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ORIGINAL ARTICLES

Radiofrequency vessel-sealing system versus the clamp-crushing technique in liver transection: results of a prospective randomized study on 100 consecutive patients

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Abstract

Background: Liver transection is considered a critical factor influencing intra-operative blood loss. A increase in the number of complex liver resections has determined a growing interest in new devices able to 'optimize' the liver transection. The aim of this randomized controlled study was to compare a radiofrequency vessel-sealing system with the 'gold-standard' clamp-crushing technique.

Methods: From January to December 2012, 100 consecutive patients undergoing a liver resection were randomized to the radiofrequency vessel-sealing system (LF1212 group; $N = 50$) or to the clamp-crushing technique (Kelly group, $N = 50$).

Results: Background characteristics of the two groups were similar. There were not significant differences between the two groups in terms of blood loss, transection time and transection speed. In spite of a not-significant larger transection area in the LF1212 group compared with the Kelly group (51.5 versus 39 cm^2, $P = 0.116$), the overall and 'per cm^2' blood losses were similar whereas the transection speed was better (even if not significantly) in the LF1212 group compared with the Kelly group (1.1 cm^2/min versus 0.8, $P = 0.089$). Mortality, morbidity and bile leak rates were similar in both groups.

Conclusions: The radiofrequency vessel-sealing system allows a quick and safe liver transection similar to the gold-standard clamp-crushing technique.

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Introduction

Excessive blood loss during a liver transection and the need for blood transfusions have been shown to be correlated with higher morbidity and mortality rates and with a worse long-term outcome.[1] Hepatic pedicle clamping and maintenance of a low central venous pressure during a liver transection are commonly used procedures in order to minimize the blood loss.[2,3] The technique of a liver transection is considered another critical factor influencing intra-operative blood loss. Randomized studies comparing the clamp-crushing technique with other techniques [Cavitron ultrasonic surgical aspirator (CUSA), the hydrojet dissector and the radiofrequency dissecting sealer (RFDS)] have shown that the clamp-crushing technique, usually associated with hepatic pedicle clamping, resulted either in similar or lower blood loss and transfusion requirements.[4–6] Thereafter, the clamp-crushing technique associated with bipolar humid coagulation is generally considered to represent the reference standard against which new methods must be compared.[7]

Over the years, there has been an increasing extension of the indications for hepatic resection and in the use of pre-operative chemotherapy. The progressive increase in the rate of complex hepatic resections on a liver damaged by pre-operative chemotherapy has determined a growing interest in new devices able to shorten the transection time, to facilitate bloodless

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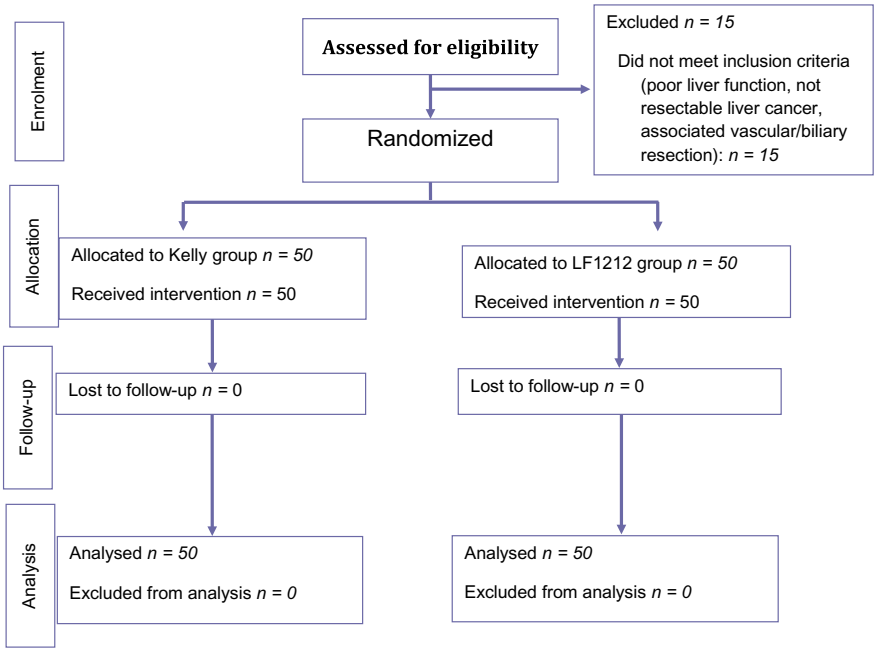

Figure 1 Study flow chart of a liver resection using Kellyclasia plus humid bipolar coagulation (Kelly group) versus by Ligasure[tm] Small Jaw Instrument (Covidien) (LF1212 group)

transections even without hepatic pedicle clamping and to reduce bile leak.[8]

The Ligasure™ Small Jaw Instrument (LF1212) (Covidien, Boulder, CO, USA) is a vessel sealing system that can fuse vessels, up to and including 7 mm, lymphatics and tissue bundles. The LF1212 device has a Kelly shape that allows accurate liver crushing in the standard fashion of the 'classic' clamp-crushing technique. Moreover, some data seem to suggest that this type of vessel sealing system may reduce the risk of bile leakage.[9]

The aim of this randomized controlled trial was to identify the most safe and efficient device in terms of overall and 'per cm^2' blood loss during a liver transection and in terms of transection time and speed.

Materials and methods

At the Department of Surgical Oncology, Institute for Cancer Research and Treament (IRCC) and at the Hepato-Biliary-Pancreatic Surgery and Liver Transplantation Unit, University of Modena and Reggio Emilia, Modena (Italy), from January to December 2012, all patients considered for a curative liver resection were enrolled in this study, after giving written informed consent. A total of 100 consecutive patients whose liver tumours appeared resectable on intra-operative ultrasonography were randomly assigned to undergo a liver transection using kellyclasia plus humid bipolar coagulation (Kelly group: 50 patients) or the Ligasure[tm] Small Jaw Instrument (Covidien) (LF1212 group: 50 patients) by the surgeon (Fig. 1). There were 62 men, and the median (range) age was 64.7 (32.5–84.8) years.

Randomization took place in the operating room after a laparotomy, when the patients were deemed resectable. Patients not eligible for a liver resection after a laparotomy were excluded from the study. Patients were assigned to treatment at the ratio of 1:1 according to a computer-generated randomization list by means of STATA software (version 10 ©; StataCorp LP, College Station, TX, USA). Randomization was restricted by blocking with randomly varying block size and stratified by centre.

Study design

The procedure was approved by the ethical committee of the hospital.

Eligibility criteria included a liver resection either for benign or malignant tumours, 'good hepatic function' defined as Child–Pugh class A and a ICG Test ≤15%, an acceptable clotting profile (platelet count 90×10^3), and adequate cardio-respiratory and renal function. Patients requiring a bile duct resection, vascular resection or undergoing emergency liver surgery were excluded from the study.

Liver transection time and blood loss were calculated from the beginning to the end of the liver resection. The amount of blood loss was measured from the volume of blood in the suction container and from the weight of the soaked gauzes. At the end of liver resection, the area of the transection surface was measured: the transection surface was marked on a piece of transparent plastic sheet and then transcribed to a piece of paper containing marks of square millimeter for the measurement of the area of the liver transection surface.