the evaluation method after TAE are needed to assess the complications more accurately.

In conclusion, TAE with NBCA for acute bleeding from pancreatic arteries is efficacious and safe; however, mild pancreatic complications including mild pancreatitis and focal pancreatic infarction were observed more frequently in the pancreatic body and tail region than in the pancreatic head.

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Figure legends

Fig. 1 A case of selective embolization using NBCA for acute bleeding from the small branch of the dorsal pancreatic artery. A man in his 60s with a history of pancreatitis presented with a chief complaint of abdominal pain. a: Contrast-enhanced CT shows a pseudoaneurysm at the body of the pancreas (black arrow). b: Angiography from the splenic artery shows a pseudoaneurysm near the splenic artery (white arrow). c: Selective angiogram shows a pseudoaneurysm (white arrow) of the small branch of dorsal pancreatic artery (white arrowhead). d: Digital angiography showed that a small branch of the dorsal pancreatic artery (white arrowhead) and pseudoaneurysm (white arrow) was embolized with a 14% NBCA-lipiodol mixture. e: Angiography from the celiac artery confirmed the disappearance of the pseudoaneurysm (white arrow).

Fig. 2 A case of embolization with NBCA in combination with metallic coils to prevent non-targeted embolization to normal branches. A man in his 40s presented with a chief complaint of acute abdominal pain. a: Contrast-enhanced CT scan shows a massive hematoma in the retroperitoneum, suggesting a ruptured aneurysm (black arrow). b: Selective angiogram from inferior pancreaticoduodenal artery shows an aneurysm of the anterior inferior

pancreaticoduodenal artery (AIPDA) (white arrow). c: Microcatheters were advanced near the aneurysm from both the celiac artery and superior mesenteric artery (SMA). Normal arterial branches near the aneurysm were embolized with metallic coils to prevent non-targeted embolization, using a microcatheter advanced from the celiac artery (white arrow). d: Digital angiography showed that an aneurysm of the AIPDA was embolized with a 33% NBCA-lipiodol mixture. e: Angiography from the SMA confirmed the disappearance of the pseudoaneurysm (white arrow).

Fig. 3 Focal lack of pancreatic parenchymal enhancement on contrast-enhanced CT. A man in his 70s underwent embolization using NBCA for pseudoaneurysm of the splenic artery due to pancreatitis. a, b: Contrast-enhanced CT before and after embolization. b: Contrast-enhanced CT on postprocedural day 9 showed a well-defined low-density region around the embolized area (white arrow) without the worsening of pancreatitis. All the high-density structures seen in the pancreatic parenchyma are NBCA-lipiodol casts.

Table 1. Details of patients' characteristics

Variable		Value (n=33)
Age (years)		62.4 ± 13.9
Sex		
	Male	27
	Female	6
Underlying causes		
	Pancreatitis	11
	Duodenal bleeding	8
	Postoperative bleeding	7
	Ruptured aneurysm	5
	Others	2
Shock index; HR (bpm) /SBP (mmHg)		
	More than 1.0	5
	Less than 1.0	28
Massive Transfusion		
	RBC ≧ 10 units	10
Serum amylase level (U/L)		
	Before embolization	151.5 ± 142.3

Data are presented as numbers or mean ± standard deviation.

Abbreviations: HR, heart rate; SBP, systolic blood pressure; RBC, red blood cell.

Table 2. Modified CT severity index

Prognostic indicator	Points
Pancreatic inflammation	
- Normal pancreas	0
- Intrinsic pancreatic abnormalities with or without inflammatory changes in peripancreatic fat	2
- Pancreatic or peripancreatic fluid collection or peripancreatic fat necrosis	4
Pancreatic necrosis	
- None	0
- ≤ 30%	2
- > 30%	4
Extrapancreatic complications (one or more pleural effusions, ascites, vascular complications, parenchymal complications, or gastrointestinal tract involvement)	2

Abbreviations: CT, computed tomography.

