The Loop Electrode: In Vitro Evaluation of a Device for Ultrasound-Guided Interstitial Tissue Ablation Using Radiofrequency Electrosurgery

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Rationale and Objectives. I developed and tested in vitro a device for ultrasound-guided monopolar radiofrequency (RF) electrosurgical interstitial tissue ablation.

Methods. The current was applied to an electrode with a distal loop form (radius = 1 cm). The superelastic properties of the electrode allowed cannula introduction in the experimental medium (calf liver) before subsequent rotation of the electrosurgical cutting electrode, resulting in cutting off and isolation of a spherical lesion interstitially. The optimal setting of the RF unit and the optimal cutting speed were evaluated. Under ultrasonographic guidance and monitoring, approximately 150 lesions were produced with different loop designs and sizes. The gross appearance was evaluated and correlated to ultrasonography.

Results. An output effect of 200 W was optimal for resection and cutting with the loop electrode. An ellipsoid loop configuration could produce an almost spherical lesion with a diameter of 2.0 cm interstitially. Ultrasonography could guide the introduction of the loop electrode into tissue and visualize the upper part of the lesion.

Conclusion. The loop electrode is a technique for percutaneous ultrasonographically guided tissue ablation. It was proved to be efficient in vitro by producing 2-cm liver lesions.

Key Words. Radiofrequency; loop electrode; tissue ablation; ultrasonography; liver.

Surgical resection of hepatocellular carcinomas and colorectal liver metastases is still considered the treatment of choice because it has improved the survival rate of patients affected by these diseases [1, 2]. On the other hand, liver resection is a major surgical procedure with a mortality rate of approximately 5%, and open surgery may not always be technically possible, either because of multiple liver tumors or because of the patient's condition.

This has led to the development of several less invasive methods for the interstitial destruction of liver tumors, such as intraoperative cryosurgery [3]; percutaneous techniques, such as laser [4], microwaves [5], and injec-

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tion of ethanol or hot saline [6, 7]; and a noninvasive method involving high-focused ultrasound [8]. The use of radiofrequency (RF) electrosurgery in interstitial tissue ablation has been limited to monopolar coagulation around the tip of an uninsulated needle [9–15].

In this article, I discuss a technique for interstitial tissue ablation using monopolar RF electrosurgery in the cut mode in an in vitro study performed under ultrasound guidance. The RF current was applied to a loop-shaped electrode, with superelastic properties allowing cannula introduction before subsequent rotation of the electrosurgical cutting electrode resulting in cutting off and isolation of a spheric lesion interstitially.

MATERIALS AND METHODS

The loop electrode is made of a 0.5-mm metal thread having superelastic properties (Cook Europe, Bjaeverskov, Denmark). The proximal straight part of the electrode is 155 mm long. At the distal end, the electrode has a shape of an open loop with a radius of 1 cm. The proximal 5 mm of the straight part is inserted into the fitting of a handle, which is connected to the RF generator with a 0.75-mm^2 laboratory cable (Fig. 1A). The superelastic properties of the electrode make it possible to straighten the loop for insertion into a 16-gauge insulated introducer cannula, which is 150 mm long (Figs. 1B and 1C). After loop straightening, the metal thread will tend to conform to the preshaped loop form. The superelastic properties of the metal thread are not affected by room or body temperature; however, high temperatures and stress may affect superelasticity.

Fresh calf liver was placed on a neutral plate connected to an RF electrosurgical generator (Erbotom ICC 300; Erbe USA, Atlanta, GA). In the cut mode, the generator produces an unmodulated sinusoid waveform of RF voltage with a frequency of 350 KHz. The output power can be changed from 0 to 300 W with a voltage output of up to 350 V depending on the tissue impedance. The operator can limit the maximum voltage output in four steps (levels 1–4) ranging from 150 to 350 V.

