Diagn Interv Radiol 2011; 17:169–173

Percutaneous management of malignant biliary disease: factors influencing the ability to overcome the stricture

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PURPOSE
To determine the factors affecting the ability to cross malignant biliary obstructions in percutaneous transhepatic interventions.

MATERIALS AND METHODS
In this study, 256 patients with 310 obstructive malignant biliary lesions from May 2006 to January 2009 were analyzed retrospectively. All of the patients had undergone percutaneous transhepatic cholangiography and intervention. Obstructions crossed in two or fewer sessions were classified as technically easy obstructions, whereas obstructions that required more than two sessions for crossing were classified as technically difficult obstructions. Possible factors thought to affect the ability of malignant biliary obstructions to be crossed were compared according to the obstruction type (technically easy or difficult obstructions).

RESULTS
Of the 310 malignant biliary obstructions studied, 79% (246) were technically easy to cross, and 21% (64) were technically difficult to cross. Lesions located between the hilum and the cystic duct and beak-shaped malignant biliary lesions were easily crossed, but suprahilar localized lesions and flat or ovoid-shaped lesions were difficult to cross. The histological nature of the malignant biliary obstruction, the direct-to-total bilirubin ratio, the entry segment for the intervention, the largest bile duct diameter proximal to the obstruction, and the length of the obstruction were not found to influence the ability of the stricture to be overcome.

CONCLUSION
In patients with malignant biliary obstructions, the factors that can negatively affect obstruction crossing are lesions with suprahilar localization and flat or ovoid-shaped lesions. We also conclude that after five ineffective attempts have been made to pass the stricture, treatment of malignant biliary obstruction should proceed to external biliary drainage.

Key words: • *interventional radiology* • *bile duct obstruction, malignant* • *bile ducts*

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Received 17 December 2009; revision requested 24 December 2009; revision received 25 April 2010; accepted 27 April 2010.

Published online 9 August 2010
DOI 10.4261/1305-3825.DIR.3259-09.3

The majority of patients with malignant biliary obstructions have unresectable tumors, such as metastatic cancers, cholangiocarcinoma, pancreatic adenocarcinoma, and gall bladder carcinoma, or have a high risk for surgery at the time of diagnosis. Percutaneous transhepatic and endoscopic biliary interventions are safe and effective techniques for the relief of obstructive symptoms and are non-surgical palliative treatment alternatives to surgery. In patients with a high-level obstruction and in patients with low-level obstruction for whom endoscopic intervention is not suitable, the percutaneous transhepatic approach is the palliative treatment of choice. Indications, technical procedures, related complications, and success rates of percutaneous intervention have been discussed in detail in previous studies (1–8).

To achieve near-total physiologic drainage, the bile must be directed to the small intestine. Because of this, the malignant biliary obstruction must be crossed. Crossing the obstruction cannot always be achieved easily. Failure to traverse biliary strictures has been found to be unrelated to the stricture type or location in previous studies (9, 10). Mueller et al. reported that the likelihood of successful stricture recanalization could not be predicted based on the initial cholangiographic appearance (11).

Determining the possible factors that make it technically easy or difficult to cross an obstruction is important because it enables prediction of the course and outcome of the interventions. It must be taken into consideration that both the intervention team and the patient will be affected by irradiation during the procedures.

Our study was designed to explore the crossing of malignant biliary tract obstructions and factors affecting the ability of such obstructions to be crossed. A secondary purpose of this study was to determine the optimal number of attempts that should be made to cross the lesion, considering the influential factors.

Materials and methods

Patients and lesions

Data from a total of 256 patients with 310 obstructive malignant biliary lesions, treated from May 2006 to January 2009, were analyzed retrospectively. Written, informed consent was obtained from all patients. The study was approved by the institutional review board. All patients had undergone percutaneous transhepatic cholangiography and intervention for the palliative relief of obstructive symptoms. Most of the patients (228/256, 89.06%) were not suitable for surgery because of advanced disease at the time of referral. In 69 patients (30%), more than one non-coaxial obstruction was crossed. The patient population included 177 (69.2%) males and 79 (30.8%) females, with a median age of 62.7±13.24 (range, 20–87) years. Patients with anatomical bile duct variations were not included in the study. The obstructions were

classified into two categories. Obstructions crossed in two or fewer sessions were classified as technically easy obstructions, whereas obstructions that required more than two sessions were classified as technically difficult obstructions. We attempted to traverse the obstructions in the first session for all patients, but in some patients, we waited for decompression of the bile ducts before attempting to cross the obstructions in the second session.

