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Transpapillary Dilation of Refractory Severe Biliary Stricture or Main Pancreatic Duct by using a Wire-guided Diathermic Dilator (with video)

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Running title: Transpapillary dilation using a wire-guided diathermic dilator

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Each author's contribution to the following criteria for authorship

Kawakami H designed the research, managed the patients, performed the endoscopic examination, collected the data and wrote the paper; Kuwatani M, Kawakubo K, Eto K, Haba S, Kudo T, Abe Y, and Kawahata S provided collected data and clinical advice; Sakamoto N supervised the research; all authors approved the final manuscript for publication.

Keywords:

ERCP; dilation; bile duct; pancreatic duct; strictures

Abbreviations:

BD, bile duct; PD, pancreatic duct; ERCP, endoscopic retrograde cholangiopancreatography; IQR, interquartile

Benign and malignant tumors generally cause strictures in the bile duct (BD) or the pancreatic duct (PD) and result in jaundice or abdominal pain. An appropriate technique for dilation of these strictures is therefore necessary. Endoscopic stent placement has been reported to improve the severity of abdominal pain in selected patients with benign and malignant BD and PD strictures.[1] During endoscopic retrograde cholangiopancreatography (ERCP), a guidewire is passed through the stricture into the proximal BD or PD. Subsequently, a plastic stent (s) or self-expandable metallic stent is placed at the stricture. While these stents are sometimes placed after dilation of the stricture, dilation may be unnecessary in most cases. Severe ductal strictures can usually be dilated using balloon dilation or a dilation catheter. However, this type of dilation is not possible when the BD or PD stricture is severe; in such refractory cases, only the guidewire can pass through it, and a screw drill may be used.[2-3] Several investigators have recently described the dissection of difficult PD strictures using a needle-knife or wire-guided snare forceps.[4-6]

Diathermic dilators, which are commonly used for pancreatic fluid collection drainage, are effective for creating and enlarging the fistula channels between the stomach or duodenum and a pancreatic pseudocyst, pancreatic duct, or gallbladder.[7-8] We recently reported our experience using a diathermic dilator to treat severe BD

strictures.[9] The current prospective observational cohort study was conducted to evaluate whether a wire-guided diathermic dilator could pass through BD or PD strictures. We also evaluated the rate of adverse events after diathermic dilation of BD or PD strictures.

PATIENTS AND METHODS

A total of 851 therapeutic ERCPs were performed in our hospital between April 2011 and March 2013. During this period, 690 patients required biliary drainage for benign or malignant biliary obstruction, and 83 patients required pancreatic drainage for benign obstruction. Of the 690 who required biliary drainage, selective BD cannulation during ERCP was unsuccessful in 10 patients. Of these 10 patients, precut was attempted for selective BD cannulation in 8 patients, and it was successful in 2 patients only. Of the 6 patients who had unsuccessful BD cannulation using the precut technique, the percutaneous transhepatic biliary drainage (PTBD) rendezvous procedure with successful BD cannulation was performed in 4, and surgery in 2 patients (pancreatic cancer or cholelithiasis with choledocholithiasis). In 2 patients with advanced gastric cancer, the duodenal papilla could not be accessed endoscopically, and both patients refused PTBD. Initial selective PD cannulations for PD strictures were successful in all

patients, by using with a standard ERCP catheter or sphincterotome. Twenty-two consecutive patients out of the total number of patients who underwent successful BD or PD drainage were candidates for decompression with a wire-guided diathermic dilator (Fig. 1).

Eligibility criteria

The study included patients who required biliary or pancreatic drainage. Exclusion criteria included age less than 20 years, a performance status value greater than 3 according to the Eastern Cooperative Oncology Group scale, mental disability, contrast medium allergy, severe heart disease (New York Heart Association class III or IV heart failure), severe pulmonary disease (peripheral oxygen saturation of <90%), ampullary neoplasm, infiltration of the papillary area by pancreatic cancer, acute pancreatitis, chronic pancreatitis with an acute exacerbation at the time of the ERCP, Roux-en-Y reconstruction, actual or possible pregnancy, women wishing to become pregnant, nursing mothers, and refusal to provide informed consent.

