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Original Article

Percutaneous transthoracic needle biopsy of very small pulmonary nodules

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Abstract: Objective: The purpose of this study was to evaluate the diagnostic performance and complications of percutaneous transthoracic needle biopsy (PTNB) for very small (≤1.0 cm) under iGuide Cone-beam (CBCT) guidance. Methods: From Jan 2011 to Jan 2017, a total of 60 patients with solid lung nodules were retrospectively enrolled to undergo PTNB procedures. The mean diameter of lesions was 0.83 ± 0.15 cm (range, 0.50-1.00 cm). The needle path was carefully planned and calculated on the CBCT virtual navigation guidance system, which acquired 3D CT-like cross-sectional images. The PTNB procedures were performed under needle guidance with fluoroscopic feedbacks. Diagnostic performance, complication rate and radiation exposure were investigated. Results: The technical success rate of PTNB under iGuide CBCT virtual navigation system was 98.3% (59/60). The sensitivity, specificity, and accuracy of PTNB of very small nodules under the iGuide CBCT virtual navigation guidance were 97.9% (47/48), 90.9% (10/11) and 96.6% (57/59), respectively. The number of pleural passages with coaxial needle, biopsies and CBCT acquisitions were 1.08 ± 0.28, 1.18 ± 0.47, and 2.77 ± 1.21, respectively. Complications occurred in 11 (18.3%) cases, with pneumothorax in seven and hemoptysis in four cases respectively. The mean total procedure time was 12.25 ± 3.69 min (range, 6 to 20 min), resulting in a mean exposure dose of 8.2 ± 3.1 mSv. Conclusion: Our study shows that CBCT needle guidance enables reliable and efficient needle positioning and progression by providing real-time intraoperative guidance for very small pulmonary lesions in clinical practice.

Keywords: Interventional, biopsy, lung, computer applications-3D

Introduction

Percutaneous transthoracic needle biopsy (PTNB) is a well-established and commonly used procedure in the work-up of pulmonary nodules, regardless of nodule size [1, 2]. Although PTNB can be performed with fluoroscopic or ultra-sonographic guidance, CT-guided and CT fluoroscopy-guided PTNB have been widely performed in the diagnosis of small pulmonary nodules [1-3]. However, conventional CT guidance has limitations in the lack of real-time monitoring and gantry tilting for a more accessible needle pathway to the target lesion [4-6]. To overcome the disadvantages of conventional CT guidance, CT fluoroscopy has been introduced, and this modality enables real-time monitoring of target lesions and gantry tilting [4]. Hiraki et al. [5] showed the overall accuracy of CT fluoroscopy-guided PTNB was 95.2%. Nevertheless, limitations include the small gantry bore, radiation exposure to operators, and limited imaging plane orientation [7].

Nowadays, flat detector (FD) equipped angiographic CBCT systems can be used to acquire CT-like cross-sectional images directly within the interventional suite [8, 9]. Along with the development of CBCT, a novel technique for PTNB guidance recently emerged. It combines advanced needle path planning with 3D CBCT images. The CBCT systems offer real time visualization of PTNB procedures and more flexibility in the orientation of the detector system around the patient compared to traditional CT systems. Therefore, the PTNB procedures assisted by advanced 3D needle guidance systems can be performed in a sterile workspace with flexible system angulation capability as well as instantaneous fluoroscopic feedbacks [10]. This technique offers high spatial resolution of less than 1 mm, as well as contrast reso-

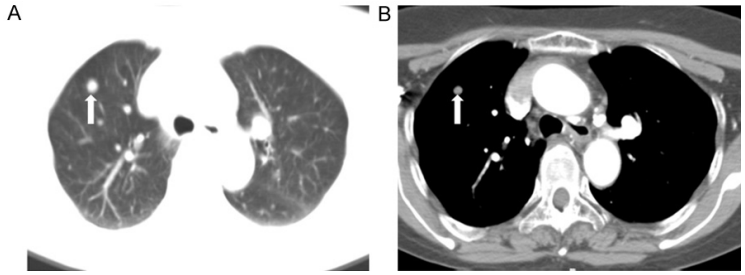

Figure 1. A 66-year-old patient, preoperative CT showed a right upper pulmonary nodule (size 0.50 cm).

