 PURPOSE: To evaluate the feasibility of Interactive Scan Control (ISC), a new MR image navigation system, during percutaneous puncture in cryosurgery.

MATERIALS AND METHODS: With the ISC system in place, percutaneous MR-guided cryosurgery was performed in 26 cases, with the ISC system being used in 11 cases (five renal tumors, three uterine fibroids and three metastatic liver tumors). The ISC system comprised infrared cameras and an MR-compatible optical tracking tool that was directly connected to a cryoprobe. Tumor sizes ranged from 1.2 cm (metastatic liver tumor) to 9.0 cm (uterine fibroid), for a mean size of 3.9 cm. With ISC, one to three cryoprobes with a diameter of 2 mm or 3 mm were advanced into the tumors with the guidance of an MR fluoroscopic image. Two freeze-thaw cycles were used for cryosurgery. During the cryosurgery, the formation of iceballs was monitored on MR images. Follow-up dynamic CT or MRI as well as physical examinations were conducted after two weeks and six weeks.

RESULTS: Placement of probes was successfully performed under the control of the ISC system. During cryosurgery, engulfment of the tumors by iceballs was carefully monitored by MRI. Necrosis of the cryoablated area was confirmed in all renal tumors by follow-up dynamic CT. The size regression of the uterine fibroids was observed through follow-up MRI. Two of the three cases of metastatic liver tumor were ablated completely. Additional therapy for a residual tumor was performed on one patient with a metastatic liver tumor. A small amount of pneumothorax was the only complication found in a patient with a metastatic liver tumor.

CONCLUSION: MR-guided cryosurgery with this new navigation system was feasible with low morbidity and allowed for safe and accurate puncture with a cryoprobe.

KEYWORDS: interactive scan control system, cryosurgery, magnetic resonance imaging, interventional MRI

INTRODUCTION

Cryosurgery provides a method for focal destruction of targeted tissue while preserving most of the surrounding normal tissue. MRI provides sufficient sensitivity for detection of iceballs in signal loss areas and allows for good visualization of the puncture route without exposing the patient and medical team to ionizing radiation. An optical tracking system can be used for preoperative planning and intraoperative scanning of the procedure. During MR-guided interventional therapies, the direction of the puncture needle must correspond exactly with the imaging plane. Therefore, navigation of the correct imaging plane is essential. We used a new MR-compatible optical tracking system, Interactive Scan Control (ISC), to navigate the probe puncture guided by a horizontal open-configuration MRI system.

MATERIALS AND METHODS

The MR imaging system used in this study was a 0.3T horizontal open-configuration MRI (AIRIS II*, Hitachi Medical Corp., Tokyo, Japan). The physician could approach the patient from either the right or left side and perform the interventional procedure from the open space.

The ISC, a new optical navigation system, comprised infrared cameras (Fig. 1a) for detecting position, a computer for calculating positional information, a reference tool (Fig. 1b) attached to an MRI gantry and a pointer tool (Fig. 1c) attached to

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ISC consists of infrared cameras (a), a reference tool attached to an MRI gantry (b) and a pointer tool connected to a cryoprobe (c) by a screw-type fixed implement (d). Infrared rays emitted from the camera are reflected by the reflective balls attached to the pointer tool and reference tool.

The infrared cameras (POLARIS®, Northern Digital Inc., Ontario, Canada) were commercially available. The reference tool and the pointer tool were made from plastic in a triangular shape provided with attached reflective balls. The cryoprobe and pointer tool are connected by a fixed screw-type implement (Fig. 1d). We originally developed these tools, the fixed implement and the software for calculating the positional information. Infrared rays emitted by the camera are reflected by the reflective balls attached to the pointer tool and the reference tool. The camera detects these reflective infrared rays and the data are transmitted as positional information to the computer along optical fiber cable at a rate of 10 frames per second. The positional information calculated by the computer is sent to the MRI.

