의학석사 학위논문

위 정맥류 출혈의 치료에서 sodium tetradecyl sulfate (STS) foam 을 사용한 플러그 보조 역행성 경정맥 폐쇄술의 안전성과 효과 평가

Safety and effectiveness of plug-assisted retrograde transvenous obliteration (PARTO) using sodium tetradecyl sulfate (STS) foam for the treatment of gastric variceal bleeding

울 산 대 학 교 대 학 원

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지 도 교 수　　황 재 철

이 논문을 의학석사 학위 논문으로 제출함.

2024 년　2 월

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의　학　과

남 정 구

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심사위원 신 상 훈 (인)

심사위원 황 재 철 (인)

울 산 대 학 교 대 학 원

2024 년 2 월

ABSTRACT

Purpose: To evaluate the safety and effectiveness of plug-assisted retrograde transvenous obliteration (PARTO) using sodium tetradecyl sulfate (STS) foam for the treatment of gastric variceal bleeding.

Materials and methods: From June 2012 to August 2023, a retrospective analysis was conducted on 44 patients (24 men and 20 women; mean age 61 years) who had undergone PARTO using sodium tetradecyl sulfate (STS) foam. Out of the 44 patients, 36 experienced recent bleeding, and 8 had active variceal bleeding at the time of the procedure. After the procedure, patients were followed up with computed tomography (CT) or endoscopy. However, eight patients did not undergo both follow-up CT and endoscopy due to their respective individual reasons. Clinical data and follow-up examination were reviewed to evaluate technical success, as well as early and late clinical success, and to identify procedure-related complications.

Results: The technical success rate was 100% (44/44). Three patients died within a few days after the procedure; hypovolemic shock (n=1), rebleeding (n=1), and progression of hepatorenal syndrome leading to multiorgan failure (n=1). This resulted in an early clinical success rate of

93.5% (41/44). All 36 patients who underwent follow-up CT scan showed complete obliteration of gastric varices with no recurrent bleeding, resulting in a late clinical success rate of 100% (36/36). In eight patients with active gastric variceal bleeding, all underwent technically successful procedures, but one patient died within an hour after the procedure. There were no major complications related to the procedure or the sclerosing agent. There were several minor complications, such as pain (n=3) and fever (n=17), which subsided within a few days with conservative treatment. Worsening of esophageal varices and ascites were observed in 7 (19.4%) and 8 (22.2%) of the 36 patients, respectively.

Conclusion: PARTO using STS foam is a technically feasible, safe, and effective treatment for patients with gastric variceal bleeding, even in cases of active bleeding.

Keywords: Gastric varix, variceal bleeding, PARTO, STS foam

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INTRODUCTION

Gastroesophageal variceal bleeding is a major complication and a life-threatening condition that can develop in cirrhotic patients with portal hypertension. Gastric varix bleeding is less frequent than esophageal variceal bleeding, accounting for approximately 20-30% of all variceal bleeding. However, it tends to be more severe, requiring more transfusions, and endoscopic treatments are often difficult, resulting in a higher mortality rate than esophageal variceal bleeding (1-4).

According to current therapeutic guidelines for patients with acute gastric variceal bleeding, endoscopic treatments, including band ligation, gastric variceal sclerotherapy, cyanoacrylate injection, or a combination, are initially considered. However, if endoscopic hemostasis is not achieved, various interventional radiological approaches, such as transjugular intrahepatic portosystemic shunt (TIPS) , balloon-occluded transvenous obliteration (BRTO), and percutaneous variceal embolization, may be attempted (5-8) .

