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CASE REPORT

Plug-assisted Retrograde Transvenous Obliteration-II for Gastric Varices: A Case Report

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Abstract:
We present a case of gastric varices successfully treated with modified plug-assisted retrograde transvenous obliteration. A 45-year-old male patient had isolated fundal gastric varices caused by alcoholic cirrhosis. Contrast-enhanced computed tomography showed that the gastric varices were drained mainly via the gastro-renal shunt. The gastric varices were treated via plug-assisted retrograde transvenous obliteration using an IMPEDE vascular plug with a modified coil-assisted retrograde transvenous obliteration-II procedure. There were no complications during the procedure, and an endoscopic examination 3 months after the procedure revealed that the gastric varices had disappeared. To our knowledge, this is the first report on the application of plug-assisted retrograde transvenous obliteration-II using a newly designed IMPEDE vascular plug to avoid migration of the sclerosant.

Keywords:
balloon-occluded retrograde transvenous obliteration, IMPEDE vascular plug, shape-memory polymer, gastric varices, plug-assisted retrograde transvenous obliteration

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Introduction

Gastric varices (GVs) are a major complication of portal hypertension associated with massive bleeding events and high mortality rates. Transjugular intrahepatic portosystemic shunting (TIPS) and balloon-occluded retrograde transvenous obliteration (BRTO) are well-known effective treatment modalities for preventing gastric variceal bleeding. Although TIPS is well accepted in Western countries, it is not commonly performed in Japan because of the risk of major complications and because it is not covered by Japanese public insurance. BRTO is one of the most effective treatments for GVs that prevent their rupture [1-3]. Modified BRTO techniques, known as plug- and coil-assisted retrograde transvenous obliteration (PARTO and CARTO, respectively), have received increased attention because of their comparatively low complication rates. Kim et al. and Yamamoto et al. introduced CARTO-II [4, 5] using multiple coils and an inflated balloon catheter.

Here we report a modified PARTO procedure (PARTO-II) using a newly designed vascular plug (IMPEDE vascular plug, Shape Memory Medical Inc., Santa Clara, CA, USA) to prevent migration of the sclerosant. Plug embolization of the draining vein is performed after injection of the sclerosant under balloon occlusion, and the balloon catheter is ultimately deflated and removed according to the CARTO-II procedure [4, 5].

Case Report

A 45-year-old man with an 8-year history of alcoholic cirrhosis was referred to our institution for management of gastric variceal bleeding. An isolated fundal GV was detected on endoscopy at our hospital (**Fig. 1a**) and classified as F3 according to the variceal criteria proposed by the Japanese Society for Portal Hypertension. Preprocedural contrast-enhanced computed tomography (CT) revealed isolated fundal GVs with a 13-mm-diameter efferent gastrorenal (GR) shunt (**Fig. 1b**). The patient had a Child-Pugh score of 6.

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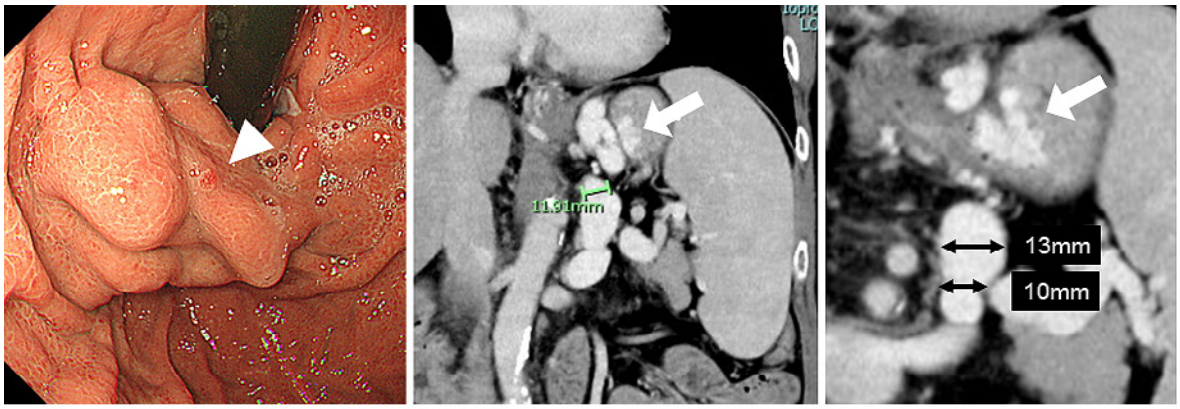


Figure 1.
(a) A 52-year-old man with gastric varices. Emergent endoscopic examination showing nodular gastric fundal varices with a cherry red spot (arrowhead).
(b) Coronal sectional image of gastric varices on contrast-enhanced computed tomography (CE-CT) along the fundus (arrows; b, c).
(c) The gastro–renal shunt is calculated as 10–13 mm in diameter using the CE-CT coronal sectional image.