Parallel to the connected pointer tool is an imaging plane on which the cryoprobe is continuously visualized. The tip of the cryoprobe is located at the center of the field of view (FOV) of the imaging plane.

The site of the skin puncture was determined by finger marking with MR fluoroscopy. After the puncture point was determined, the cryoprobe was advanced with the guidance of MR fluoroscopy. The following sequences were suitable for probe navigation with ISC:

1. T₁-weighted gradient echo-EPI (RSSG-EPI) TR/TE 25/11.8 ms, flip angle (FA) 30 degrees, matrix 100 × 228, 10 mm slice, time of acquisition (TA) 2 s/slice
2. T₁-weighted gradient echo ((RSSG) TR/TE 30/11.5 ms, FA 35 degrees, matrix 192 × 128, 10 mm slice, TA 4 s/slice
3. T₂-weighted gradient echo (TRSG) TR/TE 16/25.4 ms, FA 50 degrees, matrix 192 × 128, 10 mm slice, TA 2 s/slice.
Percutaneous cryosurgery was performed with a cryoablation system (CRYO-HIT, Galil Medical Ltd., Yokneam, Israel). This system comprised a computer workstation, a gas distribution system, temperature sensors and needle-shaped cryoprobes. It used high-pressure argon gas for freezing, producing $-185^\circ$C at the tip of needle probe by means of the Joule-Thomson effect. Thawing of the tissue was performed with high-pressure helium gas, which generates heat at temperatures up to 70°C. The gases were delivered through an MR-compatible cryoprobe with a diameter of 2 mm or 3 mm. Each cryoprobe was provided with a thermocouple for monitoring of the needle tip temperature throughout the freezing and thawing. The needle tip temperature was displayed on the monitor of the main unit. Five cryoprobes could be frozen and thawed simultaneously and independently.

Following installation of this system, percutaneous MR-guided cryosurgery was performed on 26 cases according to a protocol approved by the institutional review board. Among them, the ISC system was used in 11 cases (five renal tumors, three uterine fibroids and three metastatic liver tumors; Table). Informed consent was obtained from all patients in advance of the procedures.

Procedures were performed following administration of 2% lidocaine hydrochloride as local anesthesia. For pain control, epidural anesthesia was also administered to one patient with a uterine fibroid. Patients lay on the MR table in the supine or prone position, as well as an oblique position if warranted by the location of the tumor. A cryoprobe with its corresponding access sheath (Fig. 2) was inserted with the guidance of an MR fluoroscopic image with ISC. Additional cryoprobes were placed if required to treat the tumor. Depending on tumor size, the number of cryoprobes ranged from one to three.

Repetition of the freeze-thaw cycle is well known to be an important factor in effective therapy; we performed two freeze-thaw cycles for cryosurgery based on our protocol of clinical trials. Freezing time was less than 20 min, varying mainly with the size of the tumor, while the thawing time was less than 10 min. MR imaging was performed every 2–4 min in at least two planes to monitor the growth of iceballs and tumor coverage. The probe was removed after two freeze-thaw cycles and the access sheath was packed with absorbable gelatin sponge to facilitate hemostasis.

On the morning following the procedure, a plain CT was performed in order to evaluate any complications. A follow-up dynamic CT (for patients with renal tumor or liver tumor) or an MRI (for uterine fibroid) and a physical examination were performed at two and six weeks following surgery. After the procedure, the patients remained in hospital for 24 hours for follow-up. If no complications were revealed in the follow-up CT or clinical examination, the patients were discharged on the day after the procedure.

Results

A total of 19 punctures with a cryoprobe were performed on 11 patients (Table). Cryoprobe placement was performed successfully in all patients. No procedures were prematurely terminated before completion of probe placement and all patients tolerated the probe insertion well. The
only complication was a small amount of pneumothorax found in one patient with a metastatic liver tumor located in segment 7 (Case 8, Table). The size of the lesions ranged from 1.2 cm (metastatic liver tumor) to 9.0 cm (uterine fibroid), for a mean size of 3.9 cm. The smallest lesion was 1.2 cm in a patient with a metastatic liver tumor located in segment 6 of the liver (Case 7, Table). It was punctured successfully without complications.