Conventional BRTO, which involves inserting a balloon catheter into the shunt outflow and injecting a sclerosing agent such as ethanolamine oleate or sodium tetradecyl sulfate (STS) foam, has the inconvenience of patients needing to maintain the balloon catheter for a long

duration and the potential for complications associated with the sclerosing agent itself (9-14). Therefore, a modified approach to BRTO, known as plug-assisted retrograde transvenous obliteration (PARTO), was introduced (15). This method involves the use of a permanent vascular plug instead of an indwelling balloon catheter and injection of gelatin sponge instead of sclerosing agent, with the aim of reducing procedure time, simplifying post-procedure monitoring, and minimizing complications related to sclerosing agent. Although PARTO has some advantages in terms of technical aspects, previous studies have shown a higher recurrence of gastric varices in PARTO compared to BRTO using sclerosing agents such as ethanolamine oleate or STS foam (16). This is thought to be attributed to the differing mechanisms of action between the gelatin sponge, which acts as a matrix for thrombus formation to induce clotting, and a sclerosing agent that causes endothelial damage (17,18).

Thus, we supposed that using sclerosing agent such as STS in the PARTO procedure would provide both technical advantages and better clinical outcomes, potentially resulting in a lower recurrence rate. To our knowledge, there have been no published studies specifically focused on the effectiveness of the sclerosing agent in the PARTO procedure.

Therefore, the purpose of this study is to evaluate the safety and effectiveness of PARTO using STS foam for the treatment of gastric variceal bleeding.

MATERIALS AND METHODS

Patient population

The study was approved by the Institutional Review Board (2023-10-021) of Ulsan University Hospital and the requirement for informed patient consent was waived.

Forty-four patients (24 men and 20 women; mean age 61 years; range 34–85 years), who underwent PARTO using STS foam for the treatment of gastric variceal bleeding between June 2012 and August 2023, were retrospectively reviewed. All patients had gastrorenal shunt and gastric varices confirmed on pre-procedural computed tomography (CT) scan.

Out of the 44 patients, 36 had experienced recent bleeding, and 8 were identified to have active variceal bleeding at the time of the procedure through endoscopy.

The baseline demographic and clinical characteristics of the 44 study patients are presented in Table 1.

Table 1. Patient demographics

Characteristics	Number
Sex (M:F)	24:20
Age (mean)	34–85 (61)
Underlying liver disease	
HBV cirrhosis	10
HCV cirrhosis	4
Alcoholic cirrhosis	18
Other*	12
Concomitant malignancy	
Hepatocellular carcinoma (HCC)	12
Common bile duct cancer	1
Child–Pugh classification	
A	14
B	23
C	7

*Cryptogenic cirrhosis (n=7), autoimmune hepatitis (n =3), biliary cirrhosis (n=2)

Procedure technique

All procedures were conducted with conscious sedation using intravenous pethidine hydrochloride 25 mg (Pethidine; Hana Pharmaceutical, Seoul, Korea) and local anesthesia applied at the puncture site using lidocaine hydrochloride (Lidocaine; Jeil Pharmaceutical, Daegu, Korea).

