Laparoscopic versus open hemihepatectomy: The ORANGE II PLUS multicenter randomized controlled trial


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Background

Surgical resection forms the mainstay of curative treatment for cancers involving the liver. The laparoscopic approach to major liver resections is increasingly being performed. Randomized evidence to show superiority of laparoscopic (LH) compared to open hemihepatectomy (OH) for perioperative and oncological outcomes is lacking.

Methods

Patients undergoing hemihepatectomy for accepted indications (principally known or suspected cancer) were randomized 1:1 to either LH or OH in 16 European centers. Patients and ward personnel were blinded until postoperative day 4. The primary endpoint was time to functional recovery (TFR). The definition included being independently mobile with adequate oral intake and normalizing liver function. Secondary outcomes included length of hospital stay (LOS), postoperative 90-day morbidity, 90-day mortality, resection margin status and 3-year survival. All analyses were by intention to treat (ITT).

Results

179 eligible patients were randomly assigned to LH and 173 to OH between October 2013 and January 2019. 135 (75%) of 179 patients in the LH group and 142 (82%) of 173 patients in the OH group had cancer: 162 colorectal liver metastases (CRLM), 47 hepatoma, 47 cholangiocarcinoma, 21 other metastases. Primary ITT analysis included 327 patients (LH 164 vs OH 163) and demonstrated a significant reduction in TFR: LH 4 days (IQR 2-6) vs OH 5 days (IQR 3-7), P< 0.001. LOS was similarly different: LH 5 days (IQR 2-8) vs OH 6 days (IQR 4-8), P= 0.002. In the LH group 15% (24/164) of patients experienced complications > Clavien-Dindo IIIa within 90 days of surgery vs 18% (30/163) in the OH group, P= 0.36. There were 5 deaths (3.0%) within 90 days of surgery in the LH group vs 5 (3.1%) in the OH group, P= 0.99. For all cancers, resection margins ≥1 mm were attained for 107/133 (81%) patients in the LH group vs 121/138 (88%) patients in the OH group (OR 1.73, 99% CI 0.72-4.14, P= 0.11). At a median follow-up of 37 months (IQR 24-50 months) 3-year survival rate was 58% for LH vs 65% for OH (HR 1.16, 99% CI 0.68-1.98, P=0.49).

Conclusions

LH is superior to OH in terms of TFR and LOS. No significant differences in oncological outcomes were observed but follow-up continues to permit a mature survival analysis.

Clinical trial identification

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Legal entity responsible for the study

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Disclosure
All authors have declared no conflicts of interest.

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