Endoscopic protocol

Diagnostic ERCP was performed using a duodenoscope with 15° backward

oblique with an elevator function (TJF-260V; Olympus Medical Systems Corp, Tokyo, Japan). After selective BD or PD wire-guided cannulation,[10] the stricture was evaluated by ERCP and then dilated by endoscopic intervention. A guidewire was passed across the BD or MPD stricture and dilation of the stricture was subsequently performed with (1) a standard ERCP catheter or sphincterotome; (2) a tapered ERCP catheter; (3) a standard balloon catheter; (4) a biliary dilation catheter; and (5) a screw drill. If none of these devices could be passed through the BD or PD strictures, dilation using a wire-guided diathermic dilator was scheduled. An internal stent or nasobiliary/nasopancreatic drainage catheter was inserted after diathermy to provide BD or PD drainage (Fig. 2).

All the procedures were performed on an impatient basis. Our institute's review board gave study approval. All patients provided written, informed consent. Endoscopic procedures were performed on an inpatient basis, under conscious sedation with fentanyl citrate and midazolam. The diathermic dilation was performed by a skilled therapeutic endoscopist (H.K.) who had experience performing more than 2,000 ERCPs.

Endoscopic equipment

A standard ERCP catheter was used corresponding to the 0.025 and 0.035-inch guidewire (endoscopy catheter article no. 0120211, 1.6 mm diameter; MTW Endoskopie, Wesel, Germany). A small-caliber ERCP catheter was used corresponding to the 0.025-inch GW (PR-V420Q, 3.5F tip diameter; Olympus). A CleverCut3V^{TM} with a tip length of 7 mm and a cutting wire length of 20 mm was used as a sphincterotome (KD-V411M-0720, Olympus). A 0.025-inch hydrophilic hard-type guidewire (VisiGlide, Olympus), with the same stiffness as a regular 0.035-inch guidewire, was used for ease of manipulation. A Hurricane^{TM} RX Biliary Balloon Dilation Catheter (1.3 mm (4F) tip diameter; Boston Scientific Japan, Tokyo, Japan) was used as a balloon catheter. A Soehendra biliary dilation catheter (SBDC-6, 1.3 mm (4F) to 2.0 mm (6F) diameter; Cook Japan, Tokyo, Japan) was used as a dilator, and a Soehendra stent retriever (SSR-7, 2.3 mm (7F) tip diameter; Cook) was used as a screw drill for the BD or PD strictures. A wire-guided 6F diathermic dilator, coaxial with the guidewire, was used as a diathermic dilator (Cysto-Gastro-Set; Endo-Flex, GmbH, Voerde, Germany; Fig. 2). The distal end of the outer dilator contained a metal electrocautery tip.

Diathermy protocol

The 6F diathermic dilator was advanced over the guidewire under fluoroscopic

guidance to the level of the BD or PD stricture. BD or PD stricture dilation was performed using an electrosurgical HF-generator (ESG-100, Olympus). The diathermy current, in cut mode (30 watts in pulse cut slow mode) similar to the setting of endoscopic sphincterotomy, was applied until the dilator passed through the stricture. After the diathermic dilator was successfully advanced over a guidewire through the BD or PD stricture, we discontinued the current and tried to advance to the stricture without current (Fig. 3, Video 1). If a 6F diathermic dilator could not be advanced through a refractory stricture, additional current was applied until the tip passed the stricture, after which the current was turned off and the diathermic dilator was advanced through the stricture if possible during the same session in all cases, and subsequently, stenting was performed.

Outcome measurements

Technical success was defined as the passage of a diathermic dilator through a BD or PD stricture. Clinical success was defined as drainage of BD or PD strictures. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy guidelines[11] were used to define other adverse events. Diagnosis and severity of pancreatitis were defined according to the criteria proposed by Cotton et al.[12]

This trial was registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000009932).

