



Is salvage Plug-Assisted Retrograde Transvenous Obliteration (PARTO) safe and effective for bleeding gastric varices ?- A preliminary single-center experience

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Abstract

Background Vascular plug-assisted retrograde transvenous obliteration (PARTO) obliterates the gastric varices and porto-systemic shunt, thus resulting in a lower rebleeding rate than endoscopic glue/sclerotherapy.

Aims To evaluate the safety and efficacy of PARTO as salvage therapy in liver cirrhosis with gastric variceal bleed (GVB) after failed endotherapy. We assessed the clinical success rate and changes in liver function at 6- months.

Materials and methods Patients who underwent salvage PARTO after failed endotherapy for GVB (between December 2021 and November 2022) were searched and analyzed from the hospital database. Clinical success rate and rebleed rate were obtained at six months. Child–Pugh score (CTP) and Model for end-stage liver disease (MELD) score were calculated and compared between baseline and 6-month follow-up.

Results Fourteen patients (n = 14, Child–Pugh class A/B) underwent salvage PARTO. Nine had GOV-2, and five had IGV-1 varices. The mean shunt diameter was 11.6 ± 1.6 mm. The clinical success rate of PARTO was 100% (no recurrent gastric variceal hemorrhage within six months). No significant deterioration in CTP (6.79 ± 0.98 vs. 6.21 ± 1.52 ; $p = 0.12$) and MELD scores (11.5 ± 4.05 vs. 10.21 ± 3.19 ; $p = 0.36$) was noted at 6 months. All patients were alive at 6 months. One patient (n = 1, 7.1%) bled from esophageal varices after three days of PARTO and was managed with variceal banding. 21.4% (3/14) patients had progression of esophageal varices at 6 months requiring prophylactic band ligation. Three patients (21.4%) had new onset or worsening ascites and responded to low-dose diuretics therapy.

Conclusions PARTO is a safe and effective procedure for bleeding gastric varices without any deterioration in liver function even after six months. Patient selection is critical to prevent complications. Further prospective studies with larger sample size are required to validate our findings.

Keywords PARTO · Vascular plug · Retrograde transvenous obliteration · Gastrorenal shunt · Bleeding gastric varices · Salvage · Cirrhosis · Portal hypertension

Introduction

Gastric variceal bleeding (GVB) accounts for 10–30% of all variceal bleeds in patients with liver cirrhosis. Although gastric varices bleed less frequently than esophageal varices, it has a higher risk of uncontrolled bleeding, higher transfusion requirements, rebleeding, and death than esophageal varices (EVs) [1]. Endoscopic glue therapy (N-butyl cyanoacrylate) is considered the treatment of choice for bleeding gastric

varices but with a rebleeding rate of 8–28% [2]. Transjugular intrahepatic portosystemic shunt (TIPS) is not considered an effective intervention in controlling GVB since gastric varices bleed even at lower portal pressure. Therefore, TIPS is usually combined with variceal embolization in the case of GVB [3]. However, TIPS deteriorates hepatic function and aggravates hepatic encephalopathy. Retrograde variceal obliteration (RVO) seems very useful in secondary prophylaxis of GOV2 and IGV1 varices associated with a gastrorenal shunt. Techniques of RVO include balloon (BRTO)/vascular plug (PARTO) or coil (CATRO) assisted retrograde transvenous obliteration. RVO exhibits a lower rebleeding

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rate than endoscopic glue therapy [4]. Compared to BRTO, PARTO utilizes a vascular plug to occlude the gastric renal shunt, reducing post-procedural monitoring time and eliminating the risk of balloon rupture, as seen with BRTO [5].

BRTO has already been used as salvage therapy in GVB; however, data regarding PARTO as salvage therapy in bleeding gastric varices are lacking [6, 7]. This study aims to evaluate the safety and efficacy of salvage PARTO after failed endotherapy in bleeding gastric varices.

Materials and methods

It was a retrospective study with relevant data collected from an ongoing prospective project approved by our Institutional review board (T/IM-F/22–23/14). Medical records of all patients with liver cirrhosis who underwent salvage PARTO after failed endotherapy for bleeding gastric varices (diagnosed on upper GI endoscopy) from December 2021 to November 2022 were analyzed. Due to its retrospective nature, written informed consent was waived. Patients with a minimum follow-up of 6 months were included in the study. All patients underwent a triple-phase CT of the abdomen after endoscopy to assess the feasibility of PARTO. Patients not feasible for PARTO were offered TIPS with variceal embolization. A total of 14 patients were included in the study. All cases of PARTO were performed within 24 h of endoscopic diagnosis of bleeding gastric varices. All patients received resuscitative measures and other standard therapy per the recommended treatment guidelines. The standard treatment algorithm for acute GVB is summarized in Fig. 1.

