Factors Associated with Short-Term Local Recurrence of Liver Cancer after Percutaneous Ablation Using Irreversible Electroporation: A Prospective Single-Center Study

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ABSTRACT

Purpose: To evaluate the risk factors associated with short-term local recurrence of malignant liver lesions after irreversible electroporation (IRE).

Materials and Methods: Thirty-nine consecutive patients (79 malignant liver lesions) were treated with IRE, of whom 14 were excluded from the analysis (including 12 without 6 mo of follow-up and two with incomplete ablation). The remaining 25 patients (aged 59.4 y ± 11.2) had 48 malignant liver lesions, including 22 hepatocellular carcinomas (HCCs), six cholangiocellular carcinomas, and 20 metastatic liver cancers. Multivariate analyses were used to evaluate the associations of risk factors with early recurrence. The characteristics of patients, lesions, and IRE procedures were assessed by logistic regression.

Results: Fourteen of the 48 treated lesions (29.2%) showed early local recurrence after 6 months. Tumor volume (< 5 cm^3 vs ≥ 5 cm^3; $P = .022$) and underlying disease type (HCC, cholangiocellular carcinoma, or metastatic disease; $P = .023$) were independently associated with early local recurrence. However, distances to the surrounding portal veins (< 0.5 cm vs ≥ 0.5 cm; $P = .810$), hepatic veins ($P = .170$), hepatic arteries ($P = .761$), and bile ducts ($P = .226$) were not significantly associated with local recurrence.

Conclusions: Because short distances to the surrounding vessels were not associated with early local recurrence, percutaneous IRE might provide an alternative treatment option for perivascular tumors. However, patients with larger tumor volumes appeared to be poor candidates for percutaneous IRE. Regarding the different types of treated lesions, patients with HCC had significantly better outcomes.

ABBREVIATIONS

BMI = body mass index, EOB-DTPA = ethoxybenzyl diethylenetriamine pentaacetic acid, HCC = hepatocellular carcinoma, IRE = irreversible electroporation, RF = radiofrequency

Percutaneous ablation techniques, such as radiofrequency (RF) and microwave ablation, have become an established component of multimodal therapy regimens for primary and secondary liver cancer (1,2). However, because these techniques rely on a thermal ablation mechanism, there are some remaining limitations to their use and effectiveness. Indeed, as a consequence of the heat-sink effect, the rate of complete tumor necrosis decreases to less than 50% when there are larger vessels

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abutting the tumor (3,4). In addition, lesions that are proximal to vital structures (ie, major bile ducts, portal vein, and hepatic veins) and liver lesions that are subcapsular or centrally located continue to pose a challenge to the use of thermal modalities, as thermal protection of the adjacent organs or central bile ducts cannot be guaranteed (5,6).

Irreversible electroporation (IRE) is an innovative nonthermal ablation technique that offers certain advantages over other ablation techniques and has gained widespread attention (7). Instead of thermal energy, IRE delivers a number of electrical pulses that have millisecond durations. The pulses disturb the cell membrane potential by creating irreversible nanopores, leading to apoptosis (8,9). Although IRE is believed to destroy all cells within the ablation zone, a number of preclinical animal studies showed that its nonthermal ablation mechanism results in the preservation of proteins in the extracellular matrix of the supportive connective tissue. Therefore, the structural integrity of adjacent or contained vital structures (such as blood vessels, bile ducts, and nerves) appears to be unaffected by IRE (8,10–17). In the past 2 years, the literature reporting clinical experiences with IRE has grown considerably. The first clinical studies have demonstrated promising results regarding its safety and efficacy (18–24).

However, although the risk factors for early recurrence have been extensively evaluated for thermal ablation, the same information has not been available for IRE. Several clinical studies of thermal ablation (1,25–27) identified tumor size and complete ablation with an adequate tumor-free margin as the most important predictors of local recurrence. Other risk factors for local recurrence after thermal ablation include proximity to large vessels and subcapsular location or poor differentiation of the tumor (6,28). Because IRE relies on a fundamentally different mechanism of ablation, the risk factors for early local recurrence after thermal ablation are unlikely to also apply to IRE. Therefore, the aim of the present study was to evaluate the risk factors associated with early local recurrence after percutaneous treatment with IRE.

MATERIALS AND METHODS

A prospective, single-center clinical trial was conducted to evaluate the risk factors associated with early local recurrence within 6 months after an IRE procedure. The study addressed the main hypothesis that several factors influence the frequency of early local recurrence of malignant liver lesions after IRE, but that proximity to vascular structures is not among them. The study received institutional review board approval.

Patients with primary and secondary liver cancer were treated with IRE between December 2011 and March 2013. All patients were poor candidates for surgical options and thermal ablation in view of tumor location and/or preceding surgery. Each case was reviewed in a multidisciplinary tumor conference to ensure that all the treating physicians agreed with the proposed IRE treatment plan before the patient was included in the study. The following inclusion criteria were applied: written informed consent from each patient, age $>$ 18 years, maximum lesion diameter $<$ 5 cm, adequate liver and renal function, and an American Society of Anesthesiologists health status score of 0–3. Before IRE, each patient's disease was staged based on a contrast-enhanced computed tomography (CT) scan of the chest, abdomen, and pelvis to rule out extrahepatic tumor manifestation. In addition, dedicated magnetic resonance (MR) imaging of the liver was performed before the ablation procedure to rule out additional malignant liver lesions that might have been undetectable on CT imaging. The MR imaging scan was performed with liver-specific contrast medium (gadolinium [Gd] ethoxybenzyl diethylenetriamine pentaacetic acid [EOB-DTPA]; Primovist; Beyer Schering, Berlin, Germany). Contraindications to IRE treatment in this study were the presence of a defibrillator or a pacemaker, a history or presence of cardiac arrhythmia, recent myocardial infarction, severe heart failure, and severe coagulation disorders (platelet count $>$ 50,000/cm^3; partial thromboplastin time $<$ 50 seconds, or International Normalized Ratio $<$ 1.5). In addition, any characteristics that contraindicated general anesthesia were also contraindications for IRE treatment, as was the presence of extrahepatic or multifocal hepatic disease.

During the study period, a total of 83 patients underwent percutaneous treatment with IRE, microwave ablation, or RF ablation, of whom 39 patients with 79 lesions received IRE. Of these 39 patients, we excluded 12 patients (21lesions) without follow-up imaging at 6 months and two patients (10 lesions) for whom incomplete ablation was documented at the 6-week follow-up examination. Forty-eight lesions were treated in the remaining cohort of 25 patients (four women and 21 men; mean age, 59.4 y ± 11.2 [standard deviation]; age range, 22–80 y; **Table 1**).

The lesions had a mean volume of 6.2 cm^3 ± 8.2 (range, 0.2–37.8 cm^3) and a mean largest diameter of 1.7 cm ± 0.7 (range, 0.7–3.6 cm; **Figs 1** and **2**). Twenty-two lesions were hepatocellular carcinoma (HCC; 45.8%), six were cholangiocellular carcinoma (12.5%), and 20 were metastatic liver cancer (41.7%).

Ablation Procedure and Follow-up

All patients were treated percutaneously with IRE by using the NanoKnife system (AngioDynamics, Latham, New York) and received general anesthesia with deep paralysis to prevent muscle stimulation. All IRE electrodes were percutaneously placed into the target area under CT fluoroscopy (CareVision, Somatom 16;

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