Received:
10 August 2017

Revised:
06 January 2018

Accepted:
17 January 2018

<https://doi.org/10.1259/bjr.20170585>

Cite this article as:

Song KD, Rhim H, Lee MW, Kang TW, Lim S. A radiofrequency device for tract ablation after liver biopsy: a single-institution human feasibility study. *Br J Radiol* 2018; **91**: 20170585.

FULL PAPER

A radiofrequency device for tract ablation after liver biopsy: a single-institution human feasibility study

¹KYOUNG DOO SONG, MD, ¹HYUNCHUL RHIM, MD, ¹MIN WOO LEE, MD, ¹TAE WOOK KANG, MD and
²SANGHYEOK LIM, MD

¹Department of Radiology and Center for Imaging Science, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea

²Department of Radiology, Guri Hospital, Hanyang University College of Medicine, Guri, South Korea

Address correspondence to: Dr Hyunchul Rhim
E-mail: rhimhc@skku.edu

Objective: The need for liver biopsy has been increasing because genetic testing of specimens has become important for determining prognosis and management in patients with hepatic malignancy. We evaluated the feasibility of a device for biopsy tract ablation in patients with hepatic masses.

Methods: This prospective single-center pilot study was approved by our institutional review board and patients provided written informed consent. Between September 2015 and March 2016, 10 patients (6 males and 4 females, 35–66-years-old) who had hepatic masses and normal range of platelet count and prothrombin time were enrolled. After percutaneous ultrasound-guided biopsy, the biopsy tract was ablated with the device which consists of an insulation sheath and a radiofrequency applicator. Complications were evaluated with Doppler ultrasound immediately after the biopsy, with noncontrast abdominopelvic CT the

day after the biopsy, and with a telephone interview 7 days after the biopsy.

Results: Tract ablation did not cause any pain in seven patients and caused minimal pain in three patients. Tract ablation was performed for a mean of 4.8 s (range, 4–6 s). No adverse events occurred during the procedure. Bleeding through the biopsy tract was not apparent on Doppler ultrasound, and abnormal fluid was not detected in the abdominal cavity on CT. Procedure-related complications were not reported on telephone interview.

Conclusion: Biopsy tract ablation with the device is technically feasible. If the device is used appropriately considering its potential advantages, it may help to reduce the risk of complications associated with liver biopsy.

Advances in knowledge: It is technically feasible to perform biopsy tract ablation with the radiofrequency ablation device after liver biopsy.

INTRODUCTION

Noninvasive diagnostic tools such as blood tests or imaging studies have become widely available and have replaced liver biopsy in some clinical settings. Elastography with ultrasound has almost replaced liver biopsy for assessment of the degree of liver fibrosis.^{1–3} Contrast-enhanced CT and MRI are used widely for noninvasive diagnosis of hepatocellular carcinoma (HCC).^{4–7} One of the reasons why liver biopsy has been replaced by noninvasive tools is that there is a risk of complications. According to previous studies, the incidence rate of moderate-severe bleeding ranged from 0 to 5.3%,⁸ and the incidence of tract seeding ranged from 2.1 to 5.1%.^{9–12} However, in recent years, genetic testing of specimens has become important for determining prognosis and management in patients with hepatic malignancy. Therefore, the need for liver biopsy has been increasing.

In the early days of radiofrequency (RF) ablation for hepatic tumors, the tract seeding was reported to be as high as 12.5%.¹³ However, the tract seeding rate has reported to be as low as 0–1.1% since tract ablation was performed after RF ablation.¹⁴ In addition, cauterization with RF energy is commonly used for hemostasis during the operation. Based on these facts, a device for RF ablation of biopsy tract has been developed assuming that tract ablation with RF energy would decrease the risk of bleeding and tract seeding after liver biopsy.¹⁵ Although the device was effective in hemostasis after liver biopsy in animal study, the thick outer diameter of the device (11-gauge) was problematic in its clinical use. Recently, a device with diameter of 17-gauge has been developed, and an *in-vivo* porcine liver model study showed that the device reduced post-biopsy bleeding, even with a bleeding tendency.¹⁶ However, no human study using this device has been reported.

The purpose of this study was to evaluate the feasibility of the device for biopsy tract ablation in patients with hepatic masses.