Table 3. Blood vessels that caused bleeding

Arteries	Number (%)
PA-H (n=24)	
Pancreaticoduodenal artery (PDA)	22 (60%)
Gastroduodenal artery	2 (5%)
PA-BT (n=13)	
Arteries of the pancreatic body and tail	9 (24%)
Greater pancreatic artery	3
Transverse pancreatic artery	3
Dorsal pancreatic artery	2
Caudal pancreatic artery	1
Splenic artery	4 (11%)
Total	37 (100%)

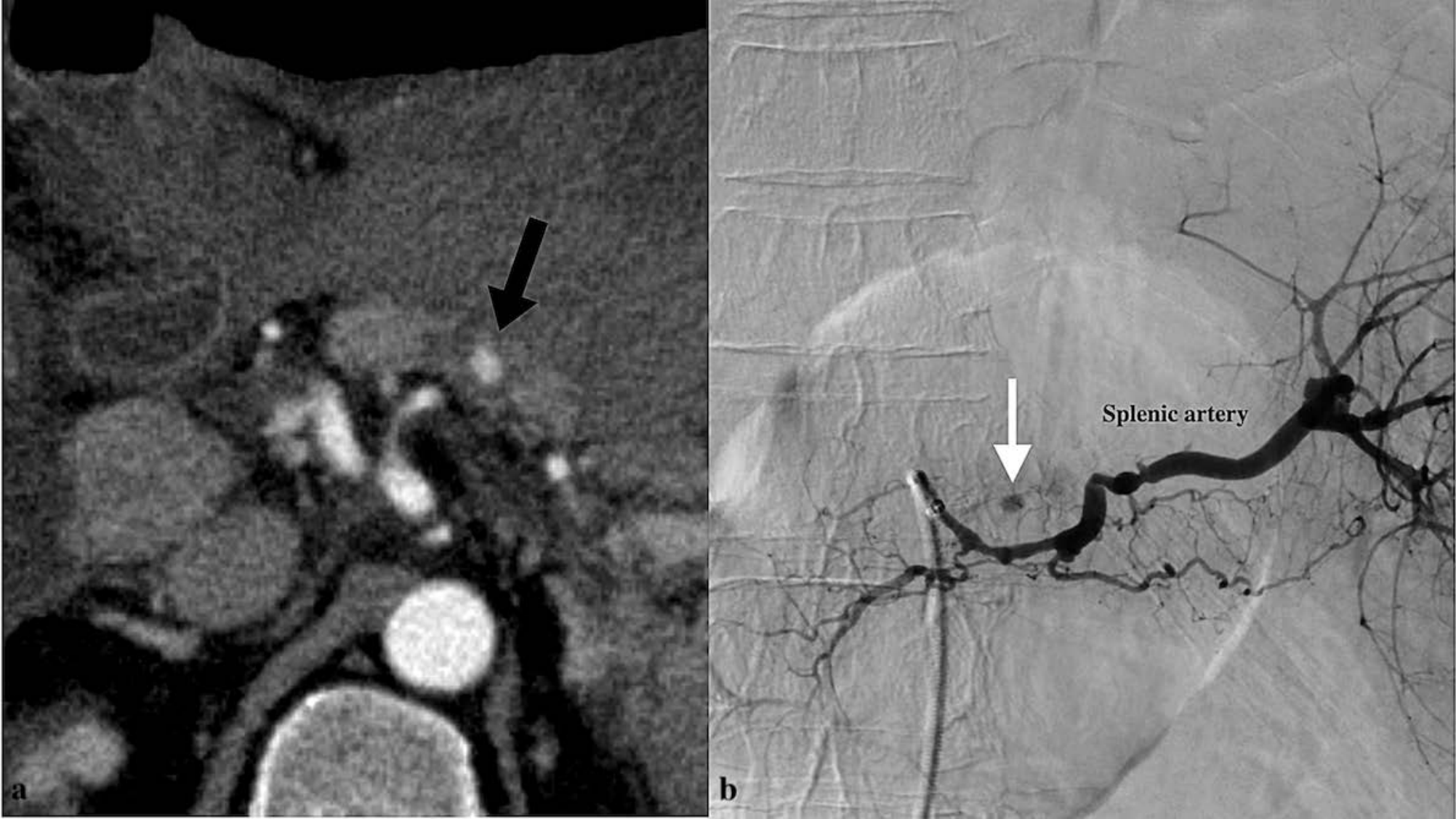
Abbreviations: PA-H, arteries of the pancreatic head and its parent artery; PA-BT, arteries of the pancreatic body-tail and its parent artery.