The first series was undertaken to evaluate the optimal setting of the RF electrosurgical unit, defined as the output power level at which the highest resection velocity was achieved when the loop electrode was affected by an appropriate constant force. This part of the study was performed under standardized conditions: The loop electrode was suspended in the laboratory cable and was placed vertically over the liver surface (Fig. 2). A small incision was made in the liver with a scalpel, and the loop part of the electrode was inserted. The straight part of the electrode was fixed to an attachment, and a constant horizontal pull (0.24 N) was applied by a weight (24.4 g). The loop electrode was connected to the monopolar socket of the RF generator via the laboratory cable. During different settings of output power and maximum voltage, RF current was applied to the loop electrode. During a 10-sec period, the horizontal movement of the resecting and cutting loop electrode was observed and the traveled distance

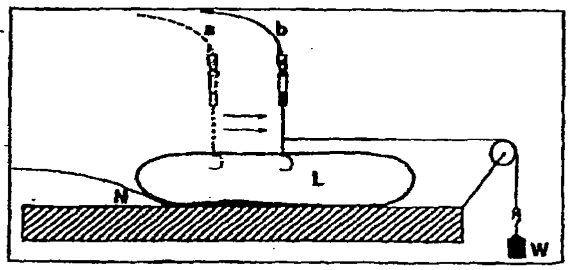
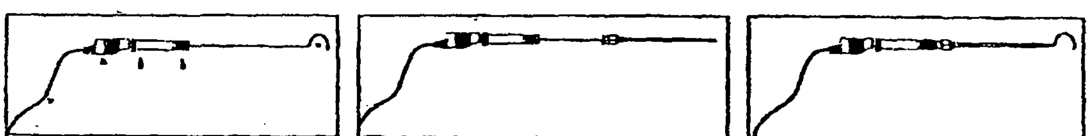


FIGURE 2. Schematic drawing of the experiment used to optimize the setting of the radiofrequency generator. In 10 sec, the loop electrode traveled (resected) from position a to position b. The electrode was fixed in such a position that the distal loop part was perpendicular to the travel direction. L = calf liver, N = neutral plate, W = weight.



A B C

FIGURE 1. *A*, Drawing of the loop electrode inserted into the handle (*arrows*), which is connected to the radiofrequency generator via a laboratory cable (*arrowheads*). The asterisk indicates that the loop part of the electrode has a semiellipsoid form (radii = 10 and 12.5 mm longitudinal and transverse, respectively) with a minor distal overcorrection of 5 mm or 30°. *B*, The loop part of the electrode has been straightened and mounted in the introducer cannula, which is ready for tissue insertion. *C*, After being further advanced through the introducer cannula, the exposed loop tended to return to its original, predetermined form because of the material's superelastic properties.

measured with a ruler. With the maximum voltage set at 350 V, the output power was gradually increased from 0 to 300 W in 25-W increments. In each setting, five measurements of the traveled distance were obtained. This part of the experiment was videotaped for documentation and further analysis. For statistical analysis, linear regression was used to test for a linear increase in electrode travel as a function of output power.

In the second series, experiments were performed interstitially in the calf liver guided and monitored by ultrasound (System 3535, 7.5-MHz curved array transducer with mountable needle guide; B&K Medical, Gentofte, Denmark). The introducer cannula was loaded with the loop electrode and via the needle guide was inserted in the liver parenchyma under ultrasound control to a predetermined depth of 1 cm beneath the liver surface. The loop part of the electrode was then advanced farther into the liver through the introducer cannula. The RF generator was switched on for approximately 2 sec, during which the superelastic properties of the electrode allowed it to cut its way through the parenchyma and conform to its preshaped loop form. The RF generator was switched on again and the handle rotated 360° in one to four steps. During this part of the procedure, a liver mass was cut off and isolated interstitially. The lesion was separated from the surrounding liver parenchyma by a cleavage created by rotating the electrosurgically active loop. The loop electrode was retracted through the introducer cannula, which subsequently was retracted, leaving only a puncture mark on the liver surface. A final sonogram of the lesion was obtained. Different loop designs and loop sizes were evaluated in terms of gross appearance of the intrahepatic lesion. Characteristics such as size, form, and thickness of the coagulation zone were recorded. Measurements were done with a slide gauge or ruler. Approximately 150 lesions made with different loop designs and sizes in 15 calf livers were evaluated. Changes in loop design and size were done at the manufacturer's facility. No statistical analyses were performed in this part of the study because the data were mostly qualitative.

