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Percutaneous transhepatic portal embolization using foam ethanolamine oleate and carbon dioxide (CO_2): a pilot study

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Abstract

Background: Percutaneous transhepatic portal embolization (PTPE) can induce atrophy of the embolized- and hypertrophy of the residual area. These effects are advantageous in patients scheduled for extended hepatectomy.

Purpose: To evaluate the clinical safety and effectiveness of foam sclerotherapy with foam ethanolamine oleate (EO) and carbon dioxide (CO_2) for PTPE before hepatectomy.

Material and Methods: We performed sclerotherapy for PTPE in 15 patients with: hepatocellular carcinoma (HHC; $n = 9$), bile duct carcinoma ($n = 5$), or metastatic liver tumor from colon cancer ($n = 1$). The foam contained 5% EO iopamidol (EOI) and CO_2 at a 1:2 ratio. We compared the percentage of the pre- and post-PTPE future liver remnant (FLR) volumes and calculated the percent FLR volume (%FLR) increase after PTPE.

Results: The amount of EOI used (range, 14–20 mL; median, 16.8 mL) was based on the volume of the target portal vein. Technical success was achieved in 14 of 15 patients (93%); the other patient presented with computed tomography evidence of recanalization 1 week after PTPE. The FLR volume before and after portal vein embolization was 599 ± 342 and $691 \pm 318\,cm^3$, respectively ($P < 0.01$); the mean %FLR volume increase was 29.5%. There was no significant difference in the mean platelet count, total bilirubin, total aspartate aminotransferase, and total creatinine before and after PTPE. One patient suffered intra-abdominal bleeding that required transcatheter arterial embolization. No other patients developed major complications higher than grade 3.

Conclusion: Sclerotherapy using foam EOI and CO_2 is clinically safe and effective for PTPE before hepatectomy.

Keywords
Vascular, angiography, embolization, vein, adult

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Introduction

To achieve complete and curative resection (1), patients with hepatocellular carcinoma (HCC), liver metastases, and biliary cancer are subjected to major hepatectomy. Percutaneous transhepatic portal embolization (PTPE) has been performed to expand the indications for hepatic resection (2).

A sclerosant in endoscopic injection sclerotherapy for esophageal varices (3) is 5% ethanolamine oleate (EO) with iopamidol (EOI). The sclerosing agent is a mixture of 10% EO (Oldamin, Mochida

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Pharmaceutical, Tokyo, Japan) and the same dose of a non-ionic contrast medium (Iopamiron 300) . While the embolic material *per se* does not induce greater liver hypertrophy, it does elicit atrophy, resulting in hypertrophy of the remnant liver (4).

Foam sclerotherapy has been used for more than 50 years to treat patients with lower extremity varicose veins (5). Viscous or creamy sclerosing agents can be expected to remain longer along the venous wall than liquid sclerosants and there is substantially less systemic spillage (6). Side effects decreased significantly when CO_2 rather than air was used to produce the sclerosing foam for the chemical ablation of superficial veins of the lower extremities (7,8).

The lower amount of EO in foam EOI plus CO_2 may decrease hemolysis. The purpose of this study was to investigate the clinical safety and effectiveness of foam sclerotherapy with foam EOI and CO_2 for PTPE in patients scheduled for extended hepatectomy.

Material and Methods

Patients

Our institutional review board approved this retrospective study; prior written informed consent was obtained from all patients (12 men, 3 women; age range, 59–80 years; mean age, 68 years). All underwent a preoperative indocyanine green (ICG) test that consisted of injecting 0.5 mg/kg of ICG into a peripheral vein. During the first 5–10 min post-injection we used a pulse spectrophotometer to determine the blood ICG concentration at each pulse interval. The clearance-rate constant and retention rate at 15 min (R15) were calculated automatically from the time course of the blood ICG concentration (8). PTPE before hepatic resection was indicated in patients whose ICG R15 was 10% or less, in patients whose non-tumorous volumetric resection rate was estimated to be greater than 65%, and in patients with an ICG R15 of 10–20% and an estimated non-tumorous volumetric resection rate greater than 40% (4,9).

Between September 2011 and December 2012, we performed 15 PTPE procedures on 15 consecutive patients (HCC, $n = 9$; bile duct carcinoma, $n = 5$; liver metastasis from colon cancer, $n = 1$). As shown in Table 1, all had a history of chronic liver disease; four (27%) with hepatitis B, three (20%) hepatitis C, and eight (53%) without any hepatitis virus. The hepatic reserve was evaluated using the Child-Pugh classification (10); 13 (87%) of the procedures were performed in patients recorded as Child-Pugh A and two (13%) in patients with Child-Pugh B. The median ICG R15 was 15.2% (range, 5.5–23.0%). The nine HCC patients who underwent multimodal therapy comprised combined PTPE and transarterial chemoembolization (TACE).