Table 4. Univariate analysis of patient and TAE characteristics as regards pancreatic complications after embolization

Characteristics	Overall (n=33)	Pancreatic complication (-) (n=23)	Pancreatic complication (+) (n=10)	*p*-value
Age (years)	62.4 ± 13.9	64.9±14.53	56.9 ±10.7	*.065*
Sex				*.336*
Male	27	20	7	
Female	6	3	3	
Underlying causes				*.240*
Pancreatitis	11	6	5	
Other causes	22	17	5	
Shock index; HR (bpm) / SBP (mmHg)				*1.000*
More than 1.0	5	4	1	
Less than 1.0	28	19	9	
Massive transfusion				*.682*
RBC ≥10 units	10	8	2	
Number of bleeding arteries				*1.000*
Single	29	20	9	
Multi	4	3	1	
Embolic materials				*.443*
NBCA only	23	17	6	
NBCA with coils	10	6	4	
Concentration ratio of NBCA-Lipiodol				*.258*
More than 33% NBCA	17	10	7	
Less than 33% NBCA	16	13	3	
Embolized arteries (by area)				*.025**
PA-H	20	17	3	
PA-BT	13	6	7	
Embolized arteries (by embolization start position)				*1.000*
Pancreatic arteries (PA)	27	19	8	
Parent arteries of the PA	6	4	2	
Serum amylase level (U/L)				
Before embolization	151.5 ± 142.3	125.9 ± 125.5	210.2 ± 160.0	*.068*

