

Adjuvant Radiotherapy for Resected
Hepatocellular Carcinoma With MVI

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Objectives: Marginal resection frequently occurred in hepatectomy for hepatocellular carcinoma (HCC), which led to increased local recurrence, especially among patients with microvascular invasion (MVI). Stereotactic body radiotherapy (SBRT) shows effective in tumor controlling, while limited research reported the efficacy of SBRT as adjuvant setting for HCC. This prospective randomized controlled study aims to investigate the efficacy of SBRT as adjuvant setting for HCC patients with MVI and positive resection margin.

Design: This is a single center, prospective, randomized controlled clinical trial measuring the efficacy of SBRT as adjuvant therapy for early HCC with MVI after surgery.

Methods: Participants with HCC and MVI receiving marginal resection were randomly assigned to postoperative adjuvant SBRT group or surgery alone (SA) group. Patients in SBRT group received SBRT targeting on the resection marginal parenchyma one month after surgery. The disease-free survival (DFS) and overall survival (OS) were compared between the groups and the adverse events (AE) in the SBRT group were recorded.

Protocol

1. Adult patients diagnosed with hepatocellular carcinoma, suitable for partial hepatectomy were considered as potential candidates while the patients were referred to hospital (n=263).
2. In-hospital examination includes physical status, liver function and tumor stage. Patients with Child-Pugh A liver function, ECOG physical status 0/1, and BCLC stage 0/A were good candidates for surgical resection. These patients would be put forward to surgery and waiting for the postoperative pathological examination. Marginal resection was applied while tumor was adjacent to major vasculature or severe cirrhosis existed. We routinely mark the unsafe resection margin with silver clips for potential adjuvant postoperative therapy.
3. Once pathological examination proved micro-vascular invasion in paratumoral tissue, which meant a higher incidence of early recurrence for the patient, the patient would be considered as a candidate for enrollment.
4. The protocol and detail of the trial would be clearly explained to the patient and the written informed consent were collected if the patient agreed to be enrolled.
5. Randomization: Randomization was carried out using the random sequence method of EXCEL, keeping a 1:1 ratio in groups. Two nurses on daily duty accomplished the randomization and allocation work. Participants in SBRT group would be sent to a separate team of radiologists who carried out the radiotherapy and follow-up survey (n=76).
6. Concealment: Concealment was not attached in the SBRT group and blinding was not applied due to the SBRT procedure.
7. Surgery: The conventional open partial hepatectomy was applied in this study. After removal of the tumor, silver clips were imbedded to mark where resection

margin was narrow and absent. The marginal liver resection was defined as the minimal distance from tumor edge to the cut surface $<5\text{mm}$, regardless of the margin was positive or not.

8. Radiotherapy: SBRT was delivered by the CyberKnife® system (Accuray Inc., Sunnyvale, CA, USA) with tumor tracking devices. All the patients received fiducial marker implantation in operation for the tumor tracking technique.
9. Follow-up: All the participants received follow-up every 3 months until recurrence or censored.

