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Radiofrequency ablation of small breast tumours: Evaluation of a novel bipolar cool-tip application

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Abstract

Background: Although radiofrequency ablation (RFA) is promising for the local treatment of breast cancer, burns are a frequent complication. The safety and efficacy of a new technique with a bipolar RFA electrode was evaluated.

Methods: Dosimetry was assessed *ex vivo* in bovine mammary tissue, applying power settings of 5–15 W with 10–20 min exposure and 3.0–12.0 kJ to a 20-mm active length bipolar internally cooled needle-electrode. Subsequently, in 15 women with invasive breast carcinoma ≤2.0 cm diameter ultrasound-guided RFA was performed followed by immediate resection.

Results: An ablation zone of 2.5 cm was reached in the *ex vivo* experiments at 15 W at 9.0 kJ administered energy. Histopathology revealed complete cell death in 10 of 13 patients (77%); in 3 patients partial ablation was due to inaccurate probe positioning. In 1 patient a pneumothorax was caused by the probe placement, treated conservatively. No burns occurred.

Conclusions: Ultrasound-guided RFA with a bipolar needle-electrode appears to be a safe local treatment technique for invasive breast cancer up to 2 cm. Ways to improve placement of the probe and direct monitoring of the ablation-effect should be the aim of further research.

Keywords: Breast cancer; Minimally invasive techniques; Radiofrequency ablation (RFA)

Introduction

The trend towards local breast cancer treatment with minimally invasive approaches has led to the introduction of radiofrequency ablation (RFA) as a possible substitute for surgery. RFA uses electrodes to deliver an alternating current that generates ionic agitation, localized frictional tissue heating and cell death.[1] Not the electrode, but the surrounding tissue is the source of heat. The heat transfers conductively to more distant tissue, creating an ellipsoid region of necrotic tissue aligned with the needle-electrode tip. This technique was first introduced for breast cancer treatment in 1999 by Jeffrey et al.[2]

Several feasibility studies have indicated the potential of RFA to replace surgical resection as local treatment for small breast cancer. In initial studies RFA was followed by immediate surgery and subsequent assessment of the tumour cell viability by (immuno)histological examination.[3–11] These

Abreviations: RFA, radiofrequency ablation; APC, automatic power control; US, ultrasound; W, Watt; kJ, kilojoules; MRI, magnetic resonance imaging; Tc, technetium; H&E, haematoxylin eosin; CK8, cytokeratin 8.

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studies commonly suggest that RFA might be useful for the local control of small, well-localized breast cancer because of its effective cell destructive ability in a fairly predictable volume of tissue, with a success rate ranging from 84 to 100% ablation of tumours ≤2.0 cm.[3–11] Ensuing studies with a delayed excision, at intervals ranging from 7 to 202 days, showed similar results.[12–16] All previous studies however, used monopolar electrodes, in either the form of a needle-type or a multi-array umbrella-shaped probe.[17] This method requires a cutaneous neutral electrode and a grounding pad at arm or thigh to create a closed electrical circuit. Aside from causing tissue necrosis around the active electrode, the current flows through the patient to the neutral electrode. Therewith, this method not only requires a large amount of admitted power, but also carries the risk of uncontrolled electrical current paths through the whole body and concordant undesired thermal tissue damage, for example to adjacent organs or skin along the path. Previous studies have indeed shown a relatively high percentage of skin and muscle burns at the site of the grounding pad or pectoral muscle, in up to 30% of patients.[8]

An alternative method is a bipolar RFA technique in which both electrodes are located on one applicator. Consequently, the radiofrequency energy is exclusively applied to the target tissue.

Previous clinical studies were able to show that bipolar RFA with internal cooling can be conducted on patients in a safe and uncomplicated manner for tumours in liver and pancreas.[18,19] A thorough study of the novel bipolar system's dosage/effect relationship in mammary tissue with the objective to obtain an overview of the inducible lesion sizes was however lacking.

The first goal of this study, therefore, was to determine the optimal power settings in a bovine model to acquire an adequate lesion diameter with RFA and to monitor tissue temperature changes during ablation. Subsequently, this study aimed to evaluate the safety and efficacy of this bipolar RFA technique for the local treatment of small breast carcinomas.

Methods

To determine the optimal power settings to acquire an adequate lesion diameter, first an *ex vivo* study was performed. Subsequently, we continued with the *in vivo* clinical evaluation.

Ex vivo study set up

Fresh bovine mammary tissue of 5 × 5 × 5 cm was cut in two equal slices and placed watertight in a temperature bath at 37 °C with a BD Lauda thermostat. The RFA procedure started when a tissue core temperature of 35–37 °C was reached. Six Luxtron 790 Fluoroptic thermo probes (Luxtron Corporation, Santa Clara (CA), USA) were fixed on an Elastofix bandage at distances of 0.5 cm; 1 cm; 1.5 cm; 2 cm and 2.5 cm from the edge. Hereby, temperatures to a distance of 2.5 cm from the probe were measured.

At intervals of 1 s, energy output and temperature measurements were performed and displayed in real-time. After each ablation procedure, the acquired ablation length and width were measured macroscopically, along with the size of the transition zone.

Radiofrequency ablation procedure

A bipolar radiofrequency ablation system was used (CelonProSurge 150-T20, Olympus Winter & Ibe GmbH, Hamburg, Germany). We used a 15-gauge, bipolar needle-type probe where a current flows exclusively between the two electrodes, separated from each other by an insulator, at the tip of the probe. The conducting part of the bipolar applicator was 20 mm, including both electrodes and the insulator. The high-frequency current flows between the two electrodes at the tip of the bipolar applicator and heats up the tissue surrounding the electrodes. The use of grounding skin pads to close the electrical circuit was therefore dispensable. A peristaltic pump, set at 30 ml/min, circulates sterile saline (at room temperature) solution to provide internal cooling of the probe.

The probe was connected to a resistance controlled automatic power control (APC) unit working at 470 kHz (CelonLab POWER, Olympus Winter & Ibe GmbH, Hamburg, Germany).[20] This power control unit is able to automatically regulate the optimum power output based on the tissue resistance measured. In this way, the desiccation of the tissue and thus the premature termination of the power output were prevented.

If the impedance increased beyond a limit value, indicating a dehydration status around the electrodes, the power output was automatically reduced, until a stabile resistance value was reached. Then the power was again automatically increased to the pre-set output value. If another significant change in resistance occurred at a later stage in the process, this procedure could be repeated as often as necessary. At power settings <10 W APC was switched off, allowing the device to generate a continuous energy output.

RFA was performed at a pre-set power level. The mean power, the amount of energy emitted and the duration of application were automatically measured and indicated. In the first series, power settings of 5, 7, 10 and 15 Watt (W) were applied for a pre-set period of 10, 15 or 20 min.

In the second series, identical power settings were applied, until a pre-set amount of introduced energy was reached; a power of 5 W was applied until 3.0, 6.0 and 9.0 kJ was reached and powers of 10 and 15 W were applied until 6.0, 9.0 and 12.0 kJ were reached. To enlarge reproducibility and validity, the series with the best results was repeated once.

In vivo study

In a clinical study, a treat and resect protocol was conducted. Adult women with core-biopsy proven invasive