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Postbiopsy Bleeding in a Porcine Model: Reduction with Radio-frequency Ablation—Preliminary Results[1]

PURPOSE: To test a biopsy needle modified for use of radio-frequency (RF) energy to produce hemostasis after core biopsy of liver or kidney.

MATERIALS AND METHODS: RF energy was applied to a partially insulated 17-gauge needle, and tip temperature was monitored with a thermocouple. Domestic Yorkshire pigs ($n = 4$; mean weight, 23.4 kg) were anesthetized, and their livers and kidneys were exposed. Needles were inserted 2 cm into hepatic and renal parenchyma and retracted, either with or without tract ablation to 65°C, in normal tissue, animals treated with anticoagulants, and an animal with acute inferior vena caval occlusion to produce portal hypertension. Blood loss was assessed by weighing surgical sponges with blood from the puncture sites. Significant differences in blood loss between control and ablated biopsy specimens in each scenario were tested by using a Wilcoxon matched-pairs signed rank test.

RESULTS: Mean blood loss for each group was as follows: In the liver, control biopsy specimens ($n = 18$) lost 0.30 g while ablated biopsy specimens lost 0.00044 g ($P < .01$), and control biopsy specimens treated with heparin ($n = 26$) lost 0.45 g while biopsy specimens treated with heparin and ablation lost 0.27 g ($P = .03$). For inferior vena caval occlusion, control biopsy specimens lost 1.23 g, while ablated biopsy specimens lost 0.00 g. In the kidney, control biopsy specimens ($n = 28$) lost 0.82 g, while ablated biopsy specimens lost 0.24 g ($P = .01$), and control biopsy specimens treated with heparin ($n = 14$) lost 1.04 g, while biopsy specimens treated with heparin and ablation lost 0.19 g ($P = .02$).

CONCLUSION: Tract ablation with thermocouple-monitored RF energy decreased postprocedural hemorrhage after hepatic and renal biopsy.
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Percutaneous biopsy is an important diagnostic procedure in modern medicine. Some of the more common indications for abdominal biopsy are the need to obtain a tissue diagnosis in patients with focal disease (eg, to rule out hepatic metastasis) or diffuse disease (eg, native liver or kidney disease). Biopsy is also used commonly for the diagnosis of graft dysfunction in hepatic or renal transplants, including those in patients with acute and chronic rejection.

The risk of major complications from percutaneous biopsy is generally considered to be acceptably low (0.1%–3.6%); complications (primarily hemorrhage) may cause substantial morbidity when they occur, and they often necessitate blood transfusions and/or surgical or interventional radiologic procedures (1–7). Hemorrhage is fatal in 0.01%–0.10% of biopsies (5,8). Hemorrhage occurs less frequently in cases in which fine-needle aspiration biopsy is performed with 20–25-gauge needles. Fine-needle aspiration biopsy, however, yields insufficient tissue for many conditions that necessitate needle biopsy, including staging of cirrhosis, diagnosis of native renal disease, and evaluation of graft dysfunction in transplant recipients.

The risk of postbiopsy hemorrhagic complications is particularly great in patients with coagulopathy or therapeutic anticoagulation, such as patients undergoing dialysis, those with hepatic failure, or those with transplants (5–7,9). In these patients, percutaneous biopsy is often needed to determine the cause and degree of organ or graft dysfunction. Therefore, a device or technique that could reduce postbiopsy complications would help reduce additional morbidity in patient populations with health that is already compromised.

Two strategies have been proposed in an attempt to reduce bleeding after biopsy. The first approach is to occlude the biopsy tract with a hemostatic agent, such as absorbable gelatin sponge, fibrin sealants, or coils, as the needle is withdrawn (10–12). At present, these methods are not used widely because of concerns about potential immunologic interactions with tissue-based agents and the increased time, sheath size, and technical complexity required to introduce the agent into the tract. The second approach is to apply radio-frequency (RF) energy to cauterize the tract as the biopsy needle is withdrawn (13). This approach takes advantage of the cauterizing effect of RF energy. The main limitation to this method has been damage to the tissue specimen contained within the biopsy needle caused by the high RF energies needed to sufficiently ablate the tract (13). The purpose of this study was to test a biopsy needle modified for use of RF energy to produce hemostasis after core biopsy of liver or kidney.

