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Inconclusive Result from CT Guided Transthoracic Needle Aspiration and Biopsy: Affecting Factors and Final Outcome

Purpose: Inconclusive results from computed tomography (CT)-guided transthoracic needle aspiration and biopsy (TNAB) performed for lung lesions presents a clinical dilemma. The purpose of this study was to determine the factors affecting an inconclusive result from a CT guided TNAB, and to evaluate the final outcomes of these inconclusive results. **Materials and Methods:** The medical records and radiologic features of 331 patients with lung lesion who received CT guided TNAB were analyzed retrospectively. The results of the TNAB were classified as conclusive (malignancy or specific benign diagnosis) or inconclusive (nonspecific benign or nondiagnostic). **Results:** Of the 331 cases, 269 (81.3%) were diagnosed as a malignancy (210) or a specific benign lesion (59) after the first TNAB. The remaining 62 (18.7%) were inconclusive. Benign disease, a lesion size ≤15 mm, and morphology of the consolidation type were features significantly correlated with inconclusive results. Of these 62 inconclusive cases a second TNAB was performed in 23, and conclusive diagnoses were obtained in 19 (82.6%). Surgery or radiographic follow up was done in other cases. Finally, among the 62 inconclusive results on the first CT guided TNAB, 16 lesions were diagnosed as malignant, 26 were classified as specific benign disease, and the remaining 20 were defined as nonspecific inflammation. Age over 50 and morphology of a nodule or a mass type were significantly correlated with a malignancy in these 62 cases with inconclusive results on the first TNAB. **Conclusion:** A final diagnosis of benign disease was significantly higher after the CT guided TNAB was inconclusive for lesions ≤15 mm that had consolidation type morphology. Despite the application of core biopsy procedures, there continue to be appreciable numbers of inconclusive results after the first CT guided TNAB. A repeat CT guided TNAB had a high diagnostic yield in these cases and therefore should be considered for cases with inconclusive results. **(J Lung Cancer 2011;10(2):94－101)**

Key Words: Computed tomography, Transthoracic needle biopsy, Inconclusive result

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INTRODUCTION

Image guided transthoracic needle aspiration and biopsy (TNAB) is a commonly used invasive technique for tissue diagnosis of a lung lesion of unknown etiology (1,2). The sensitivity, specificity and adequacy of tissue sampling for malignant lesions are expected to be more than 75% (3-7). The false positive rate and false negative rate are expected to be less than 1% and less than 10%, respectively (8,9). Imaging modalities used for TNAB are fluoroscopy, computed tomography (CT) and ultrasound (10,11). CT is commonly used for difficult lesions; the use of CT imaging has extended the application of biopsy procedures (12). CT allows for the visualization of the aspiration or biopsy needle tip within the lesion; in addition, it permits determination of the optimal cutaneous entry point so that transgression of a pleural fissure or puncture of large vessels, bronchi and the esophagus can be

avoided. Some studies have found that CT-guided TNAB for small lung lesions can produce a diagnostic yield comparable with larger lesions (13,14). In addition, the diagnosis of specific benign diseases can also be made with a high success rate (4,15). However, inconclusive results such as nonspecific or nondiagnostic benign results after TNAB are not uncommon and present a clinical dilemma (16,17). The clinician must decide whether to proceed to another invasive diagnostic procedure for confirmation of the lesion type or to a more conservative regular imaging follow up with inconclusive results. Many previous studies on TNAB have focused on the diagnostic accuracy of the procedure (2-6,13,14). However, only a few studies have addressed the dilemma of inconclusive results (16,18). The aim of this study was to determine the factors affecting inconclusive results such as nonspecific, benign or nondiagnostic results after CT-guided TNAB and to evaluate the final outcome of these inconclusive results.

MATERIALS AND METHODS

1) Study population

Between June 2003 and August 2005, 337 consecutive patients had a CT-guided TNAB for tissue diagnosis of lung lesions at our hospital. We retrospectively reviewed the medical records, radiological images and pathology reports of these cases. Of the 337 patients who had a TNAB during the study period, a final diagnosis was made in 331, and six were lost to follow up. The final analysis included 331 cases. The study was approved by our institutional review board committee, and our committee does not require informed consent from individual patients in a retrospective study like this.

