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Original Article

Utilization of the track embolization technique to improve the safety of percutaneous lung biopsy and/or fiducial marker placement☆,☆☆

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ABSTRACT

Purpose: The purpose of the study was to describe and present outcomes of the track embolization technique with absorbable hemostat gelatin powder during percutaneous computed tomography (CT)-guided lung biopsy and/or fiducial marker placement versus the standard of care (no track embolization) in an attempt to decrease rates of pneumothorax (PTX), chest tube placement, hemorrhage and/or complications, and average cost per patient.

Materials and methods: An institutional review board-approved, case–control, retrospective study was performed in which 125 consecutive patients who underwent track embolization were compared with 124 consecutive controls at one institution. For subjects in whom the track embolization technique was utilized, it was performed passively through a coaxial needle as it was removed. All procedures were performed by one of three attending interventional radiologists. For each group, medical records and procedure images were reviewed for PTX occurring postprocedure, PTX requiring chest tube placement, and occurrence of minor or major complication and/or hemorrhage. Comparison was made with published complication rates, and a cost-per-patient analysis was performed. Statistical analysis was performed utilizing Fisher's Exact Test.

Results: In track embolization cases versus controls, there were statistically significant reduction in PTX (8.8% vs. 21%; $P = .007$) and reduction in PTX requiring chest tube placement (4% vs. 8.1%; $P = .195$). This compares favorably to previously published rates of PTX and chest tube placement of 8%–64% and 1.6%–17%, respectively. None of the pneumothoraces occurring at time of needle placement increased in size with use of the track embolization technique. There were no major complications (including neurological sequela) in the track embolization group. In track embolization cases versus controls, there was a statistically significant reduction in both the rate of major hemorrhage (0% vs. 4%; $P = .029$) and average cost per patient ($262.40 vs. $352.07; $P = .044$).

Conclusions: CT-guided percutaneous lung biopsy and/or fiducial marker placement were safer utilizing the track embolization technique during trocar removal. In addition, this technique was cost effective in the study population.

1. Introduction

Lung cancer is the third most common cancer in the United States and is the leading cause of cancer-related death, accounting for approximately 28% of all cancer-associated mortality [1,2]. Death from lung cancer is often related to the initial stage at diagnosis, with the average 5-year survival rate being highest when the disease is diagnosed early [1,2]. However, only 15% of lung cancer cases are diagnosed at an early enough stage to impact prognosis [1]. The most recent iteration of the United States Prevention Screening Task Force (USPSTF) lung cancer screening guidelines, updated in December of 2013, now recommends annual screening computed tomography (CT) of the chest for all adults between the ages of 55 and 80 who have a 30-pack-year or greater smoking history and who currently smoke or have quit smoking within the past 15 years [1,2].

CT-guided percutaneous transthoracic core biopsy and/or fiducial marker placement have become widely accepted methods in establishing the etiology of lung masses/nodules and/or assisting in treatment [3]. The procedure is generally regarded as safe, with limited associated morbidity and extremely rare mortality [4,5]. Among the complications, pneumothorax (PTX) remains the most frequent, with a minority requiring treatment with chest tube placement [4]. The frequency of PTX after CT-guided lung biopsy is variable in the literature, with reported rates ranging from 8% to 64% [4]. Furthermore, between 1.6% and 17% of these pneumothoraces require chest tube placement [6]. Treatment of PTX with chest tube drainage adds radiological costs (equipment,

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pre- and postprocedure imaging, professional fees, etc.), pharmacy expenses (fluids, anesthetic agents, etc.), nursing care, and hospitalization charges.

The purpose of our study was therefore to evaluate a new and simple technique for passive track embolization with the use of commonly available absorbable hemostat gelatin powder (Surgifoam, Ethicon, Somerville, NJ, USA) during percutaneous CT-guided lung biopsy and/or fiducial marker placement to reduce the rate of complications. This study compares the rate of iatrogenic PTX, chest tube placement, and minor and major hemorrhage rates in patients undergoing passive track embolization with a control group who did not receive track embolization. In addition, we evaluated the average cost per patient of this technique. To our knowledge, this specific technique and material have not been previously studied for CT-guided lung biopsy and/or fiducial marker placement.

2. Materials and methods

2.1. Study design and study period

A single-institution, retrospective review of all CT-guided lung biopsies and/or fiducial marker placements was conducted in which 124 consecutive control patients were compared to 125 consecutive track embolization patients. The study included all patients who underwent percutaneous CT-guided lung biopsy and/or fiducial marker placement during the study period at our institution. One hundred twenty-four consecutive control patients underwent procedures (March 2007–August 2009), who were then compared to 125 consecutive track embolization patients (July 2012–August 2013). Imaging data were collected and analysis was performed after August 2013. Approval for the study was obtained from our institutional review board. All procedures were performed by one of three board-certified interventional radiologists with 2, 3, and 22 years of attending experience. Patient medical records and procedural imaging were reviewed by two radiology residents and one attending interventional radiologist for iatrogenic PTX and rate of chest tube placement. In addition, the occurrence of minor complications and/or hemorrhage (no consequence, no or nominal therapy, overnight admission for observation) and major complications and/or hemorrhage (requiring therapy, minor hospitalization $<$48 h, major therapy, unplanned increase in level of care, prolonged hospitalization $>$48 h, permanent adverse sequelae, death) was classified as per Society of Interventional Radiology (SIR) criteria [7]. The study was ended upon completion of the study period.

