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Development of a New Coaxial Balloon Catheter System for Balloon-Occluded Retrograde Transvenous Obliteration (B-RTO)

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Abstract

Purpose: To develop a new coaxial balloon catheter system and evaluate its clinical feasibility for balloon-occluded retrograde transvenous obliteration (B-RTO).
Methods: A coaxial balloon catheter system was constructed with 9 Fr guiding balloon catheter and 5 Fr balloon catheter. A 5 Fr catheter has a high flexibility and can be coaxially inserted into the guiding catheter in advance. The catheter balloons are made of natural rubber and can be inflated to 2 cm (guiding) and 1 cm (5 Fr) maximum diameter. Between July 2003 and April 2005, 8 consecutive patients (6 men, 2 women; age range 33–72 years, mean age 55.5 years) underwent B-RTO using the balloon catheter system. Five percent ethanolamine oleate iopamidol (EOI) was used as sclerosing agent. The procedures, including maneuverability of the catheter, amount of injected sclerosing agent, necessity for coil embolization of collateral draining veins, and initial clinical results, were evaluated retrospectively. The occlusion rate was assessed by postcontrast CT within 2 weeks after B-RTO.
Results: The balloon catheter could be advanced into the proximal potion of the gastrorenal shunt beyond the collateral draining vein in all cases. The amount of injected EOI ranged from 3 to 34 ml. Coil embolization of the collateral draining vein was required in 2 cases. Complete obliteration of gastric varices on initial follow-up CT was obtained in 7 cases. The remaining case required re-treatment that resulted in complete obstruction of the varices after the second B-RTO. No procedure-related complications were observed.
Conclusion: B-RTO using the new coaxial balloon catheter is feasible. Gastric varices can be treated more simply by using this catheter system.

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Since its introduction by Kanagawa et al. [1], balloon-occluded retrograde transvenous obliteration (B-RTO) has been accepted as a useful and less invasive treatment than TIPS (transjugular intrahepatic portosystemic shunt), PTO (percutaneous transhepatic obliteration) or TIO (transileocolic obliteration) for gastric varices. The treatment strategy and techniques have been established by several previous reports [2–7]; however, we have sometimes experienced technically difficult cases due to a large and tortuous shunt or many collateral vessels. The technical success of variceal obliteration depends on sufficient stagnation of the sclerosing agent in the variceal cavity, but infusion of a large amount of agent carries a risk of renal dysfunction. Coil embolization of many collateral vessels, on the other hand, makes procedures complicated. It is considered that occlusion of a gastrorenal shunt at its proximal portion with a balloon catheter can reduce the amount of sclerosing agent, and can avoid complex procedures. However, there are often technical difficulties and a risk of vessel injury in advancing a large balloon catheter into a tortuous gastrorenal shunt. We have devised a new type of balloon catheter to occlude a gastrorenal shunt at the proximal portion safely, and here evaluate the efficacy of the catheter.

Materials and Methods

Instruments

The coaxial balloon catheter (Medikit, Miyazaki, Japan) had previously won approval from our institutional review board. The catheter consists of a 5 Fr sized balloon and guiding catheter. A 5 Fr catheter has a high flexibility and can be coaxially inserted into

