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A prospective randomized controlled trial to compare two methods of selective hepatic vascular exclusion in partial hepatectomy

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Abstract

Background and aim: Selective hepatic vascular exclusion (SHVE) has not been widely used because of difficulty in extrahepatic isolation of hepatic veins. This study aims to compare the results of SHVE using tourniquets or Satinsky clamps on major hepatic veins in partial hepatectomy for liver tumors involving the roots of hepatic veins.

Methods: Between June 2008 and March 2012, a randomized controlled trial was performed on patients undergoing liver resection to compare selective hepatic vascular exclusion using tourniquets or Satinsky clamps in partial hepatectomy. In the tourniquet group, the hepatic veins were completely isolated and occluded with tourniquets. In the Satinsky clamp group, the hepatic veins were dissected on the anterior and side walls only and they were clamped directly by Satinsky clamps.

Results: The time for dissecting hepatic veins was significantly shorter in the Satinsky clamp group $(7.5 \pm 6.6 \text{ min vs } 21.3 \pm 7.4 \text{ min})$ than the tourniquet group. In the tourniquet group, 5 hepatic veins could not be completely isolated and encircled. In 4 additional patients the hepatic vein was slightly torn during dissection. These 9 patients received successful occlusion using Satinsky clamps. In the Satinsky group, all occlusion of the hepatic vein was successful. There was a significant difference in the success rate in hepatic vein occlusion using the Satinsky and the tourniquet groups 60/60 vs 51/60, P = 0.0018.

Conclusions: Both techniques of hepatic vein occlusion were safe and efficacious. As the use of Satinsky clamps is safer, easier and took less time, it is recommended.

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Keywords: Liver neoplasm; Hepatic vein; Vascular control; Hepatectomy

Introduction

In difficult partial hepatectomy, intraoperative massive hemorrhage remains a serious and potentially lethal problem.^{1–3} Total hepatic vascular exclusion (THVE), which involves occlusion of the hepatic vascular inflow combined with occlusion of the supra- and infra-hepatic inferior vena cava (IVC), has been proposed as a solution to limit intraoperative blood loss.⁴ This technique, however, may cause hemodynamic instability and is not tolerated by some patients.^{5,6} Selective hepatic vascular exclusion (SHVE) is a technique which only occludes the hepatic vascular inflow and outflow with preservation of caval flow, so that hemodynamics of the patients remain stable.^{7–11} Unfortunately, SHVE is not widely used because of technical difficulties in extrahepatic dissection of hepatic veins.^{12,13}

From January 2003, Satinsky clamps have been used to occlude hepatic veins during major hepatectomy in our unit. The Satinsky clamp method provides a safe and easy approach to occlude hepatic veins.^{14,15} This randomized controlled trial aimed to compare the operative and perioperative outcomes of partial hepatectomy using two hepatic vein occlusion techniques: the Satinsky clamp and the tourniquet techniques.

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Methods

Trial design

This study was approved by the Institutional Review Board of the Eastern Hepatobiliary Hospital. This was a single-blinded study and only patients were blinded to the randomization. Patient's decision to participate in the study was voluntary, and informed consent was obtained from each patient. The study was registered with the Chinese Clinical Trial Registry and the registration number is ChiCTR-TRC-11001569.

From June 2008 to March 2012, all patients aged between 16 and 65 years who had a preoperative diagnosis of liver tumor encroaching or involving the roots of hepatic veins (at least one major hepatic vein was compressed or invaded) and were suitable for partial hepatectomy at the Third Department of Hepatic Surgery, Eastern Hepatobiliary Surgery Hospital were considered to be included into the study (Fig. 1). Only patients who met the following inclusion criteria were enrolled: (1) elective liver resection; (2) no other concomitant major surgical procedures, such as bowel or bile duct resection; and (3) compensated cirrhosis with Child-Pugh Class A or B.

Sample size calculation

According to the published literature, the sample size was estimated basing on a 25% difference in success rate

between the Satinsky clamp and tourniquet techniques.^{14,15} Assuming a type-I error of 5% ($\alpha = 0.05$), a power of 80% for a 2-tailed log-rank test ($\beta = 0.2$), and about 10% post-randomization dropout, the sample size was 120 patients, with 60 patients in each group.

Randomization

All eligible patients were randomly assigned by an operating theater nurse who was not involved in this research to the tourniquet group or the Satinsky clamp group using computer-generated numbers. Randomization was carried out intraoperatively when abdominal exploration and intraoperative ultrasound confirmed resectability of tumor.

Preoperative investigations

All patients had a chest x-ray, ultrasonography, and contrast computed tomography scan or magnetic resonance imaging of the abdomen. Laboratory blood tests including hepatitis B surface antigen, antibodies to hepatitis C, serum alpha-fetoprotein, carcinoembryonic antigen, carbohydrate antigen 19-9, serum albumin, serum total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and prothrombin time were obtained, and the Pugh's modification of Child's criteria was determined. Further investigations were carried out only when there was clinical suspicion of extrahepatic metastases.



Figure 1. Flow chart.

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