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GUIDELINE

The Guidelines for Percutaneous Transhepatic Portal Vein Embolization: English Version

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Abstract:
Preoperative portal vein embolization is a beneficial option to reduce the risk of postoperative liver failure by promoting the growth of the future liver remnant. In particular, a percutaneous transhepatic procedure (percutaneous transhepatic portal vein embolization) has been developed as a less-invasive approach. Although percutaneous transhepatic portal vein embolization is widely recognized as a safe procedure, various complications, including rare but fatal adverse events, have been reported. Currently, there are no prospective clinical trials regarding percutaneous transhepatic portal vein embolization procedures and no standard guidelines for the PTPE procedure in Japan. As a result, various methods and various embolic materials are used in each hospital according to each physician's policy. The purpose of these guidelines is to propose appropriate techniques at present and to identify issues that should be addressed in the future for safer and more reliable percutaneous transhepatic portal vein embolization techniques.

Keywords:
percutaneous, preoperative, portal vein, embolization, guideline

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1. Introduction

Preoperative portal vein embolization (PVE) is performed before extensive liver resection to reduce the risk of postoperative liver failure by promoting the growth of the future liver remnant (FLR). The theoretical background of PVE is based on an animal experiment published in 1920, which showed that portal vein ligation causes the atrophy of the ligated lobe and hypertrophy of the nonligated lobe [1]. The first clinical application of preoperative portal vein ligation was described in 1975 [2], and percutaneous transhepatic portal vein embolization (PTPE) was developed as a less-invasive approach to obtain FLR hypertrophy in the 1980s [3-6]. Currently, the Japanese Society of Hepato-Biliary-Pancreatic Surgery's guidelines for the management of biliary tract cancer recommend this procedure for patients with biliary carcinoma who are scheduled to undergo right lobectomy or resection volume of more than 50%-60%. Additionally, preoperative PVE is also indicated for hepatocellular carcinoma, cholangiocellular carcinoma, and liver metastases [7-11].

PTPE is widely recognized as a safe procedure. However, several complications related to the embolization procedure or portal vein puncture have been reported [9, 10]. Among them, rare but fatal adverse events are included [11].

Currently, there are no prospective clinical trials regarding PTPE procedures and no standard guidelines for the PTPE procedure and various methods and various embolic materials have been used in each hospital.

The purpose of these guidelines is to propose appropriate PTPE techniques at present and to identify issues that should be solved for a future goal of standardization of PTPE techniques and perioperative managements to establish a safer and reliable PTFE procedure.

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In addition, this is the English version of the Japanese guidelines for PTPE (2017) [12].

2. Information for the Use of These Guidelines

(1) Attribution of responsibility

The Board of Directors and Guideline Committee of the Japanese Society of Interventional Radiology are responsible for the contents of these guidelines. However, in clinical practice, the physician in charge of the patient shall be responsible for the selection of procedures and the use of embolic materials not covered by Japanese health insurance, with sufficient informed consent, after the approval of the institutional ethics committee, if necessary.

(2) Collection of literature

A literature search was performed in PubMed until February 2016 with key words of percutaneous transhepatic portal embolization =percutaneous[All Fields] AND transhepatic [All Fields] AND portal[All Fields] AND "embolization, therapeutic" [MeSH Terms] OR "embolization" [All Fields] AND "therapeutic" [All Fields] OR "therapeutic embolization" [All Fields] OR "embolization" [All Fields]. After primary screening, 40 out of 255 articles were selected, and through the primary screening, 9 references were added. Furthermore, to identify rare adverse events in Japan, abstracts of Japanese regional meetings were searched from the Japanese database "Ichushi Web" provided by Japan Medical Abstracts Society. Through this process, 127 abstracts were listed and 19 articles remained after checking for duplicates with PubMed search. Finally, 68 articles were included in this analysis.

(3) Evidence level and recommendations

These guidelines were prepared in accordance with the Minds Handbook for Clinical Practice Guidelines Development 2014 as shown below.

Evidence level: A (strong), B (moderate), C (weak), or D (very weak).

Recommendation: 1 (strong) or 2 (weak).

(4) Revision

The content of a set of guidelines is not permanent and needs to be reviewed periodically based on new research findings.

(5) Publication

These guidelines will be published on the website of the Japanese Society of Interventional Radiology.

