

Diagnostic accuracy and complication rates of percutaneous CT-guided coaxial needle biopsy of pulmonary lesions

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PURPOSE

The aim of this retrospective study was to evaluate and compare diagnostic accuracy and complication rates of percutaneous computed tomography (CT)-guided biopsies of pulmonary lesions 10–35 mm, 35–50 mm, and >50 mm, using the coaxial biopsy technique.

METHODS

Over a 4-year period, 235 lung biopsies were performed using the coaxial biopsy technique with 18G semi-automated true-cut needle. There were 163 (69.4%) male and 72 (30.6%) female patients, with a mean age of 64.01±9.18 years (18–85 years). The mean lesion size was 59.6±29.3 mm. The lesions were stratified into three groups according to size: lesions <35 mm (n=42, 17.9%), lesions 35–50 mm (n=53, 22.5%), and lesions >50 mm (n=140, 59.6%). Diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated for all biopsies, and for each group separately, as well as the incidence of complications.

RESULTS

The overall diagnostic accuracy was 95.4%, with 95.52% sensitivity, 100% specificity, 100% PPV, and 47.37% NPV. For lesions <35 mm, diagnostic accuracy, sensitivity, and PPV were 100%. The lowest diagnostic accuracy was 93.9% in lesions >50 mm, with 93.65% sensitivity, 100% specificity, 100% PPV, and 42.86% NPV. An adequate sample was obtained in 219 core biopsies (93.2%), while 16 biopsies (6.8%) were nondiagnostic due to necrosis (4.25%) and insufficient biopsy material (2.55%). The most frequent complication was minor pneumothorax, which was seen at a rate of 19.1%; pneumothorax requiring chest tube placement occurred in 3 patients (1.3%).

CONCLUSION

Diagnostic accuracy decreased with increasing lesion size. On the other hand, complication rates were higher in smaller lesions, more distanced from the pleura.

Computed tomography (CT)-guided percutaneous needle biopsy is a well-established method in the diagnostic algorithm of various pulmonary lesions, with two types of biopsy techniques employed, fine-needle aspiration biopsy (FNAB) and core biopsy (CB). Both techniques yield high diagnostic accuracy for carcinomas, from 89% in FNAB to 98% in CB (1). Coaxial biopsy technique has a reported overall diagnostic accuracy for both malignant and benign lesions ranging from 82.6% to 95% (2–4).

Besides the needle type, other factors such as lesion size, nature of the lesion, experience and skills of interventional radiologist influence the diagnostic accuracy. Lesion size ≤1 cm is reported as a significant risk factor decreasing diagnostic accuracy, but in published data lesions >5 cm and even ≥3.1 cm, are also identified as factors that decrease the diagnostic accuracy mainly due to the higher rates of necrosis (4, 5).

The most frequent complication in lung biopsy is pneumothorax, with the reported pooled rate 25.3% for CB and 18.8% for FNAB (6).

The aim of this retrospective single-center study was to determine diagnostic accuracy and complication rates of percutaneous CT-guided coaxial lung biopsies of pulmonary lesions stratified by lesion size into <35 mm, 30–50 mm, and >50 mm lesions, as well as to identify the relevant risk factors.

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Methods

From January 2015 to December 2018, we performed a total of 235 core lung biopsies in 235 patients. All patients signed informed consent before the procedure, and the study was approved by the institutional ethics committee (protocol number 06-04-9-44023).

The inclusion criteria for the study were patients with lung mass whose CT images of the biopsy procedure, written pathologic report, and relevant clinical data in the hospital database were available (surgical report, response to oncologic or medicament therapy, post-biopsy imaging). Patients lost to follow-up were excluded from the study.

Uncooperative patients, or those with severe respiratory failure and uncorrectable coagulopathy were considered non-eligible for biopsy.

In the first two years of research, the biopsies were performed on a dual-slice CT machine (Emotion Duo Siemens), and later on a 128-slice MDCT (Optima 128 GE). All patients had findings of international normalized ratio (INR) <1.5, platelet count (>50,000), and activated partial thromboplastin time. Spirometry was performed prior to the biopsy within the standard clinical evaluation of the patient. Forty-five patients (19.0%) had underlying emphysema.

Previous noncontrast and contrast-enhanced CT scans were available for lesion evaluation and biopsy path planning in all patients. As only a few patients had PET-CT scans before biopsy, these were not routinely used for evaluation of the pulmonary lesion vitality. We used 18G coaxial true-cut semi-automatic core-biopsy needles for all biopsies.

