Foam Sclerotherapy Using Polidocanol (Aethoxysklerol) for Pre-operative Portal Vein Embolization

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Directed by Professor Do Yun Lee

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<ABSTRACT>

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Purpose: To evaluate the clinical safety and effectiveness of foam sclerotherapy using polidocanol for preoperative portal vein embolization (PVE) before lobectomy of the liver.

Materials and Methods: From March 2006 to October 2008, foam sclerotherapy using polidocanol was performed in 16 patients [M:F=12:4, age range 48 - 75 years (mean, 62 years)] for PVE. The foam was composed of a 1:2:1 ratio of 3% polidocanol (Aethoxysklerol; Kreussler Pharma, Wiesbaden, Germany), room air, and contrast media (Xenetix; Guerbet, Aulnay-Sous-Bois, France). The total amount of polidocanol used (2 - 8 mL; mean, 4.6 mL) was varied according to the volume of the target portal vein. We calculated the volume of future liver remnant (FLR) before and after PVE and evaluated complications associated with the use of polidocanol foam sclerotherapy for PVE.

Results: Technical success was achieved in all patients. All patients were comfortable throughout the procedure and did not experience pain during sclerotherapy. No peri-procedural morbidity or mortality occurred. Patients underwent a liver dynamic CT scan 2 - 4 weeks after PVE. FLR increased significantly after PVE using polidocanol foam from 19.3% (16-35%) before PVE to 27.8% (23-42%) after PVE (P=0.001).

Conclusions: Foam sclerotherapy using polidocanol is clinically safe and effective for pre-operative PVE.

Key words : polidocanol, foam sclerotherapy, portal vein embolization

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I. INTRODUCTION

Complete resection of hepatic tumors is the first choice for curative treatment of primary and secondary liver malignancies. Resectability is determined by a remnant liver volume sufficient to support postoperative liver function [1-4].

Preoperative portal vein embolization (PVE) to improve the functional reserve of the future liver remnant (FLR) before surgery minimizes abrupt increases in portal venous pressure to the functional liver remnant during resection that can cause hepatocellular damage. Furthermore, PVE reduces the risk of postoperative metabolic changes caused by hypertrophy of the nonembolized segments before hepatic resection [5, 6]. Thus, PVE reduces the risk of postoperative liver failure after major liver resection and increases the number of resectable patients [1, 3, 7]. Various substances (gelatin sponges, coils, cyanoacrylate, polyvinyl alcohol, fibrin, polidocanol, and lipiodol) have been used for PVE, and use of these various substances results in different rates or degrees of hypertrophy of unembolized segments [8-17]. Among these, polidocanol was first developed as a local anesthetic for painless sclerotherapy [18, 19]. When the embolic effects of different agents were compared, it was found that the combination of polidocanol with a gelatin sponge (n=8) produced the best effects, followed by cyanoacrylate (n=4), a gelatin sponge (n=9), and fibrin

(n=2) [17]. Although polidocanol can be used either as a foam or a liquid, sclerotherapy with foam generally produces better results because of the increased contact of the foam with the venous endothelium, allowing greater efficacy at lower concentrations and a lower total quantity of sclerosant [20-22]. However, no prior studies have evaluated foam sclerotherapy using polidocanol with radioopaque contrast media under fluoroscopic intervention for preoperative PVE.

Thus, the purpose of our study was to evaluate the clinical safety and effectiveness of foam sclerotherapy using polidocanol for preoperative PVE before lobectomy of the liver.

