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Robotically assisted lung biopsy under CT fluoroscopy: lung cancer screening and phantom study

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Abstract. Lung cancer is an important clinical problem and lung cancer screening may lead to an early diagnosis. CT fluoroscopy-guided lung biopsy is a popular method for obtaining a tissue sample for lung cancer diagnosis. However, the radiation exposure for the physician associated with CT fluoroscopy may limit more widespread adoption of this technique. The use of a robotic needle driver that can hold the needle in a steady and precise manner on the CT fluoroscopy scan plane may provide accurate needle placement without exposing the physician to radiation. This paper will provide background on lung cancer screening, review the CT fluoroscopy-guided lung biopsy procedure, and present the results of the first phantom study to use a robotic needle driver. An interventional radiologist used a robotic needle driver under joystick control to accurately place needles into a simulated lesion in a respiratory motion phantom under CT fluoroscopy guidance.

Keywords: lung cancer; CT fluoroscopy; biopsy; medical robotics

1. Lung cancer screening

Lung cancer is the leading cause of cancer-related death in the United States. There were approximately 170,000 new cases diagnosed and approximately 150,000 predicted deaths from the disease in 2003, accounting for more deaths than breast, colon, and prostate cancers combined (1). Prognosis in patients with lung cancer is most closely related to the stage of the disease at diagnosis, as indirect evidence suggests that surgical resection of early stage disease confers a significant survival benefit. Unfortunately, the diagnosis is typically made based after cancer-related symptoms have developed, when the disease is already advanced in stage. Consequently, five year survival rates for lung cancer patients, at approximately 10%, are extremely poor, and there has been little improvement in this figure over the last several decades (2, 3). Presumably, detection of even a small percentage of asymptomatic, early stage lung cancers could result in many

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lives saved. Thus, numerous clinical trials have been undertaken to investigate the effectiveness of lung cancer screening.

Current public health policy in the United States has been based largely on the decades-old Mayo Lung Project, the first randomized, controlled trial to specifically evaluate the efficacy of chest radiography in lung cancer screening (4). This study failed to show an improvement in disease-specific mortality with screening (1, 3). However, this study and other less influential studies were badly flawed by various forms of statistical bias (1, 2, 5, 6). After the Mayo study, the pursuit of effective lung cancer screening protocols was largely abandoned. No authoritative medical body currently recommends screening for lung cancer (1, 5, 6).

However, improvements in spiral computed tomography have created a resurgence of hope for an effective means of mass lung cancer screening because, unlike chest radiography, this sensitive modality can detect small pulmonary nodules in asymptomatic individuals. Preliminary data from the Mayo Clinic CT Screening Trial and the Early Lung Cancer Action Program – two prominent, recent cohort studies that have evaluated the effectiveness of low dose computed tomography (LDCT) in lung cancer screening – have demonstrated that LDCT can detect small, early-stage lung cancers (3, 7).

Many health professionals believe, despite the current consensus created by the outcome of the Mayo Lung Project, that the preliminary results of these more recent studies favour screening. Therefore, lung cancer screening is being performed by those who assert that it would be unethical to delay screening pending the results of current trials (2, 8). Informal screening protocols have even been designed (2).

2. CT fluoroscopically-guided lung biopsy

In screened patients with positive LDCT findings that warrant tissue diagnosis, minimally invasive techniques are preferred over higher-risk procedures involving thoracotomy. Therefore, as lung cancer screening becomes more prevalent, these techniques will become more popular. Percutaneous transthoracic needle biopsy is a well-established, minimally invasive technique for sampling of peripheral nodules, and can be performed using a variety of modalities for guidance, including fluoroscopy, ultrasound, or CT. The sensitivity of such percutaneous techniques is extremely high for both benign and malignant disease (9). CT fluoroscopy-guided needle biopsy is also gaining popularity because it combines real-time monitoring with cross-sectional imaging of a target lesion.