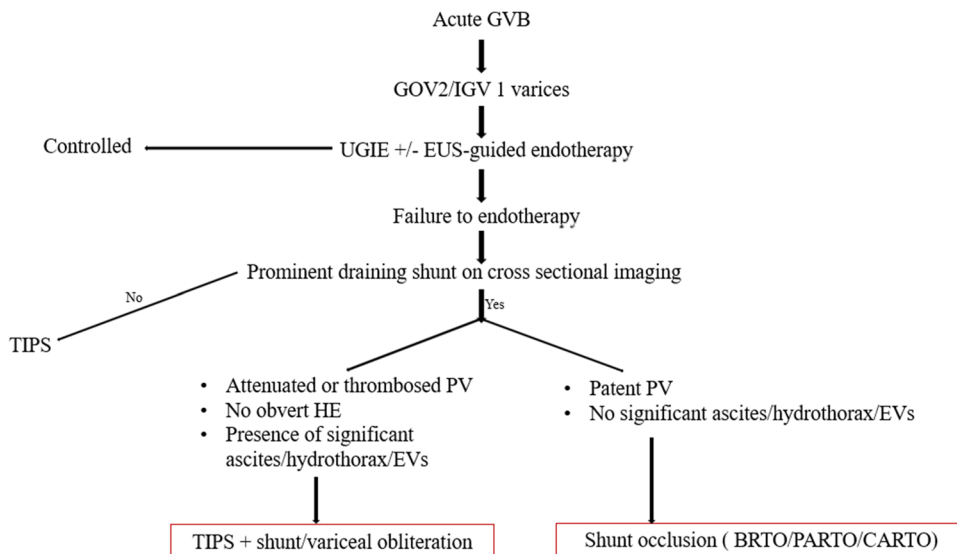
The primary endpoint was to determine the rebleed rate after salvage PARTO. Secondary endpoints were to

determine the effects of PARTO on hepatic reserve and function at six months and transplantation-free survival rate at six months. Clinical success was defined as no recurrent gastric variceal bleeding and/or complete shunt obliteration on follow-up imaging /endoscopy.

PARTO procedure

After written informed consent, all PARTO procedures were performed in the interventional radiology (IR) suite of the radiology department under local anesthesia and analgesia (Paracetamol). PARTO was performed via the right femoral or right internal jugular vein. The gastrosplenic shunt was cannulated via the left renal vein using a 5F angiographic catheter/0.035" hydrophilic guidewire combination. Over a 0.035" J-tipped stiff guidewire (Cook), an 8F or 10F long vascular sheath was advanced into the shunt. A 2.7Fr microcatheter was advanced into the shunt. Keeping a microcatheter ahead, an appropriate-sized vascular plug (oversizing by 30–50%, Cera vascular plug, LifeTech) was deployed at the narrowest point of the shunt near drainage into the left renal vein. A thick gelfoam slurry was injected through the microcatheter to block the crevices in the mesh of the vascular plug. Once adequate stasis is achieved within the shunt, a mixture of Lipiodol, 3% sodium tetradecyl sulfate, and air in a ratio of 1:2:3 was injected into the shunt. In all cases, 10–15 ml of sclerosant mixture was used (Figs. 2 and 3). The endpoint of embolization was decided based on Cone-beam CT (CBCT) findings. Embolization was considered complete when there was an adequate spread of sclerosant mixture through the entire varices and shunt, as seen on intraprocedural CBCT. PARTO procedure-related complications were defined per the Society of Interventional Radiology (SIR) guidelines [8].