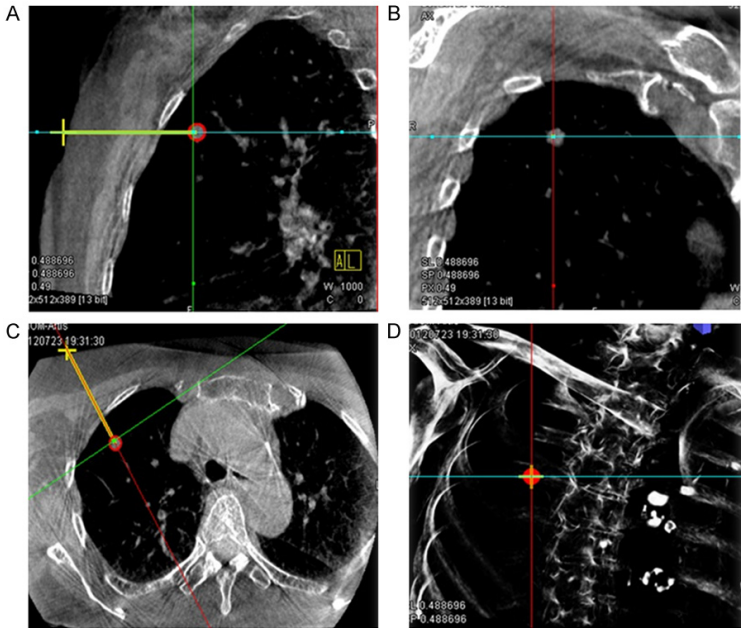

Figure 2. CBCT orthogonal multiplanar images with graphics showing planned needle path (yellow line) into target lesion (red circle) (A-C). The cross indicated the skin entry site and the circle indicated the target lesion site. The needle position relative to the anatomical structures was displayed in 3D using volume rendering technique (D).

lution of 10 HU, which is adequate for lung imaging as lung inherently has a high contrast (soft tissue against air). This paper describes our preliminary experience with PTNB for very small (≤1.0 cm) pulmonary nodules biopsy under iGuide CBCT guidance system.

Material and methods

Patients

This retrospective study was approved by the ethical committee of The First Affiliated Hospital of Zhengzhou University, Zhengzhou University with waiver of patient informed consent. From Jan 2011 to Jan 2017, a total of 60 patients with solid pulmonary nodules were retrospectively enrolled to undergo PTNB procedures. 60 consecutive patients (41 males and 19 females, mean age 52.37 ± 10.81 years; age range, 30-76 years) with CT or MRI confirmed solid pulmonary lesions were retrospectively enrolled in this study. Among them, 57 cases had chest CT, 2 cases had chest MRI and 1 case had both CT and MRI before the procedures (**Figure 1**). Lesion size was defined as the maximum diameter in the image data of lesions on lung window setting images (window level, 700 HU; window width, 1500 HU). The averaged diameter of lesions was 0.83 ± 0.15 cm, ranging from 0.50 cm to 1.00 cm.

Image acquisition

As the first step, 3D CBCT images of the patients were acquired with a rotational angiographic system (Artis Zeego, 30 × 40 cm FD detector, Siemens Healthcare, Forchheim Germany). The resulting raw projection images were then automatically transferred to a workstation (Syngo X Workplace, Siemens Healthcare) for 3D volume reconstruction. As a result, the CBCT images were reconstructed with 1 mm thickness and presented in axial, sagittal and coronal orientations. The time from the end of the data acquisition to the presentation of multiplanar images on the workstation ranged between 43 s to 45 s.

Needle path planning and guidance procedure

As the second step, the needle path was planned on the same workstation using commercially available software (Syngo iGuide, Siemens Healthcare). **Figures 2-4** demonstrated this procedure for a 0.50 cm pulmonary lesion. The reconstructed 3D volume was first loaded. In the orthogonal multiplanar images, the skin entry point and target lesion positions were manually selected and marked by a cross

