Balloon-Occluded Retrograde Transvenous Obliteration for Gastric Variceal Bleeding: Its Feasibility Compared with Transjugular Intrahepatic Portosystemic Shunt

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Objective: To assess the feasibility of balloon-occluded retrograde transvenous obliteration (BRTO) in active gastric variceal bleeding, and to compare the findings with those of transjugular intrahepatic portosystemic shunt (TIPS).

Materials and Methods: Twenty-one patients with active gastric variceal bleeding due to liver cirrhosis were referred for radiological intervention. In 15 patients, contrast-enhanced CT scans demonstrated gastrorenal shunt, and the remaining six (Group 1) underwent TIPS. Seven of the 15 with gastrorenal shunt (Group 2) were also treated with TIPS, and the other eight (Group 3) underwent BRTO. All patients were followed up for 6 to 21 (mean, 14.4) months. For statistical inter-group comparison of immediate hemostasis, rebleeding and encephalopathy, Fisher's exact test was used. Changes in the Child-Pugh score before and after each procedure in each group were statistically analyzed by means of Wilcoxon's signed rank test.

Results: One patient in Group 1 died of sepsis, acute respiratory distress syndrome, and persistent bleeding three days after TIPS, while the remaining 20 survived the procedure with immediate hemostasis. Hepatic encephalopathy developed in four patients (one in Group 1, three in Group 2, and none in Group 3); one, in Group 2, died while in an hepatic coma 19 months after TIPS. Rebleeding occurred in one patient, also in Group 2. Except for transient fever in two Group-3 patients, no procedure-related complication occurred. In terms of immediate hemostasis, rebleeding and encephalopathy, there were no statistically significant differences between the groups ($p > 0.05$). In Group 3, the Child-Pugh score showed a significant decrease after the procedure ($p = 0.02$).

Conclusion: BRTO can effectively control active gastric variceal bleeding, and because of immediate hemostasis, the absence of rebleeding, and improved liver function, is a good alternative to TIPS in patients in whom such bleeding, accompanied by gastrorenal shunt, occurs.

Index terms:
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The prevalence of gastric varices in patients with portal hypertension is approximately 30% (1–3), lower than that of esophageal varices. The frequency with which gastric varices bleed is 3–30% (4–8), and because of the greater and faster blood flow - and in spite of various treatment modalities - the rupture of gastric varices results in a higher mortality rate (45–55%) than in cases in which esophageal varices rupture (4, 8–10).

Shunt surgery, endoscopic injection sclerotherapy and transjugular intrahepatic portosystemic shunt (TIPS) have been used for gastric varices. Shunt surgery, however, is invasive, and patients with poor hepatic functional reserve are contraindicated for surgery (11, 12). Endoscopic injection sclerotherapy is usually ineffective for varices located in the gastric cardia and fundus: an easy endoscopic approach is not possible,

and fast intra-variceal blood flow causes the rapid loss of sclerosing agents (13, 14). TIPS was developed in order to overcome the limitations of surgery and endoscopic injection sclerotherapy (15, 16), but has not always induced the regression of gastric varices (17).

Shunt surgery and TIPS are aimed at relieving portal hypertension by redirecting portal blood flow into systemic circulation. Consequently, these treatments result in decreased portal hepatic blood flow, which may cause liver failure and can aggravate hepatic encephalopathy (18–20).

Kanagawa et al. (14) recently introduced a less invasive radiological procedure for the obliteration of gastric varices. Involving a gastrorenal or gastrocaval shunt and known as balloon-occluded retrograde transvenous obliteration of gastric varices (BRTO), the procedure increases portal blood flow in the liver, leading to improved liver function. Satisfactory results for gastric varices accompanied by or without hepatic encephalopathy have been reported (3, 7, 21–25). Although BRTO was in most cases performed as a prophylactic measure, one report claimed that it was effective in urgent cases involving acute gastric variceal bleeding (26). To the best of our knowledge, however, no published report has compared the use of BRTO and TIPS in cases involving active gastric variceal bleeding.