2.2. Procedure technique

All procedures were performed under CT guidance (SOMATOM Sensation 64, Siemens Medical Systems, Erlangen, Germany) with the patients in the prone, supine, or lateral decubitus position, depending on the location of the lesion. Patient positioning for each procedure was determined by the attending interventional radiologist during each case. A biopsy track was chosen to avoid pulmonary blebs, fissures, pulmonary vessels, and superficial vessels if possible. All patients met periprocedural anticoagulation criteria as outlined in the SIR practice guidelines [8]. Moderate sedation with administration of intravenous fentanyl and midazolam was induced in anxious patients, and a subcutaneous injection of 1% lidocaine with sodium bicarbonate was used in all patients for local anesthesia.

All biopsies were performed using a coaxial method with either a 17- or 19-gauge introducer needle as guidance (Bard TruGuide, Covington, GA, USA), with appropriate length depending on the depth of lesion. Core biopsy samples were obtained using an 18- or 20-gauge automated biopsy device (Bard Max-Core, Covington, GA, USA). In patients scheduled to receive stereotactic radiation therapy (CyberKnife, Accuray, Inc., Sunnyvale, CA, USA), a 17-guage needle and/or marker kit were used for all biopsies and fiducial placements (Fiducial Marker Kit, CIVCO Medical Solutions, Orange City, IA, USA). A cytopathologist was present during all procedures, and specimens were immediately processed and stained to determine if there was sufficient tissue for analysis. When specimens were deemed insufficient, additional cores were obtained after adjusting the needle utilizing the same track.

2.3. Track embolization technique

The track embolization technique involves passive deposition of an absorbable hemostat gelatin powder into the biopsy and trocar path as the trocar is withdrawn. The technique adds approximately 1–2 min to the overall procedure time. Under sterile conditions, during the procedure, 6 ml of sterile saline was mixed with 1 g of hemostat gelatin powder to form a ball of paste in the supplied container. The ball was then removed and back loaded into a 20-ml syringe. The paste was once again back loaded from the 20-ml syringe into a 1-ml syringe. After biopsy and/or fiducial placement were completed, the hemostat gelatin paste was injected into the needle track via the trocar utilizing the 1-ml syringe until resistance was felt. Next, the syringe was detached from the trocar, and the stylet was replaced into the proximal shaft of the trocar. Finally, the hemostat gelatin paste was passively deployed to fill the track as the trocar was withdrawn over the stylet, similar to how most inferior vena cava filters are deployed (Fig. 1a–b). The hemostat gelatin paste conforms to the needle track (Fig. 1c–d). A sterile adhesive bandage was then applied to the skin surface.

2.4. Postprocedure imaging and care

After the biopsy was completed and needle removed, a short-volume CT acquisition was performed to evaluate patients for immediate complications (Fig. 2). If the scan was normal with no significant PTX and the patient was asymptomatic, the patient was transported to the postprocedure monitoring unit. Patients were kept recumbent throughout the monitoring period. All patients were monitored for 1 h postprocedure and then underwent an expiratory anteroposterior (AP) upright chest radiograph at that time. In symptomatic patients (shortness of breath, dyspnea, and/or chest pain), significant PTX was defined as those who demonstrated iatrogenic PTX following immediate CT follow-up scan or on 1-h postprocedural chest radiograph. In asymptomatic patients, significant PTX was defined as rapidly expanding PTX on serial imaging. In both these groups, chest tube placement was performed. A small PTX (without symptoms) would be followed with a second chest radiograph to confirm stability. Upon discharge, all patients were provided with a direct physician phone number to call if they had any questions or experienced any symptoms and/or complications.

2.5. Data analysis

All CT images and postprocedure chest radiographs were retrospectively reviewed to identify study outcome measures. Images were initially and independently reviewed by two radiology residents and then reviewed separately by a blinded board-certified attending interventional radiologist to ensure a consensus read. Data parameters collected included patient age on date of service, gender, procedure side, operator, biopsy and/or fiducial marker placement, introducer needle gauge, biopsy device gauge, mean dimensions (AP $\times$ transverse) of nodule/mass on CT, mean distance of nodule/mass from pleura, and procedure traversing lung fissure. Outcomes for both groups including procedure-related PTX, postprocedure minor and/or major hemorrhage, and chest tube placement were recorded, and statistical analysis of the two groups was performed utilizing the Fisher's Exact Test with a P value less than .05 considered statistically significant. A medical record review was performed to identify any delayed or missed complications, and the clinical outcomes of the patients were determined and recorded. A cost-per-patient analysis was performed comparing the average