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ORIGINAL ARTICLE

Complications and diagnostic accuracy of CT-guided 18G tru-cut versus end-cut percutaneous core needle biopsy of solitary solid lung nodules

José Javier Echevarria-Uraga
Gorka del Cura-Allende
Karmele Armendariz-Tellitu
Cristina Berastegi-Santamaria
Mikel Egurrola-Izquierdo
Ane Anton-Ladislao

PURPOSE

Percutaneous biopsy has demonstrated a high accuracy in the diagnosis of lung nodules, but the technique is not innocuous and a yield decrease in lesions smaller than 20 mm has been reported. We carried out a prospective study to evaluate and compare the complications and effectiveness of percutaneous core needle biopsy (CNB) of solitary solid lung nodules, which was performed with 2 types of automatic guns.

METHODS

A total of 330 consecutive CT-guided CNBs were included. Tru-cut or end-cut 18G devices were used alternatively. Nodules were categorized by their size: ≤10 mm, 11-20 mm, and >20 mm. Incidence of complications such as pneumothorax or hemoptysis and factors influencing them (nodule size and depth within lung parenchyma) were evaluated. Diagnostic accuracy of CNB achieved in nodules of different size categories with the 2 different needles were calculated, statistically evaluated, and compared.

RESULTS

We performed 68 CNBs in nodules ≤10 mm, 130 in nodules 11-20 mm, and 132 in nodules >20 mm. Pneumothorax appeared in 24.2% of them, but only 5.7% required drainage. Hemoptysis developed in 9.4%, and abundant hemoptysis with hypoxemia was observed in only 4.2% of patients. Regarding appearance of complications between the 2 needle types, no significant differences were found. A higher risk of hemoptysis was observed in nodules ≤10 mm (odds ratio [OR], 3.87; 95% CI, 1.24-12.06; *P* = .019) and in those located deeper in the pulmonary parenchyma (OR, 2.21; 95% CI, 1.04-4.69, *P* = .038). End-cut needles reached a diagnostic accuracy of 93.7%, 92.1%, and 98.3%, in nodules sized ≤10 mm, 11-20 mm, and >20 mm, respectively. Corresponding results for tru-cut were 84.7%, 88.5%, and 92.1%. In spite of differences reaching up to 9% in smaller nodules, intragroup results were not significant.

CONCLUSION

Both needles have a similar complication rate. Although statistically significant differences between the 2 types of needles were not observed, end-cut devices have demonstrated a higher diagnostic yield in all 3 size categories of nodules and could be a more suitable option, especially for CNB of nodules ≤10 mm.

From the Departments of Radiology (J.J.E., ✉ *fizer.echevarria@gmail.com*, G.d.C., K.A. C.B.) and Pulmonology (M.E.), Osakidetza Basque Health Service, Galdakao-Usansolo Hospital, Galdakao, Spain; Biocruces Bizkaia Health Research Institute (J.J.E., G.d.C.), Barakaldo, Spain; Osakidetza Basque Health Service Research Unit (A.A), Galdakao-Usansolo Hospital, Galdakao, Spain; Health Services Research on Chronic Diseases Network-REDISSEC (A.A.), Spain.

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Detection of a pulmonary nodule in an imaging test forces us to establish its benign or malignant etiology, which often requires a cyto-histological study. Percutaneous needle biopsy, guided by imaging techniques such as computed tomography (CT), is an essential tool in the diagnosis of nodules and other pulmonary abnormalities. Both percutaneous fine needle aspiration biopsy (FNAB) and core needle biopsy (CNB) show a high diagnostic yield, with sensitivity and accuracy rates of 82%-99% and 64%-97%, respectively.[1-3] However, CNB supplies more abundant tissue samples, which allows more accurate histological and molecular tumor characterization, implying a considerable advantage of CNB over FNAB.[2]

The size of a nodule is a relevant characteristic in its diagnosis. The likelihood of malignancy is much higher in larger nodules than in incidentally detected smaller ones.[4-6] Regarding diagnostic techniques, a decrease in the diagnostic yield of the percutaneous puncture in nodules smaller than 20 mm has been reported.[1-3] Furthermore, percutaneous biopsy is