The purpose of this prospective study was to assess the feasibility of BRTO in such cases, comparing the outcomes with those of TIPS.

MATERIALS AND METHODS

Patients

Between July 1999 and May 2001, 21 patients [M:F= 17:4; mean age, 57 (range, 42–80) years] were referred to our hospital for radiological intervention because of active gastric variceal bleeding due to liver cirrhosis. The cirrhosis was caused by HBV in eleven patients, HCV in six, and chronic alcohol ingestion in four. In seven patients, hepatocellular carcinoma was also present.

In order to determine an appropriate interventional procedure, all patients underwent CT scanning, and endoscopy was also performed in all patients except number 1, in whom it was impossible because of massive hematemesis. Gastric varices located in gastric cardia and the gastric fundus were detected in all patients, and active bleeding from varices was observed. At CT, a gastrorenal shunt was demonstrated in 15 patients.

The six patients without gastrorenal shunt (Group 1) underwent TIPS. One of the 15 with gastrorenal shunt, patient 21, had diffuse hepatocellular carcinoma of the liver and underwent BRTO. The 14 remaining patients were randomly assigned to one of two groups, 'TIPS' or 'BRTO'. Thus, among patients with gastrorenal shunt, seven underwent TIPS (Group 2) and eight underwent BRTO (Group 3). The patients' demographic data are summarized in Table 1, which shows that three patients had a history of hepatic encephalopathy prior to active gastric bleeding. Differences between the three groups in terms of Child-Pugh liver function score were not significant. In all cases, written informed consent to the procedures was obtained from patients or their families.

TIPS procedure

First, the patency of hepatic and portal veins was assessed by CT scanning. By means of the transjugular venous approach, venography of the right and, if necessary, middle hepatic vein was performed. To visualize portal veins, CO2-wedged hepatic venography was routinely performed. For TIPS tract creation, a Ring transjugular intrahepatic access set (Cook, Bloomington, Ind., U.S.A.) was used; in twelve of the thirteen patients, a shunt tract was created between the right hepatic and right portal vein, and in the other, between the middle hepatic and left portal vein because of bland thrombosis of the right portal vein. After puncturing the portal veins, portal venography was performed and the pressure gradient between the portal vein and right atrium was measured. Before stent insertion, the tract was dilated with a 10-mm balloon catheter (Ultra-thin Diamond ; Boston Scientific, Watertown, Mass., U.S.A.). Self-expandable stents, Wallstent (Boston Scientific) (n=8) or Niti-S (Taewoong, Seoul, Korea) (n=5), were deployed in the shunt tract prior to further dilatation with a 10-mm balloon catheter. Portal venography and pressure measurement were repeated.

BRTO procedure (Fig. 1)

The right internal jugular vein was punctured in all patients. A 7-Fr occlusion balloon catheter with maximum 12 mm ballooning (Clinical Supply, Gifu, Japan) was inserted into the left adrenal vein through the left renal vein. For confirmation of feeding veins, draining veins, and gastric varix collaterals, digital subtraction angiography was performed, with the balloon inflated. If collateral gastric variceal drainage veins were identified, they were embolized with microcoils, glue, or gelatin sponge particles to prevent leakage of the sclerosing agent into systemic circulation.

The sclerosing agent used was a mixture of 5% ethanolamine oleate (Keuk Dong Pharmaceuticals, Inchon, Korea) and iodized oil (Lipiodol(r); Laboratoire Guerbet, Riossy, France), mixed in a ratio of 3:1–6:1. The volume of sclerosing agent prepared depended on the volume of

contrast media necessary to visualize the gastric varix by manual injection. Using an occlusion balloon catheter with the balloon inflated, the agent was slowly infused into the gastrorenal shunt in a retrograde fashion until the vascular space in the gastric varices was completely opacified and feeding veins from the portal or splenic veins began to be visualized. The total of injected volume of sclerosing agent ranged from 13 to 36 (mean, 25) mL; to facilitate its complete infusion, the Sengstaken-Blakemore tube inserted for hemostasis was deflated. The injected sclerosing agent remained in the varix for three hours with the balloon inflated, and as much of it as possible was then aspirated under fluoroscopy. To confirm the cessation of blood flow within the shunt, venography was performed.