The biopsies were performed by one of the three attending interventional radiologists: the first one performed 134 (57.0%), the second one performed 93 (39.6%), and

the third one performed 8 (3.4%) biopsies. At the time, all three operators had over five years of experience in percutaneous biopsies, but no specific experience in lung biopsies. We evaluated the learning curve, technical success and occurrence of major and minor complications for all three operators.

Complications were defined as minor and major, and quality threshold defined according to the CIRSE and SIR guidelines on percutaneous needle biopsies (7, 8).

Biopsy procedure

Before the procedures, the needle path and patient position were planned on the basis of CT scan findings, and the shortest distance from skin to lesion was chosen in the majority of the cases. Of the biopsies, 142 (60.4%) were performed in prone position, 88 (37.5%) in supine position and 5 (2.1%) in lateral decubitus position. After initial scanning of the selected area with a slice thickness of 2.5 mm, the entry point was determined, checked and marked on the skin, cleaned with povidone-iodine, and covered with sterile drapes. As local anesthetic, 5 mL of 2% lidocaine was injected into the skin and underlying tissue of the thoracic wall. No. 11 scalpel was used to make a small incision on the skin. Before the needle was inserted, all patients received breathing instructions and were told to refrain from coughing. Only one pleural entry was made in all procedures; optimally three tissue samples were taken (9) and fixed in 10% formalin for pathologic examination. Only one biopsy sample was taken in four patients, and two biopsy samples in two patients, due to pneumothorax that occurred during the procedure. Microscopic analysis with standard hematoxylin and eosin (H&E) staining was performed on all specimens. Additional immunohistochemical staining with TTF1/ napsinA and p63/p40 was performed for determination of tumor subtypes in non-small cell lung carcinoma. CT controls were performed immediately after the biopsies were taken, and control chest X-ray ordered within two to four hours to check for potential complications. All patients were observed for 24 hours after the procedure; those with minor complications were treated conservatively, while patients with dyspnea and large pneumothorax were drained with chest tube insertion by thoracic surgeons and kept in the hospital until fully recovered. All minor and major complications were notified.

Data collection and statistical analysis

Lesion size, complications, sample adequacy and compatibility were presented by total number and percentage, while distance of the lesion from pleura was presented by mean and standard deviation. The statistical tests were performed in order to determine the influence of these variables on accuracy.

Analysis of potential differences was performed using nonparametric chi-square test, Fisher's exact test and Mann-Whitney U test for independent samples. The level of statistical significance was set at $p < 0.05$. 95% confidence interval was presented as necessary. Analysis was performed using the statistical package for biomedical studies MedCalc v 12.3 (MedCalc Software Ltd.).

The accuracy of the diagnostic method was determined by calculation of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and the overall diagnostic accuracy, both in the total sample and for each group of lesion.

Results

In the baseline sample, there were 163 male (69.4%) and 72 female (30.6%) patients, with a mean age of 64.01 ± 9.18 years (18–85 years). In the total sample of 235 lesions, there were 42 lesions <35 mm, 53 lesions 35–50 mm, and 140 lesions >50 mm. The smallest lesion was 14 mm, and the largest 190 mm. The mean lesion size was 59.6 ± 29.3 mm. Distance from the pleura to the closest margin of the lesion was 10.9 ± 14.5 mm, and interlobar fissure was transgressed in 3 patients (1.3%). According to the results of the chi-square test there was significant difference between male and female patients in distribution according to the lesion size ($p = 0.0001$). The larger lesions were predominant in the male population. Lesions <35 mm were found in 48.8% of male and 51.2% of female patients, lesions 35–50 mm in 60.4% male and 39.6% female patients, and lesions >50 mm in 78.8% of male and 21.3% of female patients.

Adequate samples were obtained in 219 biopsies (93.2%), while 16 biopsies (6.8%) were nondiagnostic. Overall, 198 samples (90.4%) were malignant, with predominance of primary lung adenocarcinoma. Distribution of adequate and nondiagnostic biopsies according to the lesion size is given in Table 1. In the first group of lesions <35 mm, 5 biopsies (11.9%) were nondiag-

Main points

- Coaxial biopsy technique of lung lesions has a high diagnostic accuracy for both malignant and benign lesions.
- Smaller lesion size is a significant risk factor for decreased diagnostic accuracy and increased complication rates.
- Large lesions may also decrease diagnostic accuracy due to necrosis, perilesional pneumonitis and condensed non-aerated lung tissue.

