Balloon-occluded Retrograde Transvenous Obliteration for Gastric Varices: Efficacy of Coaxial Double-balloon Catheter System

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Abstract ***Purpose:*** *To evaluate the efficacy of using a coaxial double-balloon catheter system (CDBCS) in balloon-occluded retrograde transvenous obliteration (BRTO) of gastric varices (GVs).*
Materials and Methods: *From January 2008 to December 2015, 37 consecutive patients (25 men and 12 women; mean age, 65.9 years; range, 44–88 years) who underwent BRTO of GVs via a gastrorenal shunt at three hospitals were retrospectively evaluated. Of 37 patients, CDBCS was used in 15 and a single-balloon catheter system (SBCS) was used in 22. Procedure durations and the amount of sclerosant used (5% ethanolamine oleate, EO) in the two groups were compared.*
Results: *The success rates of the CDBCS and SBCS groups were 93.3% and 95.6%, respectively. The procedure durations were significantly shorter in the CDBCS group (mean ± standard deviation, 2.9 ± 0.9 h) than in the SBCS group (3.7 ± 1.1 h; P = 0.03). However, the amount of 5% EO used was not significantly different between the two groups (CDBCS group, 20.1 ± 9.8 ml vs. SBCS group, 22.3 ± 10.7 ml; P = 0.54).*
Conclusion: *In BRTO of GVs, CDBCS appears to be effective for repairing GVs and shortens procedure duration.*

Keywords ; *Balloon-occluded retrograde transvenous obliteration, gastric varices, balloon catheter*

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Introduction

Since being first reported by Kanagawa et al. in 1991[1], balloon-occluded retrograde transvenous obliteration (BRTO) has been widely accepted as an effective and safe treatment modality of gastric varices (GVs)[2-5]. However, injecting liquid sclerosing agents into GVs is sometimes technically difficult because of leakages into collateral vessels such as the inferior phrenic and pericardiophrenic veins. In such situations, the embolization of collateral vessels is performed. However, this technique often requires the insertion of metallic coils and prolongs procedure duration.

Ethanolamine oleate (EO) has been widely used as a liquid sclerosing agent for BRTO in Japan. Severe complications, including renal tubular disturbances, cardiogenic shock, pulmonary edema, and disseminated intravascular coagulation, have been reported with the use of large amounts of EO. Therefore, the amount of EO used during BRTO should be as small as possible.

The coaxial double-balloon catheter system (CDBCS; Candis, Medikit, Tokyo, Japan), which was invented by Tanoue et al[6], is commercially available in Japan. This system comprises two 9- and 5-Fr balloon catheters that are made of natural rubber and that can be inflated to 20 mm (9 Fr) and 10 mm (5 Fr) maximum diameters. Using this system, advancing the balloon catheter beyond the collateral vessels is often possible. As a result, the amount of liquid screlosing agent can be reduced, and redundant coil embolization of collateral vessels can be avoided.

To date, to the best of our knowledge, no other published studies have investigated the efficacy of

Table 1 Clinical Features of Patients

	CDBCS group	SBCS group	p value
No. of patients	15	22	
Age (y) ※	68.3±9.8 (44–88)	64.2±9.1 (48–81)	0.20
Sex			0.54
Men	11	14	
Women	4	8	
Underlying liver disease			NA
Hepatitis C	5	14	
Hepatitis B	1	1	
Alcoholic liver disease	5	3	
Others	4	4	
Hirota classification			0.78
Grade 1	2	3	
Grade 2	1	4	
Grade 3	6	7	
Grade 4	6	8	
Grade 5	0	0	
Variceal rupture	4/15 (26.7%)	4/22 (18.2%)	0.54

Note. - CDBCS = coaxial double balloon catheter system, SBCS = single balloon catheter system.
※ Data are means ± standard deviation, with the range in parentheses.

CDBCS compared with that of conventional single-balloon catheter system (SBCS) in a relatively large number of patients. Thus, the purpose of our study was to assess the relative efficacy of CDBCS in BRTO of GVs.

Materials and Methods

Patients

This study was approved by the institutional review boards of the three participating hospitals. The requirement for written informed consent was waived because of the retrospective nature of the investigation.

Thirty-seven consecutive patients (25 men and 12 women; mean age, 65.9 years; range, 44–88 years) who underwent BRTO of GVs via a gastrorenal shunt in three hospitals from January 2008 to December 2015 were included. Of 37 patients, CDBCS was used in 15 and conventional SBCS was used in 22. Emergency BRTO was performed for ruptured GVs in eight patients (four in each group). Baseline demographic and clinical characteristics of each group are presented in Table 1.