The instruments did not adversely affect image quality or signal-to-noise ratio. The imaging quality of MR fluoroscopy and the imaging guidance updates were sufficient in all cases. The optical tracking system allowed for a fast and reliable choice of puncture route during probe insertion. It was also useful for changing the angle of the cryoprobe. The optical tracking system also allowed near real-time fluoroscopy in the plane of the instrument, which facilitated probe insertion into different anatomical lesions and various angles of approach (Fig. 3). The two-second image delay did not restrict the procedure.

The iceball was displayed as a sharply marginated area of signal loss on MR images. Intraprocedural MR images demonstrated the growth of the iceball that covered the liver or renal tumor (Fig. 4). In patients with uterine fibroid, a benign disease, there was no need to cover the entire fibroid with an iceball. Intraprocedural images of the iceball correlated well with postprocedural estimates of cryolesions that appeared as non-enhancing areas on a follow-up enhanced CT.

The outcomes were evaluated two and six weeks after the procedure by means of clinical examination and imaging with CT or MRI. The follow-up CT scans after two and six weeks showed the cryolesions as non-enhancing areas in patients with renal tumors, and tumor necrosis was confirmed (Fig. 5). Two of the three cases of metastatic liver tumor were ablated completely. The follow-up CT scan of one patient with a metastatic liver tumor showed a residual tumor and additional therapy was performed (Case 9, Table). In patients with a uterine fibroid, a follow-up MRI revealed the decreased size of the fibroid: 21.4% (4.0–34.8%) in two weeks and 33.8% (11.0–64.8%) in six weeks. Improvement of clinical symptoms was also confirmed.

In all patients, no changes occurred in hemoglobin or hematocrit level, except for a transient increase in serum level of GOT, GPT or LDH and white blood cell count. All these values had returned to near-normal levels at six weeks after the procedure.

**Discussion**

Damaging tissue with low temperatures is presumably the oldest thermal ablation method in medicine. It is based on local heat loss of biologic tissue close to a superficially or interstitially inserted cryoprobe, with the resultant formation of an iceball within this tissue. The assumed mechanisms of tissue damage are as follows:

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**Fig. 3.** (Case 6, RCC) The imaging quality of MR fluoroscopy (a, axial and b, coronal) and the updates of the imaging guidance were adequate. The optical tracking system enables fast and reliable determination of a puncture route during probe insertion (arrow).
1. intracellular freezing followed by immediate cell death;
2. extracellular crystallization of interstitial water followed by lethal cell dehydration;
3. thrombosis of small blood vessels with secondary loss of tissue nutrition; and
4. mechanical damage to cellular integrity through the expansion of large ice crystals within the interstitial space.

The important characteristics of cryosurgery in comparison with other thermal ablation methods are the simple control of ice formation, the analgesic effect of the cold, and the lack of undesirable toxic products.

To date, most cryosurgery has been performed via an open or laparoscopic approach. Cryosurgery has been performed during open or laparoscopic surgery for liver tumors and renal tumors, and ultrasound has been used for monitoring the formation of the iceball. Although ultrasound is a
real-time imaging modality, it can depict only the boundary between the iceball and surrounding normal tissue as a hyperechoic lesion, and the major part of the frozen tissue remains invisible due to acoustic shadows. Recently, it has been proved that MRI is a helpful modality for monitoring cryosurgery with high accuracy and excellent contrast between normal and frozen tissue. MRI has several advantages over CT and US. These include good tissue contrast and spatial resolution, sensitivity to blood flow and temperature, lack of ionizing radiation, and ability to image planes of any orientation.

It is reasonable to expect that open-configuration MRI will provide a valuable platform for percutaneous cryosurgery. Open-configuration MRI allows wide access to the patient, and the puncture route can be chosen in any plane.