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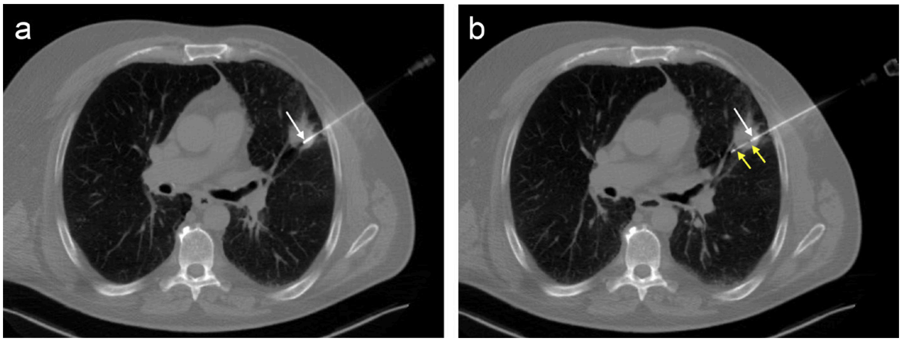

Figure 1. a, b. Coaxial puncture technique using a tru-cut device. CNB of a 28 mm nodule in the left upper lobe. The tip of the coaxial needle (*white arrow*) is located inside the nodule (**a**). CT-scan performed immediately after shooting the tru-cut needle (**b**). Distal portion of the gun with the inner slotted stylet (*yellow arrows*), in which the tissue sample is harvested, is seen into the tumor. Tip of the coaxial needle (*white arrow*).

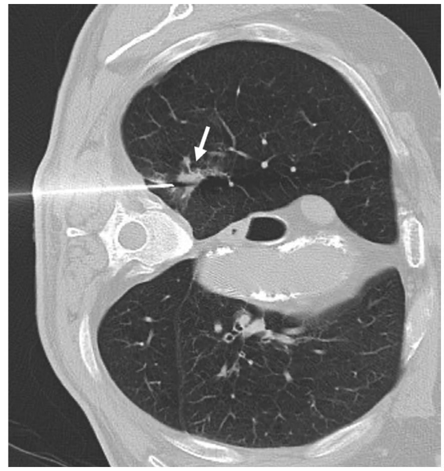

Figure 2. Patient in left decubitus position during core biopsy of a 13 mm spiculated subpleural nodule (*white arrow*) located in the right upper lobe. A 17G coaxial needle is placed next to the nodule surface.

not innocuous, its main complications being pneumothorax and pulmonary hemorrhage, with a reported incidence rate of 10%-40% and 26%-33%, respectively.[1,3,7,8]. All these circumstances oblige us to properly indicate the performance of a percutaneous biopsy in the diagnosis of a pulmonary nodule.

Numerous needle designs can be used in CNB of lung lesions. The automatic guns most commonly selected are the tru-cut needles, but other devices such as the end-cut needles can also be useful.[1,9] We believe that it is important to determine if the accuracy of the biopsy's diagnostic results are influenced by the type of the needle used.

We carried out a prospective study in 330 percutaneous biopsies which have been performed with 2 different 18G automatic guns, with the objective of evaluating whether both nodule size and the type of biopsy needle used determine complication rate and effectiveness of the percutaneous CNB in the diagnosis of a solid pulmonary nodule.

Methods

This was a prospective study conducted in a single hospital. It was approved in accordance with the ethical standards of our Institutional Research Committee (ethics approval number: 06/15) and conducted in accordance with the principles established in the Declaration of Helsinki. The study was carried out in patients in whom a solitary solid lung nodule was detected in a CT study indicated by pulmonology or oncology hospital consultation. Each patient was informed about the procedure, and they agreed to participate in the study. The recruitment was extended from September 2015 to December 2017, and 330 consecutive procedures of CNB were included.

Main points

- CT-guided core biopsy provides high diagnostic yield for solid lung nodules.
- 18G automatic guns demonstrate low rate of complications such as pneumothorax or bleeding.
- End-cut guns show better results than tru-cut devices in biopsy of lung nodules, especially in ≤10 mm lung nodules in which end-cut needles achieve a diagnostic accuracy for malignancy close to 94% (9% higher than tru-cut devices).