In each session, the duration of fluoroscopy was less than 30 minutes. In a previous study reported by Stratakis et al., it was estimated that the maximum effective patient dose is 13 mSv for 30 minutes of fluoroscopy (12). Possible factors thought to affect the of a malignant biliary obstruction to be crossed are the histological nature of the malignant biliary obstruction, the direct-to-total bilirubin ratio, the entry segment for the intervention, the largest bile duct diameter proximal to the obstruction, the length of the obstruction, the level of the obstruction, and the shape of the obstruction. In bile duct obstructions, direct bilirubin levels rise markedly. Because this rise takes place over time, it can be assumed to be related to the duration and severity of the obstruction. Because of this rise, we hypothesized that the direct-to-total bilirubin ratio could be a possible factor affecting the ability of a malignant biliary obstruction to be crossed.

Seven parameters were compared during sessions in which an attempt to cross an obstruction was made. In the study population, the malignant biliary obstructions were due to metastasis (local-lymph node-liver, n=103, 33.2%), cholangiocarcinoma (n=83, 26.7%), pancreatic cancer (n=66, 21.3%), gall bladder cancer (n=29, 9.3%), duodenal cancer (n=22, 7%) and primary liver cancer (n=7, 2.5%). Total bilirubin and direct bilirubin levels were evaluated before the intervention, and direct-to-total bilirubin ratios were classified into three groups: a) < 0.60 (n=19, 6.1%), b) 0.60–0.80 (n=217, 70%) and c) >0.80 (n=74, 23.9%). In the study population, the entry segment for percutaneous intervention was classified as the right anterior segment (n=168, 54.1%), the right posterior segment (n=76, 24.5%) and the left main segment (n=66, 21.4%). The level of the obstruction in the study population was classified as suprahilar (n=49, 15.8%), hilar (n=89, 28.7%), located between the segment from the hilum to the cystic duct (n=71, 23%) and located in the infracystic segment (n=101, 32.5%). Percutaneous transhepatic cholangiography was the main method used to document this classification. In patients for whom the obstruction could not be crossed, magnetic resonance cholangiography and multidetector computed tomography were used. The largest bile duct diameters proximal to the obstruction were calculated and classified as: a) <10 mm (n=15, 5%), b) 10–20 mm (n=216, 69.6%) and c) >20 mm (n=79, 25.4%). The shapes of the obstructions were classified into two groups: 1) beak-shaped (n=181, 58.4%) and 2) flat or ovoid-shaped (n=129, 41.6%). The lengths of the obstructions were calculated mainly by percutaneous transhepatic biliary cholangiography. The lengths of the uncrossed obstructions were calculated using magnetic resonance cholangiopancreatography and multidetector computed tomography. These were classified into three groups: a) <2 cm (n=54, 17.2%), b) 2–4 cm (n=118, 38%) and c) >4 cm (n=138, 44.8%).

