



Novel High Speed Radio Frequency (HS-RF) Tissue Ablation System-Initial Clinical Experience

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Background

Radio Frequency Ablation (RFA) has become a well established and accepted treatment for unresectable liver tumors. However several issues exist with the current RFA devices and methods. These include long ablation times, limited ablation size, and burns caused by return electrodes or grounding pads

We report an evaluation of a new and novel High Speed Radio Frequency (HS-RF) tissue ablation system (RFA Medical, Inc., Fremont California). This system is unique in both it's speed and ability to use a variety of existing RFA generators currently available in many hospitals around the world as the energy source. Our experience included various generators such as the Radio Therapeutics Corporation (Boston Scientific, Boston MA), Celon LabPower (Celon - Olympus, Teltow - Berlin Germany), and the Rita 1500 and 1500X (Rita Medical Systems, Fremont CA).

Aims

We evaluated use of the device in-vitro (explanted bovine liver), in-vivo (ovine liver), and clinically in a fourteen patient prospective study.

Materials and Methods

In this study patients which were scheduled for resection of their liver tumors underwent tumor ablation followed by the planned resection. Following the liver resection the ablated tissue was bread loafed and the ablation size was noted. The total ablation time was also recorded. Patient and procedure details for this study included gender, age, tumor type, the use of any inflow occlusion, and operative or postoperative complications. There was no significant difference within the demographics between patients.

Target Ablation Size (cm)	Ablation Size - Mean \pm SD (cm)	Ablation Time (min)
3.5	3.6 \pm 0.1	3
5	5.0 \pm 0.3	5
7	6.9 \pm 0.3	12



Fig 1. 5cm HS-RF Device (RFA Medical)



Fig 2. Device Placed in Liver

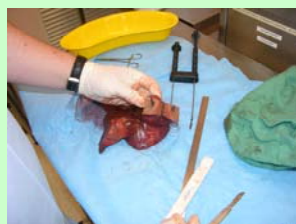


Fig 3. Dissection of Ablated Liver Tissue



Fig 4. Ablated Tumor in Liver (5cm)



Fig 5. Sectioned Liver Ablation



Fig 6. Ablated Tumor in Liver (7cm)

Results

Since the time of filing the abstract for this work, the number of treated patients increased from ten to a total of fourteen.

In each of the attempted ablations the nominal size was achieved within \pm 10%. In this effort three different size ablations were attempted. These were a 3.5 cm diameter, a 5 cm diameter, and a 7 cm diameter. Examples of these ablations are shown in figure 4 (5 cm) and figure 6 (7 cm).

The amount of time required to achieve the target ablation sizes were significantly reduced as compared to our experience with currently available RFA devices.

Use of different RF generators as the power source did not have a significant effect on the outcome. Other than small variations in their operation, there was little difference noted between the generators.

Demographics of the patients participating in this study was also unremarkable.

Conclusions

Based on our results we have concluded that this HS-RF (High Speed Radio Frequency) bi-polar tissue ablation system significantly reduces the amount of time required to create spherical ablations as compared to our experience with other ablation devices.

We further concluded that based on our results uses of this bi-polar high speed RF system is safe, effective, and requires only a small fraction of the time that current ablation devices require.