2) CT guided TNAB protocol

Two thoracic radiologists performed the CT-guided TNAB; they had eight and 12 years of experience in thoracic radiology. The biopsies were performed under CT guidance using an MX 8000 IDT scanner (Philips Medical Systems, Cleveland, Ohio, USA). At the time of biopsy, selected images of the target lesion were obtained by 3-mm-thick contiguous transverse CT sections. The procedure was performed with the patient in a prone, supine or lateral decubitus position, depending on the location of the lesion. Local anesthesia was administered by means of subcutaneous injection of 1% lidocaine (Xylocaine; Choongwae, Seoul, Korea). After the needle tip's position was confirmed to be in the lesion by CT scanning, aspiration or biopsy was performed with 22-gauge Westcott needles (MD TECH, Gainesville, FL, USA). If the tissue obtained was thought to be insufficient or an additional core biopsy was needed, the core biopsy specimen was obtained with a detachable 18- or 20-gauge automated cutting needle (ACECUT; TSK laboratory, Tochigi, Japan).

3) Classification of lung lesions

The lesion size was determined at the longest diameter of the lesion. The morphology of the lesion was classified as a nodule, a mass, consolidation, a cavitary lesion, or ground glass opacity (GGO) by two radiologists. The pulmonary lesion was diagnosed as a malignancy if the aspiration cytology or biopsy specimen showed malignant cells or was highly suggestive of a malignancy. If no malignant cells were found in the TNAB specimen, the lesions were classified into three groups according to the pathology reports: benign specific, benign non-specific or non-diagnostic (15,18). The benign specific diagnosis was used for TNAB results that led to a specific benign diagnosis such as hamartoma or tuberculosis. The benign non-specific diagnosis was used when there were no malignant cells and only inflammatory cells in the TNAB specimen. If the TNAB specimens were inadequate or insufficient for pathology examination, we defined the lesion as non-diagnostic.

4) Determination of final diagnosis

In cases with benign non-specific and non-diagnostic TNAB specimens, the final diagnosis was made according to the following criteria. If the patient had a surgical resection performed, the final diagnosis was made based on the pathology report of the surgical specimen. If there were positive microbiology results and the pulmonary lesions regressed after treatment, we diagnosed the lesion based on the microbiology results. If the lesion was clinically suspected to be pneumonia, and regressed after treatment with antibiotics, we diagnosed the lesion as pneumonia. If acid fast bacilli were seen in the specimen, culture or the polymerase chain reaction (PCR) for *mycobacterium tuberculosis* was positive, the lesion was diagnosed as mycobacterium tuberculosis. If a definitive diagnosis was not made after the TNAB specimen was evaluated,

the results of other tests such as bronchoscopic washing or biopsy were considered. If the lesion did not provide any specific diagnosis, and the size did not change during the follow up over 24 months or they regressed without treatment, the lesions were diagnosed as nonspecific inflammation.

5) Statistics

Statistical analysis was carried out with SPSS for Windows version 11.0 (SPSS Inc., Chicago, IL, USA). Statistically significant differences were identified using the chi-square test and the Yates correction. When the expected values were less than five, the Fisher's exact test was used. The independent student's t test was also used to compare means. The p-value for significance was set at $p<0.05$.

RESULTS

The study population included 221 men and 110 women with a median age of 63 years (range, 22～87 years). The mean size of the lesions was 29.4±5.2 mm (range, 5～90 mm). The pathology results of the first CT guided TNAB from 331 patients are presented in Fig. 1. Among the 331 pulmonary lesions, 210 were diagnosed as malignant, 59 specific benign, 50 benign nonspecific, and the remaining 12 were nondiagnostic. The final diagnosis of the pulmonary lesions is shown in Table 1. Of the 331 cases, 225 were finally diagnosed as malignant and 106 were benign (Table 1). Of the 210 cases diagnosed as malignant after the first CT-guide TNAB, there was one false positive case that was shown to be tuberculosis after surgical resection. Therefore, a correct conclusive specific diagnosis was made in 268 out of 331 cases by CT guided TNAB. The diagnostic sensitivity and specificity, for the malignant lesions, after the first trial of CT-guided TNAB were 92.9% and 99.1%, respectively. Overall, the diagnostic accuracy (the number of true positives and true negatives among the total number of cases) was 94.9%.

A comparison between cases, where the correct pathologic diagnoses were made or not made after the first CT guided TNAB is presented in Table 2. The final diagnosis of benign disease was significantly higher after the CT guided TNAB was inconclusive for lesions ≤15 mm that had consolidation type morphology. The mean size of the lesions was significantly different (30.7±15.3 vs. 23.5±13.5) in comparisons between the two groups. Other variables such as gender, mean age and age >50 did not correlate with a correct conclusive diagnosis.