Two interventional radiologists with more than 10 years of experience in percutaneous biopsy carried out the procedures. The biopsies were performed with coaxial technique and using automatic 18G tru-cut or end-cut needles (Figure 1). For tru-cut biopsies, Bard® Max-Core® (Bard Peripheral Vascular, Inc.) needles with a 22 mm throw-length were used. For end-cut biopsies, BioPince™ (Argon Medical Devices Inc.) needles were employed, which enable 3 options of throw-lengths, but only the 23 mm option was used. The choice of gun for each patient was randomized by using the 2 needle types successively and alternatively.

Procedures were carried out in 2 multislice CT scanners, a Somaton Sensation 10 equipment and a Somaton Definition AS scanner (Siemens Healthcare GmbH). During the procedure, the patients were laid on the CT table in a position that enabled not only the shortest pathway, but also the safest one by avoiding fissures or lobar or segmental vessels.

The following nodule characteristics were collected: localization and laterality, depth in the lung measured from the parietal subcostal pleura to the nearest surface of the nodule (subpleural, less than 15 mm; central, the remaining locations), and largest diameter in axial projection. Nodules were classified into 3 groups depending on their diameter: ≤10, 11-20, and >20 mm.

The CNBs were carried out with local anesthetic, injecting 10 mL of 2% scandicaine from the skin to parietal pleura. Regarding the puncture with the coaxial needle, distance from the skin access point to the nodule's surface (trans-thoracic needle-path length) and number of attempts to reach the nodule were assessed. During the procedure, the tip of the coaxial needle was located inside the nodule or in its surface, but in a position that could ensure the nodule being tackled by the biopsy needle (Figures 1a and 2).

After each CNB, the radiologist carried out a visual evaluation of the obtained material, and depending on its quality, the performance of additional punctures was decided.

Once the procedure was finished, a thoracic CT was performed to assess the development of complications, such as pneumothorax or bleeding. Hemoptoic sputum was not assessed (Figure 3). Hemoptysis was considered as a complication when one or more episodes of cough and expectoration of red blood developed immediately after biopsy. Bleeding complications that affected pulmonary function and required supportive oxygen therapy were classified as severe hemoptysis (Figure 4). The adverse events that developed in the first 24 hours after the CNB were also registered. All CNBs were considered for the assessment of complications.

The extracted cylinders were fixed in formalin and sent for histological analysis (Figure 5). Specimens with a diagnosis of malignancy were considered true positives (TP). Benign tumors and inflammatory or infectious pathology were considered as true negatives (TN). In cases with a histopathological result of inconclusive benignity, the decision between a semi-annual follow-up with CT for 2 years, a repeat biopsy, or a surgery depended on suspicion of malignancy. Those that were ultimately malignant were considered false negatives (FN), and benign ones were included in the TN group. Punctures with histological outcome suspected of malignancy but not corroborated by the surgical sample were considered false positives (FP). Those procedures that failed to reach the nodule due to poor technique or those with insufficient material were considered invalid.

The sensitivity and diagnostic accuracy for malignancy of the 2 types of needles were calculated according to the nodule size, considering the procedures with valid histological result and/or with image follow-up accomplished.

Descriptive statistics of sociodemographic data, nodule characteristics, and biopsy procedures were calculated using means and standard deviations (SD), with median and interquartile range (IQR) for continuous variables and frequency and percentage for categorical data. To assess the differences between results of CNBs for both types of needles, according to all variables, chi-square test (or Fisher exact test, when expected frequencies were lower than 5) and Student t test (or nonparametric Wilcoxon test, when normality was rejected) were used for categorical and continuous variables, respectively. Similarly, we evaluated the association of size and depth of the nodule with bleeding and pneumothorax. In addition, odds ratios (OR) and 95% CI were calculated for these parameters.

A stratified analysis was conducted to evaluate the procedure's yield according to the technique and the nodule size.

All effects were deemed statistically significant at $P < .05$. All statistical analyses were performed using SAS Software, Version 9.4 (SAS Institute, Inc).