Fig. 1 Treatment algorithm for management of acute gastric variceal bleed. UGIE = Upper GI endoscopy, EUS = Endoscopic ultrasound, TIPS = Transjugular intrahepatic portosystemic shunt, PV = portal vein, HE = hepatic encephalopathy, EV = esophageal varices, BRTO = balloon occluded transvenous obliteration, PARTO = Plug-assisted transvenous obliteration, CARTO = Coil-assisted transvenous obliteration of varices



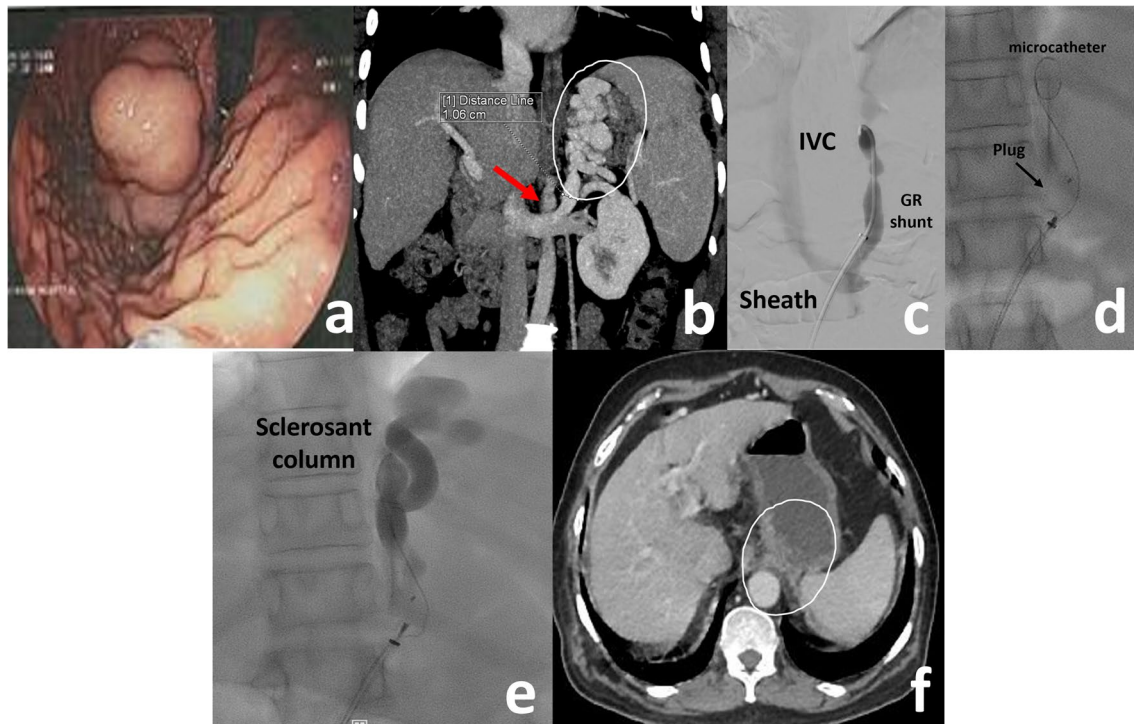


Fig. 2 A) Endoscopy image shows a large fundal varix (F3) with signs of recent hemorrhage; (b) coronal CT portal venous phase shows dilated tortuous fundal varices (white circle b) with a dominant gastorenal shunt (red arrow b). PARTO was planned; (c) Venogram showing cannulation of gastorenal shunt, followed by insertion of an 8F sheath into the shunt; (d) deployment of a 16 mm vascular

plug keeping a 2.7F microcatheter ahead of the plug within the shunt; (e) Instillation of a mixture of air, sclerosant, and lipiodol into the shunt and varices to obliterate the varices; (f) Follow up CECT at three months showing complete obliteration of the varices (white circle f)

The portal and renal vein patency and ascites were evaluated using USG regularly during the hospital stay following PARTO. Ultrasound screening was thereafter performed at follow-ups at 1, 3, and 6 months. A triple-phase CT was also performed at 3 and 6 months to evaluate the shunt status. Endoscopic examination was performed at 1, 3, and 6 months to evaluate the GV status in the form of complete/partial obliteration or recurrence and to assess any progression of EVs. CTP, MELD, albumin, bilirubin, and INR values were noted before the procedure and at six months.

Results

A total of 14 patients who underwent salvage PARTO were included and analyzed further.

Patient demography and baseline parameters

The baseline characteristics have been summarized in Table 1. Of 14 patients, 12 were male, and two were female, with a mean age of 41 ± 12 years. Alcohol was the most

common etiology of cirrhosis ($n=4$, 28.6%). PARTO was performed via the right femoral venous approach in 11 patients and the right internal jugular venous approach in 3 patients.