The diagnostic algorithm for the 62 cases, initially classified after the first TNAB as inconclusive (benign nonspecific or

Table 1. The Final Diagnosis in the Study Population

Final diagnosis	Number (%)
Malignancy	225 (68.0)
Pulmonary tuberculosis	43 (13.0)
Pneumonia	25 (7.6)
Nonspecific inflammation	20 (6.0)
Other infection*	11 (3.3)
Hamartoma	4 (1.2)
Leiomyoma	1 (0.3)
BOOP	1 (0.3)
Sclerosing hemangioma	1 (0.3)

*Paragonimiasis, actinomycosis, Nontuberculous mycobacterial disease.
BOOP: bronchiolitis obliterans with organizing pneumonia.

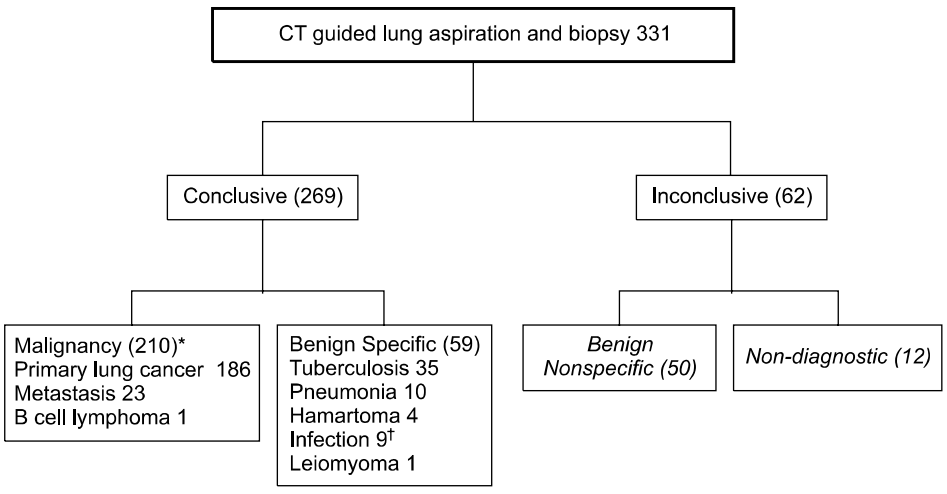

Fig. 1. Diagnostic algorithm of 331 patients with pulmonary lesions after a first trial of transthoracic needle aspiration and biopsy. *Including one false positive case of adenocarcinoma which proved to be tuberculosis after surgery, †Paragonimiasis, actinomycosis, nontuberculous mycobacterium included.

Table 2. Comparison of the Characteristics of the 331 Lung Lesions according to Whether the Correct Specific Diagnosis Was Made at the First CT Guided TNAB

Parameters	Number	Correct specific diagnosis		
		Success	Fail	p-value
Gender, M/F	331	184/85	37/25	0.189
Mean Age, yr		62.8±12.5	60.4±12.3	0.182
Age >50 yr	278	229	49	0.238
Final diagnosis				0.0001
Malignancy	225	209/225 (92.9)	16/225 (7.1)	
Benign	106	59/106 (55.7)	47/106 (44.3)	
Lesion morphology				0.0001
Nodule	124	90 (72.6)	34 (27.4)	
Mass	132	122 (92.4)	10 (7.6)	
Consolidation	32	20 (62.5)	12 (37.5)	
Cavitary lesion	24	21 (87.5)	3 (12.5)	
Ground glass opacity	19	15 (78.9)	4 (21.1)	
Lesion size, mean	331	30.7±15.3	23.5±13.5	0.001
Size over 15 mm	263	226 (85.9)	37 (14.1)	0.0001
Range of lesion size, mm				0.006
<10	12	6	6	
10~19	81	59	22	
20~29	85	70	15	
30~39	76	67	9	
40~49	38	32	6	
≥50	39	34	5	
Total	331	268	63	

Values are presented as number (%) unless otherwise indicated.
CT: computed tomography, TNAB: transthoracic needle aspiration and biopsy.