MATERIALS AND METHODS

Design Specifications

As a result of thermal damage to biopsy specimens with prior designs, we decided that it would be best to apply RF heating to the distal end of an introducer needle after the specimen had been withdrawn. Ideally, minimal modifications should be made to existing equipment because biopsy is a well-established and effective technique. The ideal temperature range for cauterizing the tract without causing excessive collateral tissue damage is 65°C–80°C. Thus, real-time temperature monitoring is a necessary component of this device. The materials used in the device must be biocompatible, sterilizable, disposable, and relatively inexpensive.
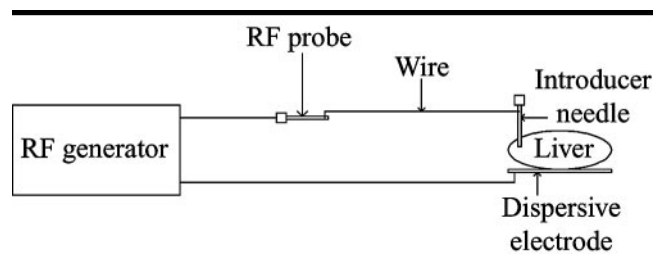

Figure 1. Diagram shows the experimental setup for ex vivo testing. A wire was connected between the RF probe of the generator and the introducer needle to allow RF energy to be delivered directly from introducer needle to tissue. Connections were made by using alligator clips.

Insulation

The introducer needle was coated with insulation, excluding the proximal and distal portions, to prevent excessive loss of energy, sticking of the needle to the tract, and heat damage to the skin entry site. The exposed distal part of the needle was used to deliver the energy, while the exposed proximal part provided a site to connect the needle to the RF source. The insulation on the needle had to have a uniform thickness with no pinholes and a low coefficient of friction (<0.2). It also had to be sterilizable, thin (<100 μm), and tightly adhered to the substrate without surface voids at the interface.

Heat shrink-wrap (eg, polyvinylidene fluoride, low-density polyethylene, high-density polyethylene, fluorinated ethylene propylene, or polyvinyl chloride) was used for ex vivo testing but was ruled out as a suitable material because it has a skill-dependent application process, is relatively thick (minimum wall thickness, ~410 μm), and is not necessarily uniform. Furthermore, autoclaving can increase the number of surface voids.

Poly-para-xylylene (Parylene; Vitek Research, Derby, Conn) was a suitable agent because it has a low coefficient of friction and is deposited in the gas phase. Therefore, it can penetrate cracks or crevices on the substrate. It is polymerized at room temperature without thermal stress. It can survive continuous air exposure for 10 years at 100°C and survives autoclaving, radiation, and gas sterilization (Vitek Research. Lubricious surfaces for biomedical applications—benefits of lubricious surfaces in biomedical uses. Available at: *www.vitekres.com/lubriciouspaper.htm.* Accessed February 15, 2002. Materials and techniques used by Vitek Research Corporation to coat laparoscopic and electrosurgical instruments. Available at: *www.vitekres.com/electrosurgicalpaper.htm.* Accessed February 15, 2002. Parylene—a

superior coating for biomedical applications. Available at: *www.vitekres.com/parylenebiopaper.htm.* Accessed February 15, 2002.). We estimated that the cost to apply the insulation was approximately $13 per needle.

Procedure for ex Vivo Testing

Three sessions of ex vivo tests were performed in bovine liver (obtained from a local slaughterhouse). RF energy was delivered with a 17-gauge introducer needle (TruGuide Coaxial Biopsy Needle; Bard, Covington, Ga) coated with heat shrink-wrap. Figure 1 shows the experimental setup. These tests were preliminary to optimize insulation, power, and time before the device was tested in vivo. Results were obtained (P.F.L. and K.R.S. with consensus) on the basis of visual inspection of ablated tracts in the bovine liver. A more uniform burn was achieved when the area where the RF energy was delivered was smaller. Higher powers allowed a more consistent burn during a shorter time and resulted in a sharper boundary between ablated and unablated tissue. More consistent burns resulted when the needle was left in the tissue for a time before retraction was initiated. This initial holding time was necessary to obtain a satisfactory burn. The radius of the thermal lesion increased with slower retraction rates.