Follow-up

Patient 1 died three days after TIPS, but the remaining twenty patients were followed up for 6 to 21 (mean, 14.4) months. We reviewed their medical records and maintained telephone contact with them. Immediate hemostasis, hepatic encephalopathy, rebleeding and survival were monitored, and changes in the amount of ascites and the Child-Pugh score before and after the procedures determined. Other than patient 10, those in whom TIPS was performed underwent Doppler ultrasonography during follow-up, and the patency of the TIPS tract and portal flow were thus assessed. In patients who underwent BRTO, CT was performed during the follow-up period, permitting evaluation of the obliteration of gastric varices and the gastrorenal shunt. Post-procedural endoscopic evaluation of gastric varices was performed in three Group-1 patients, three in Group 2, and six in Group 3. Immediately occurring procedure-related complications were also investigated.

For statistical inter-group analysis in terms of immediate hemostasis, rebleeding and encephalopathy, Fisher's exact test was used, and changes in the Child-Pugh score before and after the procedure in each group were statistically analyzed by means of Wilcoxon's signed rank test.

RESULTS

The results of the procedures are summarized in Table 1.

Group 1

After TIPS, the portosystemic pressure gradient fell to below 12 mmHg, and completion portography showed that in all patients except number 4, whose pressure gradient was 19 mmHg, gastric varices had disappeared. Patient 1 died of sepsis, acute respiratory distress syndrome and persistent bleeding three days after the procedure, but in the remaining five patients, immediate hemostasis was

Table 1. Summary of 21 Patients with Gastric Variceal Bleeding Treated by TIPS and/or Balloon-Occluded Retrograde Transvenous Obliteration

Patient No.	Age/ Sex	Gastrorenal shunt	Treatment modality	Adjunctive procedure	Follow-up (months)	Immediate hemostasis	Child-Pugh score		Ascites	Rebleeding	Hepatic encephalopathy		Survival
							Pre	Post			Pre	Post	
1	60 M	–	TIPS		3 days	No	C10	C11 or Higher	Persistent		–		Expired
2	63 M	–	TIPS		21	Yes	B8	B9	Disappeared	–	–	–	Alive
3	52 M	–	TIPS	Liver transplantation	19	Yes	C12	C14	Persistent	–	–	+	Alive
4	43 M	–	TIPS		14	Yes	B9	B8	Absent	–	+	–	Alive
5	59 M	–	TIPS		14	Yes	B8	B7	Disappeared	–	–	–	Alive
6	45 M	–	TIPS		8	Yes	B9	A6	Disappeared	–	–	–	Alive
7	58 M	+	TIPS	Balloon angioplasty of splenic vein	6	Yes	B8	B8	Absent	–	+	–	Alive
8	47 M	+	TIPS	Coil embolization of gastric varix	18	Yes	B7	B8	Disappeared	–	–	–	Alive
9	57 M	+	TIPS	Balloon angioplasty of splenic vein	20	Yes	C11	C11	Disappeared	–	–	+	Alive
10	72 M	+	TIPS		18	Yes	A6	C10	Absent	–	–	+	Expired
11	53 M	+	TIPS		19	Yes	B9	B7	Disappeared	–	–	–	Alive
12	42 F	+	TIPS		7	Yes	C10	C11	Decreased	–	–	+	Alive
13	55 M	+	TIPS	BRTO	19	Yes	C10	B7	Disappeared	+	–	–	Alive
14	60 M	+	BRTO		20	Yes	A6	A5	Absent	–	+	–	Alive
15	65 F	+	BRTO		18	Yes	B7	A5	Absent	–	–	–	Alive
16	63 M	+	BRTO	Coil embolization of collaterals	15	Yes	B7	A6	Absent	–	–	–	Alive
17	50 M	+	BRTO		14	Yes	B7	A5	Absent	–	-	–	Alive
18	80 F	+	BRTO	Glue and gelfoam embolization of collaterals	12	Yes	B8	B8	Disappeared	–	–	–	Alive
19	56 F	+	BRTO		9	Yes	B8	A5	Absent	–	–	–	Alive
20	57 M	+	BRTO	Gelfoam embolization of collaterals	8	Yes	C11	A6	Disappeared	–	-	–	Alive
21	52 M	+	BRTO	Coil and gelfoam embolization of collaterals	8	Yes	B8	B7	Absent	–	–	–	Alive