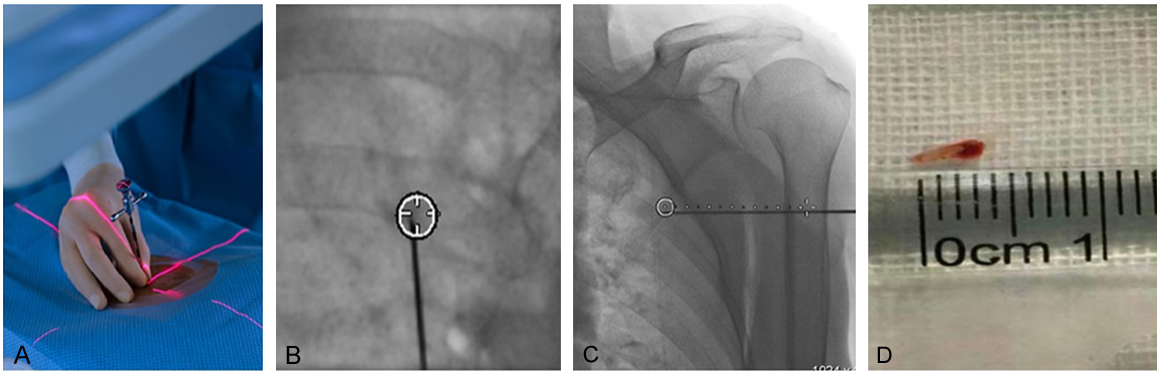

Figure 3. The laser navigation system on the Flat-panel can quickly locate the needle point on skin, Thus the skin entry point could be determined (A). Real time fluoroscopic images in Bull's Eye View (B) and 2 Progression Views (C). The needle was advanced along the planned needle path (dotted line) from skin entry site (white cross) to target lesion site (white circle). (D) Photo of the very small pulmonary nodules.

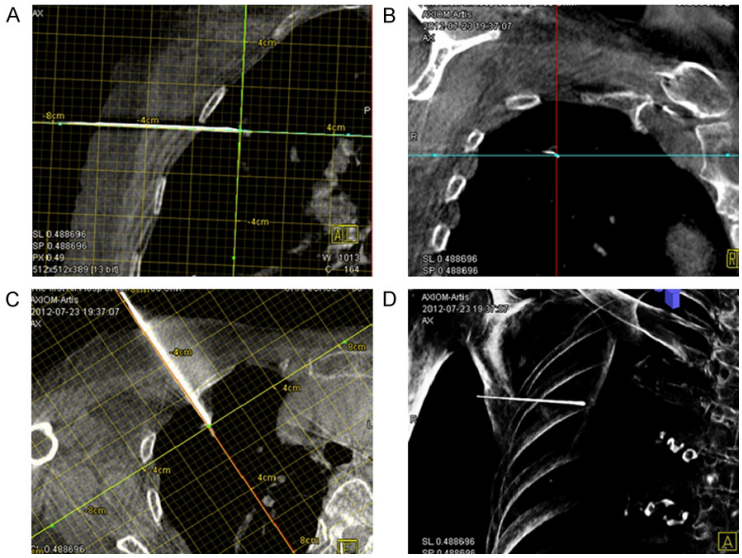

Figure 4. CBCT scan confirmed the needle position in multiplanar (A-C) and volume rendering (D) images.

and a circle, respectively. A virtual path was then generated with its angulations and length calculated and displayed. All three multiplanar images were automatically aligned to the defined path to provide in-plane views (**Figure 2**). This procedure could be iteratively performed, modified and reviewed until a satisfying path was obtained.

In order to use the planned path to align the needle in actual 3D space, the virtual path was then projected and superimposed onto the live fluoroscopic images and displayed on a dedicated live monitor (**Figure 3B** and **3C**). The software automatically calculated the C-arm angulations, table motion, image zoom, and then controlled the C-arm moving to reach the desired position. First, the C-arm rotated to the Bull's Eye View, where the C-arm was angulated in the way that the cross and the circle displayed on the live monitor completely matched and the central X-ray beam was aligned with the planned path (**Figure 3B**). The laser navigation system on the Flat-panel can quickly locate the needle point on skin, Thus the skin entry point could be determined (**Figure 3A**). The needle orientation was adjusted until both the tip and hub of the needle in the fluoroscopic image were superimposed and located at the center of the circle and the cross. Second, after the skin entry point and needle orientation were determined, the needle was advanced under fluoroscopy until the planned target lesion position was reached. The C-arm was rotated back and forth to two different angles subsequently to monitor the needle progression. These two angles provided lateral views (Progression View) of the planned needle path and helped to ensure that the needle was advanced along it (**Figure 3C**). Third, a 3D scan was acquired to confirm the final position of the needle (**Figure 4**).

