

Comparison of hydro-dissection versus ultrasonic aspirator in division of liver parenchyma in laparoscopic resection

Lap Liver Study

NCT03208192

15/05/2020

Statistical Analysis Plan

The samples size of 60 patients was calculated for 90% statistical power. Randomization in each arm was performed using envelopes. Continuous data presented as median values were compared using the Mann–Whitney U test. Two-tailed Fisher's Exact Test was used for comparing categorical variables. A P-value of less than 0.05 was considered statistically significant. SPSS version 23.0 (IBM SPSS, Inc., Chicago, IL) software package was applied for data analysis.

Inclusion criteria were benign liver tumors (hemangioma, focal nodular hyperplasia, hepatocellular adenoma, hydatid echinococcosis [only with total pericystectomy]) and malignant tumors (colorectal cancer metastases, hepatocellular carcinoma, intrahepatic cholangiocarcinoma). In addition to the standard criteria, specific exclusion criteria were liver cirrhosis and the inability to provide standard conditions for the bleeding prevention (high central venous pressure, fragile liver parenchyma due to severe steatosis and other advanced drug-induced changes). Primary endpoint was ratio of blood loss to resection area (mL/cm²). I

An addition to the exclusion criteria specified in the design of the study, the latter were expanded due to the following position: Intraoperative incidents not related to liver resection (strong adhesions leading to organ damage or insufficient vascular control, impossibility to decrease CVP due to patient condition, changing the operation plan due to intraoperative findings like invasion into adjacent organs or multiple lesions, equipment problems).

All operations were performed by a single surgeon.