Techniques

We used techniques for percutaneous intervention that have been well defined by previous authors (3–6). A 22-G Chiba needle was used for initial access and percutaneous transhepatic cholangiography. A 0.018″ guide wire was advanced from the 22-G needle to access the bile ducts. Through this guide wire, a coaxial introducer system (Accustick II Introducer System, Boston Scientific, Natick, MA) was inserted into the bile ducts. The stiffener and 4-F dilator were removed after entrance to the bile duct was obtained. The 6-F sheath was replaced with a 7-F sheath over a 0.035″ Linderquist straight-tip wire. Angled (Cobra 2, vertebral, Sones) catheters and straight 5-F catheters were introduced from the sheath to the level of the obstruction. The guide wires that were used sequentially to cross the obstructions were 0.035″ Linderquist straight-tip guide wires, 0.018″ straight-tip nitinol guide wires, 0.035″ black yellow zebra guide wires, 0.035″ straight- or angled-tip hydrophilic guide wires and 0.018″ straight- or angled-tip hydrophilic guide wires. The instrumentation used for each session and each obstruction was the same. Access to the bile duct was obtained under fluoroscopic guidance (in 245 obstructions, 79.1%) or under both fluoroscopic and ultrasonographic guidance (in 65 obstructions, 20.9%). All procedures were performed under local anesthesia with sedation (252 patients, 98.4%), except in four patients (1.6%) who underwent general anesthesia. The aim of the intervention was to cross the obstruction in the first or second session. The interval between intervention attempts was three days, and the total number of intervention sessions was less than five. Crossed obstructions were treated with external-internal drainage (in 106 obstructions, 34.2%) or metallic stenting (in 198 obstructions, 63.8%) in the same session or continuous sessions. In the six patients (2%) in whom the obstruction was not crossed after five sessions, external drainage was performed for palliation.

Statistical analysis

All of the obtained data were transferred to the statistical analysis program SPSS 14 for Windows (2005, SPSS Inc., Chicago, USA). Seven parameters thought to affect the obstruction crossing were compared with the number of sessions required to cross the obstruction according to our definitions of obstructions that were easy or difficult to cross, as given above. Statistical analyses were done with chi-square tests and multivariate logistic regression analysis. The level of significance was set at 0.05.

Results

Of the 310 malignant biliary obstructions studied, 79% (246) were technically easy to cross malignant biliary obstructions (TECMBOs), and 21% (64) were technically difficult to cross malignant biliary obstructions (TDCMBOs). The results are summarized in Table.

Of the 103 obstructions caused by metastasis, 85 (82.5%) were TECMBOs, and 18 (17.5%) were TDCMBOs. Of the 83 patients with cholangiocarcinoma, 63 (75.9%) had TECMBOs, and 20 (24.1%) had TDCMBOs. Of the patients with pancreatic cancer, 80.3% (53 of 66) had TECMBO lesions, and

19.7% (13 of 66) had TDCMBO lesions; in patients with gall bladder cancer, 72.4% (21 of 29) had TECMBO lesions, and 27.6% (8 of 29) had TDCMBO lesions; in patients with duodenal cancer, 90.0% (20 of 22) had TECMBO lesions, and 9.1% (2 of 22) had TDCMBO lesions; and in patients with primary liver cancer, 57.1% (4 of 7) had TECMBO lesions, and 42.9% (3 of 7) had TDCMBO lesions. As a result, there were no statistically significant relationships between the histological nature of the malignant biliary obstruction and the obstruction type (TECMBO or TDCMBO) ($P > 0.05$).

Preinterventional mean direct bilirubin values were 11.83±7.21 mg/dL (minimum, 0.37, maximum, 40.38 mg/dL) in the TECMBO group and 11.92±6.51 mg/dL (minimum, 3.71, maximum, 31.56 mg/dL) in the TDCMBO group. Mean total bilirubin values were 16.08±9.89 mg/dL (minimum, 1.01, maximum, 52.93 mg/dL) in the TECMBO group and 16.21±8.84 mg/dL (minimum, 4.21, maximum, 45.11 mg/dL) in the TDCMBO group. The mean direct-to-total bilirubin ratio values were 0.73±0.9 (minimum, 0.20, maximum, 0.97) in the TECMBO group and 0.73±0.7 (minimum, 0.50, maximum, 0.90) in the TDCMBO group. In the group of patients with direct-to-total bilirubin ratios less than 0.60 (group A), 17 of 19 patients (89.5%) had TECMBOs and 2 of 19 (10.5%) had TDCMBOs. In the group in which the direct-to-total bilirubin ratios ranged from 0.6 to 0.8 (group B), 167 of 217 patients (76.9%) had TECMBOs and 50 of 217 patients (23.1%) had TDCMBOs. In the group with direct-to-total bilirubin ratios greater than 0.8 (group C), 62 of 74 patients (83.8%) had TECMBOs and 12 of 74 patients (16.2%) had TDCMBOs. Thus, there were no statistically significant relationships between the direct-to-total bilirubin ratios and the obstruction type ($P > 0.05$).