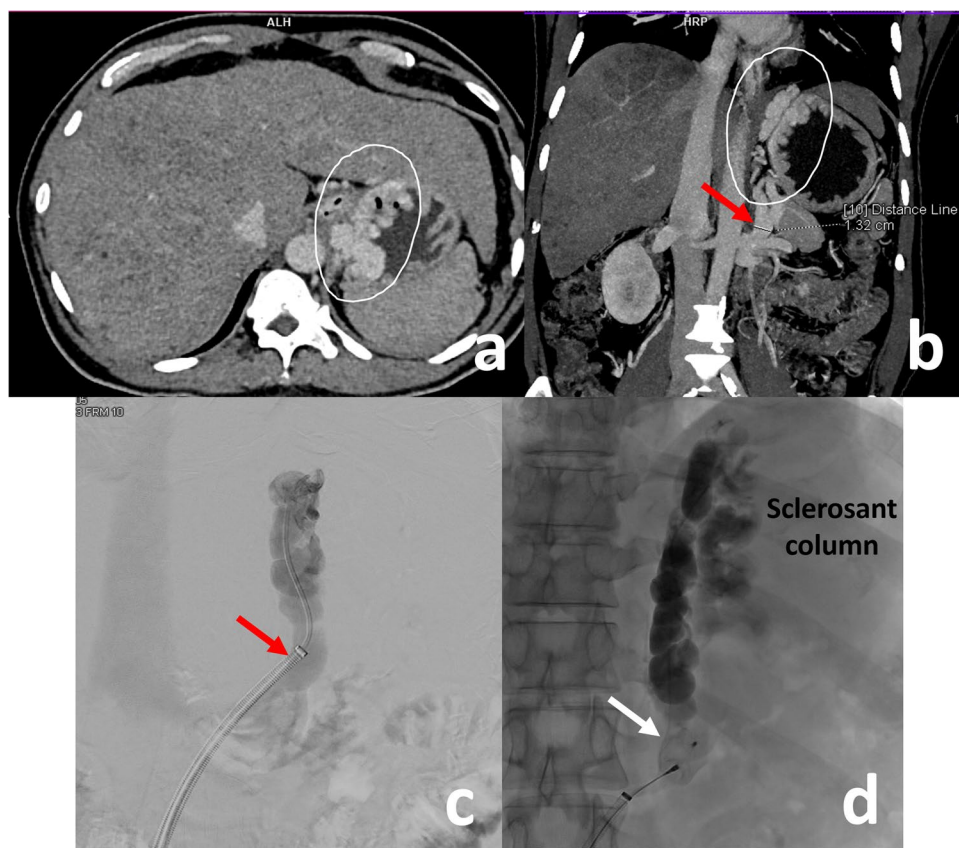
The baseline hemoglobin level of the cohort was 7.9 ± 1.75 gm/dl. All patients were either Child Class A ($n=5$, 35.7%) or Child Class B ($n=9$, 64.3%), with a mean CTP score of 6.79 ± 0.98 . The mean MELD score was 11.5 ± 4.05 . Three patients had grade 1 ascites. Of 3 patients, 2 had grade 1, and 1 had grade 2 hepatic encephalopathy (HE) at baseline.

While nine patients had GOV 2 varix, the remaining five had IGV 1 varix (Sarin Classification). The mean gastorenal (GR) shunt diameter was 11.6 ± 1.6 mm.

Outcomes at six months in terms of hepatic reserve and functions

Serum albumin, bilirubin, INR, and serum sodium levels showed no significant changes at six months following PARTO. There was a slight improvement in CTP (6.79 ± 0.98 to 6.21 ± 1.52 ; $p=0.120$) and MELD

Fig. 3 **A)** Axial and **(b)** coronal MIP CT portal venous phase shows dilated tortuous fundal varices (**white circle a, b**) with a dominant gastrorenal shunt of 13 mm (**red arrow b**). PARTO was planned; **(c)** Venogram showing cannulation of gastrorenal shunt, followed by insertion of an 8F sheath into the shunt; **(d)** deployment of a 16 mm vascular plug (**white arrow d**) followed by instillation of a mixture of air, sclerosant, and lipiodol into the shunt and varices to obliterate the varices



(11.5 ± 4.05 to 10.21 ± 3.19 ; $p = 0.363$) scores; however, it was statistically insignificant. One patient progressed to Child Class C (CTP score- 8 to 11) and had grade 2 ascites and grade 1 hepatic encephalopathy at six months. Comparison between baseline and 6-months is enlisted in Table 2.

Clinical success rate and survival outcomes

The technical success rate was 100%. The clinical success rate was also 100%, i.e., no further bleeding from the gastric varices till six months of PARTO. All patients were alive at six months (Transplant free survival-100%).

