

Transthoracic needle biopsy using a C-arm cone-beam CT system: diagnostic accuracy and safety

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Objective: The purpose of this study was to evaluate the diagnostic accuracy and safety of performing transthoracic needle biopsy (TNB) under combined fluoroscopy and CT guidance using a C-arm cone-beam CT (CBCT) system.

Methods: We evaluated the diagnostic accuracy and safety of performing TNB using a C-arm CBCT system. We retrospectively evaluated 99 TNB cases performed in 98 patients using a C-arm CBCT system with an 18-gauge automated cutting needle. We reviewed the diagnostic accuracy according to the size and depth of the lesion, incidence of complications, additional treatment for complications, procedure time, number of needle passes per biopsy and radiation dose.

Results: The final diagnoses revealed 72 malignant and 27 benign lesions. The overall malignancy sensitivity, malignancy specificity and diagnostic accuracy were 95.8%, 100% and 97.0%, respectively, and those for small pulmonary nodules <20 mm in size were 94.1%, 100% and 96.6%, respectively. There was no significant difference in the correct diagnosis of malignancy according to lesion size ($p=0.634$) or depth ($p=0.542$). For benign lesions, a specific diagnosis was obtained in 14 cases (51.9%). TNB induced complications in 19 out of 99 procedures (19.2%), including pneumothorax (16.2%), immediate haemoptysis (2.0%) and subcutaneous emphysema (1.0%). Among these, four patients with pneumothorax required chest tube insertion (2.0%) or pig-tail catheter drainage (2.0%). The mean procedure time, number of needle passes and radiation doses were 11.9 ± 4.0 min, 1.2 ± 0.5 times and 170.0 ± 67.2 mGy, respectively.

Conclusion: TNB using a C-arm CBCT system provides high diagnostic accuracy with a low complication rate and a short procedure time, particularly for small pulmonary nodules.

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Transthoracic needle biopsy (TNB) under image guidance is a well-known procedure for evaluating thoracic mass lesions, with a high diagnostic accuracy and a relatively low complication rate [1–5]. TNB can be performed under various types of image guidance, including fluoroscopy, CT and ultrasonography. The decision regarding which technique to use usually depends on the characteristics of the pulmonary lesions, such as size, location, the radiologist's preference and the accessibility of imaging systems.

Currently, CT or CT fluoroscopy is the most preferred method of image guidance for TNB. CT fluoroscopy provides real-time guidance of the biopsy needle in addition to the advantages of CT guidance, decreasing the procedure time and number of needle passes compared with CT-guided procedures [1]. However, significant radiation exposure to the operator's hands is one limitation of this procedure.

The C-arm cone-beam CT (CBCT) system is a form of flat-panel volume CT in which a cone-beam X-ray tube and a flat-panel detector are integrated within a C-arm

gantry. This provides both CT and real-time fluoroscopic guidance for TNB [6].

The purpose of this study was to evaluate the diagnostic accuracy and safety of performing TNB under combined fluoroscopy and CT guidance using a C-arm CBCT system.

Methods and materials

Patients

This study enrolled 99 consecutive patients with pulmonary lesions and 99 TNBs were performed using a C-arm CBCT system with an 18-gauge automated cutting needle between September 2009 and July 2010 at the School of Medicine, Ewha Womans University, Seoul, Republic of Korea, by 1 experienced thoracic radiologist (YK, who has 15 years of experience with TNB). There were 58 males and 40 females and the mean age [\pm standard deviation (SD)] was 58.0 ± 9.9 years (range, 30–88 years).

CBCT-guided TNB was only performed for pulmonary lesions that were visible on fluoroscopy. During the same period, fluoroscopy-guided TNB was performed for some large pulmonary lesions that could be readily biopsied under fluoroscopic guidance, based on the

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operator's decision, and neither CT nor CT fluoroscopy guided-TNB was performed for any pulmonary lesions.

Cases in which TNB was performed using different types of image guidance or using biopsy needles of different sizes or types were excluded from this study. TNB cases with non-pulmonary lesions, such as mediastinal or pleural masses, were also excluded.

Our Institutional Review Board approved this retrospective study and waived the need for patient informed consent.

