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Percutaneous low-dose CT-guided lung biopsy with an augmented reality navigation system: validation of the technique on 496 suspected lesions☆

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ABSTRACT

Purpose: To validate a CT-navigation system during percutaneous lung biopsy (PLB).
Methods: Four hundred-ninety-six patients underwent low-dose CT-guided PLB. Lesion diameter (LD), procedural time (PT), histologic validity, lesion distance from pleural surface (DPS), needle distance travelled during procedure (DTP), complications and radiation exposure were recorded.
Results: Hysto-patological diagnosis was obtained in 96.2% cases. Mean PT, DPS, DTP, LD were respectively 29.5 min, 12.4 mm, 17.9 mm, 20.7 mm. In cases of major complications (4.6%), higher values of DTP were measured.
Conclusions: CT-navigation system allowed a good success in terms of diagnosis in small lesions and when a long DTP is required.

1. Introduction

Percutaneous lung biopsy (PLB) is a well-established and commonly used method of characterization of pulmonary nodules, particularly if malignancy is suspected [1]. In PLB, Computed Tomography (CT) is the most common imaging modality used for guidance [2] followed by Ultrasound (US) for lesions abutting the pleural surface. Novel approaches using augmented reality CT guidance have recently been introduced [3]. Navigation systems are emerging as a promising tool in percutaneous imaging-guided procedures. Such systems allow electromagnetic, optical [4,5] or hybrid [6] tracking of the devices during interventions. Adequate and representative tissue samples are essential for identification of specific biomarkers and activated pathways to determine the appropriate therapy [7,8]. With potentially increased precision, navigation techniques enable the targeting of smaller or heterogeneous lesions more accurately. A decreased diagnostic accuracy for small lung lesions may be related to sampling error from increased difficulty in localizing the lesion. Relatively new navigation models, based on an infrared optical localization system, can offer a 3D-visualization to detect the position and orientation of the interventional instruments in relation to the patient and to the target lesion. However, it is unclear whether these technologies provide any advantages in standard biopsies compared with conventional image guidance. In a previous experience, we validated an optical CT-based navigation system [9] while performing PLBs. The system proved to be effective in reducing patients' radiation exposure, procedural time and complication rate compared with PLBs performed under standard CT guidance [10].

Aim of the present study is to investigate and validate the CT navigation system used in our department during PLBs in a larger sample of patients, evaluating PLB accuracy based on dimension and location of suspected lesions; moreover, we evaluated major complication rate and histological results related to the above parameters.

2. Material and methods

2.1. Patients sample

From July 2012 to March 2016, a total of 496 patients (mean age 69.4 ± 9.6; 307 male, 189 female) eligible for percutaneous CT-

Abbreviations: PLB, percutaneous lung biopsy; PTX, pneumothorax; LD, maximum lesion diameter; PT, procedural time; DPS, minimum lesion distance from pleural surface; DTP, needle distance travelled during the procedure

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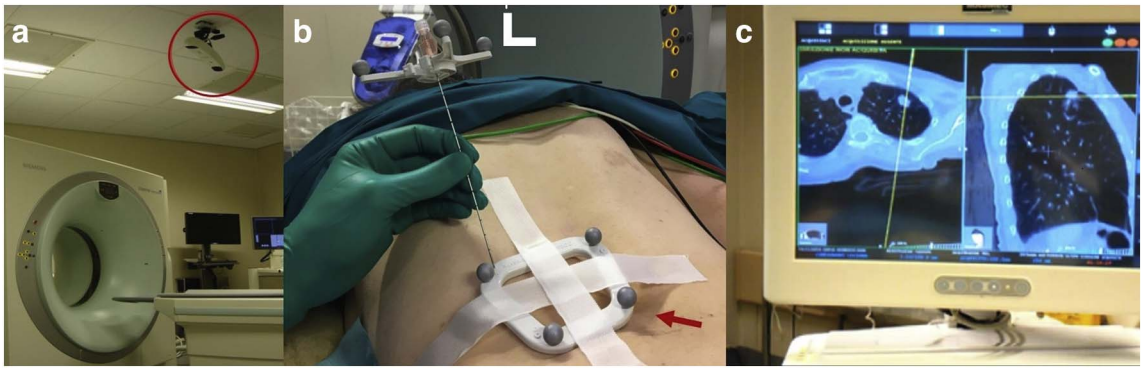

Fig. 1. Navigation system elements. A photo sensor installed in the CT room ceiling (*red circle in a*) is connected with sensors spheres positioned on the needle handle (*white arrowed in b*) and on the patient's chest (*red arrow in b*), in order to create a 3D image displayed on an elaborating unit (*c*). Needle advancements into the patient's chest are performed by following the feedback from the needle path shown on the 3D virtual model. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

guided lung biopsy were consecutively included in the study. The Institutional Review Board approved this prospective study. Each enrolled patient gave written informed consent to undergo percutaneous CT-guided lung biopsy and to be included in the study. Inclusion criteria were: age > 18 years, solid lesions or ground-glass opacities suspected to be malignant demonstrated by CT or PET-TC images, non-diagnosing bronchoscopy, unsuitability of ultrasound guidance. Exclusion criteria were: anticoagulant medication not discontinued at least 4-5 days before the procedure, history of coagulopathy, ECOG/WHO Performance Status Score > 3, no patient compliance.