Complications

A GR shunt ruptured in one patient during the procedure and was seen as persistent contrast staining. However, the procedure was completed successfully without worsening hemodynamic instability or needing further intervention. Another patient developed bleeding from esophageal varices on the 3rd day of PARTO, managed with endoscopic variceal ligation. 3 of 14 patients had new onset minimal ascites or worsening of ascites after PARTO. All of them responded to low-dose diuretic therapy.

In addition, 3 out of 14 patients (21.4%) had worsening EVs necessitating endoscopic variceal ligation by six months.

Discussion

Despite being the choice of treatment, endoscopic glue therapy may not always be successful due to several factors, including an inability to obtain a stable endoscope in a retroflexed position, retching, and patient's mobility while performing the procedure without adequate sedation and analgesia (a limiting factor where anesthetist is not available around the clock) and blood within the gastric lumen obscuring the view in case of active variceal bleeding [9, 10].

BRTO/PARTO can be used as an alternative to glue therapy. A recent randomized control trial (RCT) comparing endoscopic glue therapy vs. BRTO demonstrated a significantly lower rebleeding rate among the BRTO group at 1 and 2 years. Additionally, BRTO resulted in fewer hospitalizations, inpatient stays, and lower medical costs [11]. Another study by Choe et al. also revealed a lower bleeding rate in the BRTO group than in those who received glue therapy for primary prophylaxis of gastric varices [4].

BRTO and PARTO have similar technical and clinical success rates. The technical and clinical success rates of

Table 1 Patient demographics and baseline parameters (n = 14)

Variables	Values
Age (years)	41 ± 12
Gender (M:F)	12 (85.7%): 2 (14.3%)
Etiology of cirrhosis	
Alcoholic	4 (28.6%)
Autoimmune	2 (14.3%)
NASH	3 (21.4%)
HBV/HCV related	3 (21.4%)
Others	2 (14.3%)
Hemoglobin (gm/dl)	7.9 ± 1.75
Serum albumin (gm/dl)	3.05 ± 0.42
Serum total bilirubin (mg/dl)	1.27 ± 0.44
Total platelet counts	125.07 ± 43.22
INR	1.33 ± 0.28
Creatinine (mg/dl)	0.86 ± 0.16
Serum Na + (mEq/L)	134.64 ± 4.5
Child Pugh Class (A/B/C)	5 (35.7%)/9 (64.3%)/0
CTP score	6.79 ± 0.98
MELD score	11.5 ± 4.05
Types of gastric varices	
GOV 2	9 (64.3%)
IGV 1	5 (35.7%)
Shunt diameter (mm)	11.6 ± 1.6

NASH Non-alcoholic steatohepatitis, INR International Normalized Ratio, CTP Child Tourette Pugh score, MELD Model for End-stage Liver Diseases, GOV Gastroesophageal varices, IGV Isolated gastric varices

Table 2 Comparisons of parameters between baseline and at 6 months follow-up

Variables	Baseline	At 6-month	p-value
Serum albumin (gm/dl)	3.05 ± 0.42	3.3 ± 0.41	0.056
Serum total bilirubin (mg/dl)	1.27 ± 0.44	1.12 ± 0.19	0.124
INR	1.33 ± 0.28	1.29 ± 0.23	0.652
Creatinine (mg/dl)	0.86 ± 0.16	0.89 ± 0.13	0.102
Serum Na + (mEq/L)	134.64 ± 4.5	135.3 ± 4.43	0.508
MELD score	11.5 ± 4.05	10.21 ± 3.19	0.363
CTP score	6.79 ± 0.98	6.21 ± 1.52	0.120
Child Pugh class (A/B/C)	5/9/0	11/2/1	

INR International Normalized Ratio, CTP Child Tourette Pugh score, MELD Model for End-stage Liver Diseases

BRTO are 79%–100% and 91%–100%, respectively, while those of PARTO are 94.7%–100% and 90.6%–100%, respectively [5]. Considering a shorter procedure time and no risk of balloon rupture, PARTO is preferred over BRTO wherever feasible. Although advancing the sheath into the shunt is a rate-limiting step in PARTO, newer available hardwires have increased the over-procedural success rate [12].

BRTO has emerged as a salvage measure to control bleeding from gastric varices in failed endoscopic glue therapy cases. Mukund et al. (n = 52) reported a technical success rate of 100% with a clinical success rate of 92.3% at a 12-month follow-up in their study on salvage BRTO including 52 patients [6]. Only one patient had recurrent bleeding. Khera et al. (n = 12) also demonstrated the feasibility and efficacy of BRTO in the setting of acute variceal bleeding. BRTO was performed successfully in all but one. Rebleeding was seen only in 2 (16.7%) patients [7].