RESULTS

Patient characteristics

The patient characteristics are summarized in Table 1. Of the 22 patients, 12 were men (55%) and 10 were women (45%), and mean age was 62 (range 32–80) years.

The median length of BD strictures was 18.9 mm (interquartile [IQR], 13.3–26.6 mm), and that of PD strictures was 10.6 mm (IQR, 7.1–13.2 mm). Diathermy was attempted a median of 2 times for BD strictures (IQR, once-2.8 times), and 1.5 times for PD strictures (IQR, once-twice).

Dilation of multiple strictures with diathermic dilator was performed in 2 patients with malignant BD obstruction. The data of this subgroup are also shown in Table 1.

Outcomes

Dilation of strictures was successful in all 22 cases. The median total dilation time was 5 s (IQR, 2–7.8 s) for BD stricture (n = 16), and 6 s (IQR, 3.5–10.8 s) for PD

stricture (n = 6). Clinical success was also achieved in all cases. Jaundice or abdominal pain associated with duct strictures were resolved by performing adequate drainage in all cases (100%, 12/12). The diathermy alone resolved the BD stricture (n = 2). The data are shown in Table 2.

Procedure-related adverse events occurred in only 2 patients (9.1%). One patient with a gallbladder carcinoma had mild hemobilia (Fig. 2) and one patient with chronic pancreatitis developed mild post-ERCP pancreatitis. No deaths or severe adverse events such as major bleeding, pancreatic parenchymal damage and BD or PD perforation were observed.

DISCUSSION

In this study, we evaluated the use of a 6F wire-guided diathermic dilator for severe BD or PD strictures. Endoscopic management of BD or PD stricture generally requires conventional equipment, i.e., a small-diameter (tapered) ERCP catheter, balloon catheter, or dilator. When these devices cannot accomplish passage through a duct stricture, then a more aggressive approach such as a screwdrill, for example the Soehendra stent retriever, can be used.

The Soehendra stent retriever has proven to be useful in many therapeutic

applications, including dilating severe BD or PD stricture,[2-3] and creating a fistula for EUS-guided drainage. In addition, its use is associated with a low risk of adverse event. However, the thick tip of the Soehendra stent retriever can sometimes make dilation of the stricture impossible. Itoi et al. demonstrated the efficacy of wire-guided snare forceps for refractory PD strictures,[5] and Gao et al. also recently described the use of wire-guided needle-knife catheter for refractory BD or PD strictures.[6] These techniques seem to be effective for severe BD or PD strictures. However, some safety concerns, mainly duct perforation and the creation of a false route, have been raised because the guidewire is "non-coaxial" and because of the "difficulty of manipulating cutting snare and wire" from the tip of the catheter.[13] Gupta et al proposed the needle catheter as an option in BD stricture.[14] However, the hardness and length of this specialized needle makes its manipulation difficult as a blind technique. Along with Kraft et al., we recently reported another alternative technique using a diathermic dilator for severe refractory BD[9] or PD strictures.[15]

The diathermic dilator was first introduced for endoscopic cystogastrostomy or cystoduodenostomy.[7] This device has generally been used with 8.5 or 10F diathermic circular tip to create and enlarge a fistula between the gastrointestinal tract and a pancreatic cyst. However, the 8.5 and 10F diathermic dilator tip may be difficult to

advance into a small-caliber duct such as intrahepatic BD or PD. These large diathermic circular tips seem difficult to use for a BD or PD stricture, and therefore, a smaller sleeve diathermic catheter (i.e. 6F) has been proposed. This catheter has a high degree of usability in severe BD or PD stricture.

Adverse events developed in 2 of our patients (9.1%), but both of these adverse events were mild. The patient with post-ERCP pancreatitis had undergone deployment of fully covered self-expandable metallic stent for severe PD stricture. The relative role of diathermic effect vs. metal stenting effect in the etiology of acute pancreatitis was very difficult to determine in this patient. It is unclear, therefore, whether diathermic dilation played a significant role in this adverse event. Greater attention should be paid to the risk of hemobilia associated with tumor vasculature when using the diathermic dilator for malignant BD stricture. In our patient with hemobilia, the bleeding resolved spontaneously with conservative therapy.