Results

A total of 330 CNBs were performed in 318 patients, 80% men, mean age 67.8±9.75 years. In 8 of them, nodules were punctured twice, and in 2 patients, 3 CNBs were performed for each nodule. Overall results are summarized in Figure 6. Data related to biopsy technique and nodule characteristics are shown in Table 1.

Sixty-eight biopsies were performed in nodules ≤10 mm, 130 in nodules 11-20 mm, and 132 in nodules >20 mm. Median of coaxial puncture was 2 (IQR, 1-3). Median of extractions with biopsy guns was 3 (IQR, 2-3).

During CNB, 80 pneumothorax (24.2% of punctures) were developed, although only 19 patients (5.7%) required pleural drainage. In addition, there were 31 cases of hemoptysis (9.4%), 14 of them severe (4.2%) and treated with high-flow oxygen therapy for 60 min maximum. As a life-threatening

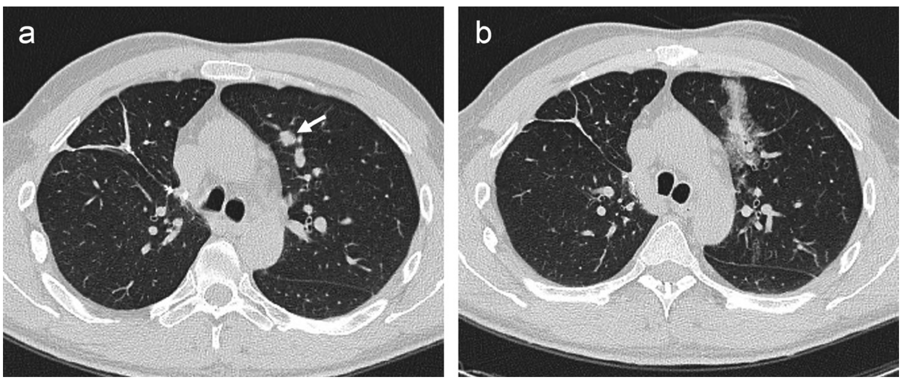

Figure 3. a, b. Biopsy of a central nodule which developed a limited subsegmental hemorrhage. CT scan (**a**) of a 9 mm solid nodule (*white arrow*) in the left upper lobe. The nodule is surrounded by several vessels and is located next to the aortic arch. The biopsy was performed with an 18G end-cut needle. CT image obtained after biopsy (**b**) shows ground-glass opacity along the needle tract in the anterior segment of the left upper lobe. The patient only presented hemoptoic sputum and the case was considered to have no complication. Histological result was compatible with adenocarcinoma.