In Vivo Procedure with Heat Shrink-Wrap Technology

A subjective preliminary study was performed in one Yorkshire pig with the same experimental setup used for ex vivo testing. Institutional animal research committee approval was obtained. Ablations were performed, and the tracts were inspected visually to determine relative optimal power settings and times of retraction. No quantitative data were col-
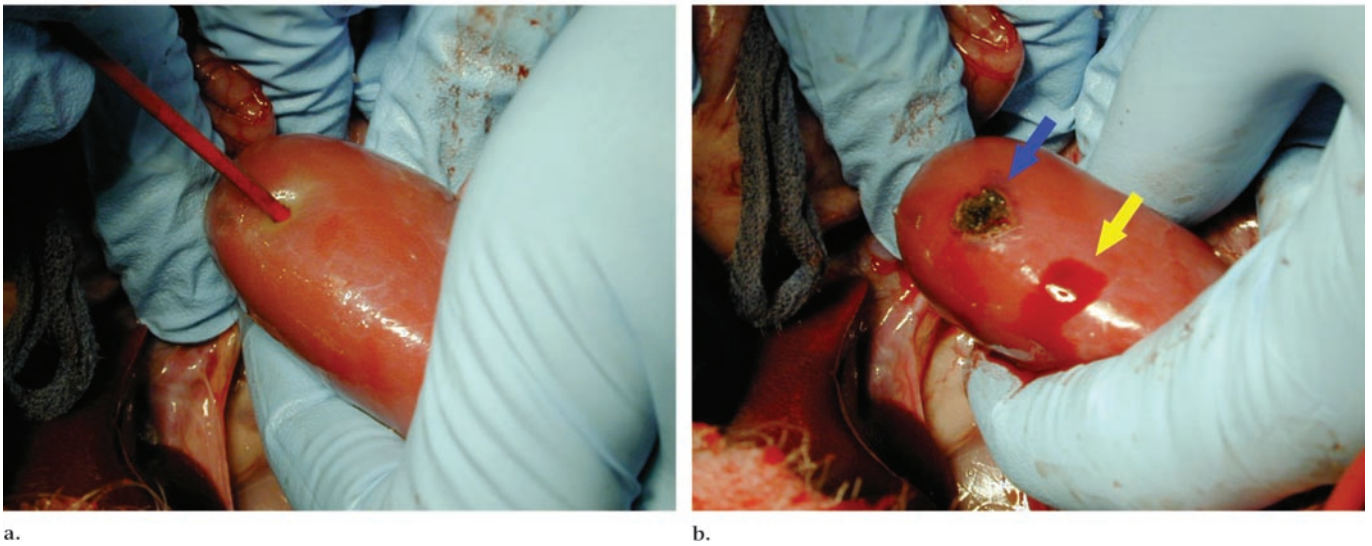
Figure 2. Photographs show the heat shrink-wrap trial. **(a)** Needle is placed in the kidney. **(b)** Minimal hemorrhage is noted from the RF ablation site (blue arrow) compared with blood from the control site (yellow arrow).
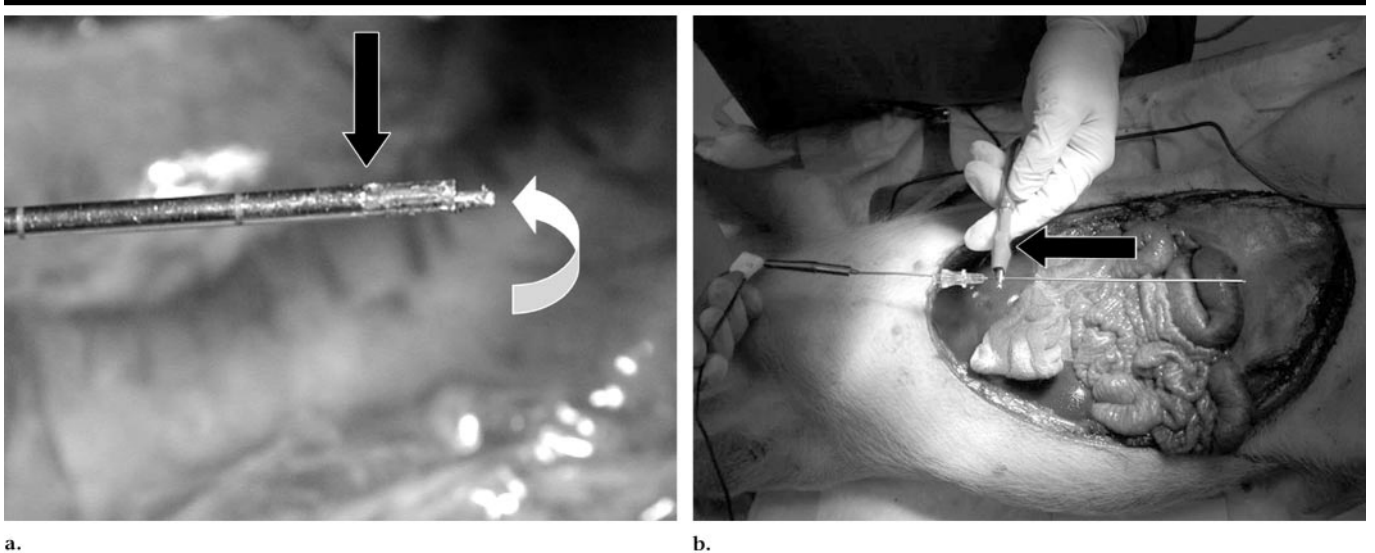