Furthermore, Arai et al. and Chikamori et al. stated the role and effectiveness of emergency BRTO in the case of gastric varices. However, BRTO in both studies was performed after endoscopic control of gastric variceal bleeding to prevent rebleed; hence, their data do not reflect the real emergent situation [13, 14]. The data on the safety and efficacy of salvage PARTO is lacking. In our study, all patients achieved hemostasis from the gastric varices following PARTO with no rebleeding from the gastric varices at the 6-month follow-up. Unlike the aforementioned study, we used CBCT to decide the endpoint of embolization, which could have led to adequate embolization in our patients and, hence, no rebleeding even after six months. Our study cohort had 100% transplantation-free survival at six months. This could be explained by the present cohort's relatively preserved hepatic function, as reflected by Child Class A/B. No one had Child Class C cirrhosis.

Shunt closure diverts the flow toward the liver. Several studies have shown an improvement in synthetic hepatic function (improvement in CTP score, MELD score, serum bilirubin, and albumin levels) following shunt occlusion [15–18]. Shunt occlusion is also shown to improve liver volume [18]. Interestingly, patients with a Child class of B/C exhibit greater improvement in hepatic function than those in Child Class A [17]. Although our study showed a slight improvement in CTP and MELD scores at six months, it was not statistically significant. Unlike other studies, there was no significant improvement in liver function at six months in the present study, which could be due to a smaller sample size and the presence of only Child Class A/B cirrhosis.

PARTO worsens portal hypertension and results in aggravation of the esophageal varices. It might cause a new onset or worsening of ascites [17, 19]. One of our patients developed esophageal variceal bleeding on 3rd day of PARTO, necessitating emergent variceal banding. 3/14 (21.4%) patients showed new onset or worsening of ascites at six months of PARTO. Fortunately, all responded to diuretic therapy without any need for paracentesis. The reported rate of EVs aggravation following shunt occlusion ranges from 20 to 53% [15–17, 19]. Our study showed a worsening of EVs in 21.4% (n = 3/14) of patients. This might be due to lower baseline portal pressure in the present study group.

The current study has a few limitations. This is a retrospective study with only a small sample size. Selection bias could have occurred due to the retrospective nature. It includes only a short-term (6 months) follow-up without any long-term follow-up. Our study included only Child Class A/B without Child C patients, which could have influenced our results. In addition, this is a single institutional study, and the patients might not represent all the characteristics of patients with gastrosplenic shunts and gastric varices. A prospective study with a larger cohort and long-term follow-up is required to validate our findings externally.

Conclusions

Pre-procedural CT is a must to evaluate the vascular anatomy and technical feasibility of PARTO. In Child Class A/B, salvage PARTO is safe and effective for bleeding gastric varices without any deterioration of liver function, even at six months. Appropriate patient selection is very crucial for optimal outcomes.

Abbreviations GVB: Gastric variceal bleeding; EVs: Esophageal varices; TIPS: Transjugular intrahepatic portosystemic shunt; RVO: Retrograde variceal obliteration; GOV 2: Gastroesophageal varices type 2; IGV 1: Isolated gastric varices type 1; BRTO: Balloon-assisted retrograde transvenous obliteration; PARTO: Plug-assisted retrograde transvenous obliteration; CARTO: Coil-assisted retrograde transvenous obliteration; CT: Computed tomography; F: French; CBCT: Cone beam CT; SIR: Society of Interventional radiology; USG: Ultrasonography; GV: Gastric varices; CTP: Child Pugh score; MELD: Model for end-stage liver disease; INR: International normalized ratio

Authors' contribution RKP and TP contributed to the design, concept, data collection, and manuscript writing.

MKP, HKN, and SCS contributed to the concept and critical review.

NDB, BP, TD and SG contributed to the design, concept, data analysis, manuscript writing, and critical review.

SG, SM and SN and PSM contributed to statistical analysis and editing.

All authors approved the final version to be published.

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Data Availability Data will be made available on demand.

Declarations

Informed consent Written informed consent was taken for the PARTO procedure; however, consent was waived off for the study due to its retrospective nature.

Ethical approval IRB waived the ethical approval due to retrospective nature of the study.

Conflict of interests None.

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