Note.— Pre = pre-TIPS or pre-BRTO, Post = post-TIPS or post-BRTO, TIPS = transjugular intrahepatic portosystemic shunt, BRTO = balloon-occluded retrograde transvenous obliteration of gastric varix

achieved. During the follow-up period, no rebleeding occurred. Post-TIPS hepatic encephalopathy occurred in one patient, number 3, who underwent liver transplantation two months after TIPS. The post-TIPS Child-Pugh score showed a decrease in three patients and an increase in the other three. Follow-up duplex sonography indicated that the patency of the TIPS tract was well maintained and there was no disturbance of portal flow. Follow-up endoscopy, performed in patients 3, 4 and 6, indicated that the varices had disappeared or become smaller.

Group 2

The post-TIPS portosystemic pressure gradient fell to below 12 mmHg, except in patient 12, whose gastric varix

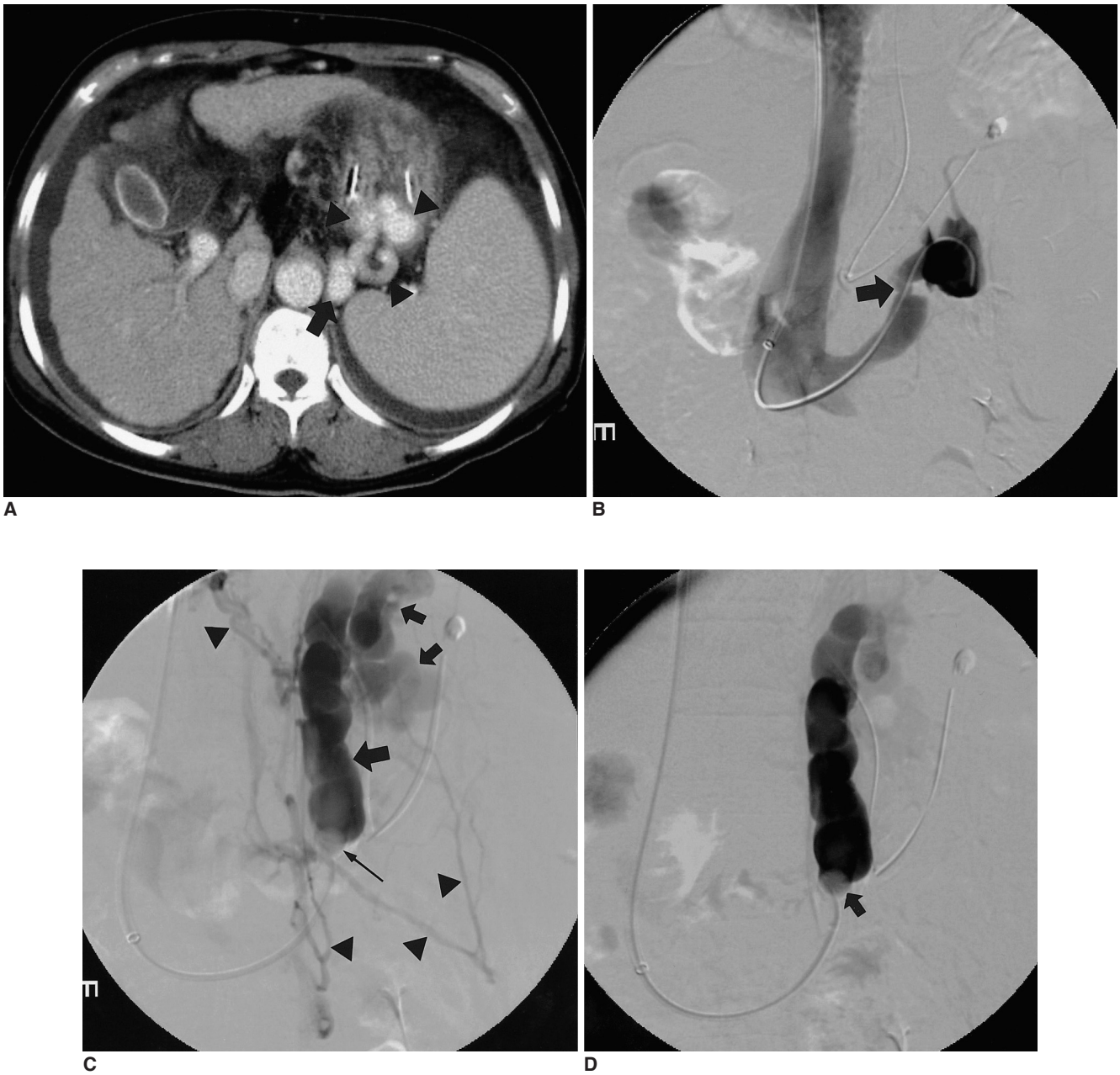
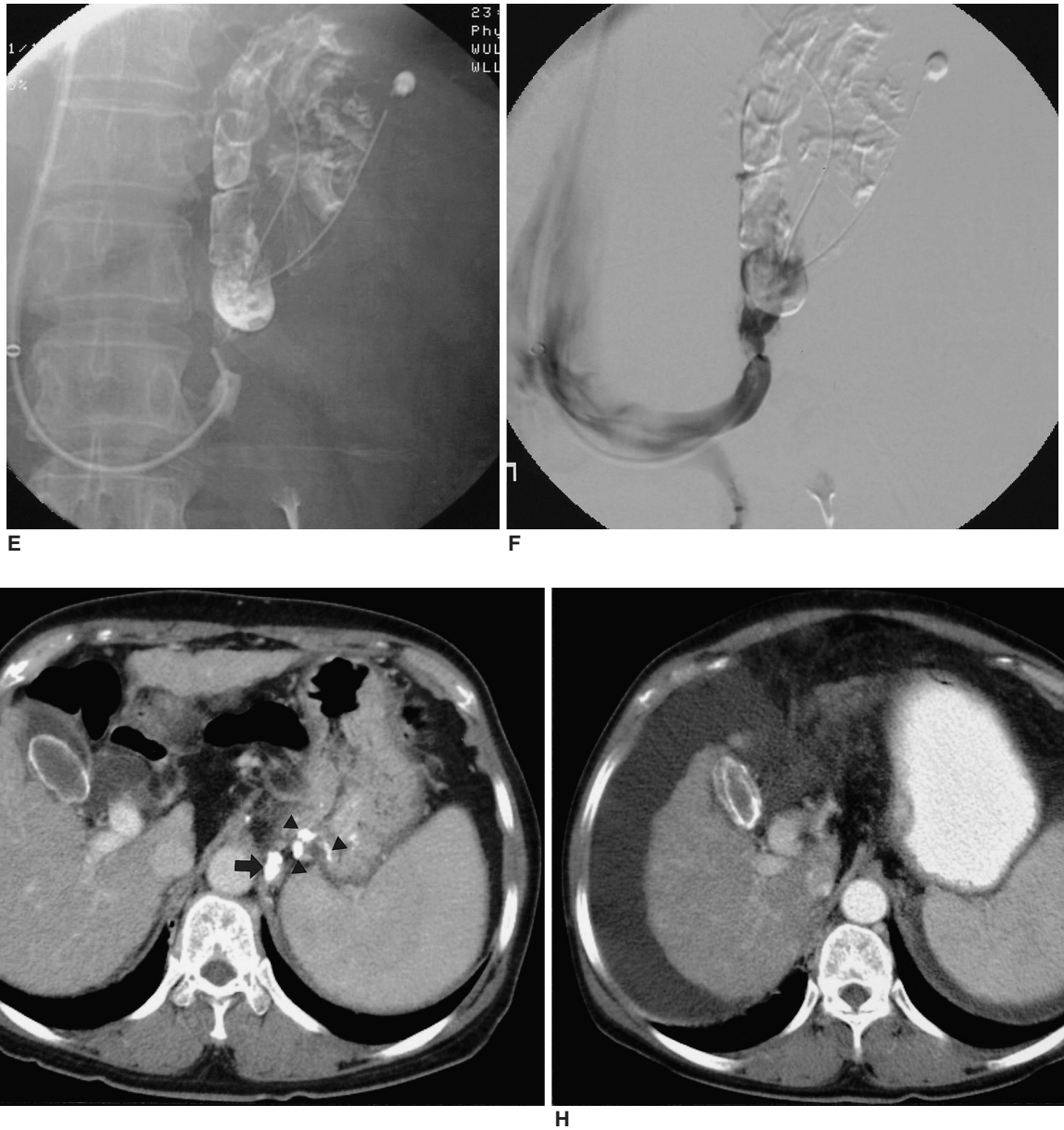