Table 1. The effect of lesion size on the adequacy of the biopsy sample in a total of 235 lung biopsies

		Adequacy of sample		Total number of biopsies	
		Adequate	Nondiagnostic		
Lesion size	<35 mm	n	37	5	42
		%	88.1	11.9	100.0
	35–50 mm	n	50	3	53
		%	94.3	5.7	100.0
	>50 mm	n	132	8	140
		%	94.3	5.7	100.0
Total	n	219	16	235	
	%	93.2	6.8	100.0	

χ^2 , result of the chi-square test.

Table 2. The effect of lesion size on the diagnostic accuracy, sensitivity, specificity, PPV, and NPV in a total of 235 lung biopsies

	Lesion size			Total
	<35 mm	35–50 mm	>50 mm	
Sensitivity, %	100.0 (90.59–100.0)	95.74 (85.46–99.48)	93.65 (87.87–97.22)	95.52 (91.42–97.69)
Specificity, %	-	100.0 (29.24–100.0)	100.0 (54.07–100.0)	100.0 (66.37–100.0)
PPV, %	100.0 (90.59–100.0)	100.0 (92.13–100.0)	100.0 (95.45–100.0)	100.0 (98.11–99.99)
NPV, %	-	96.00 (91.25–100.0)	42.86 (21.38–67.4)	47.37 (27.32–68.29)
Diagnostic accuracy, %	100.0 (90.59–100.0)	98.0 (90.0–100.0)	93.9 (85.41–95.24)	95.4 (89.54–99.0)

PPV, positive predictive value; NPV, negative predictive value.

Table 3. The effect of lesion size on the true positive, false negative and true negative results in 219 lung biopsies

		Lesion size			Total	
		<35 mm	35–50 mm	>50 mm		
Accuracy	True positive	n	37	45	118	200
		%	100.0	90.0	89.4	91.3
	False negative	n	0	2	8	10
		%	0.0	4.0	6.1	4.6
	True negative	n	0	3	6	9
		%	0.0	6.0	4.5	4.1
Total	n	37	50	132	219	
	%	100.0	100.0	100.0	100.0	

χ^2 , result of the chi-square test.

ing adequate material with regard to the lesion size, distance from pleura to the lesion, positioning of the patient, occurrence of complications, operator, and the year of performance ($p > 0.05$). We obtained necrotic material in all three groups of lesions, with no statistical significance among the groups.

Diagnostic accuracy, sensitivity, specificity, PPV and NPV were calculated based on the sample of 219 biopsies, and final diagnoses were confirmed by surgery in 66 patients (27.85%), or by imaging and clinical course of disease in 171 patients (72.15%). In these patients, control CT scans have shown progression of pulmonary infiltration or metastatic disease, less often regression or no progression of disease after chemotherapy, or complete resolution in benign inflammatory conditions after medicament treatment. The confirmation of patient's death due to pulmonary malignancy was also found in the hospital/ oncology department database.

The overall diagnostic accuracy was 95.4%, with 95.52% sensitivity, 100% specificity, 100% PPV, and 47.37% NPV. The values of sensitivity, specificity, PPV and NPV according to the lesion size are given in Table 2. Out of 219 biopsies, 200 results (91.3%) were true positive, 9 (4.1%) true negative and 10 (4.6%) false negative. We did not have false positive results (Table 3).

Sensitivity and NPV were lowest in the group with lesions >50 mm, due to false negative biopsy results in 8 patients. The pathologic finding in all 10 false negative results (4.6%) was nonspecific chronic inflammation. Diagnostic accuracy was 100% in lesions <35 mm, with 100% true positive results. We did not have true negative and false negative results in this group.

Complications occurred in 51 patients, and the overall complication rate was 21.7%. The most frequent complication was minor pneumothorax with a rate of 19.1% (Fig.). Pneumothorax requiring chest tube placement was the only major complication, with a rate of 1.3%. The mean dwelling time of the catheter was 8.7 days. The only other complication was minor parenchymal hemorrhage with a rate of 1.3%.