PTNB technique

PTNBs were performed by or under the supervision of one chest radiologist (Han XW, 20

years of experience in image guided PTNB). The patient was placed in either supine or prone position and local anesthesia was given (1% Lidocaine, ≤10 ml). A 16-gauge needle (QuickCore, Cook Medical Inc., Bloomington, IN, USA) was advanced along the planed path under real time fluoroscopy. For sampling, the stylet was removed from the guiding needle and replaced by a biopsy needle, and then approximately 0.3-1.0 cm of sample tissue was taken. A cytopathologist was not present, and our criteria were that the total samples length was more than 0.3 cm at least to meet the needs of the pathological sections. This procedure could be repeated until sufficient tissue sample was obtained. After sufficient tissue samples were obtained, the coaxial introducer was removed with a position change by placing the patient biopsy side down to reduce the complication rate of pneumothorax [11]. Thereafter, post-procedure CT images were acquired to identify procedure-related complications. The patients remained in the hospital for 24 hours for observation after the procedure. In case serious symptoms in vital signs or clinical status occurred, repeated imaging and if necessary treatment was performed.

Procedural records

We recorded several factors during PTNB; the patients' positions during PTNB, the number of pleural passages, the number of biopsies, the number of CT acquisitions, total procedure time (defined as the duration from local anaesthesia injection to the end of post-procedure CBCT). Technical success was defined as appropriate location of the coaxial needle within target nodules on procedural CBCT images and adequate tissue sampling on visual inspection. We also recorded radiation exposure dose during the entire procedure (fluoroscopy dose and CBCT dose).

Pathological results, diagnostic accuracy

The pathological reports of biopsy specimens, surgical specimens, or follow-up images were reviewed to evaluate the final diagnosis of target nodules. Final diagnosis was confirmed in four ways [12]. (1) If the patient underwent surgical resection, the pathological report decided the final diagnosis. (2) If the pathological result of biopsy demonstrated a malignant or a specific benign pathology such as hamartoma or tuberculosis, it was accepted as the final diagnosis. (3) In the cases of non-specific benign pathology (negative for malignancy, chronic inflammation, etc.), follow-up CT helped to decide whether the lesion would be truly or falsely benign, or indeterminate. If the lesion decreased 20% or more in diameter, we considered the final diagnosis as benign. (4) If a nodule of nonspecific benign pathology did not show sufficient interval decrease in size nor had follow-up images, its final diagnosis was defined as indeterminate. Any PTNB related complication such as pneumothoraxor haemoptysis was also recorded. Pneumothorax was evaluated with post-procedural CBCT and follow-up chest radiographs during the hospitalization.

All data analyses were performed using Excel 2010 (Microsoft, Redmond, WA) and SPSS software (version 13.0; SPSS, Chicago). Numeric data are reported as the mean ± standard deviation. The technical success rate, sensitivity rate, specificity rate, as well as accuracy rate were calculated as percentage data.

Results

Nodule characteristics, procedural records and radiation doses

The mean size of nodules was 0.83 cm ± 0.15 (0.50-1.00 cm). Among the 60 nodules, 57 nodules were solid and 3 ground-glass nodules (GGNs). 40 nodules were located in the right lobe and 20 nodules in the left lobe. The patients underwent PTNB in the supine position in 43 cases and in the prone position in 17 cases. The number of pleural passages with coaxial needle, biopsies and CBCT acquisitions were 1.08 ± 0.28 (range, 1-2), 1.18 ± 0.47 (range, 1-3), and 2.77 ± 1.21 (range 2-8), respectively. Mean total procedure time was 12.25 min ± 3.69 (range, 6-20 min). The technical success rate of PTNB under iGuide CBCT virtual navigation system was 98.3% (59/60). One patient with severe chronic obstructive pulmonary disease and a 0.78 cm lesion developed severe pneumothorax with a volume of approximately 50% during the PTNB procedure. This patient was not get adequate tissue sampling on visual inspection and treated with chest tube drainage. We recorded the case as technical failure. The overall procedural time ranged from 6 to 20 minutes, resulting in a mean exposure dose of 8.2 ± 3.1 mSv.