II. MATERIALS AND METHODS

1. Patients

This study was approved by the institutional review board, and all patients provided informed consent. The consent form included permission to use records, images, and data for research purposes. Between March 2006 and October 2008, 16 consecutive patients (12 male and 4 female patients; mean age, 62 years; range, 48-75 years) with liver malignancies underwent preoperative PVE by foam sclerotherapy using polidocanol under fluoroscopic intervention before hepatic resection. The preoperative diagnoses were a Klatskin tumor (n=13), gallbladder cancer (n=2), or a hepatocellular carcinoma (n=1). All diagnoses were made based on imaging findings including computed tomography (CT), magnetic resonance imaging (MRI), and endoscopic retrograde cholangiopancreatography (ERCP) findings, as well as cytological or histological findings. Fifteen of the 16 patients had neither signs nor a medical history of underlying chronic liver disease. The sixteenth patient had underlying

liver cirrhosis with a Child-Pugh Class A score. Preoperative PVE is indicated when the ratio of FLR to the total estimated liver volume (TELV) is less than 25% in patients with normal liver and when this ratio is less than 40% in patients with chronic liver disease [1, 14, 23, 24]. No patient had diabetes, which can limit hepatic hypertrophy [25, 26]. Although there is no definite contraindication for PVE, no patient had relative contraindications such as distant metastases or periportal lymphadenopathy, bilobar multiple metastases, uncorrectable coagulopathy, tumor invasion of the portal vein, a tumor preventing safe transhepatic access, uncontrolled biliary dilatation, portal hypertension, renal failure requiring dialysis, or an indocyanine green retention rate at 15 minutes (ICG R15) greater than 20% [1, 7, 23]. Right hepatectomy was planned in 13 patients and right hepatectomy extending to segment IV was planned in 3 patients.

2. PVE procedure

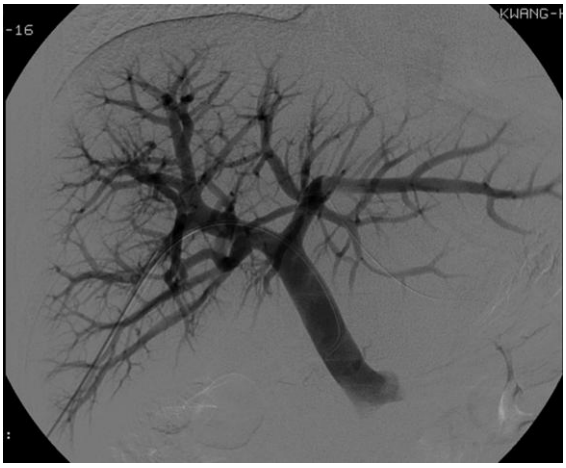
A percutaneous transhepatic ipsilateral approach to the right portal vein branch with ultrasound guidance (n=7) and fluoroscopic guidance (n=9) was performed under local anesthesia after aseptic draping. The portal vein was accessed by puncture with a 21-gauge needle (DISP Chiba needle; Cook, Bloomington, IN). After placement of a 8-F sheath (Radifocus Introducer II; Terumo Corp., Tokyo, Japan) in the portal branch, a 5-F catheter (Torcon NB Advantage Catheter; Cook, Bloomington, IN) was advanced in the main portal trunk along a 0.035 inch guide wire (Radifocus guide wire M; Terumo Corp., Tokyo, Japan), and digital subtraction portography was performed to assess the portal venous anatomy (Figure 1a). Then, a 8.5-mm balloon catheter (Standard Occlusion Balloon Catheter; Boston Scientific, Cork, Ireland) was inserted in the right proximal portal vein using the catheter-change method. Before performing sclerotherapy with polidocanol foam, the volume of the right portal vein was estimated by injecting contrast media under transient balloon occlusion. Balloon

occlusion was performed, and then the right portal vein was embolized by injection of polidocanol foam (Figure 1b). The mean time for balloon occlusion was 27.5 minutes (range; 20-30 minutes). Foam was obtained by mixing 3% polidocanol (Aethoxysklerol; Kreussler Pharma, Wiesbaden, Germany) with room air and nonionic contrast media (Xenetix 350; Guerbet, Aulnay-Sous-Bois, France) at a ratio of 1:2:1. The Tessari method was used for foam production using two disposable syringes and a three-way tap [20]. The total amount of polidocanol used depended upon the relative volume of the target portal vein (mean, 4.6 mL; range, 2-8 mL). Direct portography was acquired after foam sclerotherapy to decide the endpoint of procedure (Figure 1c). The puncture track was embolized with a few stainless steel coils 3 or 4 mm in diameter or by NBCA embolization to avoid hemorrhage. In patients scheduled for extended right hepatectomy, gelfoam and coil embolization of the S4 branch of the portal vein were performed first, and then foam sclerotherapy of the right portal vein was performed as described above. Patients were scheduled to undergo hepatic resection 4-5 weeks after PVE.