Figure 3. **(a)** Close-up photograph of the distal needle tip shows the end of the poly-para-xylylene insulation (straight arrow), with the distal 4 mm uninsulated. Note that the tip (curved arrow) of the thermocouple protrudes past the end of the introducer needle. **(b)** Photograph shows an alligator clamp (arrow) being used to apply RF energy to the proximal uninsulated first 10-mm portion of the introducer needle.

lected during this trial. However, we observed visually that RF ablation resulted in reduced bleeding from the tract (Fig 2). Higher power settings appeared to be the most effective at reducing the bleeding. The rate of retraction to achieve hemostasis varied from trial to trial. This finding indicates that there is not one optimal time for retraction but that it will vary and should be determined according to the temperature of the tissue lining the tract, since that tissue temperature shows the extent of ablation at that point in the tract.

In Vivo Procedure with Poly-para-xylylene and Thermal Feedback

A 17-gauge introducer needle was coated with a thin film of poly-para-xylylene, leaving the distal 4 mm of the needle uninsulated to allow application of the energy, and leaving the proximal 1 cm of the needle uninsulated to allow a connection to the RF energy source (model 1500 Electrosurgical Radiofrequency Generator; Rita Medical Systems, Mountain View, Calif). The temperature

was monitored (Cryocare System; Endocare, Irvine, Calif) in the tract by inserting a thermocouple down the center of the introducer needle (Fig 3).

The introducer needle and thermocouple were inserted 2 cm into the tissue. The liver in a pig that weighs approximately 23 kg is relatively thin compared with bovine or human liver. To obtain reproducible data from multiple points within one liver and to prevent complications such as puncturing of the liver on both sides with one pass, needle insertion was kept constant at 2 cm. A site of

retraction without application of RF energy served as a control.

Three Yorkshire pigs were used for these trials. In this treatment group, the needle was held stationary as RF energy with a power of 150 W and a frequency of 460 kHz was applied until the temperature increased to 65°C. The needle was then retracted during 5–10 seconds at a rate such that the temperature was approximately 80°C. Blood loss in both the control and ablation trials was assessed visually and also by weighing dry gauze pads used to soak up any blood from the puncture sites and then reweighing the gauze pads plus the blood.

The liver and kidney were sampled both before and after the administration of 300 U of heparin per kilogram of body weight. In one animal, the liver with heparin was also studied after the inferior vena cava was occluded with a vascular clamp to simulate portal hypertension.

Eighty-eight biopsies were performed for which quantitative blood-loss data were obtained. Each control biopsy site was spatially paired with a close corresponding RF ablation site such that they were performed in similar areas of the organ to reduce differences due to anatomy and vascularity within an organ. The order of biopsy (control vs ablation) in each pair was varied. Each pair was included in one of four groups: liver without heparin, liver with heparin, kidney without heparin, and kidney with heparin. Several of the paired biopsy sites were longitudinally sectioned to observe the tract. Previously published articles (14,15) give detailed histopathologic analysis of RF ablation sites.