Angiography before PTPE

Pre-PTPE angiograms showed anatomic variants of the portal vein. We performed portal-venous C-arm

Table 1. Clinical characteristics of the 15 patients.

Case	Age (years(=)/Sex	Etiology	ICG R15 (%)	Child-Pugh classification	Primary disease
1	59/M	Hepatitis B virus	11.2	A	HCC
2	80/M	Neither B nor C	10.5	A	HCC
3	56/M	Hepatitis B virus	9.9	A	HCC
4	62/M	Hepatitis C virus	22.4	A	HCC
5	70/M	Neither B nor C	12.8	A	BD
6	79/M	Hepatitis C virus	19.9	A	BD
7	65/M	Hepatitis B virus	7.9	A	HCC
8	77/F	Hepatitis C virus	22.3	A	HCC
9	64/F	Neither B nor C	18.0	A	Meta
10	75/M	Neither B nor C	–	B	BD
11	61/M	Hepatitis B virus	23.0	B	HCC
12	64/M	Neither B nor C	20.9	A	HCC
13	64/M	Neither B nor C	–	A	BD
14	64/M	Neither B nor C	9.6	A	BD
15	72/M	Neither B nor C	5.5	A	HCC

BD, bile duct carcinoma; HCC, hepatocellular carcinoma; ICG R15, indocyanine green retention rate at 15 min; Meta., metastatic liver tumor from colon cancer.

computed tomography (CBCT) (portal-venous run, RC2 catheter in the superior mesenteric artery, 25 mL iomeprol diluted with saline for an iodine concentration of 150 mg/mL, 5 mL/s flow, 20 s delay). All CBCT scans were acquired with a biplanar angiography system (AXIOM Artis dBA; Siemens Medical Solutions, Forchheim, Germany) equipped with a 30×40-cm flat-panel detector. For the CBCT runs, we used the 10-s 1 k preset option (DynaCT; Siemens Medical Solutions). The acquisition time was 10 s, the total scan angle was 222°, and the projection increment 0.8°. We used a 1 k-matrix, a zoom of 0, a field of view (FOV) of 48 cm, and a system dose per pulse of 0.36 mGy. The raw datasets from the angiographic C-arm system were transmitted to a dedicated external workstation (X-Leonardo; Siemens Medical Solutions) for reconstruction to generate CBCT images. The volume dataset produced by the workstation had a typical voxel size of 0.4 mm. For all reconstructions we used the "bone smooth" reconstruction kernel with a large FOV and artifact reduction as recommended by the manufacturer of the angiographic system for abdominal CBCT images. With these parameters, the time for CBCT image reconstruction was in the range of 3 min 40 s to 5 min 10 s. Immediately after reconstruction, the images were simultaneously displayed on the external workstation and in the angiography suite in three orthogonal planes. In addition, the dataset was reformatted interactively using maximum-intensity projection and multiplanar reconstruction; the slice thickness was 5 mm. Window and level settings could be adjusted individually during viewing; manipulation in orthogonal and oblique planes was possible.

PTPE techniques

Percutaneous and transhepatic, ipsilateral, and balloon-occluded approaches were by standard procedures with the patients under local anesthesia and mildly sedated. As an occlusion catheter was required to prevent overflow of embolic materials we primarily used a 6-Fr Serecon 3-lumen catheter with a 12-mm balloon (Terumo Clinical Supply, Gifu, Japan) (4). The ipsilateral approach can prevent future vascular injury in the liver remnant. In all patients, the ipsilateral portal vein was punctured under ultrasonographic guidance (Fig. 1) and the embolic material was delivered through a side hole in the catheter under balloon occlusion (Fig. 2).

The embolic material was a mixture of foam sclerosant and gelatin sponges (4). The foam sclerosant was prepared by using a double syringe system method (11,12). Briefly, two 20-mL Luer-Lok syringes containing 5% EOI and CO_2 in a 1:2 ratio were connected through a three-way stopcock, and their content was mixed until a homogeneous foam was obtained; 5% EOI was the sclerosant and CO_2 was used for foam formation.