Transthoracic needle biopsy

All TNB cases were performed using a C-arm CBCT system (AXIOM Artis dBA (VB31E), Siemens Medical Solutions, Forchheim, Germany) with an 18-gauge automated cutting needle without a coaxial technique. Diagnostic chest CT scans, obtained for the evaluation of pulmonary lesions, were reviewed prior to biopsy to determine the location of the nodule, suitability of the lesion for biopsy and planning a safe approach. Biopsies were performed by one radiologist experienced in this technique. The patients were placed prone or supine, depending on the location of the lesion, and were asked to hold their breath in inspiration or expiration, as appropriate, during CBCT scanning or biopsy. Biopsy was performed under alternative real-time fluoroscopy and CBCT guidance using a C-arm CBCT system and the sequences of CBCT-guided TNB were as follows (Figure 1).

For the first step, a metallic line marker was placed on an expected cutaneous entry point of the thorax under fluoroscopy. Then, a CBCT scan was performed and the exact entrance point and puncture depth of the needle were determined based on the analysis of multiplanar reformation CT images rendered on a computer workstation. The skin entrance site was then disinfected and local anaesthesia was administered. The last step involved a biopsy performed using an 18-gauge automated cutting needle without a coaxial technique (Pro-Mag™ Biopsy Needle; Angiotech Inc., Gainesville, FL) under fluoroscopic guidance.

CBCT was scanned with $0.36 \mu\text{Gy pulse}^{-1}$, 30 pulses s^{-1} and a scan time of 8 s. Post-processing of the image data to a volume data set was performed on a multimodality workplace (syngo MMWP software, series number 11690; Siemens Medical System, Erlangen, Germany) and the images were subsequently transferred to a computer workstation (Leonardo; Siemens Medical System) and analysed using the multiplanar reformation technique.

Radiation dose, procedure time and number of needle passes were measured. Patient skin doses (milligray) were automatically calculated by AXIOM Artis. The biopsy procedure time was measured from the attachment of a radio-opaque line marker to the patient's skin under fluoroscopic guidance to the removal of a needle from the thorax after specimen sampling. Quick stains of biopsy specimens were not performed during the procedure. Pneumothorax was assessed on chest radiographs obtained 1–4 h after biopsy.