(6) Conflict of interest

The costs for the preparation of these guidelines were covered by contributions from the Japanese Society of Interventional Radiology. No funding was received from companies or other specific organizations that manufacture or sell the drugs or medical devices mentioned in these guidelines, and none of the committee members who participated in the preparation of these guidelines has any conflict of interest with these companies or organizations.

CQ1. Contralateral Approach (CLA) or Ipsilateral Approach (ILA)?

Although puncture from the lobe scheduled for resection (ILA) is preferred, puncture from the nonresected lobe (CLA) may be performed if the puncture route is interrupted by a tumor or if puncture is anatomically difficult.

Evidence: D.

Strength of recommendation: 2.

Commentary

Preoperative percutaneous transhepatic portal vein embolization (preoperative PTPE) is the preoperative embolization of the portal vein of the lobe scheduled for resection to prevent postoperative hepatic failure. It is generally performed before a right lobectomy, right trisectionectomy, or left trisectionectomy. There are two main methods of approaching the portal vein: puncture of the nonresected lobe (CLA) and puncture of the lobe scheduled for resection (ILA), but the technique of PTPE is not standardized and there are no RCTs on the puncture of portal vein branches. In previous reports, Shimamura et al. [13], Farges et al. [14], Di Stefano et al. [10], and Sirichindakul et al. [15] used CLA whereas Abdalla et al. [24], Madoff et al. [16], Komori et al. [17], Nagino et al. [18], Lee et al. [19], Ebata et al. [8], Sakuhara et al. [9], and Inoue et al. [20] used ILA, but there is also a report of mixed use of both [7]. Overall, ILA is more commonly used, with CLA:ILA = 2:3 to 1:4, and ILA has been a recent trend [11].

Portal vein puncture through the right liver lobe may have a risk of pneumothorax and hemothorax. The liver tumor may disturb the optimal puncture in ILA, but ILA has a substantial advantage. In ILA, puncture-related complications such as intrahepatic hematoma and biloma will not be clinically problematic because the damaged lobe will be resected in the scheduled surgery. The bleeding risk through the puncture tract will be reduced with decreased portal vein pressure after the PTPE.

Because a retrospective study showed that the puncture of the right posterior branch was associated with a higher risk of complication, it may present a difficult situation to choose which side of the portal venous branch should be punctured when the right anterior approach is technically difficult. These guidelines recommend ILA for such situation because periprocedual damage to the nonresected liver is much more serious for the cases scheduled for hepatic lobectomy. However, there is no clear evidence to rule out the puncture of the nonresected lobe, and therefore, puncture performed through the nonresected lobe (CLA) may be considered when the puncture route is interrupted by a tumor or when puncture is anatomically difficult.

CQ2. What Embolic Materials Should Be Used for PTPE?

Fibrin glue was used in the past, but a wide variety of embolic materials is used today. There are no RCTs comparing those, and currently, it is still difficult to standardize embolic materials. Interventional radiologists should be familiar with the characteristics of each embolic agent and should select one appropriate to an individual case.

Evidence: D.

Strength of recommendation: 2.

Commentary

・*Types of embolic materials*

Embolic materials used during PTPE can be broadly classified into temporary embolic materials that are absorbed by the body and permanent embolic materials that are not absorbed by the body. Temporary embolic materials include gelatin sponge and fibrin glue (Beriplast P and Borheal) [7, 8, 17, 21], and permanent embolic materials include metal coils, NBCA [10, 14, 15, 21], PVA, and AVP. Ethanol [8, 9, 13] and EOI [22], which occlude blood vessels because of vascular endothelial dysfunction, are also classified as permanent embolic materials because of their long-term embolic effect. Those embolic materials have been used in solo or in combination with other materials, such as gelatin sponge and metal coil [10], gelatin sponge and thrombin [23], PVA and metal coil [24], and ethanol and metal coil [8]. There are also reports on the use of EOI mixed with CO_2 to form foam [20] and prolamine (Ethibloc) [25]. Radiolucent embolic materials such as fibrin glue, ethanol, and gelatin sponge are also used in combination with Lipiodol to improve visibility.