Fig. 1. Balloon-occluded retrograde transvenous obliteration of gastric varix.
A. CT scan obtained before balloon-occluded retrograde transvenous obliteration shows dilated gastric varix (arrowheads) and gastrorenal shunt (arrow).
B. Narrow segment of the shunt tract (arrow) is demonstrated at angiography.
C. Gastric varix (small arrows), gastrorenal shunt (large arrow), and its multiple fine collaterals (arrowheads) are seen at angiography. In the narrow segment, an inflated balloon catheter (long arrow) is visible.
D. With the balloon inflated (arrow), 2 ×2 ×2-mm gelatin sponge particles were injected into the gastrorenal shunt, from where they flowed into collateral veins. Subsequent angiography shows that the fine collaterals have disappeared.

was not opacified at post-TIPS portography despite an unsatisfactory gradient decrease (17 mmHg). In patient 8, because of persistent filling of the gastric varix at completion portography, post-TIPS coil embolization of the gastric varix was performed. Two patients, numbers 7 and 9, underwent post-TIPS balloon angioplasty for splenic vein stenosis. Immediate hemostasis was achieved in all patients, and no immediate procedure-related complication occurred.

During the follow-up period, rebleeding occurred in one patient (number 13) five months after TIPS because of an occluded TIPS tract. TIPS revision failed to reopen this tract sufficiently, and a satisfactory reduction in the portosystemic pressure gradient was thus not achieved. To control the varix, BRTO was thus performed, and there was no further rebleeding. In patients 9, 10 and 12, hepatic encephalopathy developed; hepatic failure 18 months after TIPS led to the death of patient 10. The post-TIPS Child-Pugh score decreased in two patients, increased in three, and showed no change in the other two. Follow-up en-



E. Three hours after the injection of ethanolamine oleate into the varix, as much as possible of the remaining sclerosing agent was aspirated. Fluoroscopy shows that some, however, was retained.
F. Immediate follow-up angiography demonstrates obliteration of both the varix and gastrorenal shunt.
G. Follow-up CT scan obtained three months after balloon-occluded retrograde transvenous obliteration depicts contraction of the varix (arrowheads) and gastrorenal shunt (arrow), with deposition of sclerosing agent.
H. One year later, there is no trace of either the varix or shunt.

doscopy in patients 9 and 10 showed that the varices had become smaller or disappeared entirely.