Table 1. Pathologic outcomes of the patients who underwent PTNB procedure with Siemens Artis Zeego iGuide CBCT needle guidance system

Total No. of patient	60		
The technical success rate (%)	59 (98.3)		
Sensitivity rate (%)	47 (97.9)		
Specificity rate (%)	10 (90.9)		
Accuracy rate (%)	57 (96.6)		
Pneumothorax rate (%)	7 (11.7)		
Hemoptysis rate (%)	4 (6.7)		
Malignant	48	Benign	11
Lung adenocarcinoma	28 (58.3)	Lung inflammation	4 (36.4)
Squamous carcinoma	8 (16.7)	Pulmonary tuberculosis	4 (36.4)
Small cell lung cancer	6 (12.5)	Hamartoma	2 (18.1)
Metastases	4 (8.3)	Carcinoid	1 (9.1)
Mesothelioma of pleura	2 (4.2)		

Pathological results, diagnostic accuracy and complications

Detailed results are listed in **Table 1**. Among the 59 nodules, 48 nodules were malignant and 11 benign. The 48 malignant lesions consisted of lung adenocarcinomas (n=28), squamous cell carcinomas (n=8), small cell lung cancers (n=6), metastases (n=4) and mesothelioma of pleura (n=2). The 11 malignant lesions consisted of lung inflammations (n=4), tuberculosis (n=4), hamartoma (n=2) and carcinoid (n=1). There were two patients misdiagnosed. One patients' initial biopsy results were squamous cell carcinoma, but was later confirmed as an adenosquamous carcinoma by post-operative pathological outcome. The initial biopsy of the other one was interpreted as lung inflammation. The nodule was enlarged more than 50% in size on follow-up chest CT. PTNB procedures were performed again and he was confirmed with lung adenocarcinoma. Finally, the sensitivity, specificity, and accuracy of PTNB of very small nodules under the Siemens Artis Zeego iGuide CBCT virtual navigation guidance were 97.9% (47/48), 90.9% (10/11) and 96.6% (57/59), respectively. One patient with severe chronic obstructive pulmonary disease and a 0.78 cm lesion developed severe pneumothorax with a volume of approximately 50% during the PTNB procedure. This patient was not get adequate tissue sampling on visual inspection and treated with chest tube drainage. We recorded the case as technical failure. Another patient with ground-glass nodule, developed post-operative pneumothorax with volume about 30% and hence underwent chest tube drainage. There were other five patients with pneumothorax volume below 5%, and no specific treatment was given as the patients were asymptomatic and clinically stable. Post-operative hemoptysis occurred in four patients, but the symptom was self-limiting and disappeared within 3 days.

Discussion

With the increasing utilisation of chest CT in clinical practice as well as in lung cancer screenings, early lung cancers manifesting as small nodules have been detected more frequently than ever before. According to a lung cancer screening trial [13], 14.5% of a screened population was observed to have nodules ≤10 mm, of which 55.5% of the detected lung cancers were these small (≤10 mm) nodules. So, the need for accurate diagnosis of these small lung nodules with a high suspicion of malignancy is evident [14].

Initial experiences suggested that CBCT-guided PTNB could be a useful, safe and accurate procedure for diagnosis of indeterminate lung nodules, with possible advantages over fluoro-CT-guided biopsy [12, 15, 16]. It is well known that limited access due to a closed CT gantry increases the difficulty of PTNB and increases radiation exposure for the operator, whereas the greater working space provided by the C-arm cone-beam system facilitates needle placement and speeds up the procedure [16, 17]. The CBCT system offers advanced needle planning under real-time needle guidance, using a combination of 3D images and fluoroscopy, with good angulation and rotation. Another advantage of CBCT is the improved resolution of images, which have superior contrast, without distortion, compared to fluoro-CT images [18]. Moreover, under CT guidance the needle path can be followed only on a single plane during needle insertion, a limitation in comparison with the 3D images offered by CBCT [16]. Furthermore, with fluoro-CT, greater

Table 2. Recent studies on C-am cone-beam CT-guided biopsy procedures in the field of chest intervention