There was no significant difference in complication rates with regard to sex or age of the patient, position of the patient, operators, and the year of performance. The interlobar fissure was transgressed only in three biopsies, without complication. Emphysema was not an independent risk

nostic: 2 (4.8%) due to necrosis, and 3 (7.1%) due to insufficient material for diagnosis. In the second group of lesions 35–50 mm, the material was nondiagnostic in 3 patients (5.7%), all due to necrosis. In the group of lesions >50 mm, 8 biopsies (5.7%) were non-

diagnostic: 5 samples (3.6%) were necrotic, and 3 samples (2.1%) were insufficient for diagnosis.

According to the result of the chi-square and Mann Whitney U tests there was no statistically significant difference in obtain-

Table 4. Analysis of the influence of the lesion size and distance of the lesion from pleura on the occurrence of complications in a total of 235 lung biopsies

			Complication		<i>p</i>
			No	Yes	
Lesion size	< 35 mm	n	23	19	$\chi^2= 18.976$ $p = 0.0001$
		%	54.8	45.2	
	35–50 mm	n	41	12	
		%	77.4	22.6	
	>50 mm	n	120	20	
		%	85.7	14.3	
Distance of the lesion from pleura (mm)	Mean	8.44	19.16	U= 5.353 $p = 0.0001$	
	SD	2.78	7.05		

SD, standard deviation; χ^2 , result of the chi-square test; U, result of the Mann–Whitney U test

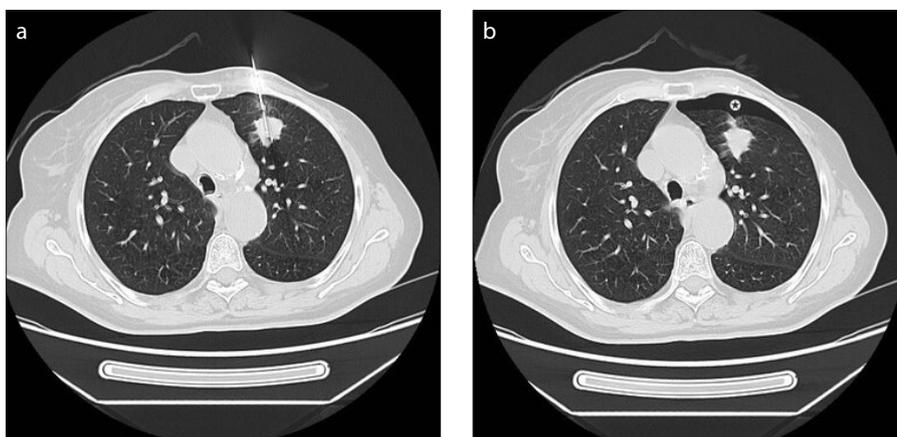


Figure. a, b. Axial CT image (a) shows the needle tip in a solid lesion in the upper left lung lobe. On the control CT scan (b) a minor post-biopsy pneumothorax is seen (white surrounded black star).

factor for the occurrence of pneumothorax or parenchymal hemorrhage in our study. We found that only two factors, lesion size and distance of the lesion from the pleura influenced the occurrence of complications (Table 4).

The highest complication rate (45.2%) was in lesions <35 mm, which was statistically significant ($p = 0.0001$). The lowest complication rate (22.6%) was in lesions >50 mm.

The distance of the lesion from the pleura of 19.16 mm was also statistically significant ($p = 0.0001$). These two factors were related, as the smaller lesions were more distanced from the pleura than the larger ones.

Discussion

In this retrospective study, we evaluated diagnostic accuracy, sensitivity, specificity, PPV, NPV, and complication rates of CT-guided coaxial core biopsy in <35 mm, 35–50 mm, and >50 mm lesions. The overall diagnostic accuracy in our study was 95.4%,

with 95.52% sensitivity, 100% specificity, 100% PPV, and 47.37% NPV. Our results were comparable to the previous studies evaluating the diagnostic accuracy of coaxial core biopsy technique (4, 10, 11).

For lesions <35 mm, diagnostic accuracy, sensitivity and PPV were 100%. There are several studies reporting small lesion size as a risk factor influencing diagnostic accuracy, while others reported high diagnostic rates for lesions ≤ 2 cm (3–5, 12, 13).

Our results are not quite comparable with these studies as we had only 9 lesions ≤ 2 cm.