Group 3

Embolization of collateral channels was performed in four patients. One patient, number 18, removed the occlusion balloon catheter herself after thirty minutes, but the injected sclerosing agent remained *in situ* without pulmonary embolism.

Immediate hemostasis was achieved in all patients. Fever developed in two, numbers 14 and 15, but subsided after conservative therapy. Otherwise, no immediate procedure-related complications occurred. The post-BRTO Child-Pugh score decreased in seven patients and showed no change in the other. During the follow-up period, neither rebleeding nor hepatic encephalopathy were encountered. Follow-up CT showed that in all patients, gastric varices were filled with sclerosing agents or obliterated. Follow-up endoscopy performed in six patients (numbers 14–17, 19, and 21) revealed that varices had either disappeared or were smaller, though in patient 16 a newly developed esophageal varix was discovered two months after BRTO.

With respect to immediate hemostasis ($p > 0.05$), rebleeding ($p > 0.05$) and encephalopathy ($p > 0.05$), there were no statistically significant differences between the groups. A significantly decreased post-procedural Child-Pugh score was found in Group 3 ($p = 0.02$), but not in Groups 1 ($p = 0.91$) or 2 ($p = 0.89$).

DISCUSSION

TIPS has been considered the standard therapy for gastric varices unresponsive to pharmacological and endoscopic treatment, but recent reports have claimed that for their management, transvenous obliteration (BRTO) is less invasive and more effective than shunt surgery or TIPS (10–25). TIPS does not always induce their disappearance, and according to one report (17), the improvement rate after TIPS is only 50%. BRTO, on the other hand, can in most cases completely obliterate these varices. Chikamori et al. (27) reported the complete obliteration of gastric varices, demonstrated at CT, in all their 52 patients treated with BRTO. Our study also demonstrated complete obliteration in all our eight patients who underwent the procedure, a finding confirmed at follow-up CT.

To date, BRTO has been applied electively, as a prophylactic measure, in the treatment of gastric varices, but in this study it was used for the emergent or urgent treatment of active gastric variceal bleeding. Immediate hemostasis was achieved and no rebleeding was noted during follow-up, and BRTO was thus as effective as TIPS in the control of bleeding.

The spontaneous portosystemic (splenorenal or gastrorenal) shunt reported to occur in 28% of patients with portal hypertension (28) can increase the risk of chronic hepatic encephalopathy (29). In such patients, TIPS can cause intractable hepatic encephalopathy due to the increased shunt volume (30). LaBerge reported an 18% incidence of hepatic encephalopathy after TIPS (31), and in our study, its incidence among Group 1 patients (gastric varix without gastrorenal shunt and TIPS) was similar. Group 2 (gastric varix with gastrorenal shunt and TIPS) showed a higher incidence, however: hepatic encephalopathy occurred in three of the seven patients. In BRTO, however, a spontaneous portosystemic shunt is occluded, and hepatic encephalopathy is thus not an obstacle. Hirota et al. (3) recommended BRTO rather than TIPS for patients with gastric varices in association with a gastrorenal shunt or hepatic encephalopathy, and in our series of gastric variceal bleeding, no case of hepatic encephalopathy arose through the use of BRTO.

The augmentation of portal blood flow in BRTO (shunt occlusion therapy) can improve liver function in cirrhotic liver (23, 32), but TIPS (shunt creation therapy), on the other hand, may decrease portal flow, leading to deterioration in liver function (33). In our study, the Child-Pugh score showed a statistically significant improvement in patients who underwent BRTO, though in three TIPS patients in Group 1 and three in Group 2, the Child-Pugh score worsened.

