



A prospective randomized controlled trial: Comparison of two different methods of hepatectomy

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Abstract

Background: Hemorrhage and liver failure are the two major complications in partial hepatectomy. The finger fracture or clamp crushing technique has been a standard technique used for transection of liver parenchyma. Hepatic vascular inflow occlusion (Pringle maneuver, PM) is often used to minimize blood loss, but hepatic ischemia-reperfusion may result with an increased risk of post-operative liver failure. The Harmonic scalpel (HS) has been shown to be effective in reducing blood loss during liver parenchymal transection without any hepatic vascular inflow occlusion.

Methods: A randomized controlled trial was carried out to evaluate the impact of the two different hepatic transection techniques. The post-operative short-term results were compared.

Results: During the study period, 160 of 212 patients who received partial hepatectomy in our hospital were randomized into 2 groups: the PM group ($n = 80$) and the HS group ($n = 80$). The numbers of patient who had a poor liver function on post-operative day 5 (ISLGS Grade B) were 30, and 18, respectively ($p < 0.05$). The post-operative complication rate was significantly higher in the PM group (41.3% versus 22.5%, $p < 0.05$). The HS group had significantly less blood loss and blood transfusion requirements than the PM group ($p < 0.05$).

Conclusions: In conclusion, liver resection carried out using HS without hepatic vascular occlusion was better than using finger fracture or clamp crushing technique with Pringle maneuver. The use of HS allowed liver resection to be safely performed, with earlier recovery of liver function, and less surgical complication.

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Keywords: Pringle maneuver; Harmonic scalpel; Liver resection; Liver function; Blood loss; Complication

Introduction

Partial hepatectomy remains the most commonly used curative treatment for malignant liver tumor. The finger fracture or clamp crushing technique has been a standard technique used in transection of liver parenchyma.¹ Hepatic

vascular inflow occlusion in the form of Pringle maneuver is commonly used in partial hepatectomy to reduce intraoperative blood loss during parenchymal transection.² The major concern in the use of hepatic vascular inflow occlusion is ischemia-reperfusion injury.

Harmonic scalpel (HS) allows sealing of small vessels during transection of liver parenchyma with resultant reduced blood loss and transection time.^{3–5} The ultrasonically activated shears seal small vessels between the vibrating blades. The coagulation effect is caused by protein denaturation, which occurs as a result of destruction of hydrogen bonds in proteins and generation of heat in vibrating tissue.⁶ Blood vessels up to 3–4 mm in diameter are coagulated.^{7,8} The tissue-cutting effect derives from a

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saw mechanism in the direction of the vibrating blades. The benefit of Harmonic scalpel without hepatic vascular inflow occlusion in open liver resection remains uncertain, and there is no randomized trial in the medical literature.

This randomized controlled study was carried out to compare the perioperative outcomes of partial hepatectomy using either finger fracture or clamp crushing technique with PM or HS without hepatic vascular inflow occlusion.

Methods

Trial design

From January 2012 to September 2012, 160 patients who underwent partial hepatectomy for liver tumors at the Third Department of Hepatic Surgery, Eastern Hepatobiliary Surgery Hospital were considered to be included into the study. The inclusion criteria were: (1) elective liver resection; (2) inflow occlusion was needed if the finger fracture and clamp crushing technique was used for transection of liver parenchyma; (3) inflow occlusion was not needed if the Harmonic Scalpel was used for transection of liver parenchyma; (4) no major concomitant surgical procedures, such as bowel or bile duct resection; (5) total or selective vascular inflow/outflow occlusion was not required because of site or extent of tumor; (6) malignant tumors, without vascular or bile duct invasion; (7) in the presence of cirrhosis, the liver function was Child-Pugh Class A or B; (8) Eastern Co-operative Oncology Group (ECOG) performance status 0–1.⁹

The operations were carried out by the same team of surgeons who had experience of over 3000 hepatic resections. The primary outcome measures were ISLGS Grades¹⁰ for liver functional status on post-operative day 5 (POD 5) and post-operative peak bilirubin >7.0 mg/dL.¹¹ Secondary outcome measures were amount of blood loss, blood transfusion and procedure-related complications.^{12,13} The study was approved by the Institutional Review Board of the Eastern Hepatobiliary Hospital. Patient's decision to participate in the study was voluntary, and informed consent was obtained. The study was registered in www.chictr.org, which is within the www. WHO. Int recommended list, www.who.int/ictrp/network/primary/en/index.html.

Sample size calculation

The sample size was estimated based on a 30% difference in the mean post-operative peak bilirubin level or worse between the 2 groups on POD 5.¹⁴ With a statistical significance of 0.05 and a power of 0.80, and using a post hoc 2-sample *t* test with a Bonferroni correction, 56 patients per group were required. Assuming the possibility of violation of protocol after randomization, 80 patients were enrolled into each arm of the study.

Randomization

When the patients were assessed to be suitable to be included into this study at operation, randomization was done by an operating theater nurse who was not involved in this study. The patients were randomly assigned to the PM group or to the HS group by drawing sealed and opaque envelopes from a box containing 160 pre-arranged envelopes. 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 (USG) of abdomen, and contrast enhanced computer tomography (CT) or magnetic resonance imaging (MRI) of abdomen. Laboratory blood tests including hepatitis B surface antigen (HBsAg), antibodies to hepatitis C, serum alpha-fetoprotein (AFP), carcinoembryonic antigen (CEA), carbohydrate antigen 19-9 (CA 19-9), serum albumin, serum total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), platelet count, prothrombin time and international normalized ratio (INR) were obtained. In the presence of cirrhosis, Pugh's modification of Child's criteria was determined. Hepatitis B e antigen (HBeAg) and its antibody, and hepatitis B virus deoxyribonucleic acid (HBV-DNA) were tested in the HBsAg positive patients.

The preoperative diagnosis of hepatocellular carcinoma (HCC) was based on AFP, CT or MRI of abdomen. Further investigations were performed to exclude extrahepatic metastases only when there was clinical suspicion.

Surgical procedure

Surgery was performed through a bilateral subcostal incision. In patients with malignant tumors, the abdominal cavity was carefully searched for extent of local disease, extrahepatic metastases, and peritoneal seeding. After mobilization of the liver, intraoperative ultrasound was performed to assess the number and the size of the lesions, and to assess the relationship of the tumor to vascular structures. Patients eligible to the study were then randomized.

Surgical resection

For the HS group of patients, liver resection was carried out without hepatic vascular occlusion. The harmonic scalpel (Ethicon Endo-Surgery, Johnson & Johnson, New Jersey, USA) was set at a high power, and blood vessels or bile ducts up to 3–4 mm in diameter were coagulated for 5–6 s. Blood vessels or bile ducts larger than 5 mm were ligated or sutured.

For the PM group of patients, the entire hepaticoduodenal ligament was encircled and tightened with a rubber

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