Candidates for this procedure typically have had a recent spiral CT scan, which can be used to position them in the gantry to provide reasonable access to the target lesion. Initial images are obtained to precisely locate the lesion. An approach to the lesion is then planned in such a way as to avoid pulmonary fissures and thus reduce the risk of pneumothorax. There is also a theoretical risk of causing tumor seeding along the needle tract; thus, it is preferable to confine the tract to a single lobe.

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Patients are sedated and monitored during the procedure. The operator remains in the room for the entire procedure. Breathing instructions are given to the patient: he is instructed to take a deep breath in, exhale, take another deep breath in, exhale, and hold at end expiration. While the patient is holding his breath at end expiration, the lesion is identified in CT fluoroscopy mode. The needle entry point is marked on the skin with an adhesive metallic marker or with the CT scanner laser grid.

After an appropriate entry point has been marked, the patient table is moved out of the gantry, the metallic marker is removed, and a visible mark is placed on the skin with an indelible marker. The skin is then disinfected and the patient is sterily draped. One percent buffered lidocaine is injected at the needle entry site to achieve local anesthesia.

Next, a 19 gauge introducer needle is advanced under CT fluoroscopy guidance into the margin of the target lesion to provide stability for the sampling needle. Between each readjustment of the introducer, the operator should step out of the field, behind a lead shield, and use CT fluoroscopy to confirm the needle position. Once the introducer needle has been placed, a 20 gauge cutting needle is advanced through the introducer and a fine needle aspiration biopsy is obtained. The needle can be moved up and down and rotated slightly in order to obtain an adequate quantity of tissue. A cytopathologist is present outside the CT fluoroscopy suite to provide immediate confirmation that adequate tissue samples have been retrieved. At the conclusion of the procedure, CT fluoroscopy is performed to assess for pneumothorax.

Perhaps the greatest advantage of this procedure is that it permits sampling of small lesions while maintaining a high sensitivity. This high sensitivity could have an enormous impact in creating a lung cancer screening program whose objective would be to obtain accurate tissue diagnosis of small, early stage lesions (9-11). CT fluoroscopy provides superior visualization of the needle tract compared with other modalities. For example, compared with CT guidance alone, CT fluoroscopy allows for significantly faster biopsies due to time saved during needle adjustments (9, 10, 12). Furthermore, while non-fluoroscopic CT-guided interventions require confirmation of needle position under “blind” conditions, CT fluoroscopy-guided procedures allow for immediate needle position adjustment during the biopsy procedure.

Though CT fluoroscopic guidance has certain advantages over other modalities, it has the particular disadvantage of exposing the operator to high radiation doses, a problem that is widely accepted as its most significant drawback (9, 10, 13). When compared with conventional X-ray fluoroscopy, CT fluoroscopy requires higher X-ray tube currents, higher X-ray tube potentials, heavier beam filtering, and shorter source-to-skin distances, factors that result in significantly higher radiation doses to both patients and operators (13). Numerous international consortia involved in establishing radiation safety guidelines are becoming increasingly concerned with this issue (14).

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3. Robotically assisted procedure

To minimize the radiation exposure to the radiologist, and to provide a steady platform for needle guidance and placement, we have been experimenting with a joystick-controlled needle driver robot under CT fluoroscopy. This robot was originally developed by the Urology Robotics (URobotics) Laboratory at Johns Hopkins Medical Institutions for percutaneous renal access under fluoroscopy (15). A more recent version of the robot was employed at Georgetown University Hospital for a clinical trial of spinal blocks (16). The robot consists of a touch screen and joystick for control, a mechanical arm, a needle driver, and a mounting base (17).

The purpose of our phantom study was to verify the ability of a radiologist to use the robotic needle driver to hit lesions in a synthetic lung. The long term goal of our work is to develop an integrated system for robotic lung biopsy.