Limitations of the present study include the small sample size and the non-double-blind clinical setting. Nevertheless, we conclude that use of a 6F diathermic dilator is feasible and safe in patients with severe BD or PD strictures. This equipment has potential for developing new standard procedures for the dilation of refractory BD and PD strictures. Studies to further evaluate its feasibility and safety are warranted.

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Table 1. Baseline patient characteristics

Age, mean	62
Range, y	32–80
Sex, male/female	12/10
Underlying disease	
Bile duct stricture	16
Unresectable/resectable disease	14/2
Multiple stricture sites, Yes/No	2/14
Malignant biliary lesion (n)	
Gallbladder carcinoma	6
Cholangiocarcinoma	5
Metastatic disease	2
Benign biliary lesion (n).	
Postoperative stricture	2
Papillitis	1
Pancreatic duct stricture	6
Chronic pancreatitis	6
Location of bile duct strictures (n)	
Intrahepatic bile duct	5
Hepatic duct	5
(extended to the intrahepatic bile duct	2)
Hilar bile duct	5

Inferior extrahepatic bile duct	1
Location of pancreatic duct strictures (n)	
Pancreatic head	6

Table 2. Procedure characteristics following diathermy

Bile duct stricture (n = 16)					
Outer diameter of the delivery system	**n**	**Treatment**	**n**	**Final treatment**	**n**
5F	8	Single ENBD placement	3	Stent free*	1
				Uncovered SEMSs	2
		Double ENBD placement	2	7F EBSs	1
				Uncovered SEMSs	1
		Triple ENBD placement	3	5F ENBD**	1
				Uncovered SEMSs	2
6F	3	Single ENBD placement	3	6F ENBD**	1
				Uncovered SEMSs	2
7F	4	EBS placement	2	Stent free***	1
				Uncovered SEMSs	1
		Uncovered SEMSs placement	2	Uncovered SEMSs	2
8.5F	1	Uncovered SEMSs placement	1	Uncovered SEMSs	1

Pancreatic duct stricture (n = 6)					
Outer diameter of the delivery system	**n**	**Treatment**	**n**	**Final treatment**	**n**
7F	5	EPS placement	5	EPS	5
8.5F	1	Fully covered SEMS placement	1	Fully covered SEMS	1

F, French size; ENBD, endoscopic nasobiliary drainage; EBS, endoscopic biliary stenting; SEMS, self-expandable metallic stent, EPS, endoscopic pancreatic stenting

* Postoperative benign biliary stricture
** Radical surgery
*** Papillitis

Figure legends

Figure 1.

Flow diagram of trial for biliary or pancreatic drainage.

Figure 2.

A. 6F wire-guided diathermic dilator (Cysto-Gastro-Set; Endo-Flex, GmbH, Voerde, Germany).

B. 6F wire-guided diathermic dilator is always coaxial with the guidewire.

Figure 3.