RESULTS

In the first experiment, a gradual increase up to 200 W in output power resulted in a significant increase in the traveled distance of the loop electrode (Fig. 3). At power levels greater than 200 W, severe sparking and smoke or steam formation were seen during the cutting procedure. A permanent deformation of the loop shape also occurred after only one cutting episode at these high settings. Below 200 W, however, permanent deformation of the loop was not observed until after two to four cutting series. When the voltage was changed from level 4 to level 3 or 2, no change in traveling distance was observed; however, at level 1 (maximum = 150 V) a decrease in the traveled distance was observed.

On the basis of these results, the output power of 200 W and a voltage level 2 was used in the interstitial experiments. No practical difficulties were observed in introducing or retracting the cannula, performing the RF lesions, or retracting the electrode into the introducer cannula after performing the RF treatment. During ultrasound, the introducer cannula and the loop electrode could be visualized in the liver before the RF generator was switched on (Fig. 4A). The interstitially placed loop part of the electrode at this time assumed a J-shaped form that was barely discernible. When the RF generator was switched on, the ultrasound image was disturbed because of electrical noise. After initial cutting, the electrode cut its way to the preshaped loop form within approximately 2 sec. This could be seen on ultrasound. However, the visualization was difficult because the steam and smoke released around the electrode appeared as tiny echogenic foci with an acoustic shadow behind. Rotation of the loop electrode was not monitored on ultrasound because this part of the procedure took place outside the initial scanning plane.

On gross examination, a slightly ovoid liver lesion (longitudinal diameter = 2.0 cm, transverse diameter = 1.7 cm) was seen when an ideal semicircular loop with a

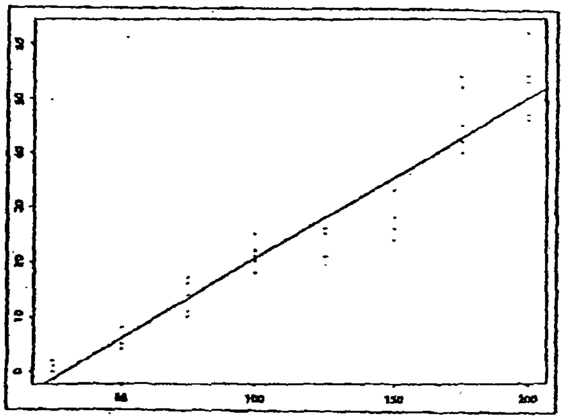


FIGURE 3. Graph shows loop electrode traveled distance in 10 sec plotted against output effect. An increase in output effect gave a significant ($p < .0001$) increase in the distance traveled. There was a high linear correlation between the traveled distance and the output effect ($r^2 = .93$). x-axis is in millimeters; y-axis is in watts.

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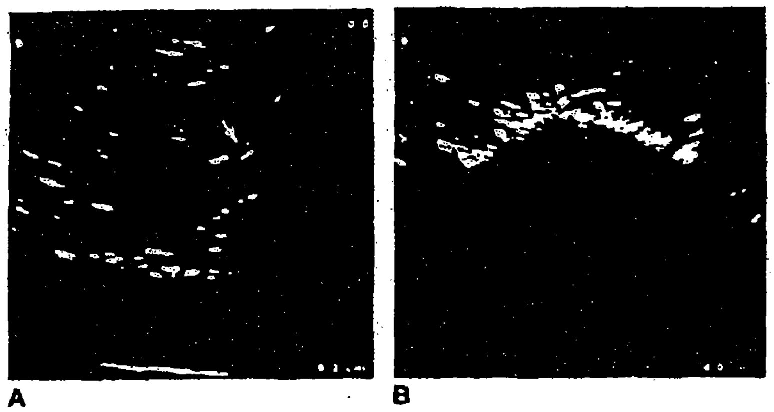

FIGURE 4. A, Sonogram showing the introducer needle in calf liver. B, Sonogram of the lesion after removing the introducer cannula and the loop electrode shows multiple small echogenic foci in an upper convex layer representing smoke and steam in the cleavage between the lesion and the surrounding liver tissue. The arrow indicates the tip of the cannula.

radius of 1.0 cm was used. However, changing the loop configuration into an semiellipsoid (longitudinal radius = 1.0 cm, transversal radius = 1.25 cm) form (Fig. 1A) resulted in an almost spherical liver lesion, with a diameter of 2.0 cm based on gross inspection (Fig. 5). Furthermore, it was found that the ideal semicircular or semiellipsoid loop could not totally separate the far end of the lesion from the surrounding liver tissue. Thus, the bottom (the site opposite the cannula) of the lesion was connected to the rest of the liver by a stalk. Using a loop shape with a distal overcorrection of 5 mm (equivalent to approximately 30°) resulted in an almost total separation of the lesion from the liver, although a delicate stalk of coagulated tissue less than 2 mm in diameter was frequently seen. Finally, rotating the handle 360° plus an additional 30–45° would ensure that the loop had made a full round trip interstitially.