Animals and Surgery

Approval for this protocol was obtained from the institutional animal research committee, and all experimentation met the National Institutes of Health Public Health Service Policy on Humane Care and Use of Laboratory Animals. Four female Yorkshire pigs (mean weight, 23.4 kg; weight range, 19.7–33.2 kg) were used in this study. Surgery was performed by one of four authors (C.D.J., P.F.L., F.T.L., T.C.W.).

The pigs were anesthetized with 7 mg/kg of tiletamine and zolazepam (Telazol; Fort Dodge Animal Health, Fort Dodge, Iowa) and 0.45 mg/kg of xylazine hydrochloride (Rompun; Phoenix Pharmaceutical, St Joseph, Mo) injected intramuscularly. Anesthesia was maintained with inhaled halothane gas (Halocarbon Laboratories, River Edge, NJ), 1% to ef-

fect. After application of a 10% povidone-iodine solution, the liver and kidney were exposed through a subcostal incision. Animals were euthanized immediately after all procedures by means of intravenous administration of 390 mg of pentobarbital sodium and 50 mg of phenytoin sodium per 100 mL (Beuthanasia-D; King Pharmaceuticals, Bristol, Tenn).

Statistical Analysis

Statistical analysis was performed with commercially available software (Instat for Macintosh, version 3.0a; GraphPad Software, San Diego, Calif). Tests for significant differences in blood loss between control and ablation biopsy sites in each of the four scenarios (kidney and liver, without and with heparin) were performed with a Wilcoxon matched-pairs signed rank test. A P value of less than .05 was considered to indicate a statistically significant difference.

For the purposes of this study, we believe it is reasonable to consider the biopsy data as independent on the basis of the safety of clinical, renal, and hepatic biopsies in the medical literature (5–9). Needle biopsy is now considered a minimally invasive intervention and is unlikely to create substantial physiologic or anatomic abnormalities. Biopsies were performed in the peripheral kidney so that even if a blood vessel was compromised, it would be a peripheral vessel outside of the vascular distribution of the next biopsy site. Hepatic biopsies were performed in the peripheral liver. Each lobe has an independent blood supply, so that damage to a vessel or other structure in one lobe is unlikely to affect other lobes.

RESULTS

Results of in vivo testing with poly-paraxylylene and thermal feedback are as follows. Raw data for blood loss from one of the four groups—kidney with heparin—are detailed in Figure 4, which shows seven paired samples. RF ablation reduced or arrested bleeding in all but three (two ablation pairs of kidney without heparin and one ablation pair of liver with heparin) of 44 cases. The mean blood loss for control and ablation groups is shown in the Table. Biopsy sites after ablation had significantly less blood loss than did control biopsy sites. The zone of ablation was demonstrated in cut sections of the organs (Fig 5). A beneficial effect was evident even with portal hy-
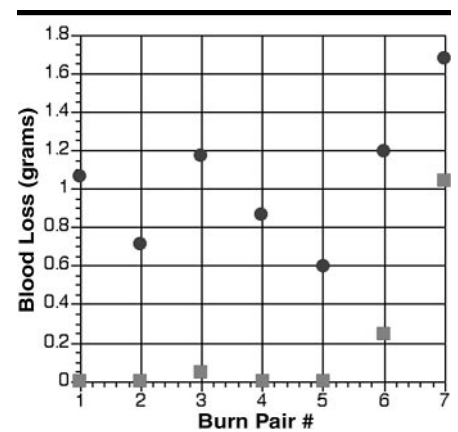

Figure 4. Graph shows blood loss for seven paired biopsies in the kidney group with heparin. Note that RF ablation reduced or arrested bleeding in all cases. ● = control, ■ = RF ablation.

pertension and anticoagulation (control biopsy site = 1.23 g, ablated biopsy site = 0 g) (Fig 6). Eighty-eight needle insertions were performed for which quantitative data were recorded: nine pairs (n = 18) for normal liver, 13 pairs (n = 26) for liver with heparin, 14 pairs (n = 28) for normal kidney, seven pairs (n = 14) for kidney with heparin, and one pair (n = 2) for the portal hypertension model of liver with heparin.

