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MRI-guided percutaneous needle biopsy with 1.2T open MRI: study protocol for a prospective feasibility study (SCIRO-1701)

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ABSTRACT

There has been growing interest in magnetic resonance imaging (MRI)-guided interventional procedures such as percutaneous needle biopsy. Although open MRI is preferable for MRI-guided procedures in terms of patient accessibility, its inferior imaging capability due to lower field strength is a substantial limitation. In this situation, the high-field (1.2T) open MRI has recently become available. This novel MRI system is expected to provide excellent image quality as well as good patient accessibility, potentially contributing to safe and accurate device manipulation. This trial is designed to investigate the feasibility of MRI-guided percutaneous needle biopsy with this system. Patients with lesions needing percutaneous needle biopsy for pathological diagnosis are included. The enrollment of ten patients is intended. The primary endpoint of this study is the feasibility of biopsy needle insertion under real-time MR-fluoroscopy guidance based on the presence of the notch of the biopsy needle within the target lesion. The secondary endpoints are adverse events, device failures, and success of specimen acquisition. Once the feasibility of MRI-guided biopsy with 1.2T open MRI is validated by this study, it may potentially encourage widespread use of MRI-guidance for biopsy procedures. Furthermore, it may lead to development of the other MRI-guided interventional procedures using this MRI system.

Keywords: magnetic resonance imaging, high-field, magnetic resonance fluoroscopy, biopsy, feasibility

Abbreviations:
MRI: magnetic resonance imaging
CT: computed tomography
US: ultrasound
AE: adverse event
BASG: balanced steady-state acquisition with rewound gradient echo

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INTRODUCTION

In recent years, there has been growing interest in magnetic resonance imaging (MRI)-guided interventional procedures such as percutaneous needle biopsy. The use of MRI-guidance has several advantages, compared with computed tomography (CT)- or ultrasound (US)-guidance. MRI provides multiplanar imaging with excellent soft tissue contrast.[1,2] Furthermore, there is no radiation exposure either to patients and physicians. MRI-guided biopsy is performed using either open or closed-bore MRI system.[1-7] The standard closed-bore MRI has a narrow cylindrical design that restricts access to the patient. When performing MRI-guided biopsy with this type of MRI system, needle manipulation is usually performed with the patient outside the magnet because of space restriction.[1] In other words, patients are moved in and out of the magnet repetitively for MRI scanning and needle manipulation during the procedure.[3] The limited patient access in the closed-bore MRI systems has hampered the widespread use of MRI-guidance for biopsies.[4] In contrast, the open MRI has a sandwich-like design with wide open sides, offering good patient accessibility.[1-3] Because of this configuration, the open MRI system enables needle manipulation under real-time MRI guidance (MR-fluoroscopy), while keeping the patient inside the magnet. Such superior patient accessibility and real-time imaging capability are substantial advantages of using open MRI for MRI-guided biopsy. However, most of the open MRI systems are of low- or mid-field strength, and therefore, the image quality of these systems is not excellent enough compared with that of high-field closed-bore MRI. MR image quality may affect the accuracy and safety of the biopsy procedures. Recently, an open MRI system with high-field strength (1.2T) has become available (OASIS; Hitachi, Tokyo, Japan) worldwide. This high-field open MRI system is expected to provide excellent quality of MR images as well as good patient accessibility, hence potentially contributing to safe and accurate device manipulation. To date, there has been no report regarding the use of this novel MRI system for MRI-guided interventional procedures. Thus, we designed a prospective study to investigate the feasibility of MR fluoroscopy-guided percutaneous needle biopsy with 1.2T open MRI. This article presents the outline of the study protocol.

METHODS

Study purpose

The purpose of this study is to evaluate the feasibility of MRI-guided percutaneous needle biopsy with 1.2T open MRI.

Study design

This is a single-center, single-arm, open-label, prospective, feasibility trial. This study is registered at Japan Registry of Clinical Trials (trial ID, jRCTs062180019).

Endpoints

The primary endpoint is the feasibility of biopsy needle insertion under MR-fluoroscopy guidance with 1.2T open MRI. The procedure is considered feasible when the notch of the biopsy needle is within the target lesion on the MR images. The secondary endpoints include all adverse events (AEs), procedure-related AEs, device-related AEs, device failures, and success of tissue specimen acquisition. AEs are graded according to Common Terminology Criteria for Adverse Events version 4.0.[8] Acquisition of tissue specimens is considered successful when the specimen amount is sufficient for pathological diagnosis.

Sample size

Because the present study is an exploratory trial, sample size is not statistically calculated. The target number of study subjects is ten: this is expected to be large enough to evaluate the feasibility and the other endpoints of the study. The period of patient recruitment is between April 2018 and March 2022.

Inclusion criteria

1) Target lesion that cannot be diagnosed by noninvasive examinations and needing percutaneous needle biopsy for pathological diagnosis.
2) Size of the target lesion larger than 20 mm.
3) Applicability of a body coil developed for MRI-guided procedures to the patient.
4) Target lesion clearly visible in the images obtained by 1.2T open MRI.
5) Target lesion from which acquisition of specimens by a cutting needle is assumed to be possible.
6) Expected survival time of the patient of more than 28 days from the registration.
7) Written informed consent provided by the patient.
8) Age of the patient 20 years old and older.

Exclusion criteria

1) Presence of contraindication of MRI.
2) Target lesion that is too small for biopsy.
3) Absence of the safe needle insertion pathway because of the presence of critical organs or vessel structures.
4) Presence of severe comorbidities of patients such as severe heart failure (New York Heart Association Classification III or IV), or active infectious disease except viral hepatitis.
5) Presence of a fever higher than 38°C.
6) Laboratory findings of white blood-cell count <2,000/μL, hemoglobin <6.0 g/dL, platelet count <50,000/μL, or prothrombin time-international normalized ratio >1.5.
7) Pregnant status.
8) Inappropriateness of the candidate for the study judged by the investigators because of other reasons.