The PARTO-II procedure was performed after one day after screening tests. First, we accessed the right common femoral vein under moderate sedation. A 10-Fr vascular sheath (Medikit, Tokyo, Japan) was inserted into the inferior vena cava and left renal vein, and the efferent shunt was accessed using a 9.5- and 5-Fr double coaxial balloon catheter system (CANDIS, Medikit, Tokyo, Japan) under the guidance of a 0.035-inch guidewire (Radifocus guidewire M, Terumo, Tokyo, Japan) through this vascular sheath. Initially, balloon-occluded retrograde transvenous venography (BRTV) was performed under occlusion of a 9.5-Fr balloon catheter. BRTV showed some isolated collateral veins but could not show the GVs (grade 3 according to Hirota's classification). Subsequently, a 5-Fr coaxial balloon catheter was inserted into the draining vein near the GVs via the GR shunt through a 9.5-Fr catheter. In selective BRTV under occlusion of a 5-Fr balloon catheter (**Fig. 2a, b**), a dose of 16 mL of sclerosing agent consisting of 5% ethanolamine oleate iopamidol (EOI), mixed with an equal volume of 10% ethanolamine oleate (Oldamin, ASKA Pharmaceutical, Osaka, Japan) and a nonionic contrast medium (iopamidol 300 mgI/mL, Iopamiron 300; Bayer Schering Pharma, Osaka, Japan), was injected into the GVs and afferent vein. After completing the EOI injection, plug embolization of the drainage vein was performed through the 9.5-Fr balloon catheter using a 10-mm-diameter IMPEDE vascular plug (IMP-10; 13-mm maximum diameter of the anchor coil) to prevent migration of the sclerosant (**Fig. 2c**). EOI was injected through a 5-Frballoon catheter, and the plug was placed from a 9.5-Fr balloon catheter. However, the 9.5-Fr balloon catheter was advanced (**Fig. 2b, c**) beyond the original position (**Fig. 2a**) using the downgrade technique; therefore, the sclerosing agent did not flow away through the collateral channels. Following plug embolization, the balloon catheter and sheath were carefully removed without migration of the sclerosant at 25 min after the EOI injection. During the EOI injection, a drip infusion of 2000 U of haptoglobin was administered to prevent renal dysfunction caused by EOI-induced hemolysis.

The patient showed no signs of complications, and he was discharged uneventfully. He had a Child-Pugh score of 6, the same as that preprocedure. A triple-phase contrast-enhanced CT of the abdomen 1-month postprocedure showed successful complete obliteration of the efferent shunt, GVs, and afferent feeding veins (**Fig. 3a**). No thrombosis was detected in the portal system, renal vein, or inferior vena cava. Three months after the treatment, endoscopic examination revealed that the varix classification was reduced from an F3 to an F1, and the red color sign had disappeared completely (**Fig. 3b**).

Discussion

To our knowledge, this is the first report on a modified BRTO technique, PARTO-II, that uses a newly designed IMPEDE vascular plug for GV treatment. GVs caused by portal hypertension are a major cause of death in patients with cirrhosis. Treatment options include pharmacotherapy and surgical, endoscopic, and interventional procedures. However, pharmacological and endoscopic treatments are often challenging, particularly for actively bleeding fundal GVs. BRTO is widely used to manage GVs, particularly in Japan. However, with the BRTO procedure, the outflow tract must remain occluded by a balloon for several hours after the injection of a sclerosing agent such as EOI. Traditional BRTO results in lengthy procedure times, requires additional hospital resources and logistics (e.g., intensive care unit beds, additional patient transport, additional interventional radiology suite time, and staff), and carries with it the innate complications associated with balloons (i.e., balloon dislocation and premature drug leakage).