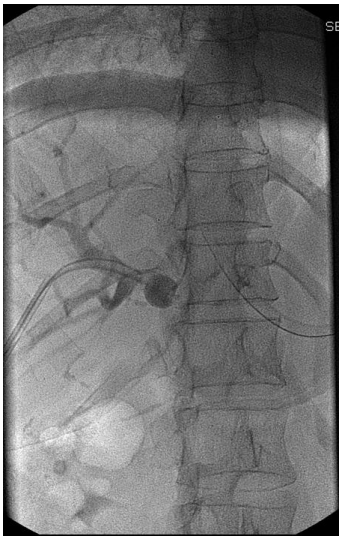
Figure 1. Procedure of foam sclerotherapy using polidocanol for pre-operative portal vein embolization with follow-up by abdominal dynamic CT

A 60-year-old man with a Klatskin tumor (Bismuth type II) was scheduled to undergo right hepatectomy and foam sclerotherapy using polidocanol was performed for preoperative PVE. (a) Portography was obtained by a transhepatic ipsilateral approach in the right portal vein. (b) Balloon occlusion of the right proximal portal vein was performed for 30 minutes with injection of foam sclerosant to the right portal vein. The right portal vein was visualized by contrast media in the foam sclerosant. (c) Portography after embolization showed total occlusion of the portal venous branches in the right lobe. Axial enhanced CT scans before PVE (d) and CT scans 3 weeks after PVE (e) revealed hypertrophy of the left lobe and atrophy of the right lobe. The white

arrow shows the bile duct drainage tube.



(a)



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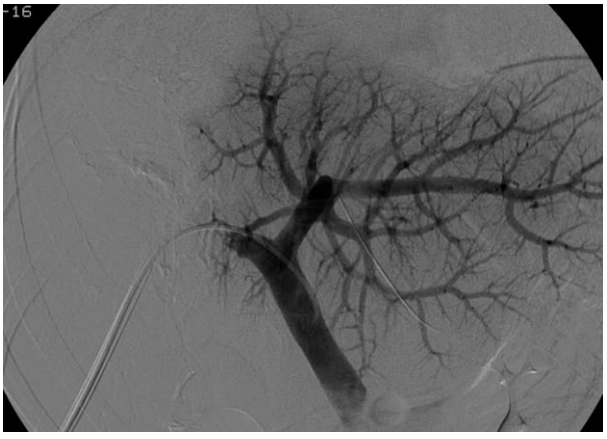

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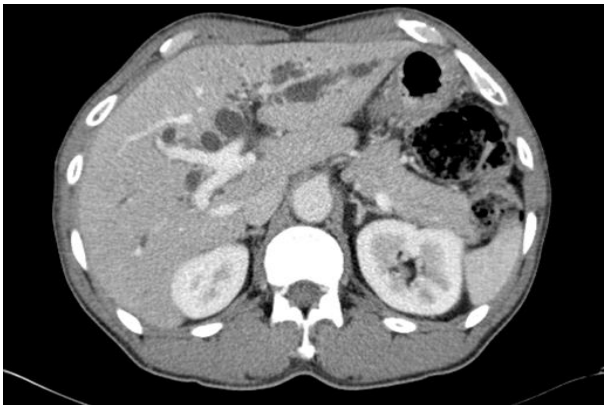
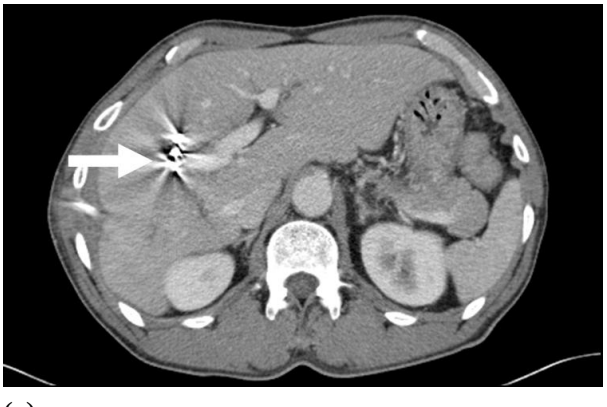