2.2. Imaging and procedure

The navigation system consists of four main parts: an infrared localization apparatus detecting position and orientation of the needle in relation to the patient; a processing unit for 3D reconstruction of the lung region; a disposable sterile kit, including patient sensor and needle sensor; a tracking system for monitoring patient's movements and breathing. System elements are reported in Fig. 1. The optical navigation system works by infrared light reflected by passive spheres located on the needle handle and on the patient's chest. Infrared light is detected by a photo sensor installed in the CT room ceiling. The navigation system manages DICOM CT-images providing the position of the passive spheres placed on the patient's chest in order to create a 3D virtual model of the patient's chest displayed on the processing unit. Needle advancements into the patient's chest are performed by following the feedback from the needle path shown on the elaborating unit, considering patient's breathing. The views provided by the device come from 3D reconstruction through proprietary algorithms ensuring reliable and high-quality output. The final result is needle advancement without the need for CT re-imaging for each needle progression.

A 64-MDCT scanner (Somatom Sensation, Siemens, Forchheim, Germany) was used in all cases applying a low-dose protocol with the following parameters: 64 × 0.6-mm detector configuration, pitch 1.4, table speed 0.81 mm/rotation, 0.33-s gantry rotation, 100 kV, 35 mAs, slice thickness 2,3 mm, reconstruction interval 1 mm. A soft tissue kernel was performed in all cases. CT imaging was limited to the target area, which was identified by reviewing the previous medical and radiological records available for each single patient. Each patient underwent 18-gauge core-needle biopsy with a 17-gauge coaxial technique.

Before procedure, intravenous contrast agent was administered in cases of solid masses with attendant necrotic portion in order to avoid sampling it or when a main chest wall vessel was near the needle track (subclavian, internal mammary, intercostal vessels). Procedures were performed under local anesthesia (10–20 mL mepivacaine hydrochloride 2% on the parietal surface of the pleura). Mild sedation was obtained by administration of 1–2 mg of midazolam.

Three interventional radiologists (R.F.G, E.F., G.L.,) with 15-year experience in CT-guided percutaneous biopsy and a second-year resident in radiology (G.F.) under the supervision of one of the three senior radiologists, randomly performed all procedures. Patent wide bore (18-G) intravenous access was obtained in all patients, with a continuous pulse oximetry and vital parameters monitoring. Patients were lying in a given position (prone, supine, or lateral) chosen to provide the shortest distance between the lesion and the pleural surface. Interposition of bone structures was evaluated before the procedure to obtain the shorter pathway for reach the target.

2.3. Data collection and statistical analysis

Evaluation of *maximum lesion diameter* (LD), lesion localization, *procedural time* (PT), histological sample validity, *minimum lesion distance from pleural surface* (DPS), *needle distance travelled during the procedure* (DTP) and recovery requirement for major complications were recorded for each patient.

The radiation dose to the patient's chest was estimated by means of the total dose-length product (TDLP) and then the effective dose was obtained by applying the following formula:

$$\text{Effective Radiation Dose} = ¼\ \text{TDLP} \times k$$

where k is the conversion factor (chest: $k = 0.0017\ \text{mGy} * \text{cm}$) [11].

Major and minor complications were recorded based on SIR standards of practice committee classification of complications by outcome [12]: major complications included hemoptysis requiring hospitalization or specific therapy transthoracic biopsy, thoracostomy tube placement requiring prolonged admission, catheter exchange or pleurodesis, air embolism.

Incidence of major complications was evaluated in the whole population and in relation to DTP, considering the average DTP in the group of patients with major complications and in the group of patients in which minor complications were recorded.

Moreover, the incidence of complications and diagnostic accuracy were evaluated in relation to both LD, dividing patients into 3 groups ($LD < 15$ mm, $15\ \text{mm} \le LD \le 25$ mm, $LD > 25$ mm, respectively) and DTP, also dividing population into 3 groups ($DTP = 0$ mm, $1\ \text{mm} \le DTP < 45$ mm, $DTP \ge 45$ mm, respectively); for the execution of this evaluation *Bonferroni procedure test* was used.

DTP and DPS were compared for the whole population, both by dividing our sample into two groups: *group 1* (241 patients), in which patients presented a bone structure interposed between lesion and skin (ribs, sternum, scapula, vertebrae); *group 2* (259 patients) in which they did not presented interposed bone structures.

Statistical analysis was performed by the *Student t-test*; difference between groups was deemed statistically significant for a $p > 0.05$. All the statistics were analyzed in MATLAB® (MathWorks, Inc.)