Data are presented as numbers or as the mean ± standard deviation. *$p < .05$

Abbreviations: TAE, transcatheter arterial embolization; HR, heart rate; SBP, systolic blood pressure; RBC, red blood cell; CE-CT, contrast-enhanced computed tomography; NBCA, N-butyl-2-cyanoacrylate; PA-H, the arteries of the pancreatic head and its parent artery; PA-BT, the arteries of the pancreatic body-tail and its parent artery; PA, pancreatic arteries.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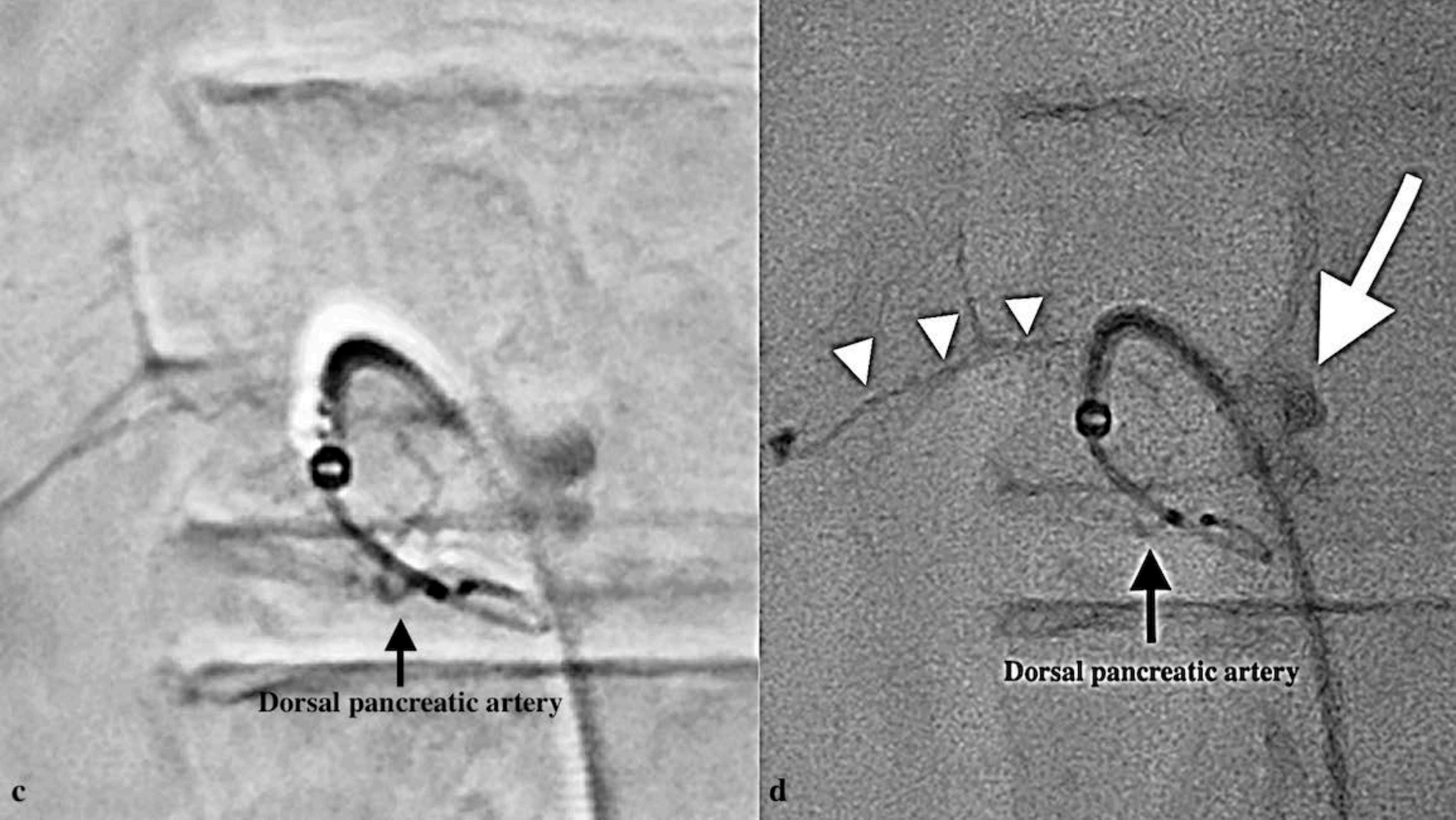
Splenic artery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