(d)



(e)

3. Liver volume data

All patients underwent a series of abdominal dynamic CT scans after intravenous administration of contrast media at a mean of 10 days (range, 7-18 days) before and 20 days (range, 14-27 days) after PVE (Figure 1d and 1e). The ratio of FLR to TELV was calculated before and after PVE with 3-dimensional volumetric reconstruction data obtained using the Voxel plus2 software package to calculate volumetry (version 2.5.5.4120, mevisys, Daejon, Korea) according to the following formula: FLR/TELV = FLR/(total liver volume – tumor volume) X 100%. The CT volumetric calculations were performed by outlining the hepatic segmental contours and tumor contours in each slice at 5-mm intervals. If it was difficult to precisely identify the margins of tumors, outlining of the suggested tumor contours was completed manually.

4. Follow-up biochemical data

Body temperature, serum total bilirubin (T-Bil), liver enzyme levels including aspartate aminotransferase (AST) and alanine aminotransferase (ALT), and prothrombin time (PT) were checked in all patients before PVE and on every day during hospitalization after PVE.

5. Analysis

To evaluate the effectiveness of preoperative PVE, the ratio of FLR/TELV was calculated before and after PVE and compared for each patient. Complications related to PVE were defined as adverse events that required further treatment or the modification of clinical status, and were investigated in all patients. Increases in body temperature, T-Bil, AST, ALT, and PT after PVE and their recovery period were compared to baseline levels before PVE in all patients. An unpaired T-test was used to compare significant differences in the ratio of FLR/TELV before and after PVE. $P<0.05$ was considered statistically significant.

III. RESULTS

Volumetric data and patient demographics are shown in Table 1. Technical success was achieved in all patients. All patients were comfortable throughout the procedure without pain during sclerotherapy. There were no complications related to PVE. Thirteen patients underwent right hepatectomy and 3 patients underwent a planned right hepatectomy extending to segment IV.

The ratio of FLR/TELV increased significantly after PVE using foam polidocanol from 19.3% (16-35%) before PVE to 27.8% (23-42%) after PVE (P=0.001) (Table 1).

Table 1. Demographics of patients and liver volume data before and after PVE.

Patient No.	Sex	Age (y)	Balloon occlusion time (min)	Histopathologic diagnosis	Underlying chronic liver disease	Type of hepatectomy	FLR/TELV ratio (%)		Ratio increase (%)
							Before PVE	After PVE	
1	M	71	30	GB cancer	No	Extended right hepatectomy	17	25	8
2	M	60	20	Klatskin tumor	No	Right hepatectomy	22	30	8
3	M	63	30	Klatskin tumor	No	Right hepatectomy	16	23	7
4	M	57	30	Klatskin tumor	No	Right hepatectomy	18	25	7
5	F	75	20	Klatskin tumor	No	Right hepatectomy	17	27	10
6	M	71	30	Klatskin tumor	No	Extended right hepatectomy	17	24	7
7	M	63	20	Klatskin tumor	No	Right hepatectomy	18	30	12
8	M	68	20	Klatskin tumor	No	Right hepatectomy	18	25	7
9	M	60	30	Klatskin tumor	No	Right hepatectomy	23	30	7
10	M	65	30	HCC	Cirrhosis	Right	35	42	7