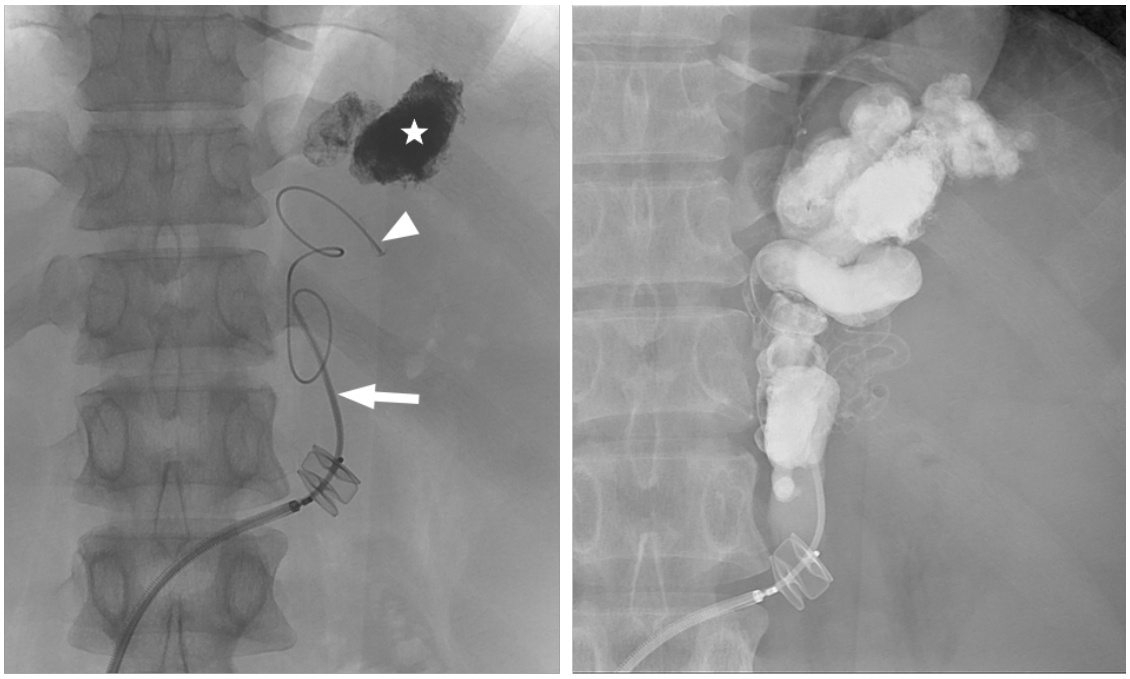
Prior to procedure, the portal phase of contrast-enhanced CT scans was reviewed to identify the gastrorenal shunt and to evaluate the anatomy of the varices in all patients. Vascular access was typically performed through the right common femoral vein. However, when the insertion of a guiding sheath was not possible via the transfemoral approach, due to an acute angle between the shunt and the left renal vein, a transjugular approach through the right internal jugular vein was attempted. After selecting the gastrorenal shunt using a 5-Fr catheter (Cobra; Cook, Bloomington, IN, USA) and a 0.035-inch, 180-cm hydrophilic guidewire (Terumo, Tokyo, Japan), venography was performed to evaluate the anatomy of the gastric varices, as well as to measure the diameter of the shunt to determine the size of the vascular plug. A 6- or 7-Fr guiding sheath (Flexor Check-Flo or Shuttle Sheath; Cook) was then inserted into the shunt for the deployment of the vascular plug (Amplatzer Vascular Plug II; Abbott, Chicago, IL,

USA). The vascular plug was deployed while maintaining a guidewire within the gastrorenal shunt, followed by subsequent over-the-wire insertion of a 4-Fr or 5-Fr catheter into the shunt, just above the vascular plug. The vascular plug should be approximately 20-30% larger than the narrowest portion of the gastrorenal shunt to prevent the migration of the vascular plug or the reflux of the sclerosing agent. We initially injected large-sized calibrated gelatin sponge particles measuring 1400-2000μm or 2000-4000μm (EGgel S PLUS; Engain, Hwasung, Korea). The gelatin sponge was used to fill the gastric varices early, thereby inducing flow stasis within the shunt and occluding small collateral veins. However, in cases where large collateral veins, such as the pericardiophrenic vein, inferior phrenic vein, or paravertebral vein, were present, and embolization of these veins with a gelatin sponge was not feasible, we conducted additional coil embolization using a microcatheter and microcoils.

Once flow stasis was achieved in the shunt, we introduced a microcatheter system coaxially and attempted to superselect the proximal portion of the shunt as close as possible to the nidus of the gastric varix (Fig 1a). And then, 3% STS (Thromboject; Yujin Ethical, Seoul, Korea), mixed with lipiodol and air in a 2:1:3 ratio, was injected through the microcatheter until the gastric varices were completely filled (Fig 1b). The embolization endpoint was the visualization of potential afferent veins, such as the left gastric vein, posterior gastric vein, or short gastric

veins. This indicated the absence of residual variceal flow, confirming complete embolization of the gastric varices. The procedure ended with the detachment of the vascular plug, which remained in place as a permanent occluder of the gastrorenal shunt.