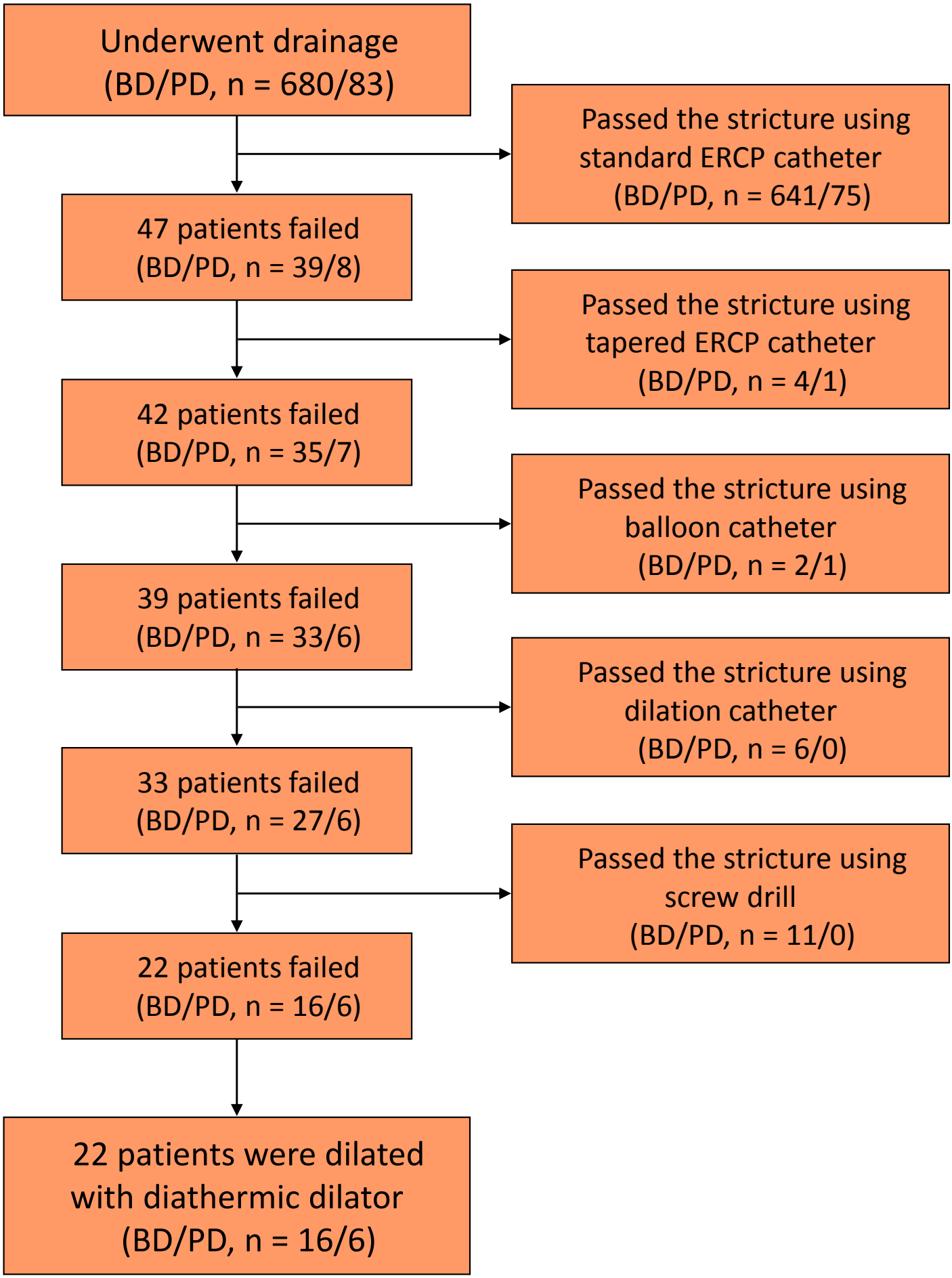
A. Cholangiography reveals a severe bile duct stricture between the left hepatic duct and the intrahepatic bile duct because of unresectable gallbladder carcinoma.