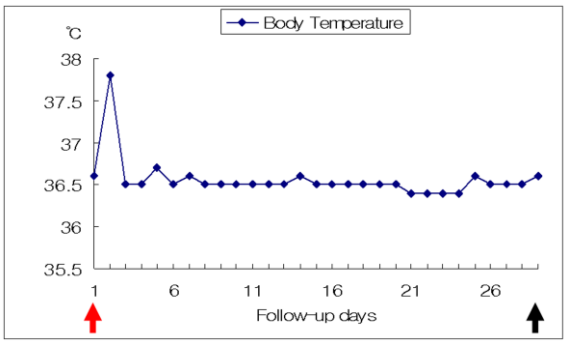
					(Child A)	hepatectomy			
11	M	58	30	Klatskin tumor	No	Right hepatectomy	18	24	6
12	F	68	30	GB cancer	No	Extended right hepatectomy	17	24	7
13	M	50	30	Klatskin tumor	No	Right hepatectomy	19	35	16
14	F	48	30	Klatskin tumor	No	Right hepatectomy	17	24	7
15	F	66	30	Klatskin tumor	No	Right hepatectomy	20	31	11
16	M	61	30	Klatskin tumor	No	Right hepatectomy	17	26	9

PVE: portal vein embolization; GB: gallbladder; HCC: hepatocellular carcinoma; FLR: future liver remnant; TELV: total estimated liver volume

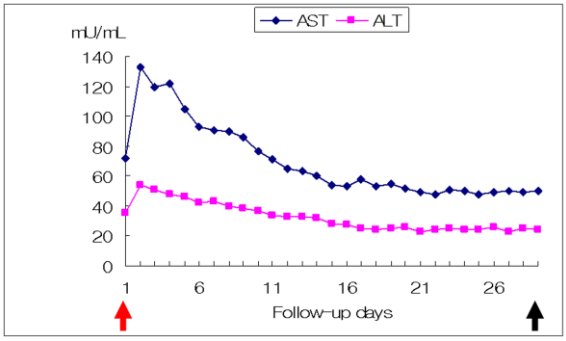
The body temperatures of all patients were transiently elevated (maximum mean 1.5°C) after PVE, but normalized within a few days. The mean AST increased to 92% (range, 63-151%) after PVE compared to baseline and the mean ALT increased to 45% (37-72%) after PVE compared to baseline levels. AST and ALT values recovered to baseline or normalized within a mean of 9 days (range, 7-12 days). The level of T-Bil decreased after PVE in all patients. There were no significant changes in the levels of PT after PVE (Figure 2).

Figure 2. Changes in biochemical test values

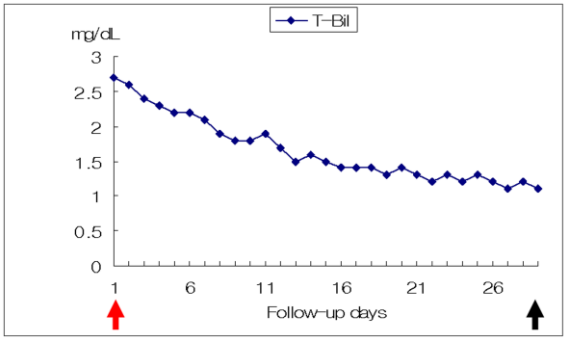
Changes in biochemical test values just before PVE and on every day after PVE until extended right hepatectomy in a 68-year old female with GB cancer extending to the right lobe and segment IV of the liver; (a) Body temperature was slightly increased (1.2°C) 1 day after PVE but normalized the next day. (b) The level of aspartate aminotransferase (AST) was increased about 85% over baseline level and the level of alanine aminotransferase (ALT) increased about 54% over baseline level. These values returned to baseline 10 days after PVE. (c) The level of total bilirubin (T-Bil) decreased gradually after PVE, probably due to insertion of a bile duct drainage tube. (d) Prothrombin time (PT) did not change markedly after PVE. The red arrow indicates when PVE was performed and the black arrow indicates the day just before hepatectomy.