Figure 1. A 45-year-old woman presented with gastric variceal bleeding and underwent PARTO using STS foam.



a. b.

(a) After the deployment of the vascular plug, the proximal portion of the gastrorenal shunt was superselected using a coaxial microcatheter system within a 5Fr Cobra catheter (arrow). The tip of the microcatheter (arrow head) was placed adjacent to the nidus of gastric varices. Note the previous endoscopic injection of histoacryl (asterisk) at the gastric fundus.

(b) Fluoroscopic image after the injection of STS foam revealed complete filling of the gastric varices with STS foam.

Follow-up evaluation

Patients were evaluated using CT scans to confirm complete variceal thrombosis and variceal obliteration. Clinicians also conducted endoscopic evaluations to assess the cessation or recurrence of gastric variceal bleeding and to evaluate the esophageal varices. Our hospital did not have a predetermined follow-up interval, thus follow-up CT and endoscopy were conducted at various time points after the procedure. The follow-up interval was determined at the discretion of the attending physician and based on the patient's condition, which included factors such as rebleeding, the presence of esophageal varices, or HCC.

Eight patients did not undergo both follow-up CT and endoscopy due to various reasons, including transfer to another hospital after the successful control of variceal bleeding (n=4), early death following the procedure (n=2), and death due to the progression of advanced HCC despite successful bleeding control through the procedure (n=2).

Medical records were reviewed to identify any recurrent bleeding after the procedure and to monitor complications. We evaluated major complications related to foam sclerosant, such as pulmonary edema, pulmonary embolism, and partial portal vein thrombosis (14,19), as well as

minor complications like abdominal pain and fever. Procedure-related complications, including hematoma, worsening of esophageal varices, or ascites, were also assessed.

Definitions

Recent bleeding was defined as bleeding that occurred within the last few days despite the absence of bleeding at the time of the procedure. Active bleeding was defined as the presence of ongoing bleeding at the time of the PARTO procedure, which was confirmed through endoscopy immediately before the procedure.

Technical success was defined as the complete occlusion of the gastrorenal shunt using a vascular plug, with sufficient injection of the STS foam into the shunt, and the formation of variceal clots without variceal flow in the shunt.

Clinical success was evaluated in terms of early and late clinical success due to the varying time intervals for follow-up CT or endoscopy. Early clinical success was defined as the cessation of bleeding through the procedure, along with the resolution of symptoms related to bleeding and the improvement of the patient's overall condition, leading to discharge. Late clinical success was

defined as the confirmation of gastric variceal obliteration through follow-up CT and endoscopy after the procedure, and the absence of recurrent gastric variceal bleeding.

RESULTS

Technical outcomes

In all patients, the STS foam was injected adequately into the shunt, leading to complete variceal thrombosis. Therefore, the technical success rate was 100% (44/44). In one patient, transfemoral approach was initially attempted but had to be switched to a transjugular approach due to the anatomical difficulty of advancing the guiding sheath into the gastrorenal shunt. A single vascular plug was enough to adequately occlude the left adrenal vein in all patients. The plug sizes used were 8 mm (n=1), 10 mm (n=7), 12 mm (n=16), 14 mm (n=14), and 16 mm (n=6). In eight patients, supplementary coil embolization of the large collateral veins, which were not adequately occluded spontaneously with the large-sized gelatin sponge particles, was performed to prevent systemic leakage of the sclerosing agent. The amount of instilled STS was 4 ml to 12 ml, with a mean amount of 6.6 ml. The mean fluoroscopy times ranged from 9.8 to 76.9 minutes (mean 37.5 minutes), varying depending on the complexity of the venous anatomy of the gastrorenal shunt.

The summary of the PARTO procedures is presented in Table 2.