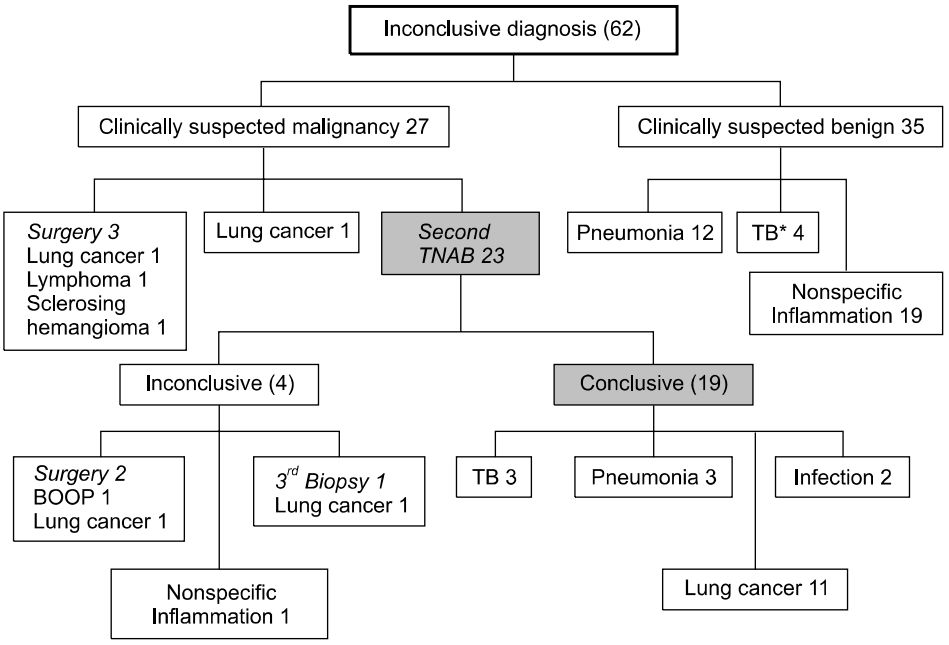

Fig. 2. Diagnostic algorithm of lung lesions with an inconclusive first CT guided TNAB result. TB: tuberculosis, BOOP: bronchiolitis obliterans with organizing pneumonia.

nondiagnostic), is shown in Fig. 2. Of these 62, 27 were clinically suspected to be a malignancy. Among these 27, a surgical lung resection was performed in three and a second CT-guided TNAB in 23. The remaining one patient refused further biopsy or surgery, and was observed with imaging follow up, and ultimately diagnosed with lung cancer. Of the

three who underwent surgical resection, one was diagnosed with lung cancer, one with lymphoma and one with a sclerosing hemangioma. Of the 23 who underwent a second TNAB, 11 were diagnosed with a malignancy, eight as specific benign lesions and four as inconclusive.

Therefore, a specific conclusive diagnosis was made in 19 (82.6%) of the 23 cases by a second CT guided TNAB. Of the four inconclusive cases that remained after the second CT guided TNAB, two had surgery and one had a third TNAB. The remaining one was observed by imaging follow up only, and finally diagnosed with nonspecific inflammation. Of the two who underwent surgical resection after the second CT guided TNAB, one had bronchiolitis obliterans with organizing pneumonia, and the other was confirmed to be lung cancer. In the remaining 35 cases thought to be benign, imaging follow up was performed. The final diagnoses were pulmonary tuberculosis in four, pneumonia in 12 and nonspecific inflammation in 19.

Finally, a malignancy was proven in 16 of the 62 cases (25.8 %) that were inconclusive after the first CT guided TNAB evaluation. Of the 62, a specific benign diagnosis was made in 26 (41.9%) cases. A comparison of cases that were finally proven to be malignant or benign is presented in Table 3. The mean size of the malignant lesions was different from the benign lesions and these differences were statistically significant (29.3±14.6 vs. 21.5±12.6 mm).

All 16 cases finally diagnosed as malignancies were suspected to be a malignancy clinically. There were significant correlations between (i) the malignancy and (ii) patient age over 50 or lesion morphology. However, gender, age, smoking, and lesions >15 mm were not significant predictors. Of the 62 cases with inconclusive diagnoses after the first CT guided TNAB, 20 patients were finally diagnosed with nonspecific benign inflammation. The characteristics of these cases and the outcome of the follow up of these 20 lesions are presented in Table 4. The follow up was from 3 months to 39 months. The lesion disappeared in two cases and decreased in size in four by CT follow up. The remaining 14 cases showed no significant changes over a follow up period of a minimum of 24 months.

The cumulative complication rate of initial and repeat TNAB was 13.1% (46/355). The total number of procedures was 355 and pneumothorax developed in 7.0% (25/355). A chest tube was inserted in 3 cases. A total of 5.3% (19/355) showed peri-lesional hemorrhage after the procedure. Both complications (pneumothorax and hemorrhage) developed in 0.8%. No serious complication developed.