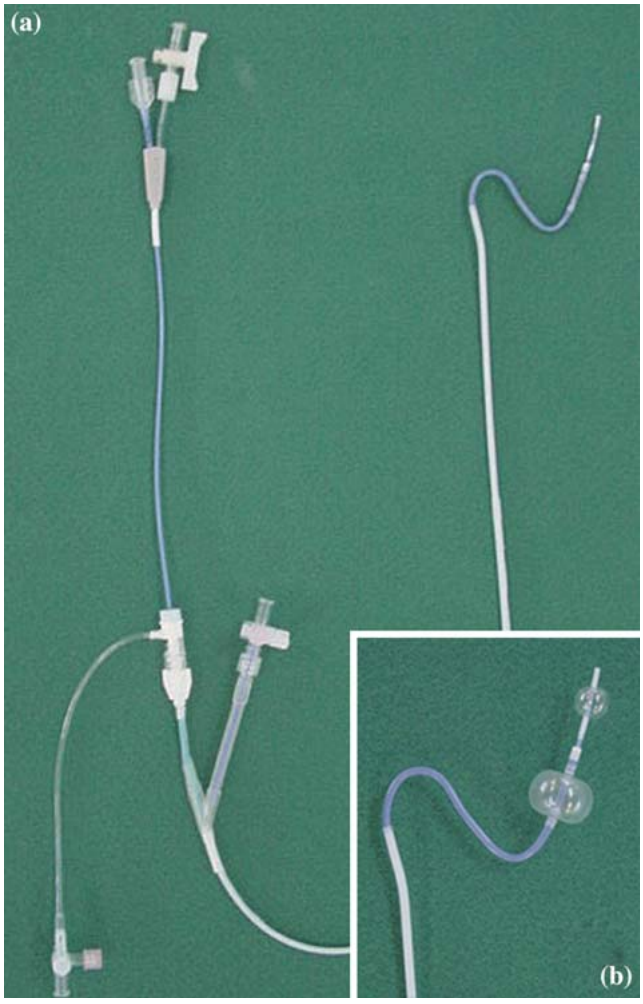

Fig. 1. A, B. Photographs of the coaxial catheter system. **A** View of the entire coaxial balloon catheter. The shaft of each catheter is made of polyamide membrane, and the shaft of the guiding catheter contained stainless wire mesh to resist kinking. **B** View of inflated balloons made of natural rubber.

the guiding catheter in advance. The guiding catheter was made of an L-shaped or hook-shaped 9 Fr catheter with occlusion balloon (Fig. 1). The shaft of each catheter is made of polyamide membrane, and the shaft of the guiding catheter contains stainless wire mesh to resist kinking. The balloons of the catheters are made of natural rubber and can be inflated to 2 cm (guiding) and 1 cm (5 Fr) maximum diameter. The coaxial catheter system is employed via a 9.5 Fr special sheath introducer (outer diameter, 3.91 mm; inner diameter, 3.41 mm; length, 25 cm).

Patients

Between July 2003 and April 2005, 8 consecutive patients (6 men, 2 women; age range 33–72 years; mean age 55.5 years) were treated using this coaxial balloon catheter system. The bases for determining whether B-RTO was indicated were endoscopic findings suggesting risk of rupture with or without a history of bleeding and the presence of a dilated gastrorenal shunt. Informed consent was obtained from all patients before treatment. Three patients were Child-Pugh class A and the other 5 were Child-Pugh class B. The cause of liver cirrhosis was hepatitis C in 3 patients and alcoholic cirrhosis in 5. The severity of the varices was classified according to the criteria for endoscopic assessment of varices proposed by the Japanese Research Society for Portal Hypertension: small straight (F1), enlarged tortuous (F2), or large coil-shaped (F3) [8]. The variceal findings on gastric endoscopy were F2 without the red color (RC) sign in 2 patients, F3 without the RC sign in 1 patient, and F3 with the RC sign in 5 patients. Four patients had experienced hematemesis in the past. According to the findings of balloon-occluded retrograde shuntography, the types of collateral vessels were classified as grade 3 in 4 patients and grade 4 in 4 patients [3]. All the patients incidentally had the high-grade type of collateral gastric varices despite the fact they were consecutive subjects.