A picture of the experimental setup is shown in Figure 1. The study was done in the CT room at Georgetown University Medical Center using a Siemens Somatom Volume Zoom CT scanner, which captures the real-time CT fluoroscopy image using a frame grabber card (Accustream 170, Foresight Imaging, Lowell, Massachusetts, USA). The robotic needle driver was mounted on the table using a specially constructed fixture.

A custom-designed respiratory motion phantom incorporating a synthetic lung was developed for this study. The phantom consists of a torso model, a rib cage taken from an anatomical bone model, a rubber-like skin layer (Limbs and Things, Bristol, UK), and a synthetic lung. The synthetic lung was molded from two-part flexible foam (FlexFoam II, Smooth-On, Easten, PA) using a plastic lung model. The respiratory motion phantom includes a one degree of freedom motion platform that simulates cranial-caudal motion, and can be programmed from a laptop computer.

Synthetic lesions were created by mixing agar and injecting it into the lung using a syringe. This technique enabled us to control the size of the lesion with some precision.

The robot was then positioned so that the needle was aligned with the CT scan plane. The respiratory motion phantom was positioned so that the lung lesion would move in and out of the scan plane. The phantom was activated with a respiratory rate of about 15 breaths per minute and an excursion distance of about 1.5 cm. The interventional radiologist activated the CT fluoroscopy imaging mode by stepping on the foot pedal and watching the image on the in-room monitor. When the lung lesion moved into the scan plane, a button was pressed on the respiratory motion controller to pause the respiratory motion for up to 30 seconds, simulating a patient breath hold. The interventional radiologist then used the joystick to command the robot to drive the needle toward the lesion. A total of 20 trials were done.

The radiologist was able to hit the lesion on all 20 trials. The average time to drive the needle was 12.1 seconds with a standard deviation of 3.1 seconds. The average tube current-time product was 955 mAs with a standard deviation of 180 mAs. The average

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dose-length-product (DLP) as a measure for the applied radiation dose was 92.5 mGycm with a standard deviation of 42 mGycm. A CT fluoroscopy image with the needle in the lung lesion is shown in Figure 2.

Fig. 1. Experimental setup showing CT fluoroscopy, robot, phantom, and needle on scan plane

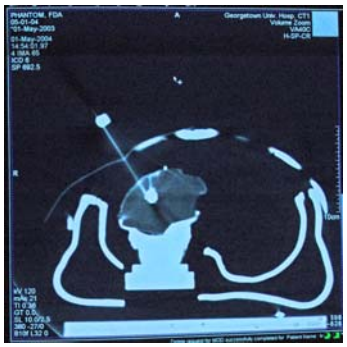

Fig. 2. Axial CT image of needle in lung lesion

4. Conclusions

Lung cancer is the leading cause of cancer-related death in the United States. CT fluoroscopy-guided lung biopsies may enable early detection; however, radiation exposure to the physician may limit the popularity of this technique. Therefore, we investigated the use of a robotic needle driver to provide accurate needle placement while keeping the radiologist away from the CT scan plane.

This study demonstrates that it is feasible to use a radiologist-controlled robotic needle driver to accurately place needles during the breath holds of a lung phantom with simulated respiratory motion. This discovery is a first step towards developing a fully automated robotic system for CT fluoroscopy-guided lung biopsy. Twenty trials were completed without difficulty and no system failures were observed using the robot. The robot provides a steady and precise holder for the needle and is capable of keeping the needle on the CT scan plane so that the procedure can be readily visualized by the radiologist while minimizing his or her exposure to radiation. The radiologist can view in real-time the location and trajectory of the needle as it is directed toward the lesion, since the radiologist's hand is not near the path of the x-ray beam.

Other methods to enable needle guidance have been proposed, such as needle holders and a CT-integrated stereotactic arm (PinPoint, Philips Medical Systems, Cleveland, Ohio). However, these methods do not give the same degree of precision and incremental motion as the actively driven robot tested here.

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The next step in our research program is to further automate the biopsy process. We have been developing an algorithm to automatically track a lesion under CT fluoroscopy and then command the robot to drive the needle to the lesion (18).

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