Table 2. Summary of PARTO procedures

	Total 44 patients
Technical success (%)	44/44 (100%)
Early clinical success (%)	41/44 (93.5%)
Late clinical success (%)	36/36 (100%)*
Mean fluoroscopy time (range)	37.5 min (9.8–76.9)
Complications (n = patients)	
Abdominal pain	1
Back pain	2
Fever	17
Worsening of esophageal varices	7/36 (19.4%)*
Worsening of ascites	8/36 (22.2%)*

*Thirty-six of 44 patients underwent follow-up CT and endoscopy

Clinical outcomes

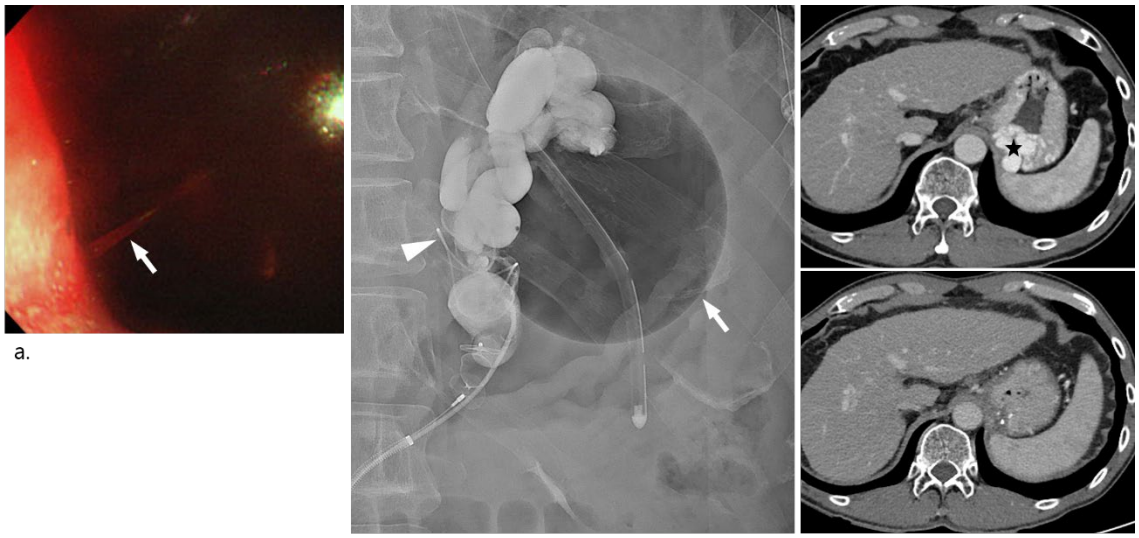
All patients experienced immediate resolution of symptoms related to gastric variceal bleeding after the procedure. However, we encountered three early clinical failures, yielding an early clinical success rate of 93.5% (41/44). These three patients died within a few days after the procedure, without being discharged. The first patient experienced cardiac arrest due to hypovolemic shock immediately after the PARTO. The second patient had recurrent massive hematemesis the day following the PARTO. The last patient expired 11 days after the procedure due to the progression of hepatorenal syndrome leading to multiorgan failure.

Of the 44 patients, eight did not undergo any follow-up CT scan. As a result, we could only evaluate the change in the gastric varix after the procedure in the 36 patients who had follow-up CT scans. Of these 36 patients, all showed complete obliteration of the gastric varices with no recurrence of variceal bleeding. Thus, the late clinical success rate was 100% (36/36).

The median interval from the procedure to the first follow-up CT scan was 204 days, with a range of 7–1,235 days. The median interval for first follow-up endoscopy was 234 days, with a range of 1–1,757 days.

Eight patients with active variceal bleeding underwent PARTO with a SB (Sengstaken-Blakemore) tube in place. All of these procedures were technically successful, but one patient died within an hour after the procedure due to hypovolemic shock. The remaining seven patients achieved both early and late clinical success, with complete obliteration of the gastric varices evident on follow-up CT scans (Fig 2). In one patient, leakage of the STS foam into the gastric lumen was observed during its injection under fluoroscopy. However, complete opacification of the gastric varix and successful hemostasis were achieved, with complete obliteration of the gastric varices confirmed on the follow-up CT scan (Fig 3).