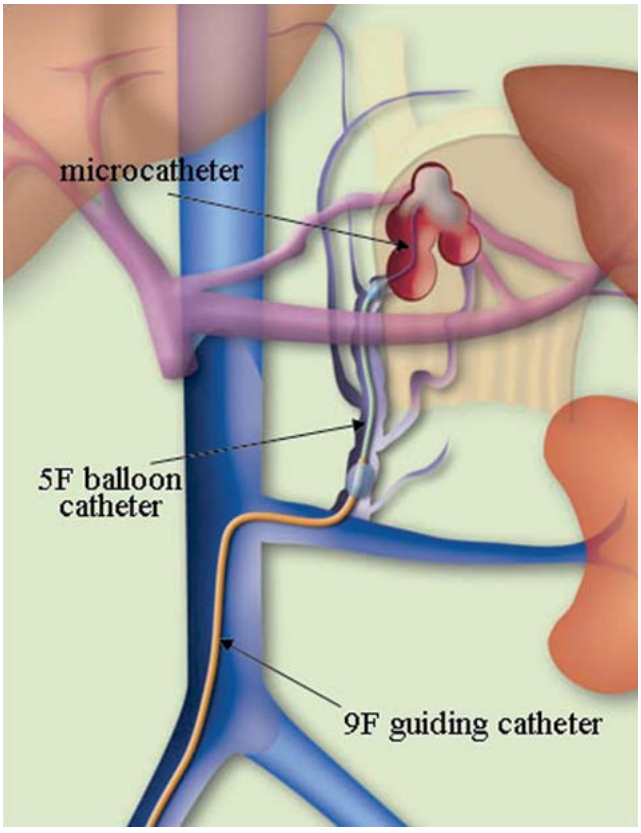

Fig. 2. Schematic drawings of the B-RTO technique. Initially, the microcatheter is advanced into the variceal cavity after confirmation of the configuration of the gastrorenal shunt by balloon-occluded shuntography. The 5 Fr catheter is advanced to the more proximal segment of the shunt over the microcatheter. Sclerosing agent is then injected via the microcatheter.

B-RTO Technique Using the Double Coaxial Balloon Catheter

Patients underwent contrast-enhanced CT and transarterial angiography to assess the configuration, size, and hemodynamics of varices and draining veins. In all patients, the balloon catheter systems were introduced via the right femoral vein through a 9.5 Fr sheath. The technical processes are summarized in Fig. 2. After

shaping 9 Fr guiding catheters to an original hook shape or L-shape, the catheters were inserted into the gastrorenal shunt. Balloon-occluded retrograde shuntography from the distal portion of the gastrorenal shunt was performed to evaluate the configuration from the shunt to the gastric varices and collateral veins draining into the systemic vein. Initially, a microcatheter (Renegade, BSJ Tokyo, Japan; or Prowler Plus, Cordis, FL, USA) was advanced into the variceal cavity through the balloon catheter system and a 5 Fr balloon catheter was advanced to the proximal portion of gastrorenal shunt over the microcatheter. We selected the main trunk of the shunt using a microcatheter with a 0.016-inch microguidewire (GT wire, Terumo, Tokyo, Japan) to avoid injuring the venous wall and confirmed the access route by injecting contrast medium. Subsequently, sclerosing agent was injected through the microcatheter under the balloon occlusion of both 9 Fr and 5 Fr catheters. As sclerosing agent, 5% ethanolamine olerate iopamidol (EOI) was used. The 5% EOI consisted of 10% ethanolamine olerate (Oldamin, Takeda Pharmaceutical) diluted into the same amount of iopamidol (Iopamiron 300, Schering). Intravenous administration of 4000 units of human haptoglobin (Green Cross) was started before infusing 5% EOI. Thirty to 60 minutes after EOI injection, as much blood and EOI as possible was aspirated via the microcatheter and the balloon catheter.

Evaluation

The following aspects of the use of the catheter system were evaluated: (a) maneuverability of the catheter, (b) amount of injected EOI, (c) necessity of coil embolization for collateral vessels, (d) initial success rate, and (e) complication rate. Maneuverability was investigated by means of the selectability of a target vessel, i.e., the guiding catheter was in the distal portion of the gastrorenal shunt and the 5 Fr catheter was in the proximal portion of the shunt close to the gastric varix. EOI was injected so as to fill the intended variceal cavity identified on balloon-occluded retrograde shuntography, and the amount of injected EOI was recorded. Initial technical success was defined as the existence of thrombosis of the variceal cavity on contrast-enhanced CT between 1 and 2 weeks after B-RTO.

