

Liver Resection versus Radiofrequency Ablation plus Transcatheter Arterial Chemoembolization in Cirrhotic Patients with Solitary Large Hepatocellular Carcinoma

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ABSTRACT

Purpose: To compare liver resection (LR) with single-step, balloon-occluded RF ablation plus drug-eluting embolics transarterial chemoembolization in cirrhotic patients with single hepatocellular carcinoma (HCC) ≥ 3 cm.

Materials and Methods: From 2010 to 2014, 25 patients with compensated cirrhosis and single HCC ≥ 3 cm (median size 4.5 cm; range, 3.0–6.8 cm) not suitable for LR or liver transplantation were treated with RF ablation plus transarterial chemoembolization in a prospective observational single-center pilot study; all patients had complete tumor necrosis after treatment. A retrospective control group included 29 patients (median HCC size 4.0 cm; range, 3.0–7.4 cm) who underwent LR. RF ablation plus transarterial chemoembolization group included more patients with severe portal hypertension (65.5% vs 35.0%, $P = .017$). Primary endpoints were overall survival (OS) and tumor recurrence (TR) rates.

Results: One death and 1 major complication (4%) were observed in LR group. No major complications were reported in RF ablation plus transarterial chemoembolization group ($P = .463$). OS rates at 1 and 3 years were 91.8% and 79.3% in LR group and 89.4% and 48.2% in RF ablation plus transarterial chemoembolization group ($P = 0.117$). TR rates at 1 and 3 years were 29.5% and 45.0% in LR group and 42.4% and 76.0% in RF ablation plus transarterial chemoembolization group ($P = .034$). Local tumor progression (LTP) rates at 3 years were significantly lower in LR group (21.8% vs 58.1%, $P = .005$). Similar results were found in patients with HCC ≤ 5 cm (TR rates 35.4% vs 75.1%, $P = .016$; LTP 16.0% vs 55.7%, $P = .013$).

Conclusions: LR achieved lower TR and LTP rates than RF ablation plus transarterial chemoembolization, but 3-years OS rates were not statistically different between the 2 groups. RF ablation plus transarterial chemoembolization is an effective treatment option in patients with compensated cirrhosis and solitary HCC ≥ 3 cm unsuitable for LR.

ABBREVIATIONS

HCC = hepatocellular carcinoma, LR = liver resection, LTP = local tumor progression, MW = microwave, OS = overall survival

Liver resection (LR) represents the mainstay of treatment for solitary hepatocellular carcinoma (HCC) > 3 cm unsuitable for liver transplantation (1). However, the feasibility and long-term effectiveness of LR are affected by liver function

and alternative therapies are needed for patients with compensated cirrhosis and contraindication to surgery (1,2). Radiofrequency (RF) ablation provides excellent results in lesions up to 3 cm in size but is less effective in larger

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lesions (3,4). Transarterial chemoembolization is considered a palliative treatment, as complete tumor necrosis is rarely attained—as shown in explants analysis of HCC treated before liver transplantation—and it is associated with high tumor recurrence rates (5). This is the reason why combinations of these techniques have been used, showing better results than RF ablation or transarterial chemoembolization alone in achieving tumor necrosis and higher survival rates (6–8). The efficacy of the combination of RF ablation plus transarterial chemoembolization compared with LR in patients with cirrhosis and single HCC ≥ 3 cm is still a matter of debate, as only a few studies addressing this issue with controversial results are available (9,10). Hence, the aim of this study was to evaluate the effectiveness and the safety of LR versus single-step, balloon-occluded RF ablation plus transarterial chemoembolization in patients with cirrhosis and single HCC ≥ 3 cm.

MATERIALS AND METHODS

Study Design

This study was approved by the institutional review board and was performed in agreement with the 1990 Declaration of Helsinki and subsequent amendments. Written informed consent was obtained from all patients. The study enrolled patients with cirrhosis and single HCC ≥ 3 cm who were included in an observational prospective single-center pilot study designed to assess effectiveness and safety of single-step combined therapy of RF ablation plus drug-eluting embolics transarterial chemoembolization. A cohort of cirrhotic patients who underwent LR whose data were collected retrospectively served as control group.