Figure 2. A 51-year-old man presented with active gastric variceal bleeding and underwent PARTO using STS foam.

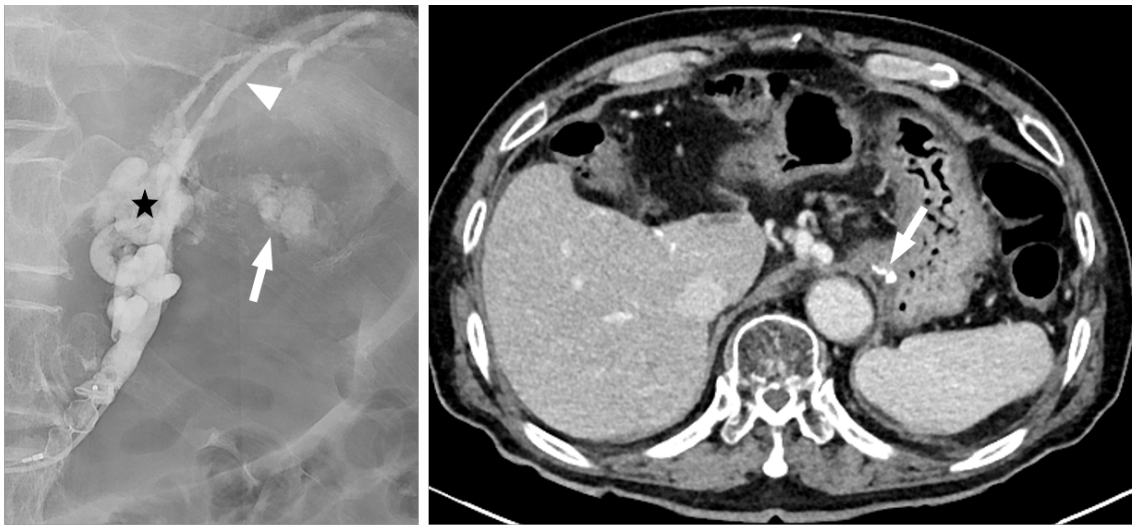


(a) The initial endoscopic image revealed a jet of blood (arrow) originating from the fundal gastric varices.

(b) A sufficient amount of STS foam was injected into the gastric varices and the gastrorenal shunt via the microcatheter (arrowhead). Note the SB tube (arrow) inserted into the gastric lumen due to active massive bleeding.

(c) Contrast-enhanced CT obtained before and two months after PARTO showed the complete obliteration of the fundal varix (asterisk).

Figure 3. A 74-year-old man presented with active gastric variceal bleeding and underwent PARTO using STS foam.



a. b.

(a) During the procedure, a leakage of STS foam into the gastric lumen was observed (arrow). However, the gastric varices (asterisk) and the inferior phrenic vein (arrowhead) were adequately filled with STS foam.

(b) Contrast-enhanced CT obtained three months after PARTO showed the complete obliteration of the fundal varix, with residual high-density embolization material present (arrow).

Complications

There were no major complications related to the procedure in any of the patients. On the other hand, there were several acute minor complications that occurred within 72 hours after the procedure, and they are as follows; fever (n=15), fever and abdominal pain (n=1), fever and left back pain (n=1), and back pain (n=1). A total of 17 patients (38.6%) had a fever with a body temperature exceeding 38.0°C. However, in all patients, the fevers subsided within the next day following conservative treatment, which included fluid resuscitation and the administration of antipyretic drugs.

In this study, follow-up CT scans and endoscopy revealed that esophageal varices worsened in 7 of the 36 patients (19.4%) and ascites worsened in 8 of the 36 patients (22.2%). New-onset ascites was detected in 5 of the 36 patients (13.9%) who had no ascites prior to PARTO, while in 3 of the 36 patients (8.3%), ascites progressed to a larger volume.