BRTO procedures

BRTO was performed by one of the five experienced interventional radiologists in the three participating hospitals. BRTO selection with CDBCS or SBCS was decided based on the discretion of each operator. BRTO techniques were almost the same for each operator as follows. After puncturing the right femoral vein or right internal jugular vein under local anesthesia, a 6–10-Fr curved sheath introducer (Medikit, Tokyo, Japan; Terumo Clinical Supply, Gifu, Japan) was inserted into the right renal vein. In patients in whom conventional SBCS was employed, a 6-Fr balloon catheter with a 20-mm balloon diameter (Selecon MP Catheter II; Terumo Clinical Supply, Gifu, Japan) was advanced into the gastrorenal shunt. In patients using CDBCS with 9- and 5-Fr balloon catheters (Figure 1), the 9-Fr balloon catheter was positioned at the shunt outlet and the 5-Fr coaxial balloon was advanced as close as possible

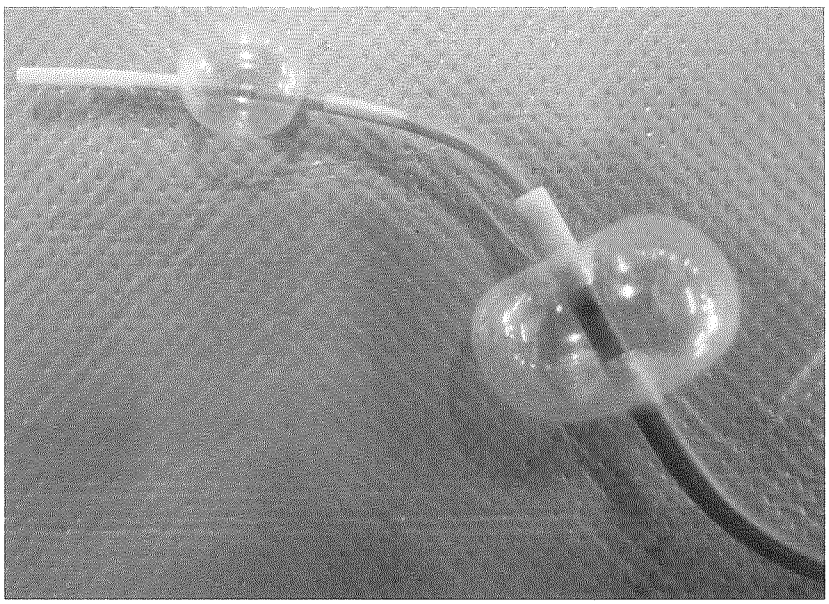

Figure 1 Coaxial double-balloon catheter system. This system comprises a stiff 9-Fr guiding balloon catheter and a flexible 5-Fr coaxial balloon catheter, which can be inflated to 20- and 10-mm maximum diameter, respectively.

to GVs. Balloon-occluded retrograde venography was performed to visualize the target GVs and collateral pathways such as the inferior phrenic and pericardiophrenic veins. If copious amounts of contrast medium drained into any collateral veins, coil embolization of those vessels was performed to prevent the leakage of the liquid screlosing agent into the systemic circulation. The sclerosant was a 5% solution of ethanolamine oleate (EO) that was prepared by diluting a stock solution of 10% EO (Oldamin, Asuka Pharmaceutical, Tokyo, Japan) with an equivalent amount of iodinated contrast medium. Contrast agents employed were either Iopamiron 300 (Bayer, Osaka, Japan), Iomeron 350 (Eisai, Tokyo, Japan), or Omnipaque 300 (Daiichi-Sankyo, Tokyo, Japan). To prevent renal failure because of EO-related hemolysis, 4000 U of haptoglobin (Green Cross, Osaka, Japan) were intravenously administered during BRTO[7].

During balloon occlusion, 5% EO was slowly administered either through a balloon catheter or coaxially inserted microcatheter until GVs were completely filled. Retrograde venography was performed at 4 hours after administering EO to confirm GV thrombosis. If GV thrombosis was insufficient, additional 5% EO was administered, and balloon catheters were placed overnight. After confirming complete GV thrombosis, the balloon was deflated, and the balloon catheters and sheath introducer were withdrawn.

A representative case of GVs treated with BRTO using CDBCS is shown in Figure 2.

Investigated parameters

For each system, we investigated the technical success rate of the procedure, procedure duration, amount of 5% EO used, whether coil embolization was necessary, the number of metallic coils required, and whether a microcatheter was employed. We defined the duration of the procedure as the period between the entrance into and the first exit from the procedure room. In addition, we investigated the cost of the devices in each group, including the sheath, catheter, guidewire, balloon catheter, and coil. The price of these devices was based on the insurance redemption price in April 2016.