All patients were > 18 years old and fulfilled the following inclusion criteria: (a) liver cirrhosis classified as Child-Pugh score A, (b) single large HCC 3–8 cm, (c) no vascular invasion or extrahepatic metastases on sectional studies performed before treatment, (d) detection of complete tumor necrosis 1 month after RF ablation plus transarterial chemoembolization session. Exclusion criteria were the following: (a) liver cirrhosis classified as Child-Pugh score B or C, (b) diuretic-resistant ascites, (c) platelet count $< 40,000/\mu\text{L}$ for LR group, (d) platelet count $< 40,000/\mu\text{L}$ for RF ablation plus transarterial chemoembolization group if a prophylactic platelet transfusion before treatment was not able to raise the platelet count to $\geq 40,000/\mu\text{L}$, and (e) chronic kidney disease stage 4 or stage 5 not on hemodialysis for RF ablation plus transarterial chemoembolization group. All patients who underwent RF ablation plus transarterial chemoembolization had been excluded from LR after multidisciplinary evaluation because of ≥ 1 of the following reasons: requirement of major resection in patients with severe portal hypertension (defined as presence of esophageal varices $\geq \text{F2}$ or gastric varices, splenomegaly with platelet count $< 100,000/\text{mL}$, or actual ascites or previous ascites successfully treated with diuretics), surgery unfeasible or hazardous owing to lesion location, concurrent severe comorbidities, or patient refusal.

Workup before Treatment and Patients' Clinical and Demographic Characteristics

The workup before treatment in both RF ablation plus transarterial chemoembolization and LR groups consisted of physical examination; laboratory tests; and imaging studies including liver ultrasound (US), radionuclide bone scan, and dynamic contrast-enhanced computed tomography (CT) of thorax and abdomen. Cirrhosis was diagnosed by histologic and/or clinical criteria (laboratory parameters, US and/or CT signs). Severe portal hypertension was diagnosed in the presence of ≥ 1 of the above-mentioned criteria excluding patients from major LR. Diagnosis of HCC was based on the guidelines in force at the time of study enrollment (1).

Patients were treated between January 2010 and December 2014. The LR group included 25 patients. During the enrollment period, 33 patients with compensated cirrhosis and solitary HCC ≥ 3 cm were treated with RF ablation plus transarterial chemoembolization; 4 patients (12.1%) were excluded because complete tumor necrosis was not achieved. Hence, the RF ablation plus transarterial chemoembolization group included 29 patients. Clinical features of patients are listed in Table 1. All patients with mild ascites were treated successfully with diuretic therapy before treatment. The RF ablation plus transarterial chemoembolization group also included 1 patient on hemodialysis and 1 patient with a platelet count of $19,000/\mu\text{L}$ who underwent platelet transfusion before the treatment. Eight patients in the RF ablation plus transarterial chemoembolization group (24.2%) and 6 patients in the LR group (20.6%) had been previously treated with other locoregional procedures (ie, transarterial chemoembolization, RF ablation, and percutaneous ethanol injection) without achieving complete necrosis ($P = .121$).

RF Ablation plus Transarterial Chemoembolization Protocol

All combined treatments were performed by the same interventional radiologist (R.I.) with 14 years of experience. A single-step combination approach was used (11). Hepatic angiography using a 6-F guiding catheter (curved C1 or C2, 65 cm in length) was performed through a right common femoral approach to map liver vascular anatomy, arterial tumor supply, and eventual arteriovenous shunts. A 0.014-inch guide wire (ChoICE; Boston Scientific, Marlborough, Massachusetts) and a low-profile monorail percutaneous transluminal angioplasty balloon ($4\text{--}5 \times 20$ mm, Muso; Terumo Corp, Tokyo, Japan) were advanced into the segmental hepatic artery feeding the lesion. An internally cooled RF electrode with a 3-cm exposed tip (Cool-tip RF Ablation System; Medtronic, Minneapolis, Minnesota) was introduced into the nodule using US guidance. The angioplasty balloon in the segmental hepatic artery was filled with saline solution and contrast material until vascular occlusion was achieved. The RF generator was activated to maintain a temperature of $90^{\circ}\text{--}115^{\circ}\text{C}$ at the exposed tip for 12 minutes. At the end of the procedure, the RF electrode was withdrawn, the occlusion

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