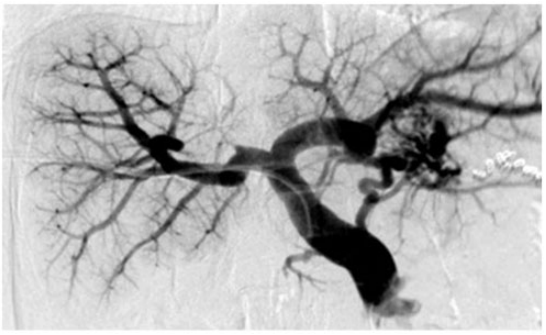

Fig. 1. Case 6. A 70-year-old man with bile duct carcinoma. Digital subtraction portography after the percutaneous approach shows the entire portal vein. The bifurcation of the right and left portal veins is clearly discernible.

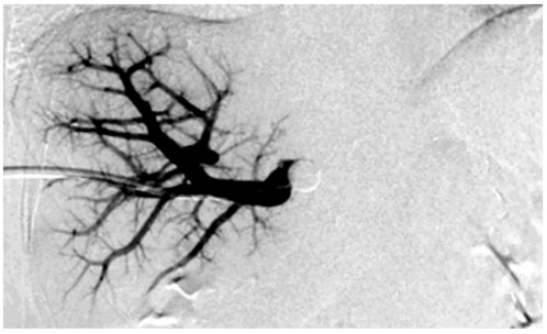

Fig. 2. Case 6. Balloon occlusion was performed in the right portal vein axis. The contrast materials and embolic agents were injected through the side hole of the triple-lumen catheter.

To reduce the mixture dose, before the injection of 5% EOI we carefully introduced 2-mm diameter gelatin sponge particles until the capacity of the peripheral portal vein was reached. The foam sclerosant was then injected slowly to perfuse the targeted portal vein. After 10-min occlusion of the vessel, the excess foam sclerosant was collected via the catheter. On completion of the procedure, the access tract was embolized with gelatin sponge particles through the vascular sheath. The procedures were performed under fluoroscopic guidance. During the procedure, each patient's blood pressure, pulse, electrocardiogram, and arterial oxygen saturation were monitored (Fig. 3).

Follow-up

The medical records of the 15 patients were reviewed. At the follow-up evaluation, we recorded incomplete obstruction and recanalization. Contrast-enhanced

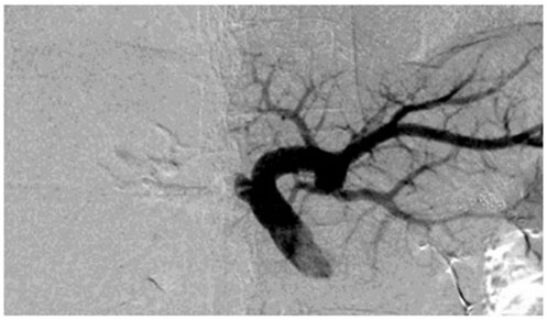

Fig. 3. Case 6. Digital subtraction portography after PTPE showed complete obstruction of the right portal vein.

dynamic CT images were obtained 1 week and 1 month after PTPE to evaluate its efficacy.

Technical success was defined as the complete obstruction of the target portal vein and an increase in the future liver remnant (FLR) volume on follow-up contrast-enhanced CT scans performed 1 week and 1 month after PTPE. Using standard laboratory methods, before and after PTPE hematologic and laboratory data such as the platelet count and the level of serum total bilirubin, albumin, aspartate aminotransferase (AST), alanine transaminase (ALT), creatinine, and the prothrombin time (PT) were recorded. Changes were calculated as the absolute difference between preoperative values and values recorded 1 month after PTPE.

Complications related to the interventional radiology techniques were classified as major and minor according to the reporting standards of the Society of Interventional Radiology (13).

Assessment of CT volumetry and outcome evaluation

Baseline contrast-enhanced CT imaging data were obtained at a mean of 10 days (range, 3–20 days) before PTPE. Follow-up imaging studies were performed at a mean of 30 days (range, 25–35 days) after PTPE using a 16-row multidetector CT unit (Symbia T16, Siemens Healthcare, Erlangen, Germany). The imaging parameters were 120 kV, 50 mA, 17.5 mm table feed per rotation, 0.7 s gantry rotation time, 1.25 mm collimation, and 1.25 mm reconstruction. The CT images for CT volumetry were obtained during the portal phase (65 s after the injection of 100 mL of 350 ug/mL iodine at 3 mL/s) after the injection of contrast media. On each image the whole liver volume (WLV), the tumor volume (TV) and the FLR were delineated manually with a cursor and their respective volumes were automatically calculated on the workstation (VertualPlace Fujin, AZE, Tokyo, Japan).