DISCUSSION

This study report PARTO that used STS foam as an embolic agent for the treatment of gastric variceal bleeding, which differs from previous research. PARTO using STS foam demonstrated a high technical success rate (44/44; 100%), along with a relatively high early clinical success rate (41/44; 93.5%) and a high late clinical success rate (36/36; 100%). These results are concordant with previous BRTO studies that used various sclerosing agents (9,10,12,14,19,24,30,31) and with PARTO studies that used gelatin sponges (15,20-22).

PARTO using STS foam is considered to be similar to PARTO using a gelatin sponge in terms of both the technical aspect and the outcomes. However, there are several advantages to using STS foam. First, using STS foam allows for complete embolization of gastric varices, significantly reducing the risk of gastric variceal recurrence. Previous study by Kim et al. (16) reported that in PARTO using gelatin sponge, gastric variceal recurrence is significantly higher compared to BRTO with sclerosing agents. Furthermore, even though gelatin sponge embolization was performed sufficiently until the afferent vein was adequately visualized, there was a case of incomplete filling of gastric varices, leading to recurrent hematemesis (21). In the present study, there were no recurrence of gastric variceal bleeding, and follow-up CT scans confirmed complete obliteration of gastric varices. This is believed to be due to the differences

in the mechanisms of the two embolic materials. Gelatin sponge acts as a matrix for thrombus formation, inducing clot formation through platelet aggregation (17), while STS rapidly causes endothelial damage and successfully generates microthrombi within 30 minutes (18). Second, using STS in PARTO may help reduce contrast extravasation. In a previous study using gelatin sponge in PARTO (21), they reported minimal contrast extravasation during the injection of the gelatin sponge in 21% of patients. This was thought to be attributed to increased intra-shunt pressure during the injection process, leading to the rupture of small collateral veins and subsequent contrast extravasation. However, in the present study using STS, contrast extravasation was not observed. This could be attributed to our procedure method that injects the sclerosant at the proximal portion of the shunt and also because STS is used in a foam mixed with air, resulting in lower intravascular pressure compared to a gelatin sponge slurry.

The technical difference between using STS foam and gelatin sponge in PARTO is the necessity of approaching the proximal portion of the gastric varices or the nidus of the gastric varix using a coaxial microcatheter system. In previous studies involving PARTO using a gelatin sponge, they injected the gelatin sponge just above the vascular plug to fill the gastric varix retrogradely (15,20-22). In contrast, we approached as close as possible to the nidus of the gastric varices adjacent to the gastric fundus. From that point, we injected STS foam, filling the

gastric varices, shunt, and afferent veins in both anterograde and retrograde directions. This technique allows for the injection of the sclerosing agent close to the inflow vein, inducing rapid thrombus formation near the bleeding point, thereby facilitating quick hemostasis. Additionally, by initially controlling the perigastric inflow veins, it can also reduce contrast extravasation through collateral veins, as mentioned above.

Ruptured gastric varices can lead to significant recurrent bleeding and increased mortality, making rapid treatment essential. Although BRTO has proven effective as an emergency treatment in several studies (26,27), its use can be challenging during active gastric variceal bleeding. This is due to the potential for the sclerosing agent to leak into the gastric lumen, sometimes necessitating endoscopic hemostasis or a second BRTO (28,29). In a previous study by Gwon et al. (20), they reported successful emergency PARTO using a gelatin sponge for patients with active gastric variceal bleeding. In the present study, eight patients with active gastric variceal bleeding underwent the PARTO using STS foam. All patients showed technical success; however, one patient died immediately after the procedure due to hypovolemic shock. This one patient had no other treatment option but salvage PARTO after the failure of endoscopic hemostasis, and died unrelated to the procedure as there was already too much bleeding before. The other seven patients exhibited no recurrent bleeding, and follow-up CT

scans revealed complete obliteration of the gastric varices. Thus, emergency PARTO with STS foam is also effective treatment for patients with active gastric variceal bleeding.