First author	Year published	Biopsy target	Number of patients	Lesion size (cm)	Needle size (G)	Technical success rate (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)	Complication rate (%)
Jinet et al. [16]	2010	Lung nodule	71	≤3.0	18	100 (71/71)	97 (35/36)	100 (25/25)	98.4 (60/61)	Phneumothorax: 25.4 (18/71) Hemoptysit: 14.1 (10/71)
Hwang et al. [12]	2010	Lung nodule	27	≤2.0	20	100 (27/27)	94.1 (16/17)	88.9 (8/9)	92.3 (24/26)	Phneumothorax: 14.8 (4/27) Hemoptysit: 3 (1/27)
Cheung et al. [20]	2011	Lung nodule	74	≤3.0	20	100 (74/74)	90.6 (48/53)	100 (21/21)	93.2 (69/74)	Phneumothorax: 25.7 (19/74)
Choiet et al. [21]	2012	Lung nodule	99	3.0 ± 1.6 (range, 0.8-8.6)	18	100 (99/99)	95.8 (69/72)	100 (27/27)	97.0 (96/99)	Phneumothorax: 16.2 (16/99) Hemoptysit: 2 (2/99)
Leeet et al. [23]	2012	Lung nodule	94	3.7 ± 2.3 (range, 8-12)	20	100 (94/94)	93.1 (54/58)	100 (36/36)	95.7 (90/94)	Phneumothorax: 25.5 (24/94)
Choi et al. [22]	2012	Lung nodule	173	≤2.0	18	100 (173/173)	96.8 (91/94)	100 (69/69)	98.2 (160/163)	Phneumothorax: 31.8 (55/173) Hemoptysit: 14.5 (25/173)
Braak et al. [19]	2012	Lung nodule	84	3.25 (range, 0.3-9.3)	18	100 (84/84)	90.0 (63/70)	100 (14/14)	91.7 (77/84)	Phneumothorax: 20.2 (17/84) Hemoptysit: 1.2 (1/84)
Choo et al. [14]	2013	Lung nodule	107	≤1.0	17	100 (107/107)	96.7 (58/60)	100 (38/38)	98.0 (96/98)	Phneumothorax: 6.5 (7/107) Hemoptysit: 5.6 (6/107)
Jiao et al. [1]	2014	Lung nodule	110	4.6 ± 3.0 (range, 0.6-15.0)	16	98.2 (108/110)	96.7 (88/91)	100 (17/17)	97.2 (105/108)	Phneumothorax: 12.7 (14/110) Hemoptysit: 6.4 (7/110)
Lee et al. [9]	2013	Lung nodule	1153	2.7 ± 1.7 (range, 0.5-13.0)	20	99.6 (1148/1153)	95.7 (733/766)	100 (323/323)	97.0 (1056/1089)	Phneumothorax: 17.0 (196/1153) Hemoptysit: 6.9 (80/1153)
Floridi et al. [15]	2014	Lung nodule	100	5.19 (range, 0.7-14)	20	95 (95/100)	91.2	100	92.5	Phneumothorax: 21% (20/95)
Rotolo et al. [24]	2015	Lung nodule	113	≤3.0	20	91.8 (113/123)	87	100	89	Phneumothorax: 29.3 (36/123) Hemoptysit: 27.9 (27/123)

patient cooperation is required to control breathing and to successfully perform the biopsy. Indeed, owing to this system's ability to facilitate more accurate and safer needle placement, it has already been shown to provide excellent diagnostic accuracy for biopsy of the lung [1, 9, 12, 14-16, 19-24] (**Table 2**).

Our study shows that the technical success rate of PTNB for very small nodule (≤1 cm) under iGuide Cone-beam CT virtual navigation system was 98.3%, and diagnostic accuracy rate of 94.7%. We observed one (1.7%) case of technical failure in our study. The patient with severe chronic obstructive pulmonary disease and a 0.78 cm lesion located in left lower lobe developed severe pneumothorax and treated with chest tube drainage. Ohno et al. [2] and Wallace et al. [10] reported the accuracy of CT-guided PTNB of small (≤1.0 cm) nodules as only 52% and 88%, respectively. And even in the case of CT-fluoroscopy-guided PTNB, the diagnostic accuracy of these small (≤1 cm) nodules has been reported to be 92.7% [25]. In our study diagnostic accuracy was 94.7% for lesions 1.0 cm or smaller. This result compares favorably with the studies by Hiraki et al. [5] and Choo et al. [14], in which diagnostic accuracy was 92.7% and 98.0% for lesions 1 cm or smaller, respectively. We believe that the advantages of cone-beam CT guidance, such as real-time imaging guidance and great flexibility in entry site selection, can contribute to high diagnostic accuracy in small lesions. The "bull's eye view" provided by the real time fluoroscopy capability of the CBCT virtual navigation system aligns the detector, the skin entry site and the target, contributing to a more accurate and safer biopsy.