DISCUSSION AND CONCLUSION

Our study showed that a correct conclusive diagnosis, either a specific malignant or benign diagnosis, was made in 268 of

Table 3. Comparison of Characteristics of the 62 Cases Where Malignancy or Benign Disease was Finally Diagnosed after an Inconclusive First TNAB

Parameters	Number	Malignancy	Benign	p-value
Patients, n	62	16	46	
Male	39	11 (68.8)	27 (58.7)	0.425
Mean ages, yr	62	62.1±7.7	58.6±13.2	0.066
Age >50 yr	50	16 (100)	34 (73.9)	0.026
Smoking				0.390
Current or ex smoker	37	11 (68.8)	26 (56.5)	
Nonsmoker	25	5 (31.3)	20 (43.5)	
Lesion morphology				0.037
Nodule	33	9 (56.3)	24 (52.2)	
Mass	10	6 (37.5)	4 (8.7)	
Consolidation	12	1 (6.3)	11 (23.9)	
Cavitary lesion	3	0	3 (6.5)	
GGO	4	0	4 (8.7)	
Lesion size (mean), mm	62	29.3±14.6	21.5±12.6	0.046
Lesion size >15 mm	37	13 (81.3)	24 (52.2)	0.074

Values are presented as number (%) unless otherwise indicated.
TNAB: transthoracic needle aspiration and biopsy, GGO: ground glass opacity.

Table 4. Characteristics of the Subjects Who Were Diagnosed with Non-specific Inflammation

Patient number	Age	Sex	Size (mm)	Underlying disease	Morphology	Smoking (py)	F/U duration (mo)	F/U results
1	63	F	5	Melanoma	Nodule	0	31	Nc
2	70	M	9		Nodule	40	27	Nc
3	45	M	5		Nodule	0	22	Decreased
4	65	F	8		GGO	0	21	Decreased
5	70	M	7	Lung cancer	GGO	90	14	Disappeared
6	74	F	10	Melanoma	Nodule	0	24	Nc
7	68	F	15		Nodule	0	3	Disappeared
8	62	F	10		Nodule	0	27	Nc
9	78	F	15		Nodule	0	22	Nc
10	62	F	15		Nodule	0	14	Disappeared
11	70	F	11	Lung cancer	Nodule	5	13	Decreased
12	48	M	13		Nodule	45	22	Decreased
13	49	M	10		Nodule	40	25	Nc
14	69	M	13		Nodule	120	31	Nc
15	60	M	10	Lung cancer	Nodule	120	31	Nc
16	35	F	27		GGO	10	25	Nc
17	67	F	32		Mass	0	24	Nc
18	62	F	35		Consolidation	0	36	Nc
19	60	M	30	Rectal cancer	Cavitary Lesion	40	33	Nc
20	55	M	33		GGO	30	26	Nc

Nc: no change, GGO: ground glass opacity, py: pack year.

331 cases after the first CT guided TNAB. The remaining 62 cases were diagnosed as inconclusive. Benign disease, lesion size $\leq$15 mm, and consolidation type morphology were correlated with inconclusive results. Twenty-three of the 62 inconclusive cases had a second CT guided TNAB, and a specific conclusive diagnosis was made in 19 (82.6%, 11 malignancies, 8 specific benign). Finally, malignancy was diagnosed in 16 of these 62 (25.8%). The risk of a malignancy among these cases with 62 inconclusive results was significantly correlated with age $>$50, lesion morphology, nodules or a mass. The mean size of the 16 malignant lesions was significantly different from the benign lesions.

According to the British Thoracic Society guidelines (8), the expected accuracy of a radiologically guided lung biopsy should be as follows. 1) The false positive rate should be less than 1%; 2) adequacy of sample should be more than 90%; 3) sensitivity for malignancy should be within the range of 85～90% in lesions over 2 cm; and 4) standards should be set and outcomes audited. Our study results fulfilled all of these criteria. There was only one false positive case for malignant lesions (0.48%). Inadequate or insufficient sampling occurred in 12 of the 331 TNAB procedures (3.6%). The sensitivity for malignant lesions of the first TNAB was 92.9%, and the specificity was 99.1%. Overall, the diagnostic accuracy (the number of true positives and true negatives among all cases) was 94.9%. Therefore, our results were consistent with the established guidelines.