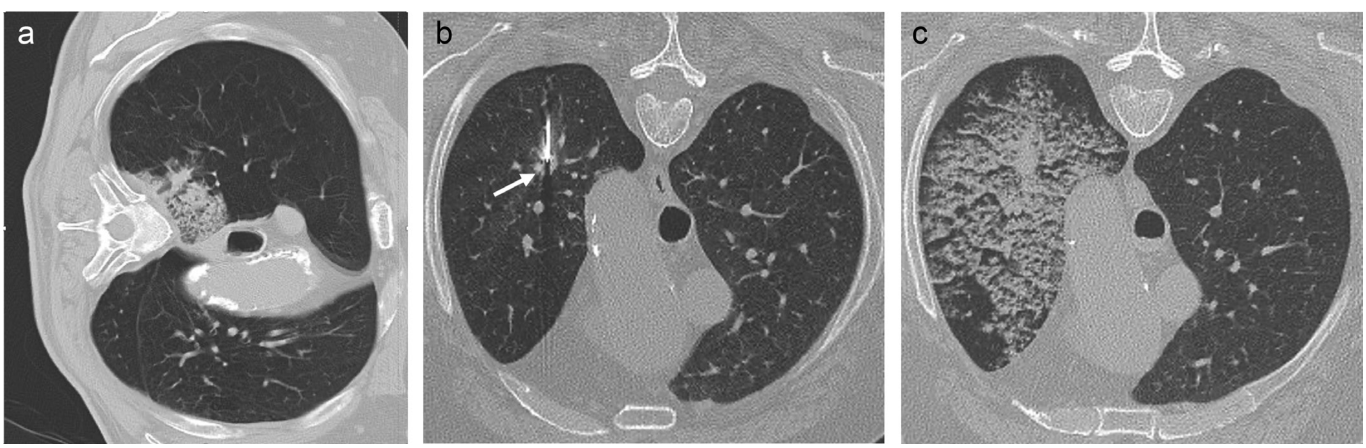

Figure 4. a-c. Hemorrhagic complications of percutaneous biopsy. CT scan performed after biopsy (**a**) using a tru-cut needle shows ground-glass opacity extending to the posterior segment (same case as Figure 2). Patient suffered from abundant hemoptysis and desaturation. Histological result was compatible with adenocarcinoma. Patient in prone position (**b**) showing the tip of the coaxial needle next to a central 8 mm nodule (*arrow*) in the left lung. After CNB using an end-cut needle, the CT image (**c**) shows ground-glass opacity extending to the left upper lobe. Abundant hemoptysis was observed. The biopsy revealed a squamous cell carcinoma based on pathological examination.

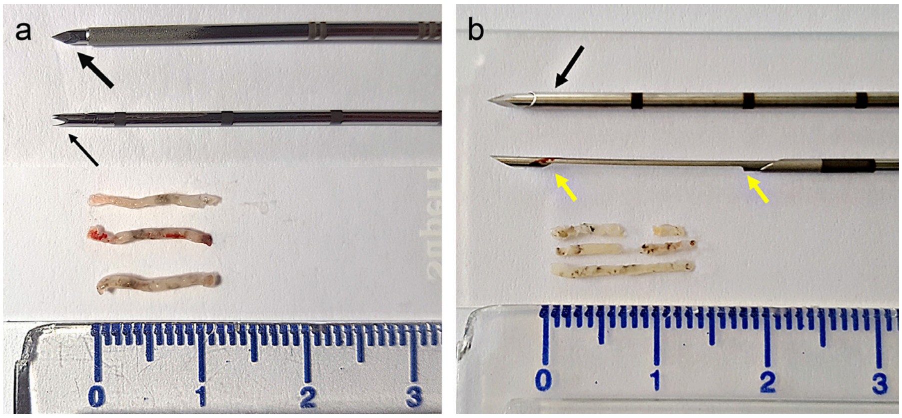

Figure 5. a, b. Tumor tissue samples obtained by a Franseen-tip end-cut device (**a**). A 17G coaxial needle (*thick arrow*) with trocar tip inner stylet and the corresponding 18G end-cut gun (*thin arrow*) are shown. Tissue samples obtained by tru-cut needle (**b**). The inner slotted stylet of the tru-cut device (*yellow arrows*) and the corresponding coaxial 17G needle (*black arrow*) are shown.

complication, a hemothorax was recorded due to intercostal artery injury that required intra-arterial embolization. This complication was produced with a tru-cut needle.

Association between nodule size and depth and development of pneumothorax and hemoptysis is shown in Table 2. There was no greater frequency of pneumothorax observed, related to nodule size or depth. However, nodules located at a greater depth (central nodules) and those of size ≤20 mm had a higher probability of hemoptysis. The risk of hemoptysis was twice as high in centrally located lesions (OR, 2.21; 95% CI, 1.04-4.69, *P* = .038) compared to the subpleural ones; nodules ≤10 mm presented almost a 4-fold higher risk of hemoptysis (OR, 3.87; 95% CI, 1.24-12.06, *P* = .019) compared with the larger ones, as well as the 11-20 mm nodules (OR, 3.82; 95% CI, 1.36-10.69, *P* = .011).

Eleven CNBs were invalid (3.3%); in 5 cases, necrotic or insufficient histological material was obtained (2 with tru-cut needle and 3 with end-cut), and the technique was poor in 6 biopsies, due to the development of pneumothorax that made it impossible to puncture the nodule (5 with tru-cut and 1 with end-cut). Four cases that required imaging controls after inconclusive biopsy were lost during follow-up.