METHODS AND MATERIALS

This was a prospective, single-arm, single-center pilot study. This study was performed to evaluate the feasibility of the device for biopsy tract ablation rather than to prove efficacy for reducing the risk of bleeding and tumor seeding. This study was approved by our institutional review board and patients provided written informed consent before study entry. This clinical trial has been registered at www.clinicaltrials.gov as NCT02521129. The device for biopsy tract ablation was manufactured by STARmed, Goyang, Republic of Korea. The device was the same instrument used in the previous animal study.¹⁶

Patients

Between September 2015 and March 2016, 10 patients (6 males and 4 females) were enrolled in the study. Patient inclusion criteria were as follows: (a) hepatic mass on CT or MRI, (b) referred for percutaneous ultrasound-guided biopsy of a hepatic mass, (c) platelet count in normal range ($\geq 150 \times 10^3$ and $\leq 300 \times 10^3 \mu\text{L}^{-1}$) and international normalized ratio (INR) (0.9–1.1), and (d) 20 to 80 years of age. Exclusion criteria were as follows: (a) pregnancy, (b) presence of ascites and (c) inability to cooperate.

Study protocol

When patients were referred to the radiology department for percutaneous biopsy of a hepatic mass, a radiologist (KDS) reviewed imaging studies and lab findings. If eligibility criteria were met, written informed consent was obtained. Patients underwent percutaneous ultrasound-guided biopsy, and biopsy tract ablation was performed with the device by a radiologist with experience in more than 200 percutaneous liver biopsies. Degree of pain during tract ablation and total time of tract ablation were recorded. Degree of pain was assessed with a numerical rating scale (NRS). We asked the patients to rate their pain from 0 to 10 with understanding that 0 was equal to no pain and 10 was equal to worst possible pain. Procedure-related complications were evaluated with Doppler ultrasound examination immediately after the procedure, with noncontrast abdominopelvic CT the next day, and with a telephone interview 7 days after the procedure.

Biopsy and tract ablation

The device for biopsy tract ablation consists of two components: an insulation sheath and an RF applicator connected to a cable (Figure 1). The insulation sheath was made of stainless steel and was coated with a polyester film. The insulation sheath was 13 cm long and the outer diameter was 17-gauge. The monopolar RF applicator was made of stainless steel without coating. The RF applicator was 15 cm long and the active tip length was 2 cm when combined with the insulation sheath. A thermocouple was embedded within the tip of the RF applicator. A cable with a connector that delivers energy and receives thermal information connects the RF applicator to the generator (VIVA RFA System, STARmed). Procedures were performed on an inpatient basis. Grounding pads were attached to the bilateral thighs. Local anesthesia with lidocaine was performed. Sedative

Figure 1. Device for biopsy tract ablation.

medications during the procedure were not used. The procedure was performed in the following order (Figure 2): (a) insert 18-gauge biopsy gun (Acecut, TSK Laboratory, Japan) into the insulation sheath, (b) target and sample hepatic mass under ultrasound guidance, (c) pull the biopsy gun out leaving behind the insulation sheath (one additional sampling was performed by reinserting the biopsy gun through the insulation sheath), (d) insert the RF applicator into the insulation sheath and (e) apply RF energy for tract ablation. During tract ablation, the power of RF energy was adjusted between 40 W and 60 W to maintain the temperature at the tip of the applicator at 70–80°C.

RESULTS

Baseline characteristics of enrolled patients are summarized in Table 1. No adverse events occurred during the procedure. Tract ablation did not cause any pain in 7 patients (NRS = 0) and caused minimal pain in 3 patients (NRS = 1 or 2). Pain control other than local anesthesia with lidocaine was not performed. Mean time for tract ablation was 4.8 s (range, 4–6 s).

Bleeding through the biopsy tract was not apparent on Doppler ultrasoundS performed immediately after ablation (Figure 3). Abnormal fluid was not detected in the abdominal cavity on noncontrast CT performed the next day. In the telephone interview 7 days after the procedure, one patient complained of vague abdominal pain. However, the patient had a large HCC measuring 13.7 cm and the pain started 3 days after the procedure. Therefore, the pain was thought to be associated with the tumor itself rather than the procedure. The remaining 9 patients did not report any symptoms associated with the procedure.