Of the 168 right anterior segment entries, 137 (81.5%) were TECMBOs and 31 (18.5%) were TDCMBOs. Of the 76 right posterior segment entries, 63 (82.9%) were TECMBOs, and 13 (17.1%) were TDCMBOs. Of the 66 left main segment entries, 46 (69.7%) were TECMBOs, and 20 (30.3%) were TDCMBOs. As a result, there were no statistically significant relationships between the entry segment for percutaneous intervention and the obstruction type ($P > 0.05$).

The mean diameter of the largest preinterventional bile duct proximal to the obstruction was 17.13± 6.07 mm (minimum, 6.00, maximum, 48.00 mm). In the group in which the largest bile duct diameter was less than 10 mm (group A), 10 of 15 patients (66.7%) had TECMBOs and 5 of 15 (33.3%) had TDCMBOs; in the group with a largest bile duct diameter of 10–20 mm (group B), 173 of 216 patients (80%) had TECMBOs and 43 of 216 (20%) had TDCMBOs; in the group with a largest bile duct diameter greater than 20 mm (group C), 63 of 79 patients (79.7%) had TECMBOs and 16 of 79 (20.3%) had TDCMBOs. Accordingly, there were no statistically significant relationships between the diameter of the largest bile duct proximal to the obstruction and the obstruction type ($P > 0.05$).

In the group of patients with an obstruction less than 2 cm in length (group A), 45 of 54 patients (83.3%) had TECMBOs and 9 of 54 (16.7%) had TDCMBOs. In the group of patients with an obstruction between 2 and 4 cm in length (group B), 92 of 118 patients (77.9%) had TECMBOs and 26 of 118 (22.1%) had TDCMBOs. Of the patients with an obstruction that was more than 4 cm in length (group C), 109 of 138 patients (79.0%) had TECMBOs and 29 of 138 (21.0%) had TDCMBOs. As a result, there were no statistically significant relationships between the length of the obstruction and the obstruction type ($P > 0.05$).

The level and shape of the obstruction were the only factors found to affect the ability of the malignant biliary obstruction to be crossed ($P < 0.05$). Of the 49 suprahilar localized malignant biliary obstructions studied, 29 (59.2%) were more difficult to cross than obstructions in other parts of the biliary tree. Of the 71 lesions localized in the region between the hilum and the cystic duct, 64 (90.1%) of the obstructions were easier to cross than obstructions found in other parts of the biliary tree. Of the 181 beak-shaped obstructions, 160 (88.9%) were crossed easily, but 43 of the 129 flat or ovoid-shaped obstructions (33.3%) were difficult to cross (Figure).

Discussion

Percutaneous management of malignant biliary disease includes external biliary drainage, external-internal biliary drainage and plastic or metallic stenting, all of which are safe and effective techniques for the palliation of

Table. Factors thought to influence the ability to overcome the stricture

Factors	TECMBO	TDCMBO
Histological nature of the malignant biliary obstruction	$P > 0.05$	
Direct-to-total bilirubin ratio	$P > 0.05$	
Entry segment for the intervention	$P > 0.05$	
Largest bile duct diameter proximal to the obstruction	$P > 0.05$	
Length of the obstruction	$P > 0.05$	
Level of the obstruction	Hilum to cystic duct localization ($P < 0.05$)	Suprahilar localization ($P < 0.05$)
Shape of the obstruction	Beak-shaped obstructions ($P < 0.05$)	Flat or ovoid-shaped obstructions ($P < 0.05$)

TECBMO, technically easy to cross malignant biliary obstruction; TDCMBO, technically difficult to cross malignant biliary obstruction