Aggravation of esophageal varices is one of the disadvantage of BRTO as well as of PARTO. Several post-BRTO complications including worsening of esophageal varices and ascites, were attributed to the increased portal flow. In this study, 8 patients (22.2%) worsened ascites and 7 patients (19.4%) worsened esophageal varices after the PARTO, respectively. Minor complications such as abdominal pain and fever occurred in several patients, however, there were no complications associated with STS foam. Therefore, this result suggests that PARTO using STS foam is a safe procedure.

This retrospective study has a few limitations. First, we were unable to conduct a comparative analysis with other procedure method, including PARTO using gelatin sponge and conventional BRTO. Second, unlike previous studies, we did not conduct follow-up CT scans and endoscopy at predetermined intervals. Therefore, we were unable to evaluate the degree of obliteration of gastric varices over time. Third, the lack of follow-up data in eight patients may have led to an overestimation of clinical outcomes, as some of them had advanced diseases or were in poor

general condition. Future research should include prospective, randomized, and comparative trials with larger sample sizes.

CONCLUSION

This study demonstrated that PARTO using STS foam is a technically feasible, safe, and effective treatment for gastric variceal bleeding in patients with portal hypertension. Furthermore, this procedure is also safe for patients with active gastric variceal bleeding in an emergency setting.

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국문 요약

연구 목적: 본 연구에서는 위 정맥류 출혈의 치료에서 sodium tetradecyl sulfate (STS) 폼을 사용한 플러그 보조 역행성 경정맥 폐쇄술 (plug-assisted retrograde transvenous obliteration, PARTO)의 안전성과 효과를 알아보고자 한다.

대상 및 방법: 2012 년 6 월부터 2023 년 8 월까지 STS 폼을 이용하여 PARTO 를 시행한 44 명의 환자 (남성 24 명, 여성 20 명; 평균 연령 61 세)에 대해 후향적 분석을 실시하였다. 44 명 중 36 명은 최근 출혈이 있었으며, 8 명은 활동성 정맥류 출혈이 있었다. 환자들은 시술 후 컴퓨터 단층촬영 (CT) 또는 내시경으로 추적 관찰하였고, 8 명의 환자에서는 추적 CT 와 내시경을 모두 시행하지 못하였다. 기술적 성공, 조기 및 후기 임상적 성공을 평가하고 시술 관련 합병증을 확인하기 위해 임상 데이터와 추적 검사 결과를 확인하였다.

결과: 기술적 성공률은 100% 였다 (44/44). 세명의 환자는 각각 저혈량성 쇼크, 재출혈, 그리고 간신증후군의 진행으로 인한 다발성 장기 부전으로 시술 후 며칠

이내에 사망하였으며, 이에 조기 임상 성공률은 93.5% (41/44)로 확인되었다. 추적 CT 를 시행한 36 명의 환자 중 모든 환자에서 CT 상 위 정맥류의 완전한 폐쇄가 확인되었고, 따라서 후기 임상 성공률은 100% (36/36)였다. 활동성 위 정맥류 출혈이 있었던 8 명의 환자 중 모든 환자에서 기술적으로 성공적인 시술이 시행되었으나 한 명의 환자는 시술 종료 후 한 시간 이내에 사망하였다. 시술 또는 경화제와 관련된 주요 합병증은 없었다. 일부 환자에서 복통 (3 명), 발열 (17 명) 등의 경미한 합병증이 발생하였으나 보존적 치료로 며칠 이내에 모두 호전되었다. 36 명의 환자 중 7 명 (19.4%) 에서는 식도 정맥류의 악화가 있었고, 8 명 (22.2%) 에서는 복수의 악화가 있었다.

결론: 위 정맥류 출혈 환자의 치료에서 STS 폼을 이용한 PARTO 는 기술적으로 실현 가능하고 안전하며 효과적인 치료 방법으로 활동성 출혈이 있는 응급 상황에서도 안전하게 시행 가능한 시술로 생각된다.