Results

Maneuverability of the Catheter

In all cases, the guiding catheter could be introduced into the distal segment of the gastrorenal shunt. Initial balloon-occluded venography, which was obtained with contrast injection via the balloon catheter at the distal portion of the shunt, demonstrated collateral veins with partial or no contrast-filling in gastric varices in all cases. Therefore all the cases were classified as grade 3 or 4. After selecting the variceal cavities by using microcatheters, 5 Fr balloon catheters could be advanced into the proximal portion of the shunts beyond the collateral veins in all cases.

Amount of Injected EOI

EOI was injected via the microcatheters advanced into the variceal cavity to fill the target varices sufficiently. The amount of injected EOI ranged from 3 to 34 ml. The mean amount of EOI was 18.75 ml.

Necessity of Coil Embolization

Coil embolization of collateral vessels was required in 2 cases to occlude outflow of EOI into systemic vein. In the other cases, the 5 Fr balloon catheters could be advanced beyond all the collateral vessels.

Initial Success Rate

In 7 of 8 cases, complete thrombosis of the gastric varix was observed on follow-up CT (Fig. 3). Therefore, the initial success rate is 87.5%. The remaining case could not be occluded by the balloon system completely due to large and tortuous collateral veins, and re-treatment was required.

Complication Rate

No procedure-related complication was encountered in this study.

Discussion

Since its introduction by Kanagawa in 1993, B-RTO has become accepted in Japan as an effective and less invasive technique for the treatment of gastric varices. The feasibility and long-term results have been well established by a number of investigators [2–7]; however, treatment of some cases by the standard B-RTO technique is technically difficult. The major cause of technical difficulty is large, elongated, and tortuous draining veins with multiple collateral veins. In such cases, advanced techniques can be required: coil embolization of collateral veins, selective injection via a microcatheter advanced into the variceal cavity, and transportal sclerotherapy with *n*-butyl-2-cyanoacrylate [3, 6, 9, 10]. Despite these technical advances, a large amount of EOI may be required to fill the variceal cavity. Furthermore embolization of many collateral veins and catheterization of the portal venous system sometimes make the procedure more complex and invasive.

Balloon occlusion of the proximal portion of the gastrorenal shunt leads to a reduction in the amount of EOI and avoids coil embolization of the collateral veins. However, advancing a conventional balloon catheter to the proximal portion of the shunt is occasionally difficult and carries the risk of vessel injury due to vessel tortuosity or complex venous networks. Initially we devised a prototype balloon catheter system which consisted of a 5 Fr balloon catheter and 8 Fr guiding catheter without a balloon. The reason for using a balloon guiding catheter as a coaxial catheter system was our experience of one unexpected case with multiple drainage gastric veins joining the gastrorenal shunt. We treated this case using a prototype single balloon catheter, but occluding one draining vein resulted in insufficient stagnation of EOI in the varix (Fig. 4). If the case had been treated using a double balloon catheter, such a collateral vessel might have been occluded by the balloon of the guiding catheter. We therefore consider that a double