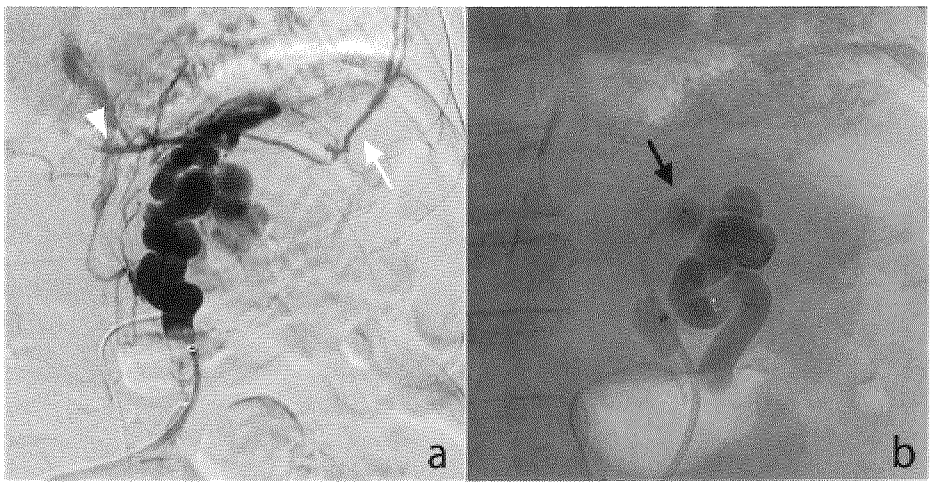

Figure 2 Retrograde transvenous venogram (BRTV) in an 80-year-old man with gastric varices who was treated by balloon-occluded retrograde transvenous obliteration (BRTO) using the coaxial double-balloon catheter system. (a) BRTV during the occlusion of the exit of the gastrorenal shunt by the larger balloon shows only partial filling of gastric varices (GVs) with the contrast medium because of leakage into the pericardiophrenic vein (white arrow) and inferior phrenic vein (white arrowhead). (b) BRTV with the smaller balloon catheter deeply inserted over these collateral veins (black arrow) shows good GV visualization; accordingly, GVs were completely thrombosed using only 5 ml of 5% EO.

The grading system suggested by Hirota et al.[8], based on the degree of GV visualization according to retrograde venography findings during balloon occlusion, was used to score GVs and collateral vein.

Statistical analysis

The investigated parameters in each system were statistically analyzed using Student's t-test or chi-square test. All statistical analyses were performed using a software (Excel2016, Microsoft, USA). P values of <0.05 were considered to be statistically significant.

Results

As shown in Table 1, there was no significant difference in clinical background between the two groups.

BRTO of GVs was successful in 14 of 15 patients (93.3%) in the CDBCS group and 21 of 22 patients (95.6%) in the SBCS group. This difference in success rates was not statistically significant (P = 0.78). In the two unsuccessful cases, the gastrorenal shunts were too tortuous to advance the balloon catheter close to GVs. In addition, because there were some collateral pathways, which were hard to occlude, EO could not be retained in GVs.

Table 2 shows data for the two different catheterization systems. The amount of 5% EO used when CDBCS was employed was 5–35 ml (mean, 20.1 ml), and the amount used when conventional SBCS was used was 7–40 ml (mean, 22.3 ml). The mean amounts of 5% EO used in the two groups were not significantly different from each other (P = 0.54; Figure 3).

In patients in whom CDBCS was used, procedure durations ranged from 1.6 to 4.8 hours (mean, 2.9 hours), while in those in whom SBCS was used, procedure durations ranged from 2.0 to 5.8 hours (mean, 3.7 hours). The mean procedure durations for the two groups were significantly different from each other (P = 0.03; Figure 4). The device cost was 151810–326610 yen (mean, 205024 yen) in the CDBCS group and 37320–188520 yen (mean, 83120 yen) in the SBCS group. The mean device cost was significantly different between the two groups (P < 0.01).

Procedure-related complications were not observed in both the groups.

Table 2 Procedual Data of BRTO

	CDBCS group	SBCS group	p value
Amount of 5% EO (mL) *	20.1±9.8 (5–35)	22.3±10.7 (7–40)	0.54
No. of metallic coils *	1.1±2.7 (0–10)	0.8±1.9 (0–8)	0.80
Use of metallic coil			0.87
Yes	3	5	
No	11	16	
Use of microcatheter			0.88
Yes	9	14	
No	5	7	
Procedure duration (hour) *	2.9±0.9 (1.6–4.8)	3.7±1.1 (2.0–5.6)	0.03
Device cost (yen) *	205024±46788 (151810–326610)	83120±41219 (37320–188520)	<0.01

Note. - BRTO = balloon-occluded retrograde transvenous obliteration, CDBCS = coaxial double balloon catheter system, SBCS = single balloon catheter system, EO = ethanolamine oleate.

* Data are means ± standard deviation, with the range in parentheses.