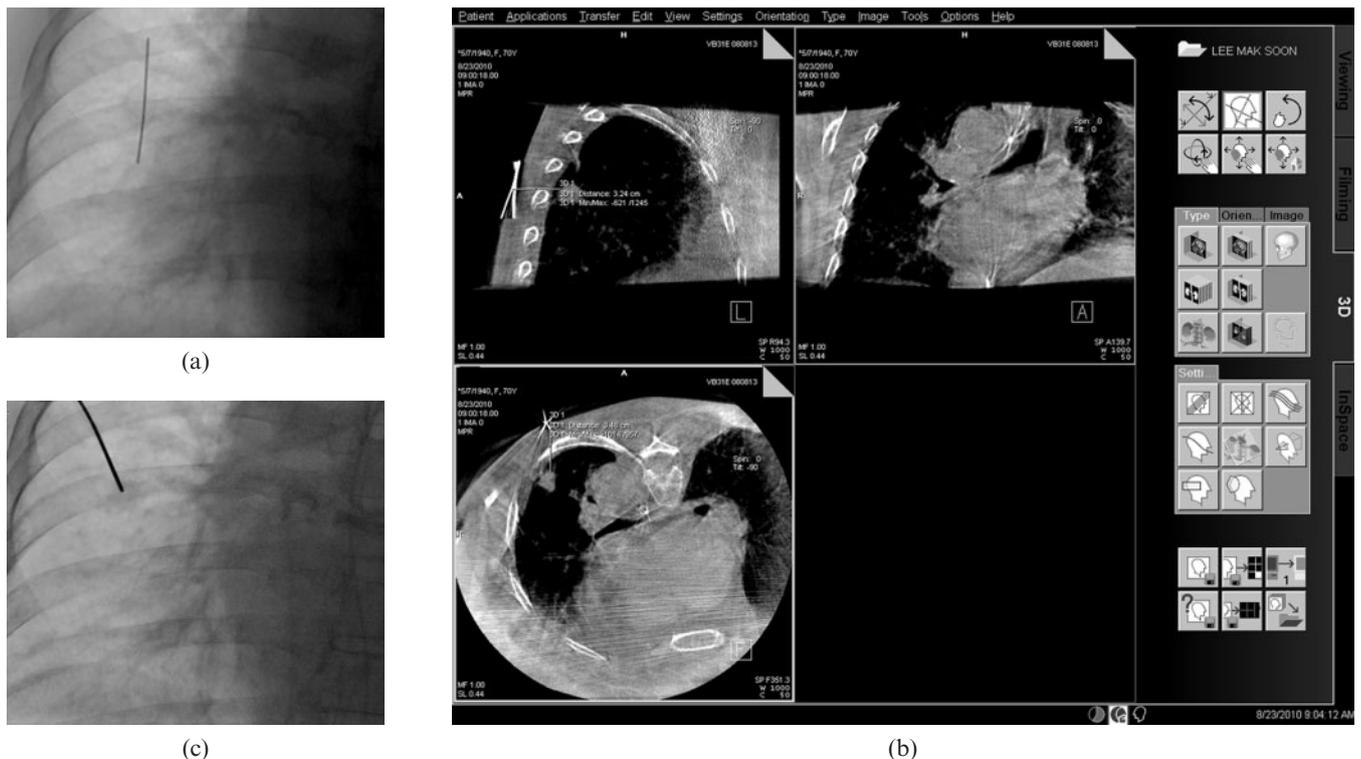


Figure 1. C-arm cone-beam CT-guided transthoracic needle biopsy in a patient with a nodule in the right upper lobe. (a) For the first step, a metallic line marker was attached to the patient's skin, covering the anticipated entrance point of the needle, under fluoroscopy guidance. (b) CT scan was performed and the exact entrance point and puncture depth of needle were determined based on the analysis of multiplanar reformation images on a computer workstation. (c) The last step involved a transthoracic needle biopsy with a 18-gauge automated cutting needle under fluoroscopy guidance.

Data analysis and statistics

Sizes and depths of the lesions were evaluated on CBCT scans. Lesion size was defined as the maximum diameter of lesions on lung window setting images (window level, 700 HU; window width, 1500 HU). Lesion depth was measured from the skin surface to the pulmonary lesion along the planned needle path. Data concerning the biopsy results, complications and final diagnosis were collected through a review of patient medical records.

Using the final histological diagnoses and the clinical and radiological courses of the diseases as references, we analysed the sensitivity, specificity and diagnostic accuracy based on lesion sizes and depths.

All statistical analyses were performed using the SPSS software (version 17.0 for Windows; SPSS Inc., Chicago, IL). Continuous data are presented as mean and standard deviation. Discrete data are given as counts and percentages. Differences between categorical variables were analysed by the χ^2 test or Fisher's exact test.

Results

Radiation dose and procedure time

The mean skin entrance dose was 170.0 ± 67.2 mGy (mean \pm SD; range, 46.3–389.0 mGy). The mean procedure time was 11.9 ± 4.0 min (range, 4–25 min). The mean number of needle passes was 1.2 ± 0.5 times (range, 1–2 times).

Overall diagnostic accuracy

Final diagnoses were made based on the results of TNB ($n=64$), operation of pulmonary lesions ($n=12$), operation of extrathoracic primary malignancy ($n=1$), bronchoscopic biopsy ($n=1$), culture of sputum or TNB specimen ($n=4$), pleural fluid cytology ($n=3$), bronchial cytology ($n=1$), lung aspiration cytology ($n=2$) and clinical follow-up ($n=11$).

The final diagnoses revealed 72 malignant and 27 benign lesions (Table 1). The TNB results of 72 malignant lesions were malignancy in 69 cases with 3 false-negatives. The sensitivity and specificity for malignant lesions were 95.8% and 100%, respectively. The biopsy results of 27 benign lesions were all benign, with 100% sensitivity and specificity and no false-negative results. The overall diagnostic accuracy of TNB was 97.0%.