Modified BRTO procedures, such as PARTO and

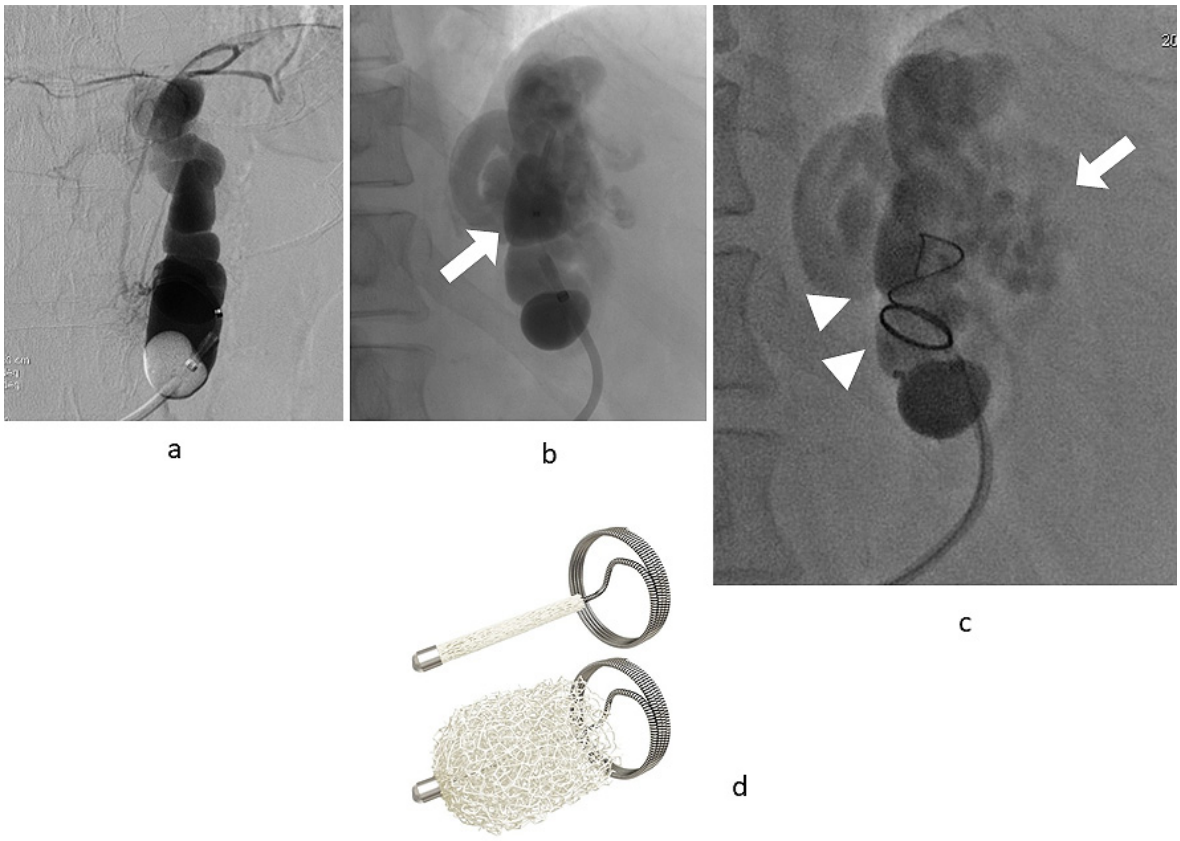
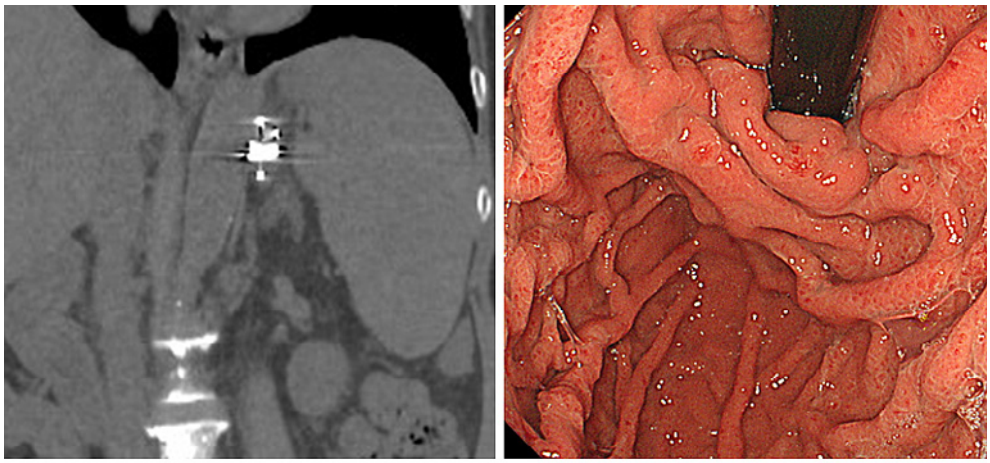