In this study, the lesion size and the final diagnosis of a malignancy were factors that significantly affected the likelihood of obtaining conclusive results after CT guided TNAB. These findings are consistent with those of Yeow et al. (6) Although Wallace et al. (14) reported that small lesions that are 10 mm or less had a high diagnostic accuracy rate, most other studies showed a significant increase in diagnostic yield as the lesion size increased (5,19). Our study results confirm that CT guided TNAB had a high diagnostic yield for malignant lesions. Most studies have reported that the diagnostic sensitivity for malignant lesions with TNAB is 70～100% (10). Of the 62 patients with an inconclusive first CT guided TNAB result, 16 were finally diagnosed with a malignancy. This false negative rate was similar to previous reports (16,18).

In addition to the diagnosis of a malignant lesion, another important role for the TNAB is diagnosing specific benign disease (16,17,20). The confirmation of a non-malignant lesion makes it possible for patients to avoid unnecessary surgery.

Prior studies reported a remarkably high success rate for a specific diagnosis of benign disease after a transthoracic core biopsy (4,15,21,22). We also performed core biopsy for diagnosis of benign disease in a majority of patients. Only 2 among 59 benign specific cases, 1 among 50 benign non-specific cases, and 1 among 12 nondiagnostic cases had aspiration cytology only. Despite the use of a core biopsy, the diagnostic yield for specific benign disease was lower than in previous reports (4,15). Although there were no false negative cases, the sensitivity for benign specific disease was only 55.7%. The reason for this relatively low diagnostic yield for benign specific disease in our study is not clear, but pathology interpretation may play an important role. Hirose et al. (22) reported that 42 of the 48 pneumonia or pneumonia-like lesions were correctly diagnosed by CT guided TNB. In our study, the first CT guided TNAB results with the diagnosis of pneumonia were classified as inconclusive in 15 of 25. In addition, an atypical granuloma like lesion was classified as inconclusive in our study. These facts may explain why consolidation type lesions, which are pneumonia like lesions, were significantly correlated with inconclusive results in this study.

Our study also emphasizes the importance of repeat CT guided TNAB in lesions with inconclusive results. Nineteen of 23 second biopsies were diagnosed conclusively with specific disease, either malignant or benign. Khouri et al. (20), in their fluoroscopic biopsy study, also reported that 85 (13%) among 650 cases underwent a second biopsy. A specific diagnosis was made in 58 (68%) of the 85.

Despite a failed first TNAB result, in cases with clinically or radiologically suspected malignancy, it is important to get tissues. In our study, nodule or mass rather than consolidation, cavity and ground glass opacity on a CT image, larger size of the lesion and age over 50 years was significantly associated with a malignancy. Regarding an aspect of the pathologic results, Lee et al. (19) said repeat biopsy might be necessary when the initial biopsy shows necrosis, atypical cells, scanty cellularity or hemorrhage. Also, repeat biopsy might be considered in cases with unexpected pathologic results on initial biopsy. Therefore, we have to consider a second biopsy taking into consideration results of the first biopsy: clinical, radiological and pathological.

Twenty subjects were diagnosed with nonspecific inflammation. All of these cases were thought to have benign disease by radiological imaging and clinical judgment. Only one case underwent a second TNAB, which was also inconclusive. This case was finally diagnosed as nonspecific inflammation after long term follow up.

The remaining 19 cases with nonspecific inflammation were finally diagnosed as benign during regular imaging follow up for over 24 months. These findings suggest that if lesions are suspected to be benign, and the results of the TNAB are nonspecific with an adequate specimen, the lesion can be followed at regular intervals as suggested previously (19,23).

There are several limitations of our study. Since our study was a retrospective review of the medical record, we cannot exclude subjective decision making by the physician before the TNAB. There were no onsite pathologists during TNAB procedures in our study. Immediate feedback on an incomplete specimen may reduce the incidence of inconclusive TNAB results. The follow up period was not long enough to exclude the possibility of a malignancy in the cases reviewed. According to recent studies, some lesions with ground glass opacities do not show a size change for a long time, and later are diagnosed as bronchioloalveolar carcinoma or adenocarcinoma (24).

In conclusion, despite the common use of core biopsy, there are appreciable numbers of inconclusive results after the first CT guided TNAB. Benign disease, a lesion size $\leq$15 mm, and morphology of the consolidation type were features that were significantly correlated with inconclusive results. Repeat TNAB had a high diagnostic yield in these cases, and should be recommended, especially in cases thought to be a malignancy.

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