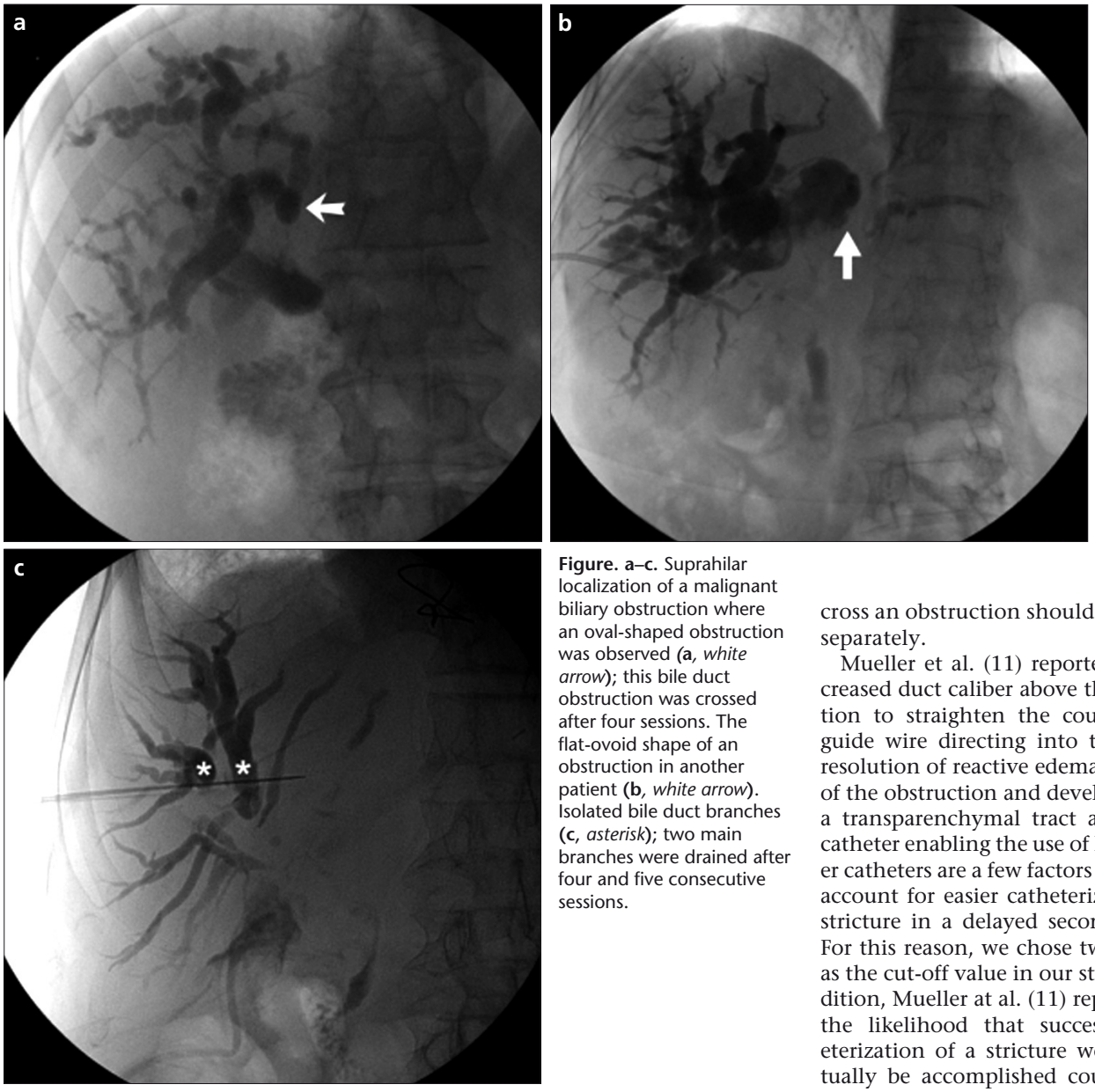

Figure. a–c. Suprahilar localization of a malignant biliary obstruction where an oval-shaped obstruction was observed **(a**, *white arrow*); this bile duct obstruction was crossed after four sessions. The flat-ovoid shape of an obstruction in another patient **(b**, *white arrow*). Isolated bile duct branches **(c**, *asterisk*); two main branches were drained after four and five consecutive sessions.