Diagnostic accuracy, sensitivity and specificity were 98.0%, 95.74%, and 100% for lesions 35–50 mm and 93.9%, 93.65%, and 100%, for lesions >50 mm, respectively. In these two groups, we had 10 false negative results (4.2%) all due to perilesional inflammatory tissue that can be found around the tumor. We did not observe significant difference in obtaining necrotic samples among

the three groups. In pre-procedural biopsy planning, necrotic parts of the large tumors were better delineated from vital tumor tissue on noncontrast- and contrast-enhanced scans than tumor tissue from the perilesional pneumonitis and condensed non-aerated lung tissue. Yeow et al. (4) report lesions >50 mm, and Hiraki et al. (5) lesions ≥ 31 mm as an independent factor for diagnostic failure.

In 6 patients (2.5%), biopsy material was insufficient for pathologic analysis. According to the literature, optimally 3 samples should be taken for achieving the highest diagnostic accuracy and to reduce patient's risk of complications, which is our standard of practice as well. In our study, less than 3 samples were taken in 6 patients, due to pneumothorax that occurred during the procedure; the samples were insufficient for histopathologic diagnosis in 4 patients (1.7%), while the specific diagnosis of malignancy was confirmed in 2 patients. In the remaining 2 patients (0.8%), biopsy material was insufficient for specific pathologic diagnosis, even though 3 samples had been taken. Our results are in accordance with data published by Wehrshuetz et al. (9).

A specific diagnosis of malignant neoplasm was reached in 198 biopsies (90.4%), and carcinoma subtypes were specified in 83.9%. Non-small cell lung carcinoma (NS-CLC) was the dominant type of lung carcinoma, and adenocarcinoma was the leading subtype, which is to be expected since adenocarcinomas are the leading group of primary lung cancers and most often peripherally located (14).

The overall complication rate in our study was 21.7%, and pneumothorax was the most frequent complication. The only other complication that occurred was a minor intrapulmonary hemorrhage. We evaluated occurrence of complications in correlation with patient's age, sex, underlying emphysema, transgression of interlobar fissure, operator, lesion size, depth of the lesion, and position of the patient. We found the lesion size and the distance from the lesion to the pleura to be a significant risk factors according to the chi-square and Mann Whitney U tests, which was also reported by some other studies (15, 16).

The only major complication in our study was pneumothorax requiring drainage, which occurred in 3 patients (1.3%). We had lower complication rates than reported in some other studies in which 18G core biopsy needle was also used (3, 15, 17).

All 3 patients with major pneumothorax had prolonged catheter dwelling time (>3 days), as long as 15 days in one case. Moreland et al. (18) reports transgression of fissure as an independent risk factor for prolonged pneumothorax drainage; but in our study fissure was transgressed only in 3 biopsies with no complication.

Although we did not prove emphysema as an independent risk factor for occurrence of complications, three patients with major pneumothorax had an underlying emphysema. Laurent et al. (16) reported emphysema and older age of patient as independent factors for higher percentage of pneumothorax requiring drainage, and Takeshita et al. (3), besides these, identified supine position of the patient as a risk factor for major pneumothorax.

Intrapulmonary hemorrhage was the second minor complication (1.3%), and it was self-limiting, not requiring any further medical treatment (19).

The reported rates of hemorrhage vary from 4%–27%, and the proposed quality improvement threshold for minor pneumothorax and hemorrhage is 45% (8, 20).

Some of the risk factors for higher grade hemorrhage, reported in the literature, are female sex, older age, emphysema, coaxial biopsy technique, lesions <3 cm and deeper location of the lesion (21, 22). Our results for both minor and major complication rates were in accordance with CIRSE guidelines on percutaneous needle biopsy and SIR recommendations for quality improvement threshold (7, 8).

Limitation of our study is its retrospective design, which may have carried some unpredicted bias. The number of lesions <35 mm, and especially lesions <20 mm was relatively small. A large number of our patients was inoperable, so the final diagnoses were determined from control CT findings, response to medical oncologic treatment, or clinical course of the disease.

In conclusion, the results of our study showed that lesion size and distance of the lesion from the pleura influenced diagnostic accuracy and complication rates. Diagnostic accuracy and NPV were lowest in lesions >50 mm, with 93.9% and 42.86%, respectively. Perilesional inflammation was

the main reason for diagnostic failure and false negative results in lesions >50 mm. Pre-biopsy evaluation of contrast-enhanced CT scans was highly sensitive in delineation of necrotic parts in large tumors and biopsy planning. Complication rates were higher in smaller lesions and those more distanced from the pleura, with minor pneumothorax being the most frequent complication.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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