DISCUSSION

In this study, we demonstrated that tract ablation with the device after percutaneous liver biopsy was technically feasible in patients with hepatic masses. Although a small number of patients without a bleeding tendency were enrolled, this study suggested the potential advantage of the device for biopsy tract ablation to reduce the risk of complications.

Bleeding through the biopsy tract after ablation was not apparent on Doppler ultrasound or noncontrast CT. A few studies reported

Figure 2. Process of biopsy and tract ablation. (a) insert biopsy gun into the insulation sheath, (b) target and sample hepatic mass under ultrasound guidance, (c) pull the biopsy gun out leaving behind the insulation sheath, (d) insert the RF applicator into the insulation sheath and (e) apply RF energy for tract ablation.

a higher than 1% moderate-to-severe bleeding rate after percutaneous liver biopsy, but most studies reported a rate less than 1%.^{17–20} In addition, we selected patients with a platelet count and prothrombin time within normal range. Therefore, it might be no wonder that there was no moderate–severe bleeding in this study. However, mild tract bleeding that stops spontaneously or by external manual compression of the biopsy site is commonly observed after liver biopsy. Some studies reported that intrahepatic or perihepatic bleeding was detectable by ultrasound in as many as 18–20% of patients after percutaneous biopsy.^{21,22} This mild tract bleeding is not of concern in most patients, but can be serious for those with a bleeding tendency. In addition, for patients with ascites, percutaneous liver biopsy requires caution because external compression at the biopsy site may not be

effective to control tract bleeding. In this study, not even mild transient tract bleeding was seen. Therefore, the ablation device may be useful in patients with a bleeding tendency or ascites in whom liver biopsy is critical for appropriate management.

Tumor seeding in the biopsy tract or peritoneal cavity is a serious complication after biopsy of hepatic tumors.²³ The possible mechanisms of tumor seeding are as follows.²⁴ First, tumor cells may be carried into the tract with bleeding. Second, viable tumor cells may adhere to a biopsy needle during retraction. Using this device, it may be possible to reduce the risk of tract bleeding. In addition, the biopsy needle is retracted within the insulation sheath after biopsy rather than through the liver parenchyma. Finally, biopsy tract ablation can kill viable tumor cells in the biopsy tract. Therefore, the risk of seeding can theoretically be reduced with the device.

An adequate biopsy specimen is generally required to minimize sampling error for both conventional histologic examination and genetic testing. However, multiple biopsies also increase the risk of complications including bleeding and seeding. In this regard, the device has an advantage. With its insulation sheath and RF applicator, the device can be used like a trocar system. Thus, multiple specimens can be obtained with a single puncture of the liver capsule.

There are considerations in using this device. First, the insulation sheath should be stably positioned in the liver between pulling the biopsy gun out leaving behind the insulation sheath and inserting the RF applicator into the insulation sheath. Otherwise, the insulation sheath can fall out of the liver. When a tumor is located near the capsule or the patient's deep breath is needed for a biopsy, caution is needed that the sheath does not fall out of the liver. Second, the device uses RF energy. Therefore, caution

Table 1. Baseline characteristics of patients

Sex (M/F)	6/4
Age (y)	59 (35–66)
Diagnosis (HCC/metastasis)	2/8
Tumor location (S3/S4/S5/S6/S8)	1/1/1/1/6
Tumor size (cm)	4.2 (1.2–13.7)
Prothrombin time (INR)	1.04 (0.97–1.12)
Platelet count ($\times 10^3 \mu\text{l}^{-1}$)	229 (179–377)
Total bilirubin (mg dl^{-1})	0.6 (0.2–4.2)
Albumin (g dl^{-1})	4.2 (3.8–4.9)
Alanine aminotransferase (U l^{-1})	35.5 (17–113)
Aspartate aminotransferase (U l^{-1})	25.5 (11–119)

HCC, hepatocellular carcinoma; INR, international normalized ratio; Data are median and range.

Figure 3. A 62-year-old female with pancreatic cancer had a 4.5 cm hepatic metastasis in S8 of the liver (a). Percutaneous ultrasound-guided mass biopsy was performed (b). There was no biopsy tract bleeding after tract ablation on Doppler ultrasound examination (c). There was no perihepatic abnormal fluid on noncontrast CT (d).

should be taken with regard to the use of this device in patients with a cardiac pacemaker or implantable cardioverter defibrillator. In addition, the safety of use in pregnant females or children has not been verified. Although the device has been applied only for liver biopsy in this study, the device could potentially find a role in other organ biopsies with understanding these precautions and the principles of this device.