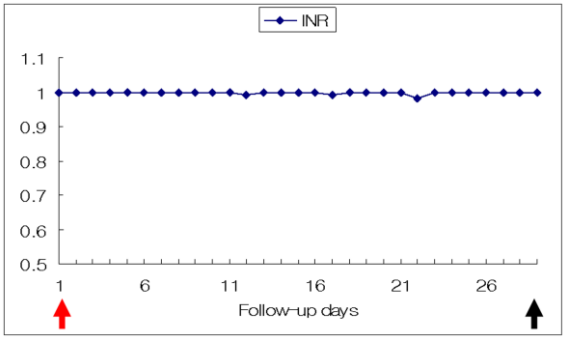
(a)


AST
ALT
mU/mL
140
120
100
80
60
40
20
0
1
6
11
16
21
26
Follow-up days

(b)


T-Bil
mg/dL
3
2.5
2
1.5
1
0.5
0
1
6
11
16
21
26
Follow-up days

(c)


INR
1.1
1
0.9
0.8
0.7
0.6
0.5
1
6
11
16
21
26
Follow-up days

(d)

IV. DISCUSSION

Polidocanol is a nonionic detergent sclerosant that consists of 95% hydroxypolyethoxydodecane and 5% ethyl alcohol. The detergent action of polidocanol results in the rapid overhydration of endothelial cells, causing vascular injury [27, 28]. The most important advantage of polidocanol is that sclerotherapy can be performed painlessly because of polidocanol's anesthetic effect [18, 19]. All patients were comfortable without pain during the sclerotherapy procedure in our study. The efficacy of polidocanol foam sclerotherapy for varicose veins has already been demonstrated [21, 29]. Recently, polidocanol sclerotherapy has been extended to the treatment of esophageal varices, bleeding gastroduodenal ulcers, and venous malformations [30, 31]. Although reports about the effectiveness of polidocanol sclerotherapy for preoperative PVE are rare, the results reported in the two previous studies were promising [17, 32]. In our study, the mean percentage increase in the ratio of FLR/TELV after foam sclerotherapy under fluoroscopic intervention using polidocanol and contrast media for preoperative PVE was 8.5% ± 2.5%. Past studies of preoperative PVE with various embolic materials have reported mean percentage increases in the FLR/TELV ratio of 6 - 13% [6, 8, 9, 11, 17, 23, 33-37]. Therefore, our results are consistent with those reported in the previous studies.

Known complications associated with the use of polidocanol sclerotherapy are hepatotoxicity, decreases in blood pressure, bradycardia, and reversible cardiac arrest [28, 30]. Among these, topical hepatic side effects are important considerations when using polidocanol sclerotherapy for local treatment of liver diseases. A previous study that examined the hepatotoxicity of polidocanol in a porcine liver model reported a significant increase in ALT and a decrease in hepatic bile flow after administration of polidocanol via the hepatic artery and portal vein [28]. In our study, although levels of AST and ALT increased relative to baseline levels just after PVE (albeit less than

2-fold), they recovered to baseline or normalized after a mean of 9 days, and no patients showed remarkable symptoms or signs of hepatitis or hepatic failure. These increases in levels of liver enzymes are not specific findings for sclerotherapy using polidocanol for PVE; studies of PVE with other embolic materials reported up to 3-fold increases in the levels of liver enzymes 1-3 days after embolization and a return to baseline levels 7-10 days after embolization [26, 38-42]. The decrease in the level of T-Bil observed in our study was probably due to insertion of a bile duct drainage tube. Cardiac complications related to polidocanol can occur due to an anesthetic reaction or allergic and anaphylactic reaction, but are extremely rare [27, 43]. In a previous study of sclerotherapy using polidocanol for the treatment of venous malformations, more than 10 mL of 3% polidocanol was used in 41.2% of total sessions for lesions larger than 10 cm in diameter, and decreases in blood pressure and bradycardia were observed in 10.2% of total sessions. The authors of this study advised against the excessive usage of polidocanol to prevent adverse reactions [30]. In our report, we used a mean volume of 4.6 mL (range, 2-8 mL) of polidocanol, and no cardiac complications were observed.