DISCUSSION

Use of electricity to reduce blood loss in surgical procedures is not a new concept. The bovie electrocauterization unit is a standard feature in operating rooms and is effective in decreasing blood loss, particularly when the parenchyma of solid organs is crossed. This concept has recently been extended to thermal ablation of tumors, where RF ablation is an increasingly popular method to treat tumors in the liver, kidney, lung, and bone. In contrast to bovie electrosurgery, where only shallow cauterization is desired, tumor ablation procedures require delivery of high-energy alternating current into a large volume area to ablate the tumor and a surrounding margin. The procedure described in the current study is more focal in nature, and existing RF generators are used to produce ablation in a fashion similar to that of bovie electrocauterization.

Since most major medical centers now have a commercially available RF generator for tumor ablation, the additional cost of ablation after needle biopsy would be limited to the cost of modifying

Mean Blood Loss for Each Group

Group	No. of Biopsies*	Control	Ablation	P Value	Ratio†
Liver					
No heparin	18	0.30 (0.002–0.72)	0.00044 (0–0.004)	.004	671
Heparin	26	0.45 (0–2.24)	0.27 (0–3.15)	.027	1.7
Kidney					
No heparin	28	0.82 (0.01–3.57)	0.24 (0–1.26)	.011	3.5
Heparin	14	1.04 (0.60–1.67)	0.19 (0–1.04)	.016	5.5

Note.—Data are the mean blood loss in grams. Numbers in parentheses are the range.
* Total number of biopsies in each scenario, consisting of *N*/2 paired biopsies (control and ablation).
† Ratio of blood loss in the control group to that in the ablation group.

Figure 5. Photographs show cross sections (white arrow = control biopsy tract, black arrow = RF ablation tract) of **(a)** liver and **(b)** kidney after needle removal. Note that the ablation zone surrounding the ablation tract is pale secondary to lysis of erythrocytes.

existing biopsy needles. This process is relatively simple and low cost, and no special manufacturing process (other than simply coating the needle with the insulator) is required to modify needles on a commercial scale. As described in this study, poly-para-xylylene is a nearly ideal insulator that could easily be used for this purpose. The addition of a thermocouple is also relatively simple and could be accomplished by means of threading a thin wire under the poly-para-xylylene coating, which should have no deleterious effect on the size of the needle.

Ablation of the biopsy tract should decrease the rate of hemorrhage, which is the most frequent serious complication of percutaneous needle biopsy. However, the deposition of energy may have other unexpected complications. The most likely complication would be a skin burn if the energy were not turned off as the uninsulated portion of the needle passes through it. This infrequent complication has been anecdotally reported with RF tumor ablation. Simple depth marks on the needle to indicate that the tip is about to pass through the skin can help prevent skin burns.

Whereas ablation of solid organs should be safe in most cases, ablation of a bowel loop runs the risk of creating an enterocutaneous fistula. Therefore, the tract should probably not be ablated in cases in which the needle has passed through bowel before entering a solid organ. In our study, we used RF energy to ablate only hepatic and renal biopsy tracts. It may be also be possible to use RF ablation in biopsy procedures in other organs. For instance, cauterization of the tract during lung biopsy may reduce pneumothorax rates.

Ex Vivo Tests

Results of the ex vivo tests indicate that the insulation should cover most of the introducer needle. A larger uninsulated surface results in less energy concentration. Moreover, the needle would stick to the tissue if the entire tract were ablated simultaneously and might exacerbate the incidence of skin burns. Heat transfer in tissue is a function of *(a)* the amount of heat that is applied and *(b)* the rate at which the heat is applied. Delivery of the same amount of energy in a shorter time (ie, by using high power) can decrease the depth of the thermal damage. With this method, the boundary between the ablated tissue and the underlying tissue is sharpened and undesirable collateral thermal damage is minimized.

In Vivo Tests

Results for our model indicate decreased bleeding when the tract is ablated after needle biopsy. RF ablation decreased or arrested bleeding in all but three of 44 trials. In these cases, bleeding occurred immediately after the needle was inserted into the organ before RF energy was applied to simulate the time necessary to perform biopsy. With this method, the tract pooled with blood and the effectiveness of the ablation decreased because the amount of energy and time required to ablate the tract were increased.