The total liver volume (TLV) was defined as the WLV minus the TV. The percent FLR (%FLR) was calculated using the formura;.

$$\%\mathrm{FLR} = \frac{\text{FLR Volume}}{\text{WLV} - \text{TV}} \times 100\%$$

The increase in FLR as a result of PTPE was defined as the FLR volume increase. The %FLR volume increase (Hypertrophy rate (%)) was calculated using the formula (4,14);

$$\%\text{FLR volume increase} = \frac{\%\mathrm{FLR}_{\text{post-PTPE}} - \%\mathrm{FLR}_{\text{pre-PTPE}}}{\%\mathrm{FLR}_{\text{pre-PTPE}}} \times 100\%$$

Statistical analysis

The results are expressed as the mean ± SD. The data were compared using the paired *t*- test. A *P* value of less than 0.05 was considered statistically significant. The StatView software program for Windows, Version 5.0 (SAS Institute, Cary, NC, USA), was used for statistical analyses.

Results

All 15 procedures were completed using the percutaneous and the transhepatic approach under local anesthesia. Balloon-occluded, ipsilateral approaches and balloon occlusion were successful in all patients. The amount of 5% EOI (range, 14–20 mL; median, 16.8 mL) was based on the volume of the target portal vein.

Our overall results are as follows: the PTPE site in 13 and two patients was the right and left portal veins, respectively; the mean volume of the 5% EOI used was 16.8 mL (range, 14–20 mL), and in one patient the child-Pugh classification changed from A to B after PTPE. Technical success was achieved in 14 of 15 patients (93%). All but one patient manifested an increase in FLR. In this patient (case 13) a technical failure was encountered. Although complete obstruction of the target portal vein just after PTPE was confirmed on portal venograms, 1 week later partial recanalization was observed on CT images. Repeating the procedure was difficult and this patient underwent scheduled hepatic resection 44 days post-PTPE, because the nontumorous volumetric resection ratio was adequate.

As shown in Table 2, there were no significant postoperative changes in the patients' mean platelet count, the level of total bilirubin, total albumin, total AST, total ALT, creatinine, and PT ($P > 0.05$).

All patients experienced mild abdominal pain and transient fever. We noted elevated ALT levels in five patients, in one patient total bilirubin was increased, total albumin was decreased in five patients as was the mean platelet count in three patients; in another patient, protrombin time (PT) was prolonged at less than grade 2. One patient (case 11) manifested intra-abdominal arterial bleeding at the puncture site that required transcatheter arterial embolization using detachable coils (interlocking detachable coils; Boston Scientific, Watertown, MA, USA). No other patients developed major complications above grade 3.

The FLR volume pre- and post-PTPE, and the %FLR volume increase are shown in Table 3.

Table 2. Laboratory data obtained before and after PTPE.

	Before	After	*P* value
Platelet count ($\times 10^3/mm^3$)	17.3 ± 7.1	14.9 ± 5.0	0.14
Total bilirubin (mg/dl)	1.14 ± 0.70	0.94 ± 0.38	0.21
Albumin (g/dl)	3.5 ± 0.5	3.6 ± 0.5	0.53
AST (IU/L)	44.7 ± 23.7	43.7 ± 24.4	0.91
ALT (IU/L)	48.1 ± 34.3	40.5 ± 20.5	0.23
PT (%)	94.3 ± 18.5	93.1 ± 20.5	0.44
Creatinine (mg/dl)	0.76 ± 0.18	0.73 ± 0.15	0.32

ALT, alanine transaminase; AST, aspartate aminotransferase; PT, prothrombin time.

After PTPE, the TLV decreased from $1319 \pm 314\,cm^3$ to $1249 \pm 301\,cm^3$, and the FLR volume increased from $599 \pm 342\,cm^3$ to $691 \pm 318\,cm^3$. The %FLR volume increase was $30 \pm 21\%$ and statistically significant ($P < 0.01$).

The clinical outcomes are shown in Table 3. In 12 of 15 patients (80%) an extended hepatectomy was performed post-PTPE. In one of the other three patients (case 5), excessive intraoperative bleeding occurred and he died from liver failure 1 month after extended hepatectomy. Two patients (cases 14 and 15) were inoperable because of celiac lymph node metastasis or severe aortic valve stenosis. In one HCC patient (case 4) the post-PTPE FLR volume was increased, but CT studies obtained during the follow-up period showed HCC in the ipsilateral lobe. It was treated palliatively by laparoscopic radiofrequency ablation.