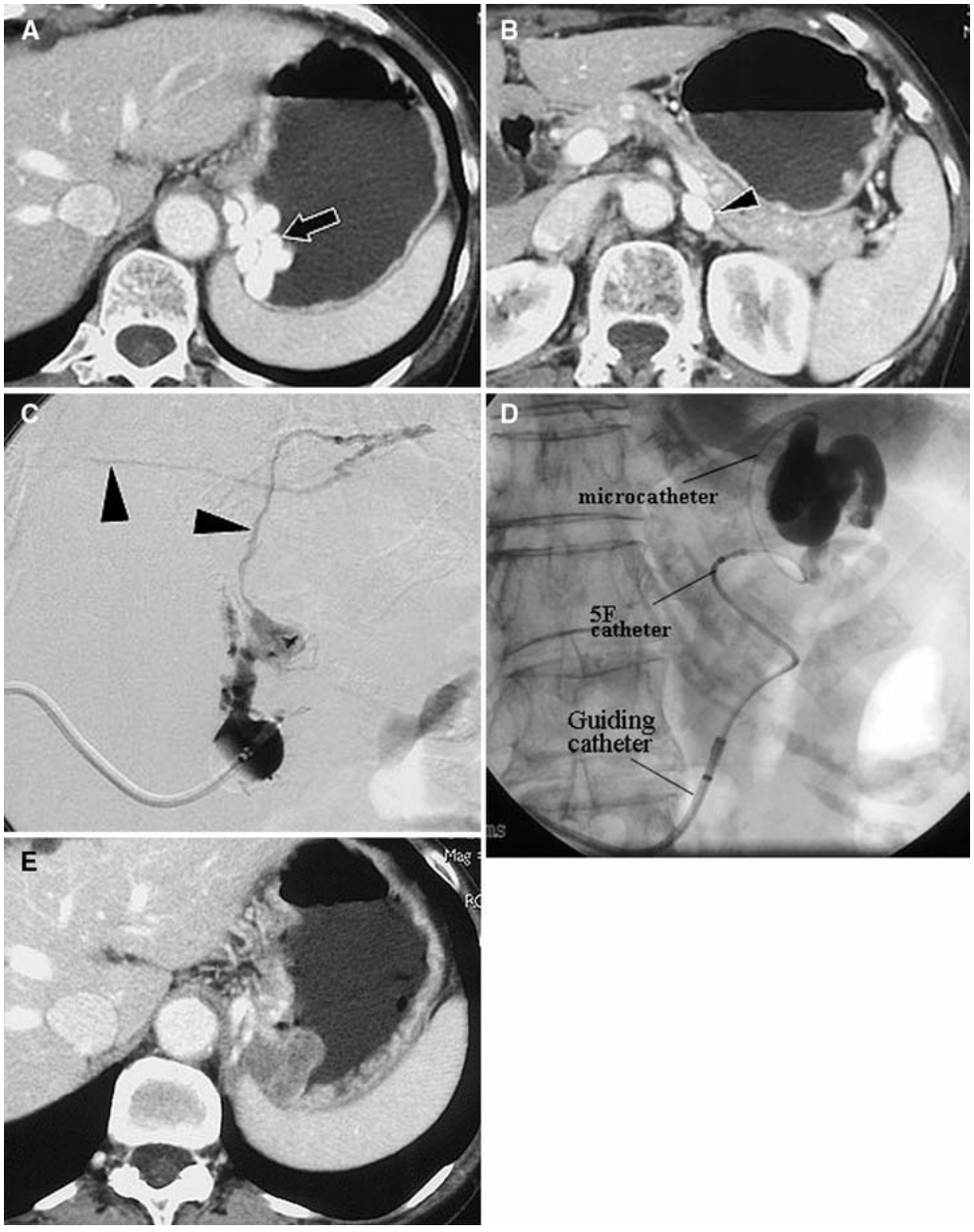

Fig. 3. A–E. A 72-year-old woman with liver cirrhosis due to hepatitis C infection. **A**, **B** Portal dominant phase of dynamic CT shows gastric varices (arrow) draining into the gastrorenal shunt (arrowhead). **C** Coaxial balloon catheter is introduced into the gastrorenal shunt. Balloon-occluded venography shows the shunt via the inferior phrenic vein (arrowhead). **D** The 5 Fr catheter is advanced to the proximal portion of the gastrorenal shunt over the microcatheter introduced into the variceal cavity. Three milliliters of 5% EOI is injected via the microcatheter. **E** One week after B-RTO, contrast-enhanced CT demonstrates complete thrombosis of the varix.

coaxial balloon system is useful for conclusive balloon occlusion.