Needle tract seeding with tumor is rare but has been reported (16,17). When seeding occurs, the effects can be catastrophic if a resectable tumor becomes unresectable. Thermal ablation of the tract as the needle is removed could, in theory, decrease the incidence of needle
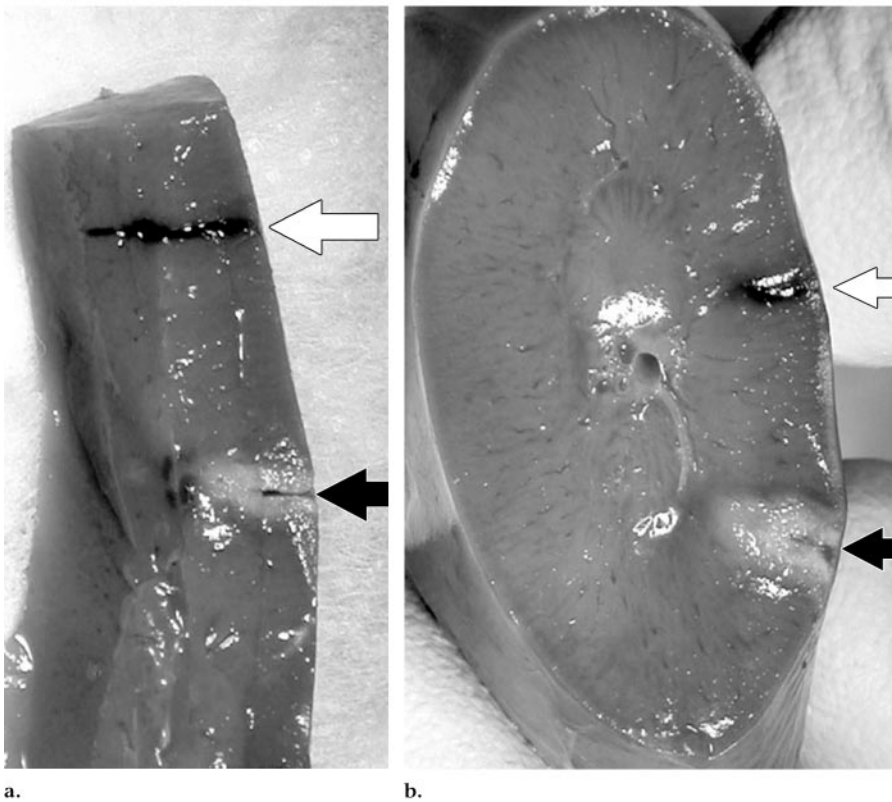
tract seeding. The high temperatures required for tract ablation would likely kill any malignant cells introduced into the tract during biopsy. To our knowledge, however, this has not been verified, and it is unclear whether RF ablation or fibrin sealants would be more effective in prevention of tumor seeding.

Results of the current study demonstrate that thermocouple-monitored RF tract ablation is conceptually a promising treatment that can be integrated into the current biopsy protocol with minimal added cost. Kim et al (13) showed electrocauterization to be an effective solution, but they observed thermal damage to the sample at high power settings because they applied the energy directly to the biopsy needle. Low power causes more collateral damage because the energy must be applied longer.

An advantage of our system over that of Kim et al (13) is that ablation is performed with the introducer needle after the histologic specimen has been resected, which removes any risk of thermal damage to the specimen. Furthermore, they did not examine the usefulness of electrocauterization performed percutaneously or during portal hypertensive or coagulopathic conditions, situations in which it may be most valuable. In their study, they also did not incorporate any means of monitoring the progress of the procedure, such as real-time thermal feedback.

A potential weakness of any thermal (or chemical) ablative system is that the organ tissue at the site of biopsy is altered by the ablation, which potentially makes performance of repeat biopsy and histologic analysis at the exact site problematic. Although of theoretic concern, we believe that this will only rarely be of practical concern, for two reasons. First, for medical biopsy of organs (eg, to rule out rejection, cirrhosis, glomerulonephritis), the physician has the entire organ as a target and should be able to avoid the previously sampled site. Second, for biopsy of focal hepatic or renal lesions, the introducer needle could be used as a guide for repeat fine-needle aspiration biopsy for cytologic analysis, with real-time confirmation of the diagnosis by the cytopathology team, before ablation was performed as the introducer needle was removed. For core biopsy, multiple coaxial cutting needle cores could be obtained before ablation, which minimizes the likelihood of nondiagnosis.