Among the 27 benign cases, TNB provided a specific diagnosis in 14 cases (51.9%). Among the 16 cases with biopsy results of non-specific inflammation, three were finally diagnosed as malignant lesions and one was diagnosed as tuberculosis (Table 1).

Diagnostic accuracy according to the characteristics of pulmonary lesions

One case in which TNB was performed in the areas of ground-glass opacity and which had a final diagnosis of pulmonary alveolar proteinosis was excluded from the analysis of diagnostic accuracy according to the lesion size and depth. The sensitivities for malignant lesions

Table 1. Results of combined fluoroscopy and CT-guided transthoracic needle biopsy and final diagnosis

Lesion type	Biopsy results	Final diagnosis
Malignant lesions		
Total number	69	72
Primary lung cancer		
Adenocarcinoma	30	33
Squamous cell carcinoma	12	13
Large cell carcinoma	2	1
Adenosquamous carcinoma	1	1
Bronchiolaralveolar carcinoma	0	1
Sarcomatoid carcinoma	3	3
Non-small cell lung carcinoma	7	6
Small cell carcinoma	4	4
Atypical proliferation of alveolar lining cells	2	1
Metastasis	8	9
Benign lesions		
Total number	30	27
Tuberculosis	6	7
Hamartoma	1	1
Haemangioma	2	2
Fungal pneumonia	2	2
Organising pneumonia	2	2
Pulmonary alveolar proteinosis	1	1
Non-specific inflammation	16 ^a	12

^aThree cases of false-negative results for malignancy are included.

and overall diagnostic accuracies according to the size and depth of lesions are described in Table 2.

The mean lesion size was 30 ± 16 mm (range, 8–86 mm) and the mean lesion depth was 52 ± 23 mm (range, 14–128 mm). The sensitivity for malignancy and diagnostic accuracy for small pulmonary nodules <20 mm in size were 94.1% and 96.6%, respectively. Those for pulmonary lesions ≥ 20 mm in size were 96.4% and 97.1%, respectively. With respect to lesion depth, the sensitivity and diagnostic accuracy for those ≥ 50 mm were 94.1% and 94.0%, respectively, while values for those <50 mm were 97.4% and 98.0%, respectively. There was no significant difference in the correct diagnosis of malignancy based on lesion size ($p=0.634$) or lesion depth ($p=0.542$).

Complications after TNB

Complications occurred in 19 cases (19.2%): 16 cases of pneumothorax (16.2%), 2 cases of immediate haemoptysis (2.0%) and 1 case of subcutaneous emphysema (1.0%). Among the patients with pneumothorax, four (4.0%) required chest tube insertion ($n=2$) or pig-tail catheter drainage ($n=2$). There was no other complication that required treatment.

For 29 cases with small pulmonary nodules <20 mm in size, complications occurred in 7 cases (24.1%): 5 cases of pneumothorax (17.2%) and 2 cases of immediate haemoptysis (6.9%).

Discussion

For more than a decade, there have been rapid developments and emerging capabilities in CT technology

Table 2. Sensitivity for malignancy and overall diagnostic accuracy according to the characteristics of pulmonary lesions

Lesion characteristics	Number of cases ^a	Sensitivity for malignancy (%)	Diagnostic accuracy (%)
Lesion size (mm)			
<10	5	100.0	100.0
10–19	24	92.9	95.8
20–29	32	95.7	96.9
30–39	18	100.0	100.0
40–49	8	87.5	87.5
≥50	11	100.0	100.0
Depth of lesion (mm)			
<50	50	97.4	98.0
≥50	48	94.1	94.0
Total	98	95.8	96.0

^aA case in which transthoracic needle biopsy was performed from areas of ground-glass opacity and the final diagnosis was pulmonary alveolar proteinosis was excluded from this analysis.

with innovative and improving structural design of the CT scanner. A unique CT scanner design is a flat-panel volume CT using a flat-panel detector. Flat-panel volume CT allows coverage of a large volume per rotation, fluoroscopic and dynamic imaging and high spatial resolution [6].