Definitive histopathological diagnosis of the remaining 315 valid punctures corresponded to malignant lesions (including an atypical adenomatous hyperplasia) in 267 cases (84.8%) and to benign lesions in 48 (15.2%) (Table 3); 243 nodules (77.1%) were categorized as TP, 48 (15.2%) as TN, and 24 as FN lesions (7.6%) (Table 4). No FP results were observed. Overall, the sensitivity and diagnostic accuracy of the CNBs were 91% and 92%, respectively. In the analysis of the results according to nodule size and needle type, the sensitivity and accuracy of the CNB performed with end-cut devices were superior to those obtained with tru-cut guns in the 3 nodule groups, highlighting the accuracy values for end-cut needles of 93.7% and 98.3% in nodules ≤10 mm and >20 mm, respectively. Nevertheless, intragroup differences were not significant.

Discussion

To perform a lung biopsy, the most frequently used core needles are tru-cut devices, which slice a sample of tissue when an outer cutting cannula is shot over an inner slotted stylet. End-cut needles instead are automatic devices that obtain a cylindrical sample when a cutting cannula is advanced into tissue, leaving the trocar stationary and maintaining the specimen within the cannula while it is withdrawn from the patient. Although both needles have the same size, end-cut needles have been reported to extract more abundant samples.[1,9] This fact could be relevant if a good quality sample can be obtained while diminishing the number of needle shots. Nevertheless, a preliminary evaluation of the complications caused by using end-cut

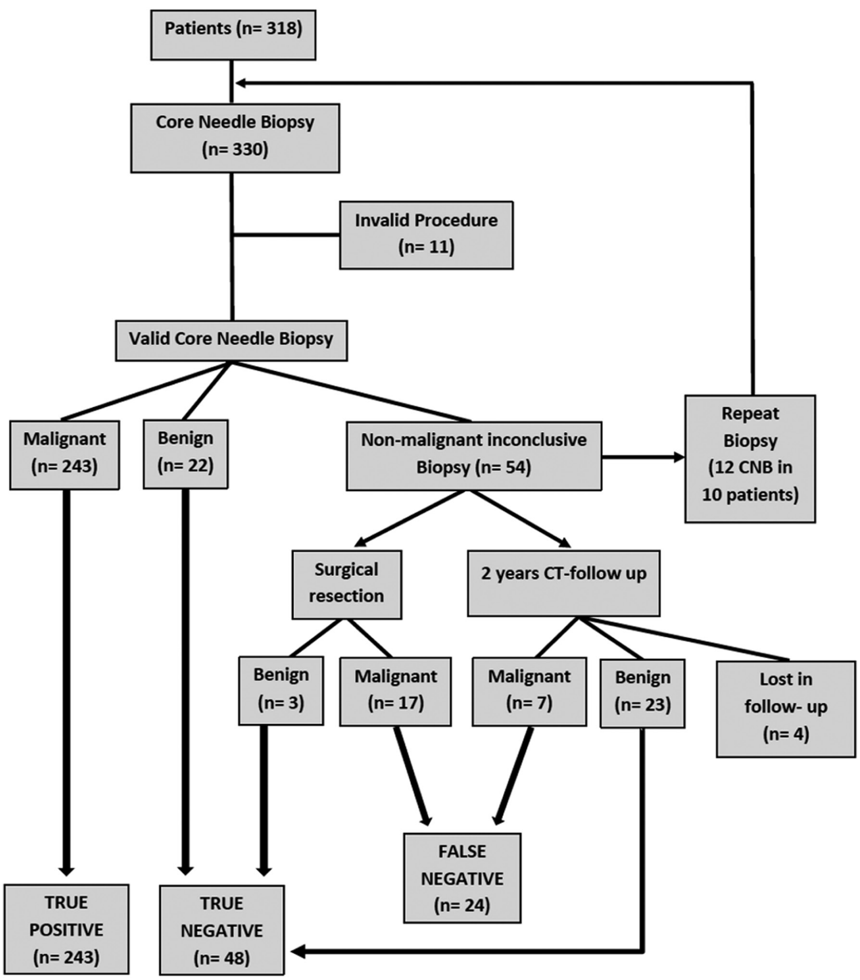

Figure 6. Flow diagram of diagnostic proceedings in the patients enrolled.