From the first experiment, in which a cutting speed of approximately 5 mm/sec was achieved (50 mm in 10 sec), it was calculated (circumference divided by velocity) that a full 360° rotation of the loop electrode with a radius of 1.25 cm could be done in approximately 16 sec plus a few seconds for the extra 30–45° degrees of rotation. Within this period of time, lesions could be made in one as well as in four steps. Rotation in four steps with an interval of a few seconds between the steps was more practical and easier than the one-step rotation. Furthermore, the one-step technique more often caused permanent deformation of the loop than did the stepwise.

The gross section of the lesion and the corresponding cavity of the liver showed an even zone of whitish, coagulated tissue that was approximately 1 mm thick. Thus, a total ablation of 2.2 cm corresponding to the spherical lesion plus 0.2 cm corresponding to the coagulated zones in the cavity was achieved with this technique. No difference in coagulation was observed between voltage levels 2, 3, and 4. When rotating the electrode with half speed, the steam and smoke production increased and the surface of the lesion was more carbonized on macro-

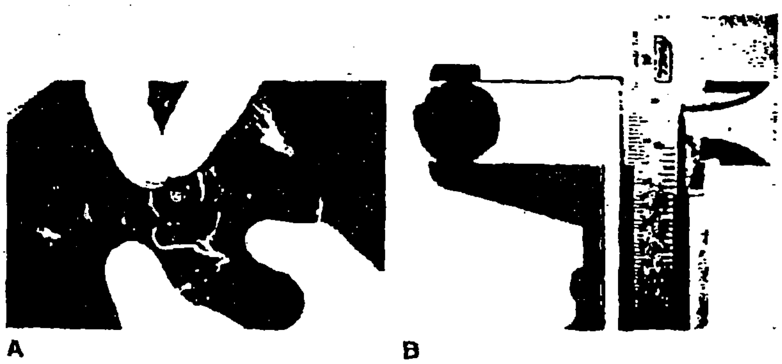

FIGURE 5. A, Gross inspection shows a spherical lesion separated from the surrounding liver tissue. B, The spherical lesion measures 2.0 cm in diameter.

scopic evaluation. The thickness of the coagulation zone, however, remained approximately 1 mm.

At the end of the procedure, ultrasound of the lesion showed an echogenic upper convex structure measuring approximately 2 cm with an acoustic shadowing behind (Fig. 4B). The corresponding gross section showed that the ultrasound finding was consistent with gas and microbubbles in the cleavage surrounding the lesion.

During formation of the interstitial lesion, a significant amount of steam and smoke sometimes escaped from the liver, either via the puncture tract or vessels communicating to the cut surface.

When a semicircular loop with a radius of 1.5 cm was tested, an irregular and incomplete lesion with a stalk of about 1 cm was observed. The same result was found when this enlarged loop was rotated at half speed.

DISCUSSION

The use of RF electrosurgical cutting as a means of tissue destruction is a well-known technique in open surgery as well as through various types of endoscopes. However, to my knowledge, an interstitial use of RF electrosurgical cutting has not been described and should not be confused with the extensively described technique of interstitial RF electrosurgical coagulation with monopolar ablation around an uninsulated needle tip [9–15; Lorentzen T, presented at the Radiological Society of North America, 1995]. The loop electrode allows interstitial isolation of spherical lesions measuring 2.0 cm in diameter by means of electrosurgical cutting. The total ablated area is, in fact, a few millimeters larger because it includes a coagulation zone of the surrounding liver tissue. In the current study, I conducted only a macroscopic evaluation of the margins. I did not perform microscopy of the lesions because this type of evaluation can show only the extension of burn and coagulation. Only microscopic studies in vivo can show secondary cellular damage and inflammatory reactions induced by hyperthermia from the cutting loop electrode.