・*Characteristics of embolic materials*

Gelatin sponge is a soluble embolic agent and is often used in combination with other embolic materials because of its high recanalization rate. Fibrin glue also dissolves within a few months and can lead to the recanalization of the portal vein. Metal coils are easy to handle but are often used in combination with gelatin sponges or other materials because plain coil embolization tends to be relatively proximal embolization. Although a systematic review article shows that the use of NBCA results in a greater % FLR volume increase compared with the other embolic materials, it requires the experience of the radiologist because delivery must be very precise to avoid catheter adhesion to the vessel wall and to prevent embolization of nontargeted branches. In the ipsilateral approach (ILA), it is difficult to obtain postprocedural portography with polymerized NBCA in the liver track. The use of ethanol is highly effective for embolization, but a flow control technique such as temporary balloon occlusion may be required (see CQ3) and it cannot be used in cases of alcohol sensitivity or intolerance. Ethanol induces a strong inflammatory reaction around the portal vein, rendering surgical resection sometimes technically more difficult.

・*Selection of embolic material*

Every embolic material has been reported to have favorable results of FLR hypertrophy with low complication rates. Although a systematic review including the surgical ileocolic approach showed that NBCA is more effective than other embolic materials [11], there are some concerns in the ipsilateral approach in PTPE (see above). Although there is no prospective randomized trial to show which material is the best for PTPE, it is important to select the embolic material according to the underlying liver disease. In cases of hepatocellular carcinoma arising from liver cirrhosis, it is sometimes difficult to obtain sufficient FLR hypertrophy after PTPE [11] and the scheduled liver resection may be canceled. In such cases, PTPE with gelatin sponge or fibrin glue may be helpful because the alternative treatments, such as transcatheter chemoembolization, can indicate after the recanalization of portal vein. Conversely, in the case of hilar cholangiocarcinoma or some hypovascular liver metastases for which transcatheter chemoembolization is not usually indicated, the permanent embolic materials may be appropriate*. Furthermore, in consideration of the handling aspect, gelatin sponge and metal coils are useful when multiselective embolization is required*. (*Committee comment)

CQ3. Is the Temporary Balloon Occlusion Necessary during the PTPE Procedure?

The need for a balloon catheter depends on the embolic material used.

Evidence: D.

Strength of recommendation: 2.

Commentary

In preoperative PVE, the migration of the embolic material into the portal branch of the FLR must be avoided. When using some liquid embolic materials such as anhydrous ethanol alone [9, 13] and EOI [22], a balloon catheter is often used to prevent backflow. Some reports showed that when ethanol [26] or NBCA [14] was used without temporary balloon occlusion, the migration of the liquid embolic material into the untargeted branch occurred in approximately 1% of cases [10]. Conversely, embolization using gelatin sponge [27], PVA [16], and/or coils is performed without a balloon catheter. In general, a balloon catheter is placed at a relatively proximal site, such as the right or left portal vein. Portal vein embolization of the left medial segment before right hepatic trisectionectomy is sometimes difficult with the balloon occlusion technique. Some anatomical variations of the intrahepatic portal vein branch may make the procedure more difficult. Although a balloon catheter is not always necessary in the PTPE procedure, it may be useful for preventing the backflow of the liquid embolic material.

CQ4. What Embolic Material Should Be Used for Puncture Tract Embolization?

In PTPE, there is a risk of hemorrhage from the puncture tract during sheath removal and liver track embolization is thought to be necessary to minimize the risk of hemorrhage. Gelatin sponge, coils, and NBCA are the common embolic materials for tract embolization.

Evidence: D.

Strength of recommendation: 2.

Commentary

A 4-6 F sheath is usually used in PTPE. To reduce the risk of intra-abdominal hemorrhage after sheath removal, track embolization is routinely performed in many institutions [7-9, 16, 28, 29]. In tract embolization, various embolic materials have been used, including gelatin sponge [9, 28], coils [8, 16], NBCA [29], and fibrin glue [7]. Although there is no comparative study regarding the efficacy and complications of each embolic material, liver track embolization is thought to be indispensable to reduce the risk of abdominal hemorrhage regardless of the type of embolic material. However, when a catheter is inserted through the FLR, the migration of the embolic material should be avoided. In some reports, tract embolization was skipped to reduce the risk of nontarget FLR branch occlusion when the PTPE was performed in CLA [10, 28].

In addition, large intra-abdominal hemorrhage or liver hematoma due to the injury of the hepatic artery occurs even after liver tract embolization [8, 9]. Delayed rupture of pseudoaneurysm may also be critical. Careful patient care is important in the following days after the PTPE procedure.

CQ5. What Is the Appropriate Duration between PTPE and Hepatectomy?

Including the surgical transileocolic approach, the interval between preoperative PVE and hepatectomy is 3 to 12 weeks, with an average of approximately 5 weeks. However, focusing on PTPE, most literatures state 2 to 4 weeks [11]. The risk of tumor growth and spontaneous recanalization of the embolized portal vein branch should be considered.