obstructive symptoms in patients with unresectable tumors (1–8). The major aims of percutaneous management are to direct the bile into the small intestine to achieve a drainage resembling normal physiological drainage and to maintain a normal enterohepatic circulation (3, 4). In previous experimental studies in rats, improved liver function and nutritional status, reduced systemic endotoxemia and improved immunity have been observed with internal biliary drainage as compared to external biliary drainage or non-biliary drainage (13–20). It is not easy to cross biliary obstructions in all patients. There are detailed guidelines and many reports on the techniques, indications, complications and management of malignant biliary obstructions. However, to our knowledge, the factors that may affect the ability of a malignant biliary obstruction to be crossed have not been discussed in detail in the existing literature (1–8). In the studies of Neal et al. (9) and Dowsett et al. (10), the ability of biliary strictures to be traversed was found to be unrelated to stricture type or location. However, in these studies, combined endoscopic and percutaneous approaches were used. Combined approaches for crossing an obstruction were not used in our study because we felt that the techniques of percutaneous and endoscopic interventions to cross an obstruction should be studied separately.

Mueller et al. (11) reported that decreased duct caliber above the obstruction to straighten the course of the guide wire directing into the lumen, resolution of reactive edema at the site of the obstruction and development of a transparenchymal tract around the catheter enabling the use of large-caliber catheters are a few factors that might account for easier catheterization of a stricture in a delayed second session. For this reason, we chose two sessions as the cut-off value in our study. In addition, Mueller at al. (11) reported that the likelihood that successful catheterization of a stricture would eventually be accomplished could not be predicted based on the initial cholangiographic appearance. However, according to our findings, beak-shaped obstructions were technically easier to cross, whereas flat or ovoid-shaped obstructions were difficult to cross. The shape of the obstruction was defined by cholangiographic images.

Berquist et al. reported that short and markedly dilated common bile ducts cause the catheter to coil and make internal decompression difficult. In addition, lesions at the bifurcation were found to contribute to unsuccessful internal drainage because of an improper angle of catheter entry. An extrahepatic duct cut down during previous surgery was another factor reported to cause unsuccessful internal drainage (21).

In our study, although seven factors were analyzed, only the level and shape of the obstruction significantly affected its ability to be crossed. Lesions localized between the hilum and cystic duct and beak-shaped lesions were crossed easily. It was difficult to cross suprahilar localized lesions and flat or ovoid-shaped malignant biliary obstructions. Because the region of the biliary tree between the hilum and the cystic duct is straighter than other parts, the guide wire may be easier to manipulate in a longitudinal fashion rather than in a radial fashion to cross the obstruction. It is difficult to apply longitudinal force in suprahilar obstructions. In the same manner, the applied longitudinal force in beak-shaped lesions is stronger than the applied force in flat or ovoid-shaped lesions. Before applying a longitudinal force, it is important to have the distal end of the guide wire in the right position with respect to the obstruction. This positioning may explain why the beak-shaped obstructions were crossed easily, while the flat or ovoid lesions were difficult to cross. In our study, we did not observe any statistically significant relationships among the remaining factors. Further studies are needed to analyze other factors that could affect the ability of biliary obstructions to be crossed.

In our study, all interventions were performed by experienced interventionalists. However, the different experience levels of the surgeons and the different manipulation techniques used to cross the obstructions may be limitations of this study. It is also important to remember that we excluded patients with biliary variations because these variations themselves are challenging risk factors that increase the difficulty of crossing an obstruction (22).

In previous studies, effective patient radiation doses of 1.8 to 12 mSv have been reported for percutaneous transhepatic interventions (12, 23). Radiation-induced cancer risk has been found to be considerable for young patients undergoing these interventions (23). Control of the patient dose also enables control of the staff dose, as the staff is at risk of repeated occupational radiation exposure.

As more sessions are required to cross the malignant biliary obstruction, more effort, higher costs and higher radiation exposure to the patient and the interventionalists are incurred. In patients with malignant biliary obstructions, we found that the shape and location of the lesion are factors that can negatively affect the ability of the obstructions to be crossed. Crossing the obstruction was especially difficult in patients with obstructions with suprahilar localization and in those with flat or ovoid-shaped lesions. These factors must be considered before or during intervention. We also suggest that after five ineffective attempts have been made to pass the stricture, malignant biliary obstructions should be treated with external biliary drainage.

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