The most important requirement for performing a minimally invasive procedure is a safe and accurate needle puncture. In MR-guided cryosurgery, the puncture route of the cryoprobe must correspond exactly with the imaging plane. Therefore, it is important to accurately navigate the correct imaging plane. Several different methods exist for real-time tracking of the needle. One is the optical tracking system, which is used in conjunction with a stereovision camera. The optical tracking system has been successfully used in MR-guided needle biopsies and injections. Ojala et al., using a method similar to ours, reported the usefulness of an optical tracking system in MR-guided bone biopsy.

The advantages of optical tracking are real-time operation and ease of use. Since a dedicated fixed implement connects the cryoprobe and pointer tool, the physician can hold the probe and pointer tool together in one hand. The fixed implement is a screw type and can be easily removed from the cryoprobe by loosening the screw. In this cryosurgery, where several cryoprobes are needed to accommodate the size and shape of the tumor, the easy replacement of the pointer tool with another probe is very useful. With this optical tracking system, infrared rays were irradiated from a camera and positional information was calculated by the infrared rays reflected from the pointer tool. As a result, no connection wire was necessary and the cryoprobe’s range of movement was not restricted. On the other hand, in a navigation system using a light emitting diode (LED), infrared rays were emitted by the LED connected to the probe. The connecting wire was needed for the LED navigation system, thus restricting the range of movement.

The disadvantages of this optical system were the need to maintain the sightline and the insensitivity to needle bending. Since the positional information is calculated from reflective infrared rays, if the pointer tool or reference tool are obscured by the radiologist’s or patient’s shadow, positional information might not be detected. The camera, however, is attached to the floor stand, so it can be moved easily. Moreover, the physician can approach from either the right or left side of the patient. On the other hand, the image plane is parallel to the pointer tool. Therefore, if the needle or probe is bent by the tumor tissue, the needle cannot be visualized on the imaging plane.

The infrared cameras are located 2 m from the center of the magnetic field and 0.5 m from the MRI table. In this location, the system could detect the refractive infrared rays from −30 to 50 degrees in the axial imaging plane and from −40 to 60 degrees in the coronal imaging plane. In the axial imaging plane, a probe was clearly visible from −30 to 50 degrees. But in the coronal imaging plane, the probe was not clearly visible from 30 to 60 degrees. In a phantom experiment, the position accuracy was less than ±1 mm. Any change in positioning accuracy that may occur if the relative positions of the ISC and the patient are changed and the procedure time is shortened was not evaluated. It is necessary to acquire data and conduct a quantitative evaluation.

Previously, we reported our initial experience with percutaneous renal cryosurgery under horizontal MRI guidance. In that series, four patients with RCC were treated successfully with MR-guided cryosurgery, with the only complication being perirenal hematoma. Campell et al. reported that a target temperature of less than −20°C was achieved 3.1 mm behind the iceball in all animal tests; a temperature of less than −20°C must be reached to kill malignant and benign renal epithelial cells reliably. Gill et al. reported the results of follow-ups of needle biopsies of cryoleisions performed after three to six months, which recognized no residual cancer in all 23 patients. Sewell et al. reported cryoablation of uterine fibroids in two patients. In that series, patients confirmed a significant reduction of their symptoms at two weeks after cryoablation. Measurements obtained from MR imaging performed after cryoablation demonstrated a 65% and 53% reduction, respectively, in the patients’ fibroid volumes at eight weeks.

Percutaneous MRI-guided cryosurgery is a feasible and effective procedure, and probe placement is an important step in this procedure. This study supports the view that probe placement with ISC is an accurate and safe procedure. The MRI-guided
procedure is radiation-free and enables multi-dimensional imaging.

Conclusion

MR guided cryosurgery with the new wireless optical tracking system combined with a horizontal MRI system is feasible with low morbidity, allowing for safe and accurate puncturing with the cryoprobe.

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