Figure 2.
(a) Balloon-occluded retrograde transvenous venography (BRTV) is performed. BRTV from a GR shunt shows some isolated collateral vein but cannot show the varices (grade 3 as per Hirota's classification) under occlusion of a 9.5-Fr balloon catheter.
(b) Selective BRTV reveals the GV under occlusion of a 5-Fr balloon catheter (arrow).
(c) Sclerosant [ethanolamine oleate iopamidol (EOI) and gelatin sponge particles] is injected into the varix (arrow) using a 5-Fr balloon catheter. A 10-mm-diameter vascular plug (arrowheads) inserted into the vein using a 9.5-Fr balloon catheter after injection of the sclerosant.
(d) IMPEDE vascular plug (Shape Memory Medical Inc., Santa Clara, CA, USA): above, IMPEDE – crimped; below, IMPEDE – expanded.

CARTO, have received increased interest for managing bleeding GVs because of their acceptable postoperative results and numerous clinical advantages over traditional BRTO procedures [6-8]. For example, using a vascular plug or coil instead of a balloon for vascular occlusion avoids some of the potential complications associated with indwelling balloon catheters. Additionally, modified BRTO techniques do not require selective embolization of the collateral veins in most cases. There are two subtypes of the CARTO procedure, CARTO or CARTO-I and CARTO-II [4, 5]. In the CARTO method, coil embolization of the draining vein is performed without balloon occlusion prior to sclerosing agent injection. In contrast, the CARTO-II method involves coil embolization of the draining vein under balloon occlusion after sclerosing agent injection, followed by deflation and removal of the balloon catheter [5].

The shape-memory polymer-based porous embolic scaffold in the IMPEDE Embolization Plug devices (IMP-devices) is a material that has not yet been used in medical devices (**Fig. 2d**). Larger-sized IMP-devices, such as IMP-10 or IMP-FX-12 and corresponding to expanded plug diameters of 12 mm, are suitable for use in the PARTO procedure. The recommended vessel diameter of these larger devices is 6-10 mm. In particular, the IMP-10 device with an anchor coil 13 mm in diameter is more suitable and has been implanted in the efferent where the narrowest location is 10 mm in diameter as in this case. However, its limitation is that it cannot be implanted in larger veins because of the risk of coil migration. The IMP-10 can be inserted through a 6-Fr guiding catheter or sheath with an internal diameter of ≥0.070 inches. Therefore, the IMP-10 could be inserted through a 9.5-Fr catheter of a double coaxial balloon catheter system in this case.

In the conventional PARTO procedure with gelfoam slurry, the recurrence rate was initially relatively high (32.8% at 1 year) compared with that in BRTO using liquid or foam sclerosants, such as EOI or sodium tetradecyl sulfate foam [5, 9]. In contrast, the PARTO technique has some advantages over the conventional BRTO or CARTO/CARTO-II procedure: the use of a smaller number of coils



a b

Figure 3.
(a) The coronal section image on CT obtained 3 months after PARTO-II shows a plug in the gastro–renal shunt.
(b) Endoscopic examination 3 months after PARTO-II shows that the previously seen GVs had disappeared.

reduces the overhead cost and procedure time [8-10]. Therefore, we performed PARTO-II according to Yamamoto's CARTO-II method in this case, as described above. In our case, only one IMPEDE plug was used to embolize the drainage vein, and the procedure took <1 h. There is a possibility of complete sclerosis of GVs in combination with EOI, because the shape-memory polymer-based porous embolic scaffold only induces fresh thrombus formation, whereas the IMP-devices provide a scaffold for tissue ingrowth. Thus, the plugs aim to minimize time to thrombus maturation by promoting initial clotting of blood within the scaffold, which will be replaced by connective tissue, potentially reducing the risk of recanalization [10]. However, its usefulness is unclear in this case alone.

In conclusion, the successful outcome of this case suggests that the modified BRTO technique, PARTO-II, is an effective treatment option for GVs.

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Clinical Investigation, MT, TK, RK, AU, and AH
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