Safety and Efficacy of Percutaneous Fiducial Marker Implantation for Image-guided Radiation Therapy

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PURPOSE: To evaluate the safety and technical success rate of percutaneous fiducial marker implantation in preparation for image-guided radiation therapy.

MATERIALS AND METHODS: From January 2003 to January 2008, we retrospectively reviewed 139 percutaneous fiducial marker implantations in 132 patients. Of the 139 implantations, 44 were in the lung, 61 were in the pancreas, and 34 were in the liver. Procedure-related major and minor complications were documented. Technical success was defined as implantation enabling adequate treatment planning and computed tomographic simulation.

RESULTS: The major and minor complication rates were 5% and 17.3%, respectively. Pneumothorax after lung implantation was the most common complication. Pneumothoraces were seen in 20 of the 44 lung implantations (45%); a chest tube was required in only seven of the 44 lung transplantations (16%). Of the 139 implantations, 133 were successful; in six implantations (4.3%) the fiducial markers migrated and required additional procedures or alternate methods of implantation.

CONCLUSIONS: Percutaneous implantation of fiducial marker is a safe and effective procedure with risks that are similar to those of conventional percutaneous organ biopsy.

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TECHNOLOGICAL advances in respiratory tracking and tumor localization have enabled the use of stereotactic radiation therapy in the treatment of extracranial and extraspinal diseases. The CyberKnife (Accuray, Sunnyvale, California) is one such technology that delivers frameless precision radiation therapy. To track tumor position throughout the respiratory cycle, radiopaque gold markers called "fiducial" markers must be implanted in the vicinity of the tumor. The fiducial markers act as internal radiologic landmarks and move with a constant relationship to the targeted tumor during therapy for the precise delivery of radiation. The purpose of this retrospective study was to describe the safety and technical success rate of percutaneous fiducial marker implantation in extracranial locations such as the lung, liver, and pancreas.

MATERIALS AND METHODS

This retrospective study was granted a waiver by the institutional review board. Data were handled in compliance with the Health Insurance Portability and Accountability Act. From January 2003 to January 2008, 132 patients (mean age, 66.4 years; age range, 23–89 years) underwent 139 procedures (**Table 1**). Five patients underwent implantations on two separate occasions for anatomically distinct tumors. Seventy-one patients were men and 61 were women. Of these 139 procedures, 44 were lung implantations, 61 were pancreatic implantations, and 34 were liver implantations. The mean overall maximum tumor diameter was 3.4 cm (range, 1–7.4 cm).

All cases were discussed at their respective tumor boards and were deemed unresectable. The patients were then evaluated by the radiation oncology team to determine their suitability for stereotactic radiation therapy. The interventional radiology team reviewed the diagnostic imaging studies to determine the best percutaneous needle approach to the tumor. All procedures were performed by using computed tomography (CT) with CT

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Table 1
Summary of Patient Demographics

Parameter	Value
Total fiducial marker implantations (n = 139)	
Mean patient age (y)	66.4 (23–89)
Sex	
No. of men	71
No. of women	61
Mean tumor size (cm)	3.4 (range, 1–7.4)
Lung (n = 44)	
Mean tumor size (cm)	2.67 (range, 1–5.1)
Non–small cell lung cancer (adenocarcinoma)	19
Non–small cell lung cancer (squamous)	14
Metastases	5
Other	6
No. of patients with underlying chronic obstructive pulmonary disease	29 (66%)
Pancreas (n = 61)	
Mean tumor size (cm)	3.8 (range, 1.9–7.4)
Adenocarcinoma	58
Other	3
Liver (n = 34)	
Mean tumor size (cm)	3.5 (range, 1–7)
Hepatocellular carcinoma	5
Cholangiocarcinoma	6
Metastases	23

fluoroscopy capability. Procedures were performed with the patient under moderate sedation (intravenous midazolam and fentanyl), which was administered by a registered radiology nurse. A preliminary unenhanced CT scan was obtained and an appropriate needle trajectory determined. The skin entry site was prepared in a sterile fashion and local anesthesia (lidocaine 1%) administered. A 19-gauge thin-wall coaxial introducer needle (Allegiance; Cardinal Health, Dublin, Ohio) was then advanced into the lesion under CT fluoroscopy guidance. Fine-needle aspiration and/or a 20- or 21-gauge core biopsy were performed in 33 of the 132 patients (25%) to confirm the diagnosis. The remaining patients had previously undergone diagnostic biopsy or had imaging and clinical findings that were pathognomonic for malignancy. After this procedure, three to five cylindrical fiducial markers measuring 0.8 mm in diameter and 5 mm in length (Alpha-Omega Services, Bellflower, California) were deposited via the 19-gauge coaxial introducer needle. The fiducials were introduced into the coaxial needle by using a curved hemostat and advanced into the lesion by using the trochar of the introducer needle. Because the CyberKnife uses orthogonal x-rays at 45° to vertical to track the tumor and fiducial markers, the markers must be placed in a non-collinear array in different sectors of the tumor milieu to define a three-dimensional space enclosing the tumor. Unenhanced CT was performed at the conclusion of the procedure to evaluate for immediate complications. Patients without any complications were monitored for 4 hours and then discharged from the hospital. Patients with complications were admitted for observation and appropriate treatment.

Treatment planning with CT simulation was done a minimum of 7 days after implantation to allow for the resolution of tissue inflammation and fiducial marker migration. A custom-made immobilization device was prescribed by the radiation oncologist. The CT simulation images were transferred to the CyberKnife treatment planning system. The tumor volume and adjacent crucial structures were outlined, and an appropriate radiation dose was prescribed. The fiducial markers were identified on the images, allowing the guidance system to calculate the exact location of the tumor in relation to the fiducial markers and surrounding structures. A treatment plan was formed on the basis of this information, which was then translated to robotic control for the precise delivery of the therapeutic dose.

The presence of chronic obstructive lung disease (as documented in the medical records and outpatient charts) was noted for patients undergoing fiducial marker implantation for thoracic tumors. Complications were documented by using the SIR clinical practice guidelines (1). A major complication was defined as that requiring therapy with hospitalization for less than 48 hours, major additional therapy, or an unplanned increase in the level of care or hospitalization for more than 48 hours and that causing permanent adverse sequelae or death. A minor complication was defined as that requiring no or nominal therapy, including overnight hospitalization for observation with no permanent consequence (1).

Technical success was defined as implantation that enabled adequate tracking of the tumor during all phases of respiration for treatment planning and CT simulation. For this, at least three non-collinear fiducials had to be present and adequately visualized on the digitally reconstructed radiographs obtained by the two orthogonal x-ray sources. Patients who were called back for reimplantation of fiducial markers or those who demonstrated the migration of most of the markers were deemed technical failures.

RESULTS

Safety and Technical Success

The median number of fiducial markers implanted for each tumor was four (range, 3–7). There were no procedure-related deaths. Major complications occurred in seven of the 139 implantations (5%). Minor complications occurred in 24 patients (17.3%). Of the 139 implantations, 133 were technically successful; in six implantations (4.3%), the fiducial markers migrated and required additional procedures or alternate methods of implantation. The results are summarized in **Table 2**.