This study has a limitation for proving efficacy of the device for reducing the risk of bleeding and tumor seeding after liver biopsy because of following reasons. First, the number of patients was small. Second, only patients without a bleeding tendency were included. Third, the follow-up period was only 1 week. Therefore, no references of our work mentioned in here should be

construed as scientifically significant in present form. To confirm the efficacy of this device, a randomized, large-scale, long-term follow-up study is necessary which will be carried out in our future studies. The results of this study can be the basis for applying this device to patients in the future research.

In conclusion, biopsy tract ablation with the device is technically feasible in patients with hepatic masses and may be effective for control of tract bleeding. If the device for biopsy tract ablation is used appropriately considering its potential advantages, it may help to reduce the risk of complications associated with liver biopsy. We also think that large scale long term follow up studies are needed to prove the advantages of this device in preventing track bleeding and seeding.

REFERENCES

1. Sandrin L, Fourquet B, Hasquenoph JM, Yon S, Fournier C, Mal F, et al. Transient elastography: a new noninvasive method for assessment of hepatic fibrosis. *Ultrasound Med Biol* 2003; **29**: 1705–13. doi: <https://doi.org/10.1016/j.ultrasmedbio.2003.07.001>
2. Foucher J, Chanteloup E, Vergniol J, Castéra L, Le Bail B, Adhoute X, et al. Diagnosis of cirrhosis by transient elastography (FibroScan): a prospective study. *Gut* 2006; **55**: 403–8. doi: <https://doi.org/10.1136/gut.2005.069153>