In our study, we used the foam-form of a sclerosant rather than a liquid form for preoperative PVE. The efficacy of sclerotherapy with foam is greater than that with liquid for the same concentration of sclerosant, because of the greater surface area and irritant nature of foam than liquid [21]. We used the Tessari method to produce foam, because this method can provide compact foam with small diameter bubbles that is easy to manipulate; furthermore, foam can be reconstituted during the procedure [20]. We mixed contrast media with polidocanol to produce foam that would allow dynamic visualization of embolization in the target portal vein. Target portal vein visualization using this foam allowed real-time assessment of embolization in all patients. Complications resulting from the passage of air in the foam to the circulation system should be considered in endovascular foam sclerotherapy. Major

complications such as deep vein thrombosis or pulmonary thromboembolism are unusual and are probably related to large doses of foam and the size of the sclerosis region [21]. Dizziness and blurred vision are minor, transient complications and are related to the total quantity of injected foam [20, 21]. No complications related to foam occurred in our study.

Complications related to PVE such as bile leakage, subcapsular hematoma, portal hypertension, non-targeted portal vein thrombosis, infection, and transient liver failure have an incidence of 0-9% [11, 14, 33, 35, 38, 44]. One study reported that the occurrence of transient liver failure was significantly higher in patients with liver cirrhosis than those without liver cirrhosis [14]. In our study, only one patient had liver cirrhosis with a Child-Pugh Class A score; however, no patient experienced liver failure after PVE. Signs and symptoms of post-embolization syndrome such as nausea, vomiting, abdominal pain, and fever are also rare [8]. Mild transient elevation of body temperature was seen in all patients in our study without signs or symptoms of post-embolization syndrome.

Limitations of our study include the small number of patients examined, the lack of randomization, the retrospective study design, and no comparison with other embolic materials. However, our study is worth because it is the first report about foam sclerotherapy using polidocanol with radioopaque contrast media under fluoroscopic intervention for preoperative PVE.

V. CONCLUSION

In conclusion, foam sclerotherapy using polidocanol is clinically safe and effective for pre-operative PVE before hepatectomy.

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<ABSTRACT (IN KOREAN)>

수술 전 간문맥 색전술을 위한 polidocanol (Aethoxysklerol)을 이용한 포말 경화치료

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정상훈

목적: 간엽절제술 전 간문맥 색전술을 위한 polidocanol을 이용한 포말 경화치료의 임상적 안정성과 효과를 평가하고자 한다.

재료 및 방법: 2006년 3월부터 2008년 10월 사이에 간문맥 색전술을 위해 polidocanol을 이용한 포말 경화치료를 받은 환자 16명을 대상으로 하였다 [남자:여자=12:4, 48-75세 (평균 62세)]. 포말은 3% polidocanol (Aethoxysklerol; Kreussler Pharma, Wiesbaden, Germany)과 공기 및 조영제 (Xenetix; Guerbet, Aulnay-Sous-Bois, France)를 1:2:1의 비율로 혼합하여 만들었다. Polidocanol의 총량은 색전하고자 하는 간문맥의 부피에 따라 조절하였다 (2 - 8 mL; 평균 4.6 mL). 간문맥 색전술 전후에 각각 future liver remnant (FLR)의 부피를 측정하였으며 간문맥 색전술을 위한 polidocanol 포말 경화치료에 따른 합병증을 평가하였다.

결과: 모든 환자에 있어서 기술적 성공을 얻었다. 모든 환자가 시술 중 편안하였으며 경화치료 도중 통증을 느끼지 못하였다. 환자들은 간문맥 색전술 2 – 4 주 후에 역동적 간 CT를 촬영하였다. Polidocanl 포말을 이용한 간문맥 색전술 후 FLR은 19.3% (16-35%)에서 27.8% (23-42%)로 의미 있게 증가하였다 (P=0.001).

결론: 수술전 간문맥 색전술을 위한 polidocanol을 이용한 포말 경화치료는 임상적으로 안전하고 효과적이다.

핵심 되는 말: polidocanol, 포말 경화치료, 간문맥 색전술

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