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Effect of underdilated-stent technique on post-transjugular intrahepatic portosystemic shunt encephalopathy

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Study Protocol

1. Research Methods

(1) Eligibility Criteria

Inclusion Criteria:

- Liver cirrhosis, defined by clinical manifestations, biochemical indicators, imaging examinations, or liver biopsy;
- History of esophagogastric variceal bleeding, or refractory/recurrent ascites;
- Intended to undergo TIPS treatment.

Exclusion Criteria:

- Non-cirrhotic portal hypertension;
- Previous treatments that may affect portal pressure, such as TIPS or surgical procedures;
- History of overt hepatic encephalopathy (West-Haven classification ⩾2);
- Malignant tumors in advanced stages;
- Concomitant irreversible heart, liver, kidney, or respiratory failure;
- Unable or unwilling to sign the informed consent form.

Withdrawal Mechanism

- Patients or their relatives may request study discontinuation during the trial.

(2) Randomization and Intervention

This study employed computer-generated randomization using sequentially numbered envelopes containing treatment protocols. Enrolled participants signed written informed consent forms and were randomly assigned to Group A or B. Participants remained unaware of their assigned group throughout the study. Both groups of patients received identical management protocols throughout the perioperative process, including preoperative consultation, preparation, monitoring, medication administration, surgical procedures, material handling, and postoperative follow-up. The sole difference was the use of 8mm (Group A) and 6mm (Group B) balloons for dilation of puncture tract and subsequently placed portosystemic stent during TIPS procedures. Neither group was administered drugs which might result in pathophysiologic affection of hepatic encephalopathy (e.g., lactulose, rifaximin, ornithine aspartate, branched-chain amino acids, or arginine) before or after TIPS.

(3) Sample Size Calculation

According to literature, the estimated 12-month incidence of overt hepatic encephalopathy following 8mm balloon full-dilation and 6mm balloon sub-dilation in TIPS patients was 54% and 20%, respectively. With a significance level of 5%, power of 80%, and a projected dropout rate of 10%, this study required 36 patients per group (two-tailed test).

(4) Follow-up and Outcomes

All enrolled patients underwent scheduled follow-up examinations at 1, 3, 6, and 12 months after TIPS procedure. The primary outcome was the incidence

of overt hepatic encephalopathy (West-Haven classification ≥2), while secondary outcomes included improvement of portal hypertension complications (e.g., esophageal variceal bleeding, worsening ascites), liver function, complications, and transplant-free survival.