In this study, all the cases could be occluded at points close to the variceal body by the 5 Fr catheters. It is thought the 5 Fr catheter is sufficiently flexible to be advanced into the proximal gastrorenal shunt and the 9 Fr guiding catheter has sufficient stability to support the 5 Fr catheter. Moreover, the microcatheters were advanced into or close to the target variceal cavity in all cases because the proximally advanced 5 Fr catheter contributes to improve controllability of the microcatheter. However, we had the subjective impression that in introducing the hook-type guiding catheter into the gastrorenal shunt, there were some difficulties in shaping the guiding catheters to the original hook shape because of the somewhat large size of the system.

The amount of EOI injected, which ranged from 3 to 34 ml (mean 18.75 ml), is not significantly less than in previous reports [2, 7, 9]. In our institution, in 71 patients treated using a conventional balloon catheter with EOI, the amount of EOI injected ranged from 8 to 66 ml (mean 26 ml) (unpublished data). There is thus no significant difference in the amount of used EOI between the new coaxial balloon group and the conventional balloon group. However, the existence of the case treated with such a minimal amount of EOI (3 ml) raises the possibility of reducing the amount of EOI by using this catheter system.

To prevent the migration of EOI into the collateral veins, coil embolization is useful when using a single balloon catheter. In our study, coil embolization of the collateral vein was required in only 2 cases (25%), despite the fact that the