Evidence: C.

Strength of recommendation: 2.

Commentary

Experimental studies showed atrophy of the hepatic lobe ipsilateral to the ligated portal branches, and compensatory hypertrophy was observed in the contralateral lobe. These phenomena have been applied to PTPE since the early 1980s. In a dog model, Ishikawa et al. showed that compensatory hypertrophy of the nonembolized lobe was maximal at week 2 and no more hypertrophy was observed thereafter when the portal vein was embolized with gelatin sponge [30]. In addition, recanalization of the portal vein started within 2 weeks and became more prominent after the fourth week. On the basis of these results, the authors stated that the appropriate timing for hepatectomy after portal vein embolization in dogs is around the second week, but considering that liver regeneration in humans takes approximately twice as long as that in dogs, the appropriate timing for hepatectomy in humans is 3-4 weeks after portal vein embolization. Nakagawa et al. [31] reported that embolization with absolute ethanol resulted in greater hypertrophy at 4 weeks than at 2 weeks after embolization (209% ± 80% and 171% ± 54%, respectively), and many literatures report that the interval between portal vein embolization and surgery was 2 to 4 weeks [7, 8, 16, 17, 23, 32, 33]. Meanwhile, it has been reported that portal vein embolization using fibrin glue showed restoration of portal blood flow in the embolized lobe after 10-14 days [34], and if a temporary embolization material is used, the hypertrophy of the nonembolized lobe may not progress after 2 weeks. However, regardless of which embolization material is used, it should be noted that the interval should not be too long, considering tumor growth. It should also be considered that patients with liver cirrhosis [10, 11], active hepatitis [34], or diabetes mellitus [7] show less hypertrophy response than patients with a normal liver.

CQ6. Is Monitoring of Systemic and Pulmonary Arterial Pressure Necessary during PTPE Procedure?

Rare but serious complications such as acute pulmonary hypertension, cardiopulmonary collapse, and death have been reported during the vascular intervention using absolute ethanol. When PTPE is performed using large amounts of absolute ethanol, frequent monitoring of systemic blood pressure is recommended to notice the early sign of cardiopulmonary collapse.

Evidence: C.

Strength of recommendation: 2.

Commentary

In preoperative PVE, the use of absolute ethanol results in a greater FRL increase compared with the other embolic materials, except NBCA [13]. Absolute ethanol has been widely used in TAE for renal cell carcinoma, renal angiomyolipoma, and arteriovenous malformations as well as direct puncture sclerotherapy for venous and lymphatic malformations and percutaneous ethanol injection therapy for hepatocellular carcinoma. Through those interventional procedures, rare but serious complications such as acute pulmonary hypertension, cardiopulmonary collapse, and death [35-39] have been reported. Usually, ethanol-induced pulmonary arterial spasm is transient [40]. Thus, fatal cardiopulmonary collapse can be avoided when ethanol injection is restricted at the early phase of pulmonary hypertension.

The dose limit of ethanol injection therapy in humans is 1.0 mL/kg [41-43], and many reports suggest 0.5-1.0 mL/kg for the arteriovenous malformations of the limbs and trunk and 0.1-0.3 mL/kg or less for renal diseases [44-46]. In intravenous bolus injection, 0.023-0.175 mL/kg of absolute

ethanol induces pulmonary hypertension. When the dose is increased to 0.14 mL/kg or higher [47], ethanol injection leads to cardiopulmonary collapse and systemic hypotension. In addition, pulmonary arterial pressure correlates with blood ethanol concentration. Shin et al. [48] stated that the treatment of arteriovenous malformations with absolute ethanol injection should be performed under systemic monitoring, including pulmonary arterial pressure measurement.

In PTPE, absolute ethanol administered in the portal vein does not directly reach the systemic circulation. Thus, it cannot be equated with the arteriovenous malformations of the extremities. However, it is favorable to monitor pulmonary arterial pressure during and several minutes after ethanol injection, taking into consideration the potential intrahepatic portovenous shunt that cannot be visualized by portography. Additionally, according to an animal experiment, ethanol-induced pulmonary hypertension and systemic hypotension occur almost at the same time [49]. Therefore, continuous or frequent systemic blood pressure measurement may be a substitute to pulmonary arterial pressure monitoring.