A larger loop diameter theoretically would result in larger lesions. However, the rotation of a larger loop results in additional temporary deformation of the loop and subsequent incomplete lesion formation, as seen with the loop with a radius of 15 mm. Temporary deformation of the loop during the rotation must be the reason an elliptical loop with a minor distal overcorrection gave an ideal spherical lesion, as judged from the subsequent gross examination. The use of other materials with superelastic properties or a different wire composition might solve the problem of both temporary and permanent loop deformation, which occurs when stress and heat are applied during rotation and electrosurgical cutting.

Ultrasonography as a means of real-time monitoring during lesion formation with the use of the loop electrode has some limitations. The electrical noise from the activated RF generator interferes with the scanner and disturbs the image, making it difficult to monitor the rotating loop electrode. The formation of steam and smoke under the cutting process is another limiting factor of the use of ultrasound. Other techniques such as fluoroscopy, computed tomography scanning, and magnetic resonance imaging may be alternatives. On the other hand, ultrasound can easily monitor the tip of the introducer cannula relative to, for example, a liver tumor before ablation. After correct positioning under ultrasound control, the rest of the procedure theoretically could be done without image guidance (Fig. 6). An alternative way of placing the loop electrode in a lesion would be to introduce the cannula tip beyond the lesion and withdraw it back over the electrode, which remains straight until RF energy is applied.

To my knowledge, the loop electrode has not been used in vivo, and several questions remain unanswered: Will the loop electrode cause interstitial bleeding during the cutting process or will the coagulation zone of approximately 1 mm in the cavity of a vital tissue make sufficient hemostasis? Will the steam and smoke that are

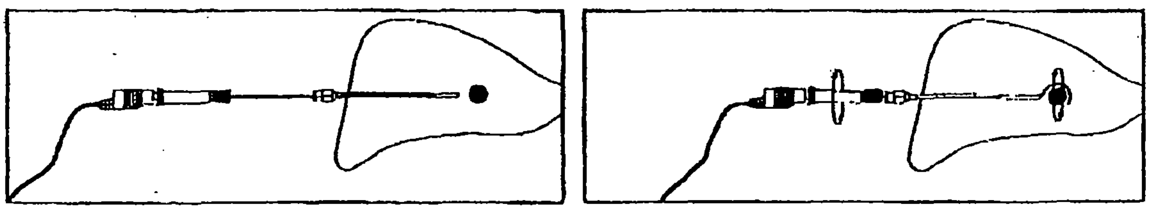

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FIGURE 6. A, Schematic drawing of the principle of a theoretical tumor (round mass) ablation in a liver. The introducer cannula with the loop electrode inside was inserted with its tip just above the tumor. B, The loop electrode was advanced into the liver and returned to its preshaped loop form after 2 sec of electrosurgical cutting. By rotating the handle simultaneously with electrosurgical cutting, a spherical lesion was made interstitially.

produced cause an embolism or interstitial air pressure dissection? Many of these gas bubbles may be absorbed in vivo in the surrounding cooler tissue, so that little external release of gases will be seen, especially when the loop rotation is done in four steps [16]. What happens after a lesion has been cut and isolated from the surrounding tissue? The lesion is physically separated from the vital tissue, and a double coagulation zone might prevent neovascularization. In theory, an ischemic necrosis of the lesion with subsequent autolysis should occur. Abscess formation could possibly occur in the region of ischemic necrosis within the residual tissue.

The loop electrode may have several advantages over other tissue-destroying devices. The loop electrode can be applied to focal disease in different organs such as the liver, the kidney, and the prostate. It can be used percutaneously or during open surgery. The total procedure lasts only a few minutes. The loop electrodes themselves might be relatively inexpensive to produce, and an RF electrosurgical unit is available in almost every surgical department.

Animal studies are warranted to further evaluate the performance of the loop electrode and to answer most of the aforementioned questions. Lorentzen et al. [17] conducted an animal study with the loop electrode and were able to answer some of the questions.

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Announcement

The Boston University School of Medicine is sponsoring **Advances in Abdominal MRI and MRA**, which will be held March 15 and 16, 1996, at the Copley Plaza Hotel in Boston, MA. Fees are $475 for physicians and $350 for all others. Fourteen hours of credit will be awarded. The course director is Joseph T. Ferrucci, MD.

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