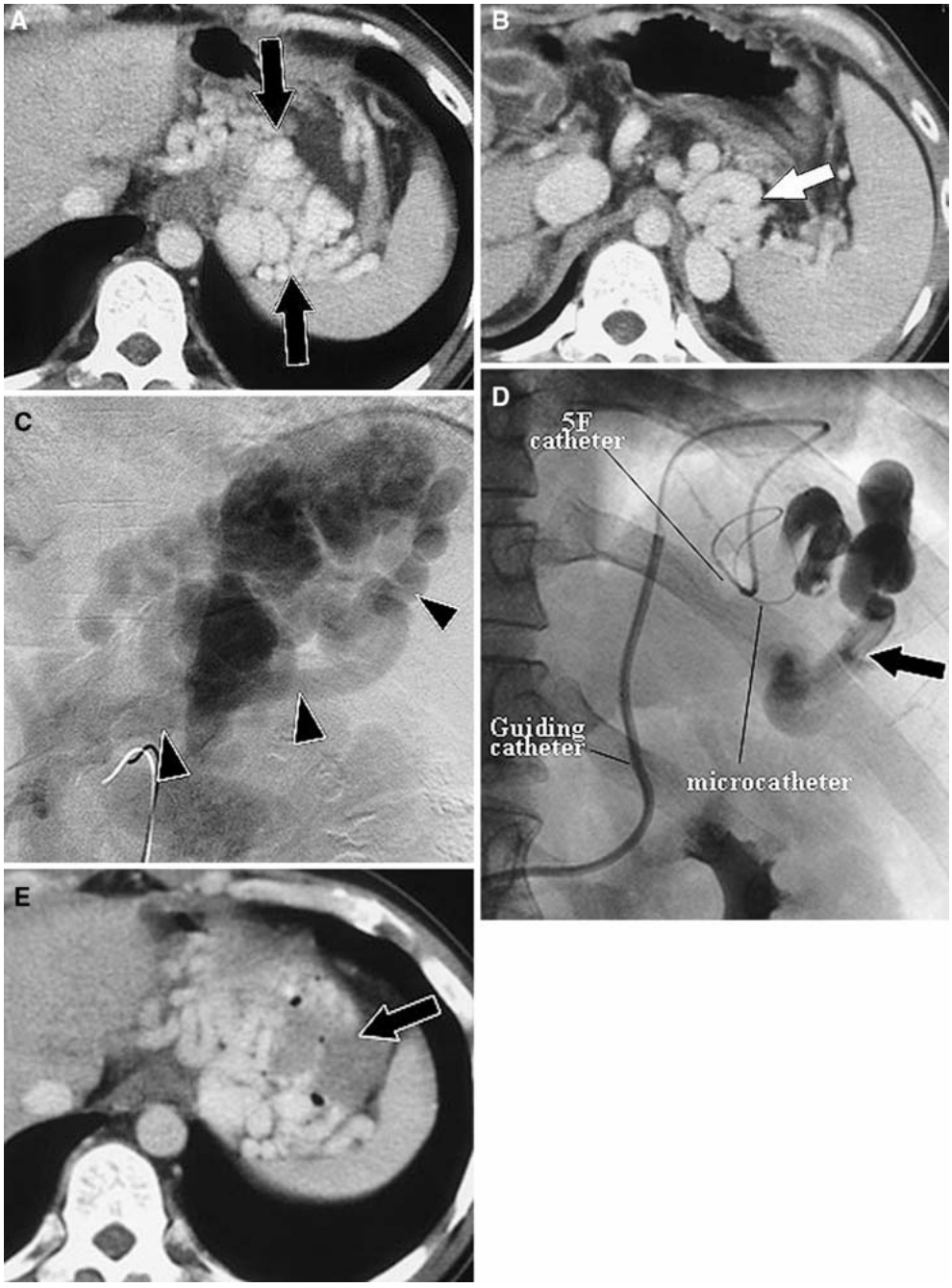

Fig. 4. A–E. A 72-year-old woman treated with a single balloon catheter. **A**, **B** Portal dominant phase of dynamic CT shows large gastric varices (black arrows) draining into the gastrorenal shunt. The shunt also has connections with other retroperitoneal veins (white arrow). **C** Venous phase of transarterial portography shows a large gastric varix draining into the gastrorenal shunt. In retrospective view after B-RTO, the variceal body has another drainage route into the gastrorenal shunt (arrowheads). **D** The guiding catheter is introduced into the gastrorenal shunt. The 5 Fr balloon catheter is introduced to the proximal draining vein and the microcatheter is advanced into the gastric varix. Five percent EOI was injected via the microcatheter. Note that a small amount of EOI escapes into another draining vein (arrow). **E** One week after B-RTO, contrast-enhanced CT demonstrated partial thrombosis of the varix (arrow).

configurations of drainage veins and collateral veins had been classified angiographically as high grade (grades 3 and 4). In contrast, 31 of 71 patients (53%) treated by a conventional balloon catheter required coil embolization for collateral veins. The amount of EOI and the necessity of coil embolization vary widely with the types of varices, i.e., the size of the variceal cavity, size of the gastrorenal shunt, and existence of collateral vessels. Further investigation in a large number of cases will be necessary to assess the efficacy regarding the amount of EOI and necessity of coil embolization.

In the present study, the initial technical success rate was 87.5%. In the remaining case, a large tortuous draining vein prevented sufficient balloon occlusion by the 5 Fr catheter. In a second B-RTO, complete obstruction of the varices was obtained by advancing the 5 Fr catheter into a more proximal and narrower part of the gastrorenal shunt. Thus, the cumulative technical success rate was 100%. Differences in the definition of technical success rate make precise comparative evaluation of different studies difficult. In previous reports, the technical success rate of the conventional B-RTO technique varied from 55.5% to 100%. Further investigation of this new catheter system in a larger number of patients is thought to be necessary; however, the result in such high-grade patients suggests a sufficient feasibility of the catheter for B-RTO, especially in gastric varices of the high-grade type.

No procedure-related complication was seen in this study. The highly flexible 5 Fr catheter is thought to be one of the reasons for the safety and effectiveness of the technique, although it must be noted that this study includes only a small number of patients and that the rate of technical success and complications can be affected by several factors, such as the anatomic morphology of the draining and collateral veins and the experience of the operator. Furthermore, decreasing the size of the catheters is thought to be necessary to make the procedure more effective and less invasive.

In conclusion, a newly developed coaxial balloon catheter system allows proximal occlusion of a gastrorenal shunt. Gastric varices can be treated more effectively and safely using this catheter system. Decreasing the size of the catheters is an issue for future research.

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