The C-arm CBCT system, in which a cone-beam X-ray tube and a flat-panel detector are integrated with a C-arm gantry, has both CT and real-time fluoroscopy image capabilities [6]. Additionally, the great flexibility of the C-arm CBCT system in orienting the detector around the patient compared with closed CT gantries and its simplicity in acquisition of CT and fluoroscopy images allows for a shortening of the procedure time.

In this study, we found that TNB of pulmonary lesions using a C-arm CBCT system, in which CT was used for the

exact localisation of pulmonary lesions and fluoroscopy was used for real-time image guidance during the advancement of a biopsy needle, can provide high diagnostic accuracy with a low complication rate and a short procedure time, particularly for small pulmonary nodules.

In this study, diagnostic accuracy was 96.6% for pulmonary nodules <20 mm; Jin et al [7], in their initial experience of C-arm CBCT-guided TNB of pulmonary nodules ≤30 mm in size, also reported a high diagnostic accuracy of 98.4%. These results are superior to those of CT-guided biopsy reported previously (Table 3). In a series of CT-guided biopsies, vanSonnenberg et al [5] reported a diagnostic accuracy of 83.9% for lesions 11–20 mm in diameter and Ohno et al [2] reported a diagnostic accuracy of 77.2% for pulmonary nodules ≤20 mm in size. Presumably the lower diagnostic accuracy of CT-guided TNB is explained by the lack of real-time visualisation of the needle during the biopsy procedure. Under CT guidance, localisation of small pulmonary nodules, particularly those located in the lower lobes and significantly influenced by respiratory movement, can be time-consuming and difficult in uncooperative patients [2, 3, 8–11].

The overall diagnostic accuracy of 97% of CBCT-guided TNB in this study is comparable with that of CT fluoroscopy-guided TNB reported previously, ranging from 94% to 96% [1, 12] (Table 3). Hiraki et al [12], in a large series of CT fluoroscopy-guided biopsies of 1000 pulmonary lesions performed with 20-gauge coaxial cutting needles, reported a diagnostic accuracy of 92.7% for 151 cases of pulmonary nodules ≤10 mm. Our study included only 5 cases of pulmonary nodules <10 mm in size and the diagnostic accuracy for these was 100%. Hiraki et al [12] demonstrated that lesions in the lower lobes had a significantly higher rate of diagnostic failure than those in the upper and middle lobes. The considerable disadvantage of CT fluoroscopy-guided TNB is that the needle path can be demonstrated

Table 3. Summary of the diagnostic accuracy and complication rates of transthoracic needle biopsy using CT, CT fluoroscopy (CTF) or a C-arm cone-beam CT (CBCT) system

Study	Radiological guidance	Number of biopsies or patients	Needle size ^a	Lesion size	Diagnostic accuracy (%)	Complication rate (%) (pneumothorax rate; %)
Choi et al ^b	CBCT	98	A	Overall	97.0	19.2 (16.2)
	CBCT	29	A	<20 mm	96.6	24.1 (17.2)
Jin et al[7]	CBCT	71	A	≤30 mm	98.4	38.0 (25.4)
Hiraki et al[12]	CTF	1000	C	overall	95.2	NA (43.1)
	CTF	151	C	≤10 mm	92.7	NA
Heck et al[1]	CTF	52	A	Overall	96.0	NA (26)
	CT	36	A	Overall	94.0	NA (38)
Ohno et al[11]	CTF	41	A	Overall	95.1	NA (29.3)
	CTF	40	D	Overall	95.0	NA (22.5)
	CT	80	A	Overall	81.3	NA (26.3)
	CT	170	D	Overall	82.4	NA (22.0)
Geraghty et al[8]	CT	324	A	Overall	96.0	NA (38)
	CT	522	B	Overall	92.0	NA (23)
Li et al[3]	CT	27	B	≤15 mm	74.0	NA (22)
	CT	70	B	>15 mm	96.0	NA (21)
Kinoshita et al[10]	CT	89 ^c	C	Overall	94.4	NA (41.6)
Ohno et al[2]	CT	162	D	≤20 mm	77.2	NA (28.4)

NA, information not available.

^aA, 18-gauge; B, 19-gauge; C, 20-gauge; D, 22-gauge.