The occlusion of a gastrorenal shunt, the main way of reducing portal venous pressure, may - if there are no other collateral vessels outside the esophageal wall or elsewhere - aggravate existing esophageal varices or lead to the development of new ones, and this is one of the most significant complications of BRTO (21, 27). In our series, for example, a new esophageal varix was detected at follow-up endoscopy two months after BRTO in one patient. These varices can, however, largely controlled by endoscopic injection sclerotherapy or variceal ligation (21).

TIPS can give rise to various procedure-related complications such as hepatic arterial injury and hemoperitoneum due to extrahepatic puncture, and stenosis or occlusion of a TIPS tract is frequently observed during follow-up. In our study, however, there were no notable TIPS-related complications.

Since BRTO requires balloon occlusion to block the outflow of the gastric varix, as well as retrograde injection of the sclerosing agent, the existence of a dilated suprarenal vein for use as the usual draining vein should be confirmed before the procedure. Also, since TIPS requires an appro-

priate portosystemic shunt tract between the hepatic and portal vein, the exact relation between these two vessels should also be pre-procedurally determined. Thin-section helical CT may play an important role in the evaluation of a gastric varix, gastrorenal shunt, and the hepatic vascular anatomy, and careful interpretation of the CT scans should help lay the groundwork for the proper interventional procedure.

The occlusion of collateral veins connected to a gastrorenal shunt is essential for successful BRTO. Hirota et al. (3) devised a five-point scale to classify the degree of progression of gastric varices and collateral veins, basing their system on the results of adrenal venography performed during balloon occlusion. Except for grade 5, in which the left adrenal vein could not be occluded by the balloon catheter because of a very large gastrorenal shunt with rapid blood flow, the appropriate embolization of collateral veins lead to successful BRTO. In our study, collateral veins were embolized in four patients, and the embolic materials used were glue, coils, and Gelfoam. When multiple fine collaterals existed, we retrogradely injected 2 ×2 ×2-mm gelatin sponge particles into the gastrorenal shunt tract while the proximal adrenal vein was occluded with an occlusion balloon catheter (Fig. 1).

Conner et al. (34) and Hoak et al. (35) reported that ethanolamine oleate promptly binds with albumin in the blood, thus becoming inactive, and decomposes to form oleic acid and ethanolamine. If only a small amount is used, it is therefore safe for local treatment. Its possible side effects include, however, pulmonary embolism, renal dysfunction, pleural effusion, pulmonary edema, hypersensitivity reaction, pyrexia, and disseminated intravascular coagulation syndrome, and it also causes hemolysis of the blood vessels, leading to free hemoglobin, which may give rise to renal tubular disturbance and renal insufficiency. In BRTO, a relatively large amount of ethanolamine oleate is used, and to prevent or minimize systemic complications it is therefore important to prevent its abrupt systemic inflow. The various preventative measures which can be used include allowing sufficient ballooning time for clotting, the aspiration of any ethanolamine oleate remaining in a gastrorenal shunt and gastric varix, and the embolization of collateral veins connected to a gastrorenal shunt. Some reports (3, 7, 14, 21–23) have described the intravenous injection of haptoglobin, which combines with free hemoglobin, to prevent renal insufficiency associated with hemolysis; in this study, we kept a balloon catheter inflated for three hours and aspirated as much of the infused sclerosing agent as possible.

Because of the small number of patients in this study and the different follow-up periods involved, there may be certain problems asscociated with statistical analysis. Even though there was no statistical difference with respect to encephalopathy between Group 1 and Group 3 ($p = 0.38$) or between Group 2 and Group 3 ($p = 0.08$), we are left with the impression that in a study involving more patients there would be significant differences between groups, especially between Group 2 and Group 3, and that the results would be more exact. To overcome these limitations, further studies involving a larger series and longer follow-up period are needed.

In conclusion, BRTO can effectively control active gastric variceal bleeding, and because of immediate hemostasis, the absence of rebleeding, and improved liver function, is a good alternative to TIPS in patients in whom such bleeding, accompanied by gastrorenal shunt, occurs.

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