Discussion

In patients with portal hypertension, collateral pathways for blood flow can develop anywhere, with GVs being one of the most popular. Treatment options for GVs include operative procedures, endoscopic procedures, transjugular intrahepatic portosystemic shunts, percutaneous transhepatic obliteration, and BRTO. In the past two decades, BRTO has become a popular procedure in Asian countries, particularly Japan, and new techniques and devices for BRTO have been concurrently developed, including CDBCS[6,9,10].

CDBCS comprises a 9-Fr guiding balloon catheter that has a stiff shaft and a 5-Fr coaxial balloon catheter with a flexible shaft. This 5-Fr catheter may more easily advance beyond the collateral vessels than conventional SBCS; therefore, the time required for coil embolization of collateral vessels may be reduced. This is most likely the main reason for the shorter procedural durations with CDBCS compared with SBCS in this study.

In this study, there was no statistical difference in the amount of EO used between the two groups. The amount of EO used for CDBCS in this study was approximately equivalent to that in the study by Tanoue et al.[6], with the amount ranging from 3 to 34 ml (mean, 18.75 ml). However, compared with CDBCS, relatively large amounts of EO were used for conventional SBCS as reported by Koito et al.[11] range, 20–60 ml; mean, 33.5 ml) and Takahashi et al.[12](range 16–35 ml; mean, 25 ml). These results may indicate that there is an effective reduction in the amount of EO used for CDBCS. Although the total amount of EO may depend on the vascular space, as determined by the anatomical structure, the 5-Fr coaxial balloon catheter tip of CDBCS may reach the more proximal portion of GVs than that of conventional SBCS because of its flexible shaft and the backup force of the 9-Fr guiding balloon catheter. Therefore, we speculate that in some cases, CDBCS could reduce the amount of EO compared with SBCS.

A potential disadvantage of CDBCS is the large diameter of the guiding catheter (9 Fr). While no procedural complications, such as puncture site hematomas or bleeding caused by vascular injury, occurred in any of the patients included in this study, decreasing the size of the system would make BRTO safer and less invasive. Moreover, CDBCS

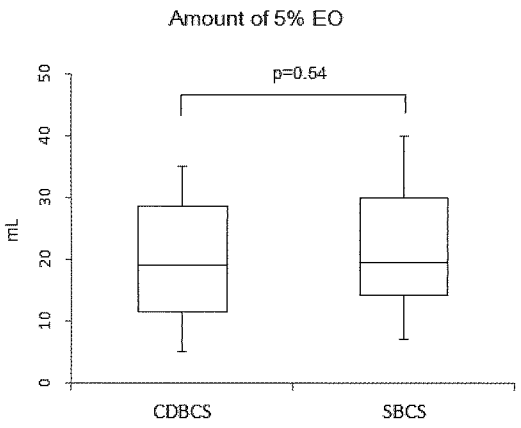

Figure 3 Box plots of the amount of 5% ethanolamine oleate (EO) used for the coaxial double-balloon catheter system (CDBCS) and single-balloon catheter system (SBCS) groups.

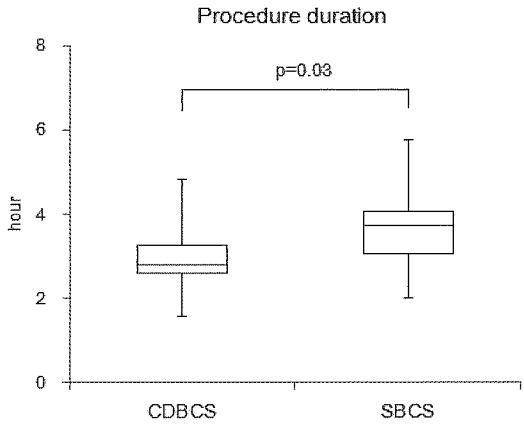

Figure 4 Box plots of procedure duration for the coaxial double-balloon catheter system (CDBCS) and single-balloon catheter system (SBCS) groups.

with smaller sized, more flexible, and easier to follow catheters can make reaching the more proximal portion of GVs easier. Accordingly, the amount of EO used in CDBCS may be reduced.

Another potential disadvantage of CDBCS is its higher cost. The double-balloon catheter system is approximately ten times more expensive than the conventional single-balloon catheter system. The price difference is nearly equivalent to that of ten pushable coils.

Our study has some limitations. First, this study was not a randomized controlled trial. Second, the sample size may be too small to detect subtle yet important differences between the two systems. Third, the procedures were performed by five different interventional radiologists; thus, procedure durations and the amount of EO used may have been influenced by their different skill levels and preferences.

In conclusion, this retrospective study found that using CDBCS is safe and effective in BRTO of GVs as it may shorten procedure durations; however, a prospective randomized study with a larger sample size will be necessary to confirm these findings. Furthermore, CDBCS with a slenderer and more flexible guiding catheter needs to be developed.

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