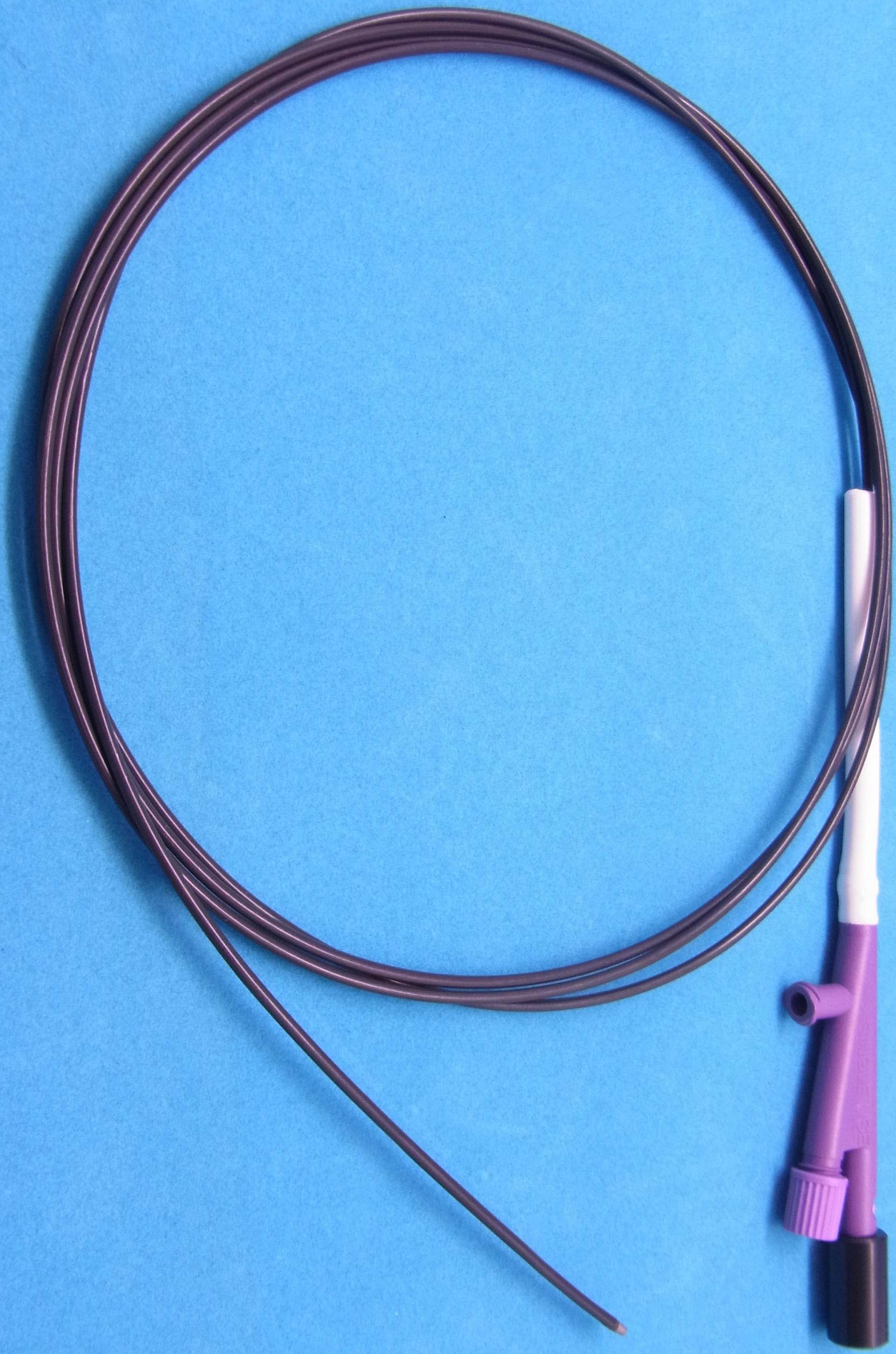
B. The 6F diathermic dilator is advanced over the guidewire under fluoroscopic guidance to the level of the left hepatic bile duct stricture.

C. The diathermic dilator is successfully advanced over a guidewire through the severe stricture without current.

D. A 7F plastic stent is placed at the stricture.

Video 1: Radiograph showing a severe pancreatic duct stricture, with a hydrophilic, 0.025-inch guidewire successfully advanced across the pancreatic duct stricture. While various other devices could not be passed through the pancreatic duct stricture, the diathermic dilator was passed through the pancreatic duct stricture. A biliary dilation catheter was also advanced through the stricture, after which a 7F plastic stent was successfully placed.