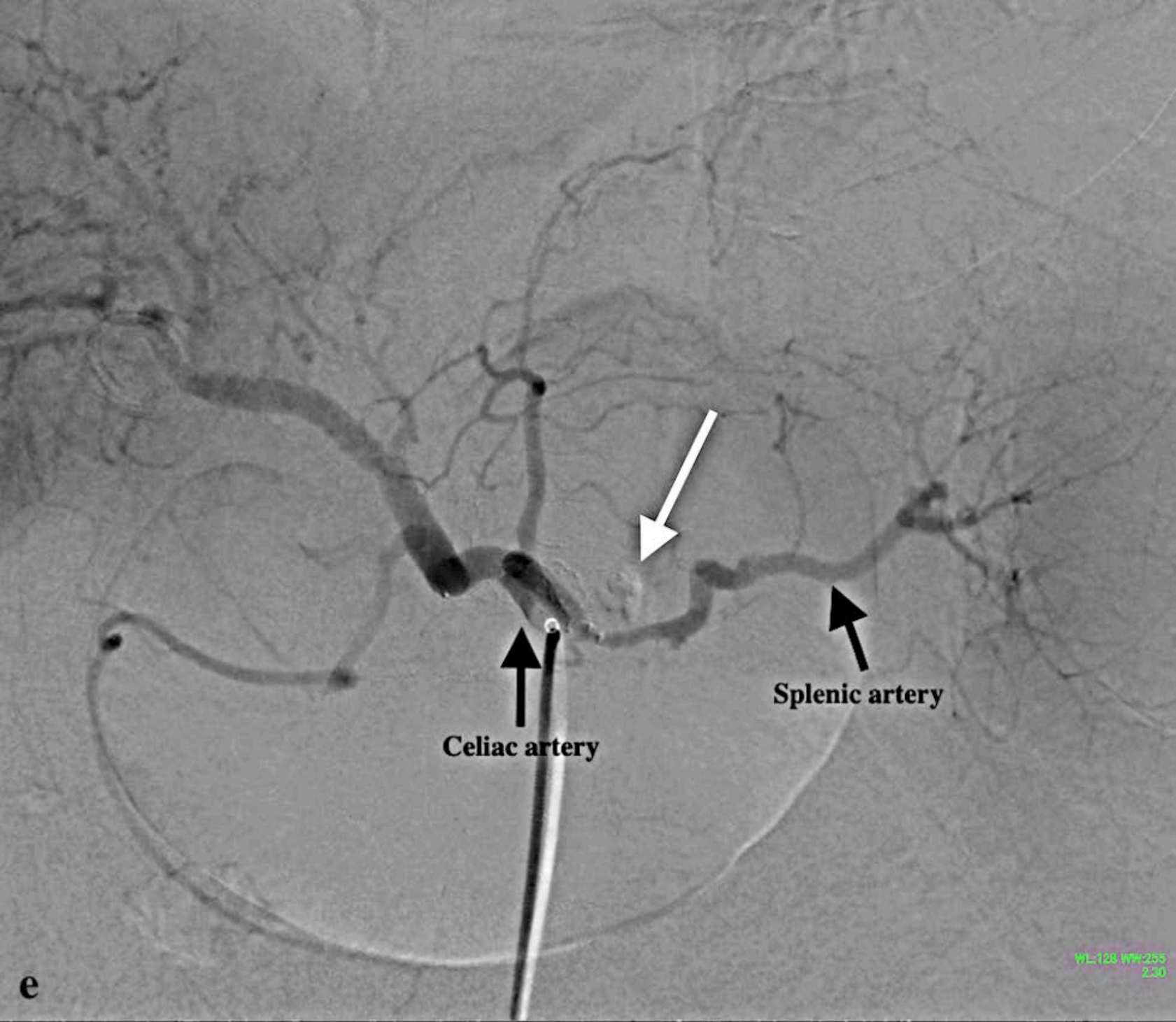
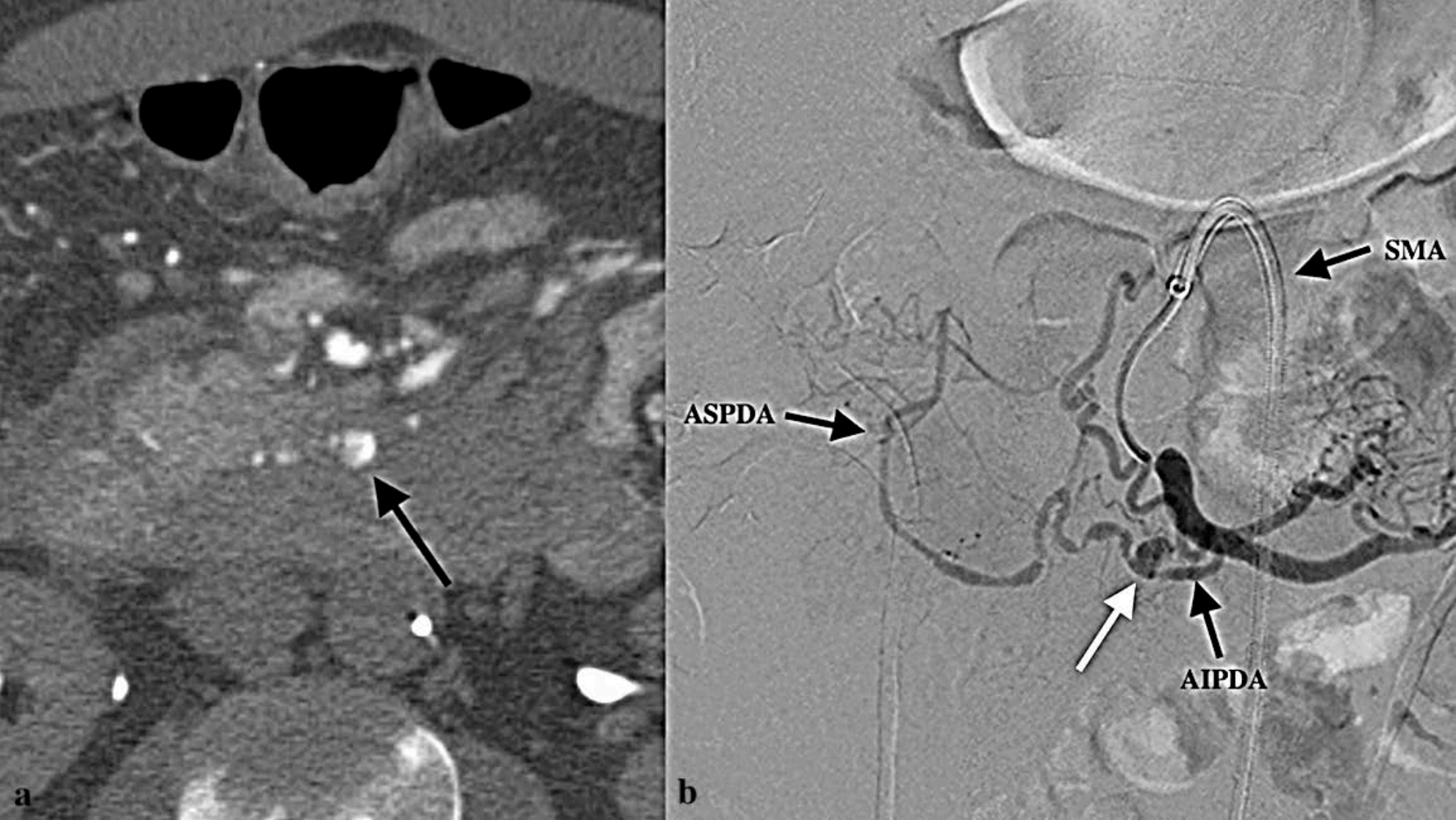
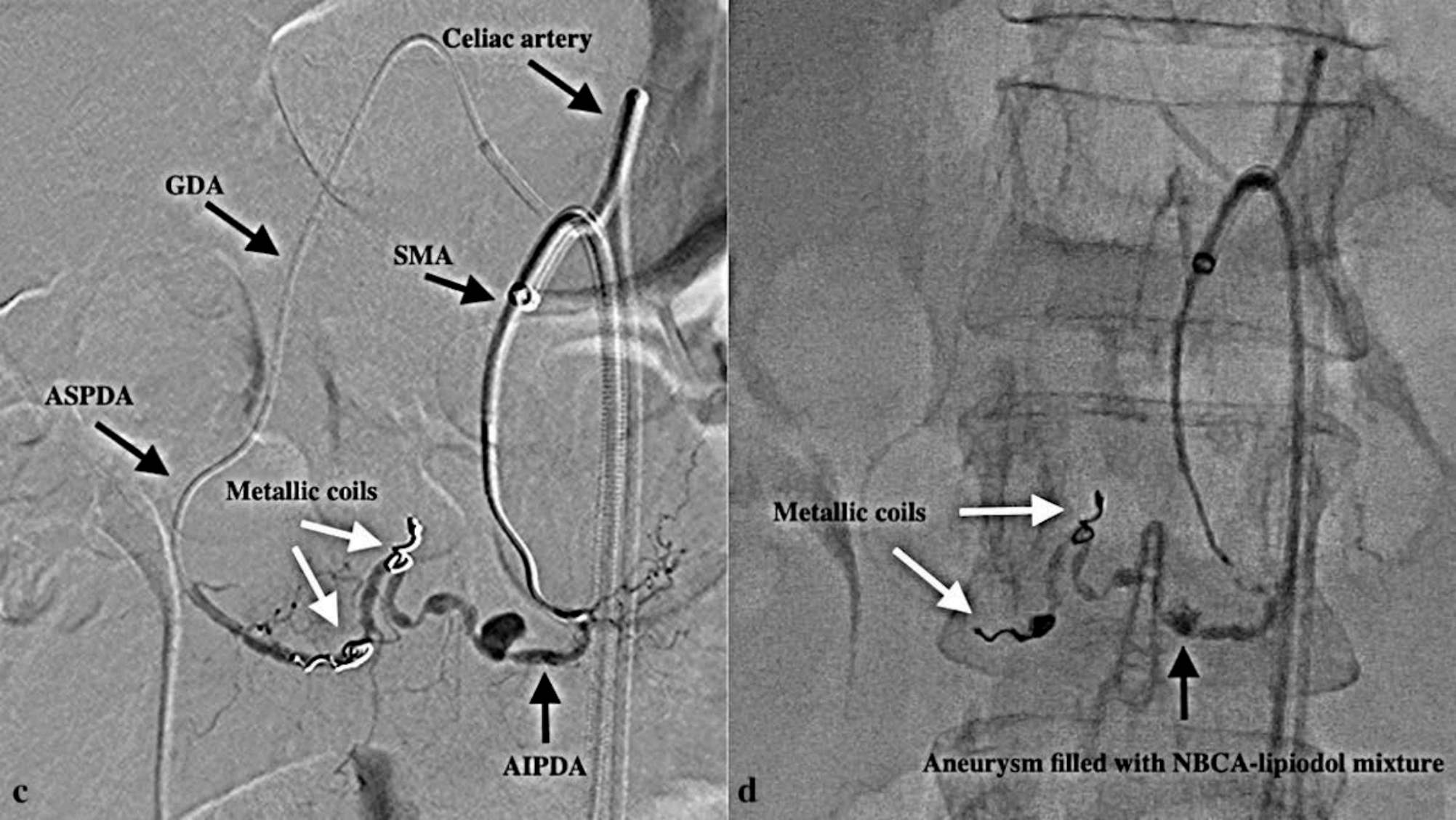
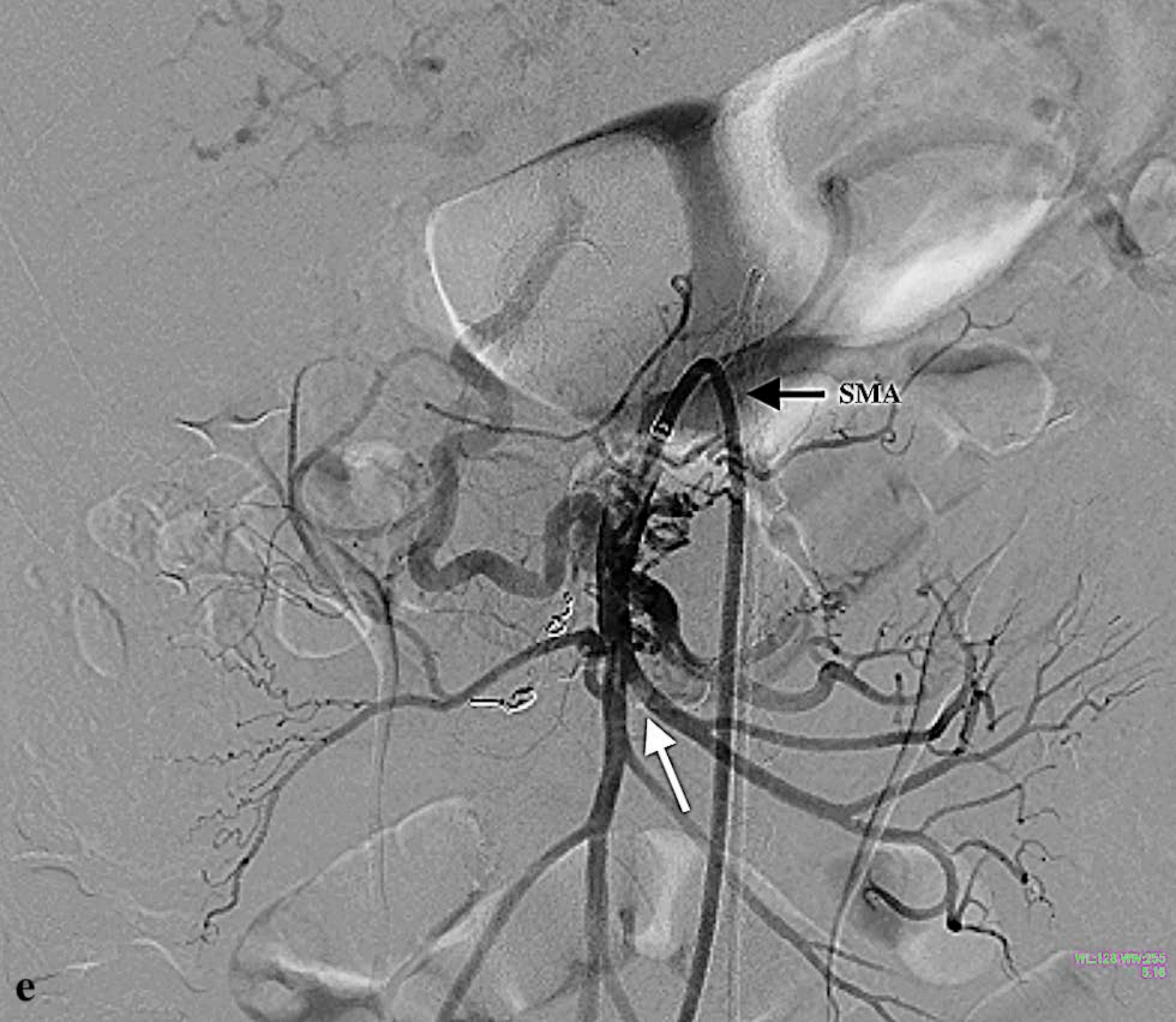
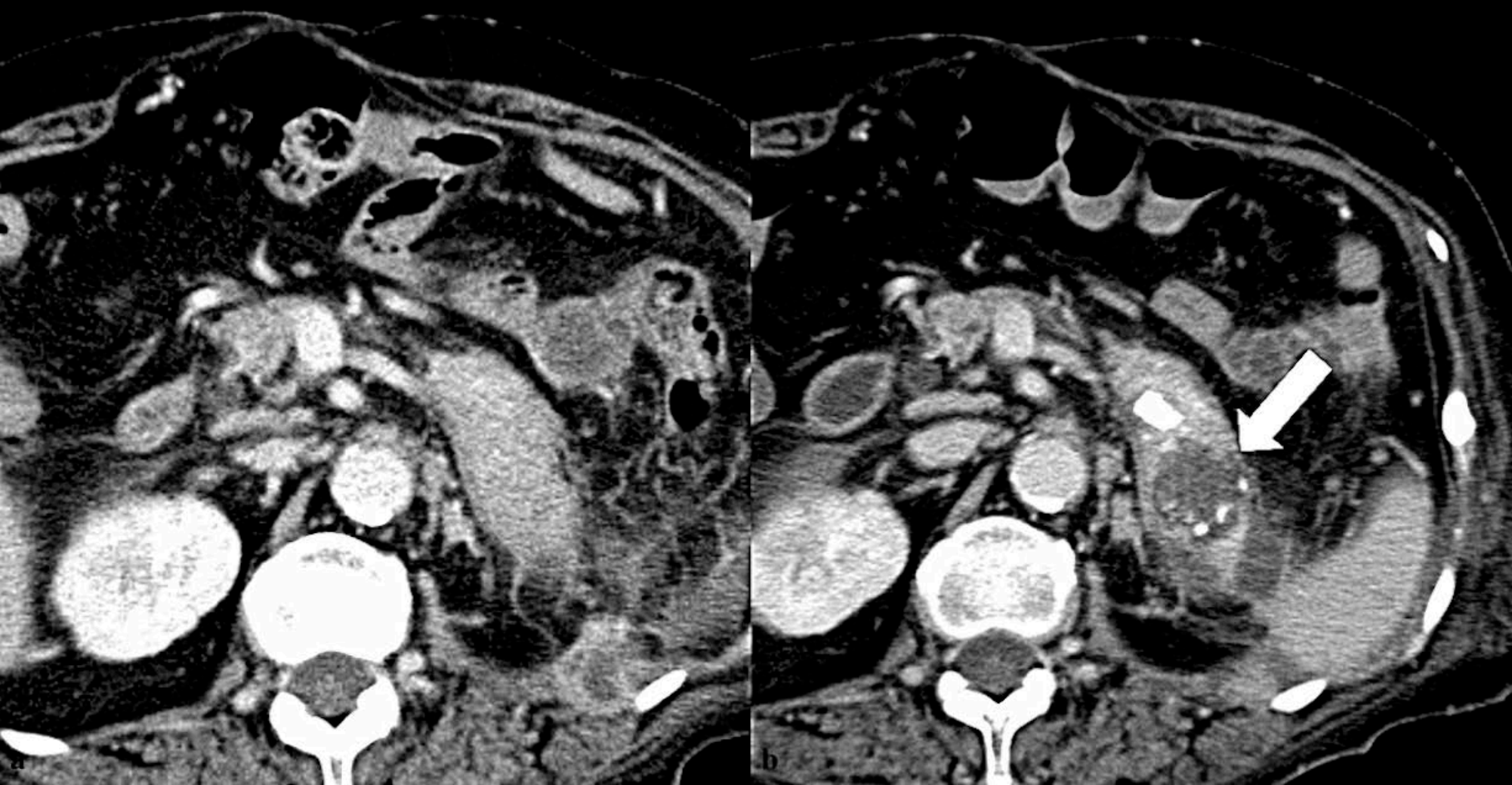

Celiac artery
Splenic artery
WL:128 WW:255
2.30
e


a
b
SMA
ASPDA
AIPDA


Celiac artery
GDA
SMA
ASPDA
Metallic coils
AIPDA
c
Metallic coils
Aneurysm filled with NBCA-lipiodol mixture
d


SMA
e


a
b