Discussion

Different substances used for PTPE yielded similar results, although the rate and degree of hypertrophy of the un-embolized segment and of associated inflammation were somewhat different (2). Embolic materials include cyanoacrylate and iodized oil, fibrin glue and iodized oil, gelatin sponges and thrombin, metal coils and polyvinyl alcohol (PVA) particles, and gelatin sponges and absolute alcohol (15).

Liquid or foam detergents have also been used as sclerosing agents. Liquid sclerosants, especially EO,

Table 3. Overall results of pre- and post-PTPE, FLR volumes, hypertrophy rates, and clinical outcomes.

Case	FLR volume pre-PTPE (cm^3)	FLR volume post-PTPE (cm^3)	Hypertrophy rate (%)	Clinical outcome
1	443	469	12.2	Extended hepatectomy
2	525	723	40.7	Extended hepatectomy
3	638	876	33.9	Extended hepatectomy
4	730	820	21.1	Laparoscopic RFA
5	509	544	19.6	Extended hepatectomy*
6	522	645	30.2	Extended hepatectomy
7	226	342	52.8	Extended hepatectomy
8	785	787	5.4	Extended hepatectomy
9	184	352	90.2	Extended hepatectomy
10	564	654	23.8	Extended hepatectomy
11	463	592	32.5	Extended hepatectomy
12	1647	1671	4.9	Extended hepatectomy
13	850	833	11.0	Extended hepatectomy
14	390	491	33.3	Inoperable because of metastasis to celiac lymph
15	506	563	30.3	Inoperable because of severe aortic valve stenosis

*Excessive intraoperative bleeding.
FLR, future liver remnant; PTPE, percutaneous transhepatic portal embolization.

have been employed traditionally for balloon-occluded retrograde transvenous obliteration (BRTO) (16,17). According to Breu and Guggenbichler (18), larger the diameter of the vein, and more viscous foam will improve the results. The advantages of foam-over liquid sclerosants include the need for a smaller amount of sclerosant, maximization of the sclerotic effect by increasing the contact surface area by including the vessel wall, even distribution, and a decrease in the balloon inflation and procedure time. Koizumi et al. (6) performed BRTO with foam EO produced by mixing 20 mL of 5% EOI and 20 mL of air; we replaced the air with 40 mL of CO_2 and used gelatin sponge particles (4). As these particles are absorbable they tend to lead to recanalization even if used together with metallic coils or thrombin. Therefore, gelatin sponge particles were injected before the injection of 5% EOI to reduce the required amount of EOI. The ideal embolic material produces permanent embolization with infrequent recanalization, is well-tolerated, and is easy to administer. From this viewpoint, EOI is a suitable embolic agent for PTPE.

On the other hand, systemic complications such as pulmonary edema and acute renal failure can occur if EO passes into the systemic circulation from the injection site. Furthermore, the intravenous injection of EO may elicit thrombogenesis as a result of chemical damage to the vascular wall and some degree of nonspecific red blood cell hemolysis may occur. To prevent renal damage due to EO-induced hemolysis, the administration of haptoglobin may be necessary (19). The lower amount of EO in foam EOI plus CO_2 decreases the degree of hemolysis.

Others (4,20) who used thrombin plus gelatin sponge powder, fibrin, and 5% EOI plus gelatin sponges, have reported incomplete obstruction and recanalization rates of 33%, 7%, and 26%, respectively. In our series, the recanalization rate was 6.7%. In one patient with technical failure (case 13), pre-PTPE angiography showed the right portal vein trunk to be short and this portion may have been insufficiently embolized. Also, as we punctured the right posterior portal vein, embolization of the access tract may have been inadequate and 1 week after the procedure there was CT evidence of partial recanalization. This suggests that in patients whose target portal vein trunk is short, the contralateral approach should be used. Yan Lienden et al. (14) reported a mean %FLR volume increase of 38% (range, 21–69%); in our study, it was 30%. This discrepancy may be associated with the effect of cirrhosis and fibrosis in our patients, two of whom were recorded as Child-Pugh B.

Our study has some limitations. First, the small size of our study population precludes meaningful statistical analysis. Second, as our study was retrospective, we could not compare ours with treatment outcomes obtained with other embolic agents used for PTPE. Nonetheless, our study demonstrated that foam sclerotherapy with EO is efficacious and safe for PTPE.

In conclusion, foam EOI and CO_2 is a safe embolic material that induces greater liver hypertrophy in patients with liver tumors subjected to PTPE. Studies are underway to determine whether the lower sclerosant dose needed for foam sclerotherapy decreases the degree of hemolysis.

Conflict of interest

None declared.

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