Underwent drainage
(BD/PD, n = 680/83)
Passed the stricture using
standard ERCP catheter
(BD/PD, n = 641/75)
47 patients failed
(BD/PD, n = 39/8)
Passed the stricture using
tapered ERCP catheter
(BD/PD, n = 4/1)
42 patients failed
(BD/PD, n = 35/7)
Passed the stricture using
balloon catheter
(BD/PD, n = 2/1)
39 patients failed
(BD/PD, n = 33/6)
Passed the stricture using
dilation catheter
(BD/PD, n = 6/0)
33 patients failed
(BD/PD, n = 27/6)
Passed the stricture using
screw drill
(BD/PD, n = 11/0)
22 patients failed
(BD/PD, n = 16/6)
22 patients were dilated
with diathermic dilator
(BD/PD, n = 16/6)

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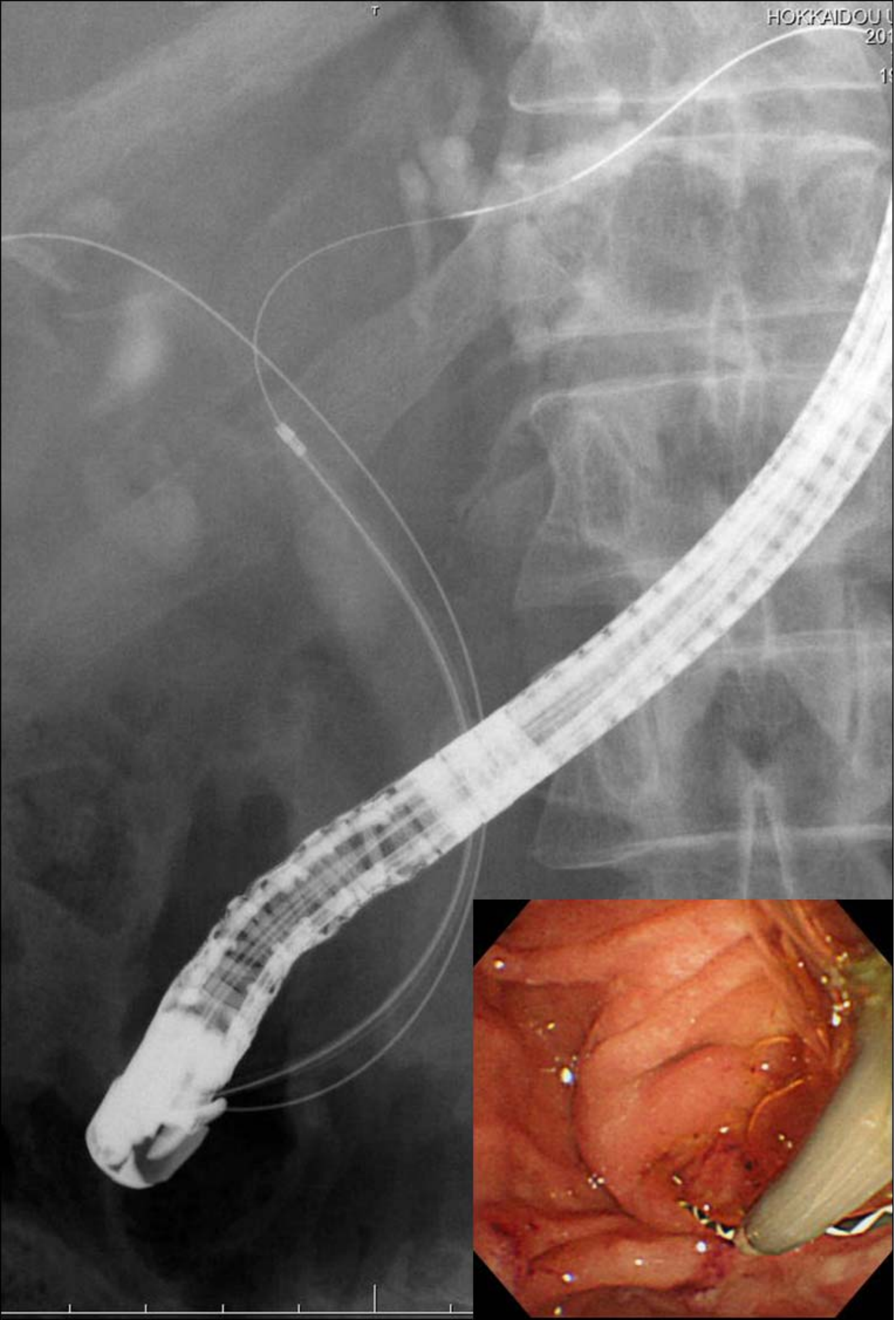
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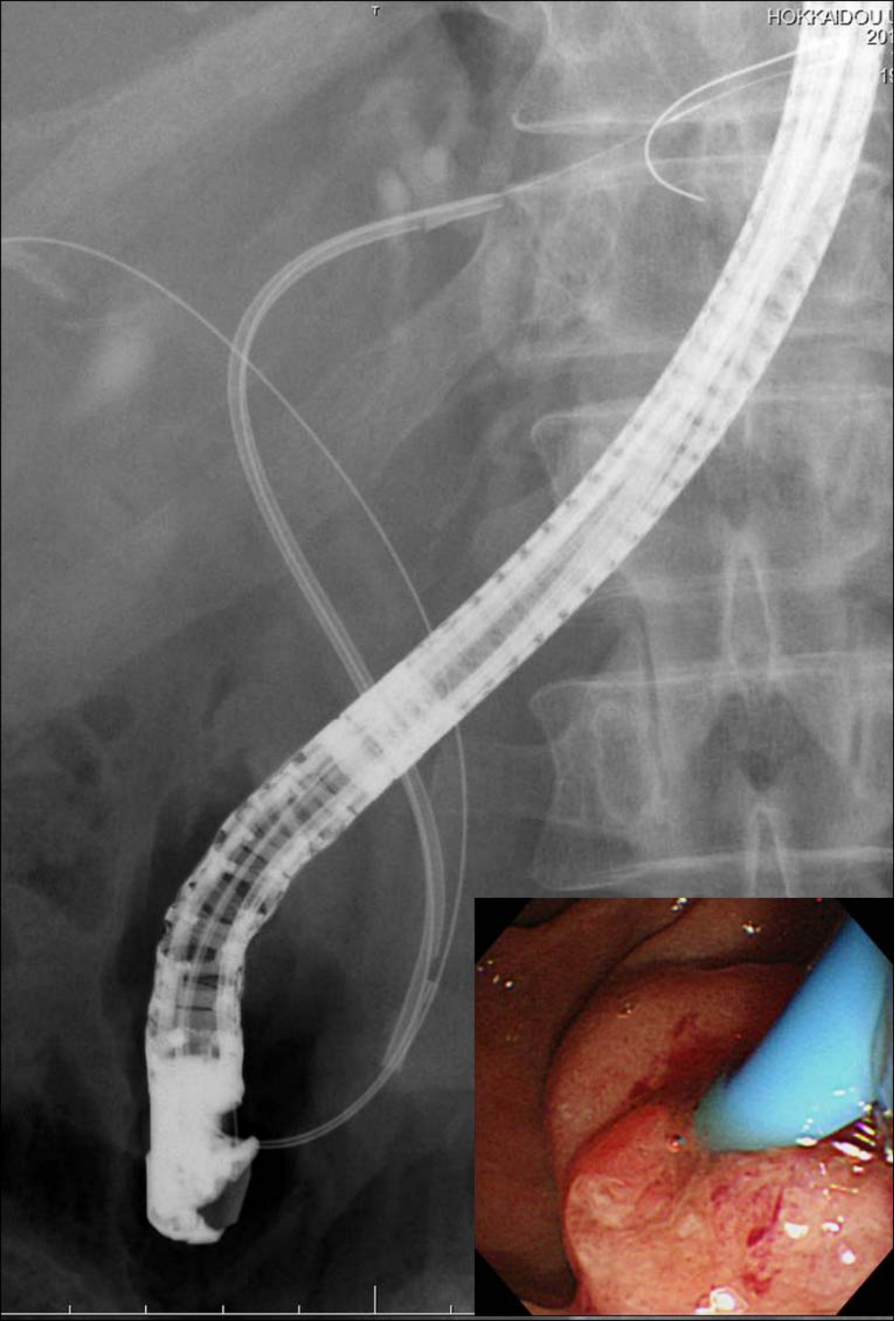
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