Table 1. Characteristics of nodules and procedures

	Total	Type of needle		
	n (%)	Tru-cut, *n*	End-cut, *n*	*P*
Total CNB	330	165	165	
Patient position for CNB				
Supine	138 (41.8)	69	69	
Prone	120 (36.4)	64	56	
Lateral	72 (21.8)	32	40	
Lesion location				
Right lung	190 (57.5)	102	88	.11
Upper lobe	76	40	36	
Middle lobe	40	23	17	
Lower lobe	74	39	35	
Left lung	140 (42.5)	63	77	.48
Upper lobe	93	44	49	
Lower lobe	47	19	28	
Lesion classification by depth				.57
Subpleural	197 (59.7)	96	101	
Central	133 (40.3)	69	64	
Lesion categorization by size				.95
≤ 10 mm	68 (20.6)	35	33	
11-20 mm	130 (39.4)	64	66	
> 20 mm	132 (40)	66	66	
Trans-thoracic needle-path length (mm), mean ± SD	66.9 ± 23.3	64.8 ± 23.2	69 ± 23.2	.081
Complications				
Pneumothorax	80 (24.2)	40	40	1
Pleural drainage	19 (5.7)	11	8	
Hemoptysis	31 (9.4)	13	18	.34
Severe hemoptysis	14 (4.2)	5	9	
Valid CNB with follow-up accomplished (if necessary)	315	157	158	1
CNB pathological diagnosis				1
Malignant	267 (84.8)	136	131	
Benign	48 (15.2)	21	27	

P values < .05 were deemed statistically significant.
CNB, core needle biopsy; SD, standard deviation.

Table 2. Association between nodule size and depth and development of complications

	Total, *n* (%)	Pneumothorax, *n* (%)	*P*	Hemoptysis, *n* (%)	*P*
Total	330	80 (24.2)		31 (9.4)	
Lesion classification by depth			.60		.034
Subpleural	197 (59.7)	50 (25.3)		13 (6.6)	
Central	133 (40.3)	30 (22.5)		18 (13.5)	
Lesion categorization by size			.17		.017
≤ 10 mm	68 (20.6)	20 (29.4)		9 (13.2)	
11-20 mm	130 (39.4)	35 (26.9)		17 (13.1)	
> 20 mm	132 (40.0)	25 (18.9)		5 (3.7)	

P values < .05 were deemed statistically significant.

Table 3. Histopathological diagnosis of valid biopsy procedures	
Histopathological results	*n*
Malignant nodules	267
Adenocarcinoma	119
Squamous cell carcinoma	90
Large cell carcinoma	9
Small cell carcinoma	2
Carcinoid tumor	4
Poorly differentiated carcinoma	4
Myoepithelial tumor	1
Atypical adenomatous hyperplasia	1
Lymphoma	4
Metastasis	33
Benign nodules	48
Chronic inflammation and fibrosis	24
Hamartoma	8
Tuberculoma	5
Necrotizing granuloma	3
Miscellaneous	8

needles for CNB compared to tru-cut needles is required.

The most common complication of percutaneous puncture is pneumothorax, which develops in approximately 10%-40% of procedures.[1,3,7,8] However, the incidence of a pneumothorax requiring chest tube placement is low at 1%-14%.[1,3,7] In our series, pneumothorax demonstrated a similar incidence for both types of needles, but only 6% of them required pleural drainage.

Pulmonary hemorrhage is also frequent and appears in up to 33% of punctures.[8] Although pulmonary bleeding can be worrisome to patients, especially if it causes hemoptysis, the majority of pulmonary bleeding is only an alveolar hemorrhage visible on CT, and it is rarely life-threatening.[10] The incidence of abundant hemoptysis ranges from 2% to 8%.[3,11] In our study, we found 9% hemoptysis, with 4% of them associated with desaturation that required supportive oxygen therapy. Regarding hemoptysis, we did not find any significant difference between the 2 needle types. Female sex, advanced age, nodule size less than 3 cm, and above all, deep location in pulmonary parenchyma have been related to the risk of developing larger bleeds.[11-14] In our series, we also observed a higher risk of hemoptysis when puncturing nodules of a more central location and in nodules smaller than 2 cm. We used 22 and 23 mm throw-length automatic guns (tru-cut and end-cut, respectively). These lengths are excessive, especially in nodules less than 10 mm, resulting in the extraction of a substantial amount of non-tumoral lung parenchyma, which could increase bleeding and explain the major risk observed in smaller nodules. The possibility of using needles with several throw-length options adapted to tumor size could be an option to reduce bleeding risk. Thus, when a CNB is indicated, especially in patients with poor lung function, all these factors should be considered.