Even when any embolic material other than absolute ethanol is used, it is essential to check the presence of intrahepatic portosystemic shunt by portography in advance.

CQ7. What Are the Complications of Percutaneous Transhepatic Portal Vein Embolization and Their Countermeasures?

PTPE-related serious complication rates have been reported in 0.4%-12.8%, including hemorrhage related to portal vein puncture, infection, portal vein thrombosis, and choleperitonitis [8-10]. Transcatheter arterial embolization for arterial hemorrhage and thrombolysis for portal vein thrombosis could be the countermeasures. Rare but serious complications such as fatal pulmonary embolism and sepsis cannot be avoided [11, 50]. Adequate informed consent and strict management through procedures are important.

Evidence: C.

Strength of recommendation: 2.

Commentary

Complications of PTPE

The mortality rate of preoperative PVE is 0.1%. Portal vein thrombosis (0.8%), unexpected embolization of nontarget vessels (0.6%), intrahepatic hematoma (0.4%), infection/abscess (0.4%), and peritonitis (0.3%) had been reported as major complications. Pyrexia (36.9%), transaminase increase (34.8%), abdominal discomfort/abdominal pain (22.9%), and nausea and vomiting (2.0%) were also reported as minor complications [11].

Sakuhara reported two pneumothorax cases, two hepatic arterial hemorrhages, two subcapsular hemorrhages, one platelet count decrease, and one progression of portal vein thrombus in 143 PTPE cases using ethanol [9]. Ebata reported 494 PTPE cases with 3 complications (portal vein thrombosis in 1, emergency laparotomy due to intra-abdominal hemorrhage in 1, and hemolysis in 1) [8]. Di Stefano reported 24 complications in 184 cases (complete portal vein occlusion in 1, prolapse of NBCA to nonembolized branches in 2, intra-abdominal hemorrhage in 1, hematobilia in 1, metastatic tumor rupture (in the gallbladder) in 1, transient hepatic failure in 6, nontarget embolization of the portal vein branches of the remnant lobe in 10, and subcapsular hepatic hematoma in 2) [10].

Abscess formation around an Amplatzer vascular plug (AVP) used for the tract closure, chest wall dissemination of hepatocellular carcinoma, hepatic necrosis, portal hypertension, rupture of esophageal varices, intrahepatic biloma, transient cardiopulmonary collapse, Guillain-Barré syndrome, and anaphylactic shock are also reported in case reports [14, 16, 22, 23, 28, 31, 33, 34, 51-62, 63].

Countermeasures

To prevent pulmonary embolism with the embolization material, portography is quite important. When a portovenous shunt is identified, shunt embolization should be performed in advance. A balloon catheter should be used to prevent the migration of the invisible embolization material (see CQ3). In a case of arterial hemorrhage, emergency arterial embolization or open surgery should be considered. Intra-abdominal hemorrhage may occur a few hours to a few days after PTPE. Therefore, careful observation should be necessary. Thrombus aspiration and thrombolysis should be performed for severe portal vein trunk thrombosis. For the extension of the thrombus to the portal vein branch of the nonresected lobe, aspiration thrombectomy is performed at the time of hepatectomy. Platelet transfusion is performed for severe thrombocytopenia. There is a report that prophylactic administration of steroids is effective against anaphylaxis reactions against the embolization materials [11], but the number of cases is limited and further accumulation of cases is desired. When absolute ethanol is used as an embolization material, ethanol infusion should be slow. Careful patient monitoring should be performed to prevent cardiopulmonary collapse (see CQ5). When the right posterior portal vein is punctured, the complication rate is more frequent than the other branch puncture [64] (see CQ1).

Considering that the PTPE is an adjunct to extended hepatectomy, a major complication such as patient death is not acceptable. However, fatal pulmonary embolism and sepsis have been reported [11]. In a Japanese domestic report, a case died 3 weeks after PTPE because of pulmonary embolism [5]. In this case, a large intrahepatic biloma developed after PTPE compressed the inferior vena cava but the mechanism of pulmonary embolism was unknown by means of autopsy [65]. Furthermore, some fatal cases of intra-abdominal hemorrhage due to the delayed pseudoaneurysm rupture are known. Close investigation is necessary to understand the mechanism of such severe situations to discuss how to prevent the fatal complications.

Prepared by

Guideline Committee, Japanese Society of Interventional Radiology

The publication of these guidelines has been approved by the Japanese Society of Interventional Radiology (JSIR).

Conflict of Interest: None
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