Biopsy procedure

The biopsy is performed using 1.2T open MRI system in the inpatient settings (Fig. 1). The body coil (Open Rigid Body Coil; Hitachi, Tokyo, Japan) which has optimal custom-made design for MRI-guided intervention is used for the biopsy procedure. Fast spin-echo T2 and/or T1 weighted images, and balanced steady-state acquisition with rewound gradient echo (BASG) images of the region of interest with 5 mm slice thickness are initially obtained for biopsy planning. After sterilization, local anesthesia is administered into the skin entry point by means of a 22G MR-compatible needle (KIM; Innovative Tomography Products, Bochum, Germany). A 16G introducer needle (KIM; Innovative Tomography Products, Bochum, Germany) is inserted under real-time MR-fluoroscopy guidance with a single slice image of 5-mm thickness updated every 1 s. BASG sequence is applied for the MR-fluoroscopy imaging. Although the needle is generally monitored on an axial plane, coronal, sagittal, and oblique planes are also available when necessary. Once the tip of the introducer needle reaches the edge of the target lesion, a 18G semi-automatic cutting biopsy needle (BIM; Innovative Tomography Products, Bochum, Germany) is advanced into the target lesion through the introducer needle under MR-fluoroscopy guidance. After confirming the appropriate needle position, the biopsy needle is fired. Acquisition

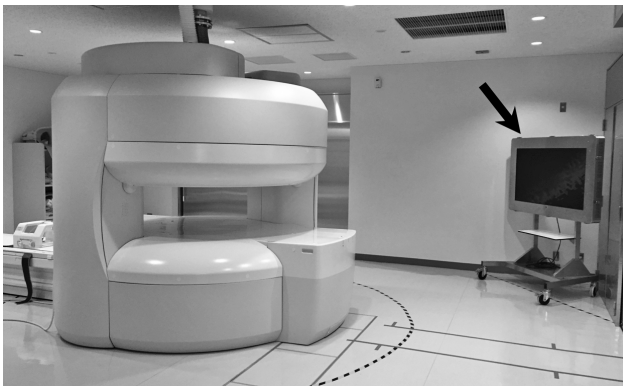

Fig. 1 1.2T open magnetic resonance imaging (MRI) system
The MRI system has open sandwich design, which is preferable for patient access. The needle is monitored on the display installed in the MRI room (arrow).

of tissue specimens can be repeated until a sufficient amount is obtained. After removal of the needles, MRI scan of the target area is performed to evaluate AEs.

Post-procedure Observations

After the biopsy procedure, the patient is carefully observed for clinical symptoms. The patient is discharged on the following day of the procedure after undergoing evaluation of clinical symptoms, AEs, and blood counts, unless AE that requires inpatient treatment occurs. In all patients, follow-up evaluation of clinical symptoms and AEs is conducted at 14 ± 7 days after the biopsy procedure.

Interim analysis and monitoring

The Data and Safety Monitoring Committee evaluates the safety after completion of the first five cases. The Data and Safety Monitoring Committee may decide on early termination of the study in case there are severe AEs in more than three of the five cases. Patient eligibility, protocol compliance, data submission, and proper reporting of AEs are ensured by in-house monitoring.

Statistical analysis

Demographic data are summarized by descriptive statistics. The feasibility rate (%) is calculated by dividing the number of patients for whom biopsy needle insertion under MR-fluoroscopy guidance is successful by the total number of patients who undergo the biopsy procedure. The rate (%) of all AEs, AEs of grade 3 or greater, procedure-related AEs, device-related AEs, device failures, and specimen acquisition success are also calculated.

DISCUSSION

Percutaneous image-guided biopsy of targets in various organs are widely used for histopathological diagnosis. CT and US are common image-guidance modalities used for biopsy. Nevertheless, each of these has its own drawbacks. For example, radiation exposure is an inevitable disadvantage of CT-guided biopsy. Lack of deep tissue penetration and acoustic shadowing are disadvantages of US-guided biopsy.[5] MRI-guided biopsy has emerged as an alternative method

with potential advantages over CT- and US-guided biopsies. Regarding the application of MRI-guided procedures, there is a distinct difference between open and closed-bore MRI systems.[9] Open MRI is preferable in terms of patient accessibility, but usually has inferior image quality. Closed-bore MRI offers better image quality, but the patient access is restricted. Incompatibility of high image quality and good patient accessibility has been a limitation of conventional MRI-guided procedures. Recently, efforts have been made to overcome this drawback. Several authors reported the use of large-bore MRI, which offers better patient accessibility than conventional closed-bore MRI.[6,7] An alternative method is the use of open MRI with high field strength, which provides better imaging quality than conventional open MRI.[3] The 1.2T open MRI system used in the present study has the highest field strength among such high-field open MRI systems currently available in a clinical setting, and has significant potential for use in MRI-guided procedures. The present study is an initial trial investigating the MRI-guided procedure using this system. Once the feasibility of MRI-guided biopsy with 1.2T open MRI is validated by this study, it may potentially encourage widespread use of MRI-guidance for biopsy procedures. Furthermore, it may lead to development of the other MRI-guided interventional procedures (e.g., tumor ablation) using this MRI system.

ETHICS APPROVAL

The study protocol has been approved by Okayama University Certified Review Board (approval number, CRB18-007).

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CONFLICT OF INTEREST

None of the authors have identified a conflict of interest directly relevant to this study.

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