3. Fraquelli M, Rigamonti C, Casazza G, Conte D, Donato MF, Ronchi G, et al. Reproducibility of transient elastography in the evaluation of liver fibrosis in patients with chronic liver disease. *Gut* 2007; **56**: 968–73. doi: <https://doi.org/10.1136/gut.2006.111302>
4. Bruix J, Sherman M. American Association for the Study of Liver Diseases. Management of hepatocellular carcinoma: an update. *Hepatology* 2011; **53**: 1020–2. doi: <https://doi.org/10.1002/hep.24199>
5. Kudo M, Matsui O, Iizumi N, Iijima H, Kadoya M, Imai Y, et al. Liver Cancer Study Group of Japan JSH Consensus-Based Clinical Practice Guidelines for the Management of Hepatocellular Carcinoma: 2014 Update by the Liver Cancer Study Group of Japan. *Liver Cancer* 2014; **3**: 458–68. doi: <https://doi.org/10.1159/000343875>
6. European Association For The Study Of The Liver, European Organisation For Research And Treatment Of Cancer. EASL-EORTC clinical practice guidelines: management of hepatocellular carcinoma. *J Hepatol* 2012; **56**: 908–43. doi: <https://doi.org/10.1016/j.jhep.2011.12.001>
7. Korean Liver Cancer Study Group (KLCSG), National Cancer Center, Korea (NCC). 2014 KLCSG-NCC Korea practice guideline for the management of hepatocellular carcinoma. *Gut Liver* 2015; **9**: 267–317. doi: <https://doi.org/10.5009/gnl14460>
8. Rockey DC, Caldwell SH, Goodman ZD, Nelson RC, Smith AD, American Association for the Study of Liver Diseases. Liver biopsy. *Hepatology* 2009; **49**: 1017–44. doi: <https://doi.org/10.1002/hep.22742>
9. Chapoutot C, Perney P, Fabre D, Taourel P, Bruel JM, Larrey D, et al. Needle-tract seeding after ultrasound-guided puncture of hepatocellular carcinoma. A study of 150 patients. *Gastroenterol Clin Biol* 1999; **23**: 552–6.
10. Takamori R, Wong LL, Dang C, Wong L. Needle-tract implantation from hepatocellular cancer: is needle biopsy of the liver always necessary? *Liver Transpl* 2000; **6**: 67–72. doi: <https://doi.org/10.1002/lt.500060103>
11. Kim SH, Lim HK, Lee WJ, Cho JM, Jang HJ. Needle-tract implantation in hepatocellular carcinoma: frequency and CT findings after biopsy with a 19.5-gauge automated biopsy gun. *Abdom Imaging* 2000; **25**: 246–50. doi: <https://doi.org/10.1007/s002610000025>
12. Huang GT, Sheu JC, Yang PM, Lee HS, Wang TH, Chen DS. Ultrasound-guided cutting biopsy for the diagnosis of hepatocellular carcinoma—a study based on 420 patients. *J Hepatol* 1996; **25**: 334–8. doi: [https://doi.org/10.1016/S0168-8278\(96\)80120-6](https://doi.org/10.1016/S0168-8278(96)80120-6)
13. Llovet JM, Vilana R, Brú C, Bianchi L, Salmeron JM, Boix L, et al. Increased risk of tumor seeding after percutaneous radiofrequency ablation for single hepatocellular carcinoma. *Hepatology* 2001; **33**: 1124–9. doi: <https://doi.org/10.1053/jhep.2001.24233>
14. Francica G. Needle track seeding after radiofrequency ablation for hepatocellular carcinoma: prevalence, impact, and management challenge. *J Hepatocell Carcinoma* 2017; **4**: 23–7. doi: <https://doi.org/10.2147/JHC.S106558>
15. Pritchard WF, Wray-Cahen D, Karanian JW, Hilbert S, Wood BJ. Radiofrequency cauterization with biopsy introducer needle. *J Vasc Interv Radiol* 2004; **15**: 2 Pt 1: 183–7. doi: <https://doi.org/10.1097/01.RVI.000019398.74740.69>
16. Lim S, Rhim H, Lee MW, Song KD, Kang TW, Kim YS, et al. New radiofrequency device to reduce bleeding after core needle biopsy: experimental study in a porcine liver model. *Korean J Radiol* 2017; **18**: 173–9. doi: <https://doi.org/10.3348/kjr.2017.18.1.173>
17. Perrault J, McGill DB, Ott BJ, Taylor WF. Liver biopsy: complications in 1000 inpatients and outpatients. *Gastroenterology* 1978; **74**: 103–6.
18. Stone MA, Mayberry JF. An audit of ultrasound guided liver biopsies: a need for evidence-based practice. *Hepatogastroenterology* 1996; **43**: 432–4.
19. Piccinino F, Sagnelli E, Pasquale G, Giusti G. Complications following percutaneous liver biopsy. A multicentre retrospective study on 68,276 biopsies. *J Hepatol* 1986; **2**: 165–73.
20. Myers RP, Fong A, Shaheen AA. Utilization rates, complications and costs of percutaneous liver biopsy: a population-based study including 4275 biopsies. *Liver Int* 2008; **28**: 705–12. doi: <https://doi.org/10.1111/j.1478-3231.2008.01691.x>
21. Firpi RJ, Soldevila-Pico C, Abdelmalek MF, Morelli G, Judah J, Nelson DR. Short recovery time after percutaneous liver biopsy: should we change our current practices? *Clin Gastroenterol Hepatol* 2005; **3**: 926–9. doi: [https://doi.org/10.1016/S1542-3565\(05\)00294-6](https://doi.org/10.1016/S1542-3565(05)00294-6)
22. Minuk GY, Sutherland LR, Wiseman DA, MacDonald FR, Ding DL. Prospective study of the incidence of ultrasound-detected intrahepatic and subcapsular hematomas in patients randomized to 6 or 24 hours of bed rest after percutaneous liver biopsy. *Gastroenterology* 1987; **92**: 290–3. doi: [https://doi.org/10.1016/0016-5085\(87\)90119-3](https://doi.org/10.1016/0016-5085(87)90119-3)
23. Chang S, Kim SH, Lim HK, Kim SH, Lee WJ, Choi D, et al. Needle tract implantation after percutaneous interventional procedures in hepatocellular carcinomas: lessons learned from a 10-year experience. *Korean J Radiol* 2008; **9**: 268–74. doi: <https://doi.org/10.3348/kjr.2008.9.3.268>
24. Stigliano R, Marelli L, Yu D, Davies N, Patch D, Burroughs AK. Seeding following percutaneous diagnostic and therapeutic approaches for hepatocellular carcinoma. What is the risk and the outcome? Seeding risk for percutaneous approach of HCC. *Cancer Treat Rev* 2007; **33**: 437–47. doi: <https://doi.org/10.1016/j.ctrv.2007.04.001>