The pneumothorax rate 18.3% (11/60) was found to be lower than CT or CTF guided TNB procedures. With respect to PTNB-related complications, pneumothorax has been reported to occur in approximately 25-40% of overall lung biopsy cases [20]. The incidence of PTNB related pneumothorax was low in our study. We believe that this low incidence of pneumothorax was possible as the virtual navigation system enabled us to select a safer and more accurate targeting route in navigating the needle approach to the target. As an example, this system can help us avoid adjacent structures such as the rib, bronchus or vessels. In addition, the coaxial needle technique also played a significant role in the reduction of complications by avoiding repeated pleural punctures or passages. Of the seven patients who had pneumothorax, 4 patients (57.1%) had pulmonary emphysema along the needle pathway, and this may suggest that considering emphysema in the needle pathway would be more likely to lead to the occurrence of pneumothorax. Post-operative hemoptysis occurred in four patients, but the symptom was self-limiting and disappeared within 3 days. Interestingly, Among the 60 nodules, There patients with ground-glass nodules all developed post-operative hemoptysis. Maybe ground-glass feature of nodules significantly increased the hemoptysis rate. We think that the relatively loose compactness of these nodules may have negatively affected the natural compression of injured tissue after biopsy and that patent airways and blood vessels within the lesion could also increase the risk of hemoptysis after cutting needle biopsy.

There were 2 cases (5.3%) misdiagnosed in the study. One patients' initial biopsy result was squamous cell carcinoma, but was later confirmed as an adenosquamous carcinoma by post-operative pathological outcomes. The initial biopsy of the other one was interpreted as lung inflammation. The nodule was enlarged more than 50% in size on follow-up chest CT. PTNB procedures were performed again and he was confirmed with lung adenocarcinoma. A negative result always poses a diagnostic challenge. A non-specific benign result does not exclude malignancy, and further evaluation is required. The lesion may be malignant, but the sample obtained may lie outside the nodule borders or come from a necrotic area, thus preventing pathologists from establishing a correct diagnosis. Clinical and radiographic follow-up are warranted. If further growth occurs after a non-specific benign diagnosis is obtained with TNB, repeat biopsy or resection is indicated [26].

In terms of radiation dose, a mean exposure dose was 8.2 ± 3.1 mSv. Recent studies on CBCT-guided percutaneous transthoracic lung biopsy revealed an average effective dose ranging 4.6 to 11.62 mSv [5, 12]. The radiation dose in our study falls within that range, and is thought to be acceptable, considering that the mean effective dose of a regular-dose chest CT has been reported as approximately 7-11.05 mSv [27, 28]. While, in the Hwang et al. study

[12] that dealt with cone-beam CT-guided biopsy, the mean effective dose was 4.6 mSv. This difference can be explained that we usually performed three CBCT scans per case at least, whereas Hwang et al. performed cone-beam CT scans only twice and did not perform a postprocedural cone-beam CT scan. To further reduce radiation exposure, there may be a few strategies that we can explore, including the use of low-quality 3D rotational angiography mode CBCT with strictly limited scanning area and number of CBCT acquisitions. In addition, iterative image reconstruction algorithms, which have not been established in CBCT systems to date, may also reduce radiation exposure in the near future by lowering image noise [29].

The limitations of this technique should be also mentioned. As patient movements may result in motion artifacts and affect the registration accuracy of the projected path, the key factor for achieving successful needle guidance is to generate high quality 3D CBCT images. To this aim, during the imaging procedure, the patient should be well stabilized. However, this requirement may not be fulfilled and limits its applications for some patients who have difficulty sustaining a breath hold for the duration of imaging. Another main limitation of the study is the small sample size (60 patients) that limits the statistical power.

In conclusion, this preliminary study show that the iGuide CBCT based 3D needle guidance enabled reliable and accurate needle positioning and progression by providing real time intraoperative guidance. This new technique has great potential for applications in PTNB procedures for very small pulmonary nodules, resulting in high diagnostic accuracy and low complication rates.

Disclosure of conflict of interest

None.

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