Nevertheless, for a small lesion, there is a possibility of nearly complete ablation of the lesion, which makes performance of future biopsy problematic. The physician should be aware of this issue before electing to use the tract ablation technology. In future investigations of this technology, ablation size and configuration could be studied in detail, as discussed earlier regarding the relationship between power deposition and depth of thermal damage.

In our study, we did not investigate the effectiveness of this technology for stopping the bleeding in tissues that overlay the organ of interest (eg, skin, muscle, and fat) because we measured bleeding directly from the surgically exposed liver or kidney. Theoretically, tract ablation should be helpful, given the long clinical experience with bovie electrocauterization of these tissues in the operating room, but this remains to be proved. Because a coaxial technique is used (the introducer needle is not inserted as deeply as are the needles for fine-needle aspiration or biopsy), hemorrhage could occur deep to the introducer needle that would not be affected by the ablation. Presumably, many (if not most) of these hemorrhages would not be clinically important because of tamponade by the overlying tissue, but occasionally they might be of clinical concern.

The preliminary results of our study in porcine liver and kidney, including those in the anticoagulated state, are encouraging. However, more work needs to be done to demonstrate that this procedure would be clinically effective. Optimal target tissue temperature and power still need to be determined. Furthermore, in our study, we used only 17-gauge introducer needles. Future tests should incorporate a variety of needle sizes to determine whether they affect procedure outcome. To our knowledge, patient tolerance for pain caused by ablation of the tract has yet to be explored. Finally, this study was performed in an open setting. It has to be determined whether it will be effective in a percutaneous setting. However, the incorporation of real-time thermal feedback brings the technology one step closer to clinical percutaneous use because it provides a method for monitoring the ablation progress without being able to physically see the tract.

Practical application: A thermocouple-monitored RF ablation needle technique decreases bleeding from solid visceral organs in which percutaneous biopsy was performed, even in the presence of anticoagulation, coagulopathy, or portal hypertension, as shown by the preliminary results of our study.
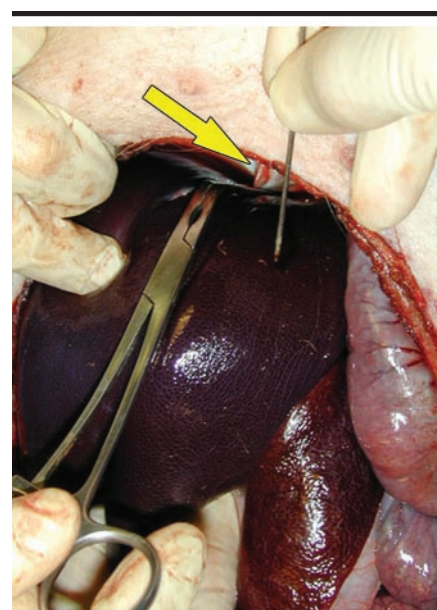
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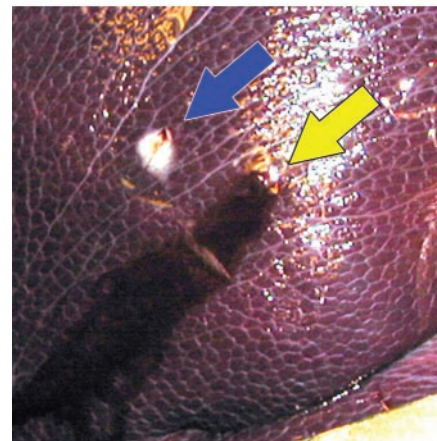
b.

Figure 6. Photographs show simulated portal hypertension. **(a)** The inferior vena cava (arrow) is clamped. **(b)** Close-up view of the liver surface shows the difference in blood loss between the control biopsy site (yellow arrow) and the RF ablation site (blue arrow). Note the lack of hemorrhage at the ablation site compared with active hemorrhage at the control site.

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