Efficacy of microwave ablation versus radiofrequency ablation for the treatment of hepatocellular carcinoma in patients with chronic liver disease: a randomised controlled phase 2 trial

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Résumé en anglais	BACKGROUND: Radiofrequency ablation is the recommended treatment for patients with hepatocellular carcinoma who have lesions smaller than 3 cm and are therefore not candidates for surgery. Microwave ablation is a more recent technique with certain theoretical advantages that have not yet been confirmed clinically. We aimed to compare the efficacy of both techniques in the treatment of hepatocellular carcinoma lesions of 4 cm or smaller. METHODS: We did a randomised controlled, single-blinded phase 2 trial at four tertiary university centres in France and Switzerland. Patients with chronic liver disease and hepatocellular carcinoma with up to three lesions of 4 cm or smaller who were not eligible for surgery were randomised to receive microwave ablation (experimental group) or radiofrequency ablation (control group). Randomisation was centralised and done by use of a fixed block method (block size 4). Patients were randomly assigned by a co-investigator by use of the sealed opaque envelope method and were masked to the treatment; physicians were not masked to treatment, since the devices used were different. The primary outcome was the proportion of lesions with local tumour progression at 2 years of follow-up. Local tumour progression was defined as the appearance of a new nodule with features typical of hepatocellular carcinoma in the edge of the ablation zone. All analyses were done in the per-protocol population. The study is completed, but patients will continue to be followed up for 5 years. This study is registered with ClinicalTrials.gov, number NCT02859753. FINDINGS: Between Nov 15, 2011, and Feb 27, 2015, 152 patients were randomly assigned: 76 patients to receive microwave ablation and 76 patients to receive radiofrequency ablation. For the per-protocol analysis, five patients were excluded from the microwave ablation group as were three patients from the radiofrequency ablation group. Median follow-up was 26 months (IQR 18-29) in the microwave ablation group and 25 months (18-34) in the radiofrequency ablation group. At 2 years, six (6%) of 98 lesions had local tumour progression in the microwave ablation group as did 12 (12%) of 104 in the radiofrequency ablation group (risk ratio 1·62, 95% CI 0·66-3·94; p=0·27). Complications were infrequent, with only two grade 4 complications (two events of arterial bleeding requiring embolisation, both in the microwave ablation group) and three grade 3 complications (pneumothorax; lesion of the umbilical vein; and intrahepatic segmental necrosis, all in the radiofrequency ablation group). No treatment-related deaths were reported. INTERPRETATION: Although we did not find that microwave ablation was more effective than radiofrequency ablation for treatment of hepatocellular carcinoma lesions of 4 cm or smaller, our results show that the proportion of lesions with local tumour progression at 2 years of follow-up was low with both tested percutaneous methods. FUNDING: Microsulis (AngioDynamics).
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