Severe complications related to the CNB are rare,[3,15] and in our series we only found one life-threatening complication.

CNB is a technique of high technical success, and almost 97% were valid in our study. However, yield and indication of puncture in nodules smaller than 15-20 mm are controversial. It has been found that the possibility of malignancy of a nodule increases in direct relation to its size and that incidentally detected nodules between 8 and 20 mm show a malignancy probability of less than 20%.[16] In addition, in percutaneous biopsy, a low diagnostic yield of 52%-88% has been observed in small nodules, in contrast with results close to 100% achieved in nodules larger than 20 mm. However, most of these studies have evaluated fine needle biopsy.[1-3,17-19] When studying the CNB guided by CT, it has been proven that the diagnostic accuracy in nodules smaller than 10-15 mm is around 90%-95%, these results being similar to those observed in larger nodules.[12,20,21] In a recent study comparing CNB performed in nodules <10 mm and 10-20 mm, high diagnostic yields for malignancy were obtained, at 93.5% and 99.3%, respectively.[22] In our series of end-cut needle punctures, the diagnostic yield

Table 4. Stratified analysis evaluating diagnostic yield according to needle type and nodule size

		Nodule size								
		≤10 mm			11-20 mm			>20 mm		
	Total *n* (%)	Tru-cut *n* (%)	End-cut *n* (%)	*P*	Tru-cut *n* (%)	End-cut *n* (%)	*P*	Tru-cut *n* (%)	End-cut *n* (%)	*P*
Valid CNB	315	32 (10.1)	32 (10.1)		61 (19.3)	64 (20.3)		64 (20.3)	62 (19.6)	
TP	243 (77.1)	24 (75)	23 (71.8)		42 (68.8)	47 (73.4)		53 (82.8)	54 (87.1)	
TN	48 (15.2)	3 (9.4)	7 (21.8)		12 (19.6)	13 (20.3)		6 (9.3)	7 (11.3)	
FN	24 (7.6)	5 (15.6)	2 (6.2)		7 (11.4)	4 (6.2)		5 (7.8)	1 (1.6)	
Sensitivity (%)	91	82.7	92		85.7	92.1		91.3	98.1	
Accuracy (%)	92	84.7	93.7	0.42	88.5	92.1	0.55	92.1	98.3	0.21

P values < .05 were deemed statistically significant.
CNB, core needle biopsy; TP, true positive; TN, true negative; FN, false negative.

was 92%-98%, and with tru-cut it was 85%-92%. Although no significant intragroup differences were observed, the results were higher for end-cut procedures, especially in smaller nodules (mean size of 8 mm in our study) in which the difference between the 2 needle types reaches up to 9%. These data demonstrate the high accuracy of CNB and mainly of the end-cut needle for all nodule sizes.

Our study has limitations. It is not a multicenter study. In addition, patient samples came from hospital consultations, not from a lung nodule screening study, thus including a low proportion of benign nodules which can affect the results. The group of nodules <10 mm was smaller than the others and may have distorted comparative analyses. However, we believe that we have obtained a sample representative enough to value the results obtained and consider them when planning a percutaneous biopsy.

In conclusion, the 2 needle types assessed have demonstrated a similar rate of complications. Nevertheless, the risk of hemoptysis is higher in nodules located deeper within the lung parenchyma and especially in nodules less than 20 mm. Using core needles with throw-length adjustable to tumor size could reduce bleeding risk. Both tru-cut and end-cut needles reach high sensitivity and accuracy rates, but end-cut devices are especially useful in nodules <10 mm, in which they have demonstrated an improvement in the accuracy of results by up to 9% compared with tru-cut needles. Further investigations are needed, but according to our results, we believe that end-cut devices could be considered the first option to perform a CNB in <10 mm solid lung nodules in order to achieve the optimal balance between procedural risk and diagnostic yield.

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Conflict of interest disclosure

The authors declared no conflicts of interest.

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