^bCurrent study.

^cThe cases biopsied using a special positioning (puncture site-down) technique were not included in this table.

only on the axial imaging plane during needle insertion and the patient's cooperation with breath-holding is critical to the success and safety of the procedure [13]. On the other hand, conventional fluoroscopy guidance by a C-arm CBCT system makes it easier to trace the advancement of a needle to a target nodule in patients who are not cooperative with breath-holding, which may provide better image guidance for small pulmonary lesions located in the lower lobes that may be more significantly influenced by respiratory movement compared with CT fluoroscopy. However, we could not determine which one would be superior because there is paucity of data on CBCT-guided TNB; further prospective studies with comparisons between the two types of image guidance should be performed to confirm our findings.

One advantage of the C-arm CBCT system is the great flexibility in orienting the detector around the patient and its simplicity in acquisition of CT and fluoroscopy images, allowing for a reduction in the procedure time. In the current study, the mean procedure time was 11.9 ± 4.0 min, which is comparable with that of CT fluoroscopy-guided TNB (12.3–23.8 min) [14–17] and much less than that of CT-guided TNB (25–26.7 min) [15, 17].

The CT and fluoroscopy capabilities of a C-arm CBCT system can be used in various ways in biopsy sequences according to the operator's experience or preference. Jin et al [7] acquired CT approximately three times per biopsy to check the appropriateness of the path to the target nodule with measurement of the lesion depth, identify the exact location of the inserted needle tip after placement of the coaxial introducer within the target and identify procedure-related complications after biopsy. In the current study, CT was acquired once per biopsy to determine the appropriate biopsy site and obtain measurement of lesion depth, but diagnostic accuracy was comparable with that of the study by Jin et al, as described above.

The pneumothorax rate in our series was 19.2%, which falls within the previously reported ranges of 13–45% for CT-guided TNB [1, 2, 10] and 22–32% for CT fluoroscopy-guided TNB [1, 16]. The pneumothorax rate for small pulmonary nodules <20 mm (17.2%) was lower than the reported pneumothorax rate of >30% in other studies [8, 18, 19]. Immediate haemoptysis was observed in only two patients (2%), in which biopsy of some normal lung tissue was inevitable because the target nodules were smaller than 20 mm and the cutting segment of the biopsy needle was 20 mm, but this did not require treatment. The accurate and fast targeting under both CT and real-time fluoroscopy guidance, which allowed a small number of needle passes, a short needle indwelling time and avoidance of biopsy of normal lung tissue in the current study, may reduce the incidence of complications.

Use of CT fluoroscopy for the guidance of TNB markedly decreases the patient radiation dose compared with conventional CT guidance but significant radiation exposure to the operator's hand is unavoidable [1, 16, 15, 20]. In the current study, the mean skin dose of CBCT-guided TNB was 168.8 mGy. In comparison with the results previously reported by Teeuwisse et al [21], this result is similar to that of CT fluoroscopy-guided TNB (mean, 130 mGy) and markedly lower than that of CT-TNB (mean, 330 mGy).

This study had some limitations. First, we included only a small number of patients. Although CBCT-guided TNB provided high diagnostic accuracy for small nodules, comparable or superior to that of CT fluoroscopy-guided TNB, further comparative studies between the two types of image guidance for TNB with a larger study population is needed for confirmation. Second, all TNB procedures in the current study were performed by only one experienced thoracic radiologist, which may have had an influence in the diagnostic accuracy or complication rate. Third, CBCT-guided TNB was performed only for nodules that were large enough to be visualised on fluoroscopy, because we used only fluoroscopic guidance during targeting and sampling of specimens. The use of CT and fluoroscopy capabilities of a C-arm CBCT system in different ways in the sequence of a biopsy procedure may also change the diagnostic accuracy or incidence of complications.

In conclusion, TNB using a C-arm CBCT system is an accurate and safe biopsy method, particularly for small pulmonary nodules. The C-arm CBCT system can provide useful image guidance for TNB, in which CT capability of the CBCT system enables exact localisation of pulmonary lesions and real-time fluoroscopy allows accurate and fast targeting with low radiation exposure to operators.

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