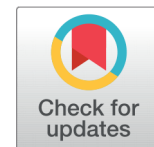


DIAGNOSTIC ACCURACY AND COMPLICATIONS RATE OF CT-GUIDED CORE NEEDLE LUNG BIOPSY OF SOLID AND PART-SOLID LESION: A SINGLE-INSTITUTION EXPERIENCE



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ABSTRACT

PURPOSE: The aim of this study was to retrospectively analyze the diagnostic accuracy and risk factors of complications of percutaneous CT-guided transthoracic lung core needle biopsy (CT-TTLB) by stratifying pulmonary lesions by their size and consistency. The secondary purpose of this study was to retrospectively evaluate the feasibility and safety of 1-hour patient discharge after (CT-TTLB).

METHODS: 170 lung biopsies were performed using a semi-automated true-cut needle. There were 116 (68.2%) male and 54 (31.8%) female patients, with a mean age of 60.9 ± 14.24 years (19–91 years). The mean lesion longest diameter was 6.08 ± 3.33 cm. The lesions were stratified into solid and part-solid lesions. Diagnostic accuracy and adequacy were calculated for all biopsies and for each group separately, as well as the incidence of complications. Complications were stratified into early (discovered within the first hour after biopsy) and delayed (after 1 hour of biopsy) to assess the safety of 1-hour discharge after (CT-TTLB).

RESULTS: The overall diagnostic accuracy was 80.6%, with no significant difference between small and large lesions, nor between solid and part-solid lesions. An adequate sample for next-generation sequencing (NGS) testing was obtained in 135 core biopsies (79.4%). The most frequent complication was perilesional intrapulmonary hemorrhage and the second most frequent complication was small pneumothorax; seen at a rate of 26% and 15.2% respectively. Large pneumothorax requiring chest tube placement occurred in one patient (1.1%). Most of the biopsy-related complications (98.9%) were discovered in the first hour of biopsy with only two patients presenting to the emergency with delayed incidence of pneumothorax, which were treated conservatively.

CONCLUSION: Diagnostic accuracy and adequacy were not affected by lesion characteristics or the number of samples. Larger gauge needles as well as smaller and deeply located nodules were found to have higher complication rates, compared to larger size, solid, and peripherally located masses. Early discharge after CT-TTLB was associated with little morbidity and no mortality.

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المخلص

الهدف من هذه الدراسة هو تحليل الدقة التشخيصية وعوامل الخطورة للمضاعفات في الخزعة اللبية الرئوية الموجهة بواسطة جهاز الأشعة المقطعية (CT-TTLB) من خلال تصنيف الأورام الرئوية حسب حجمها وتكوينها. والهدف الثانوي من هذه الدراسة هو تقييم الجدوى والسلامة لخروج المريض بعد ساعة واحدة من الخزعة الرئوية.

المنهجية:

تم إجراء 170 خزعة رئوية باستخدام إبرة شبه أوتوماتيكية القطع. تكونت العينة من 116 (68.2%) من المرضى من الذكور و 54 (31.8%) من الإناث، مع متوسط عمر 60.9 ± 14.24 سنة (91-19 سنة). وكان متوسط أقطار الأورام 6.08 ± 3.33 سم. تم تصنيف الأورام إلى أورام صلبة وأورام صلبة جزئياً. تم حساب الدقة التشخيصية والكفاية لجميع الخزعات ولكل مجموعة على حدة، بالإضافة إلى نسب حدوث المضاعفات. تم تصنيف المضاعفات إلى مبكرة (تم اكتشافها في الساعة الأولى بعد الخزعة) ومتأخرة (بعد ساعة واحدة من الخزعة) لتقييم سلامة خروج المريض بعد ساعة واحدة من إجراء الخزعة.

النتائج:

كانت نتيجة الدقة التشخيصية تساوي 80.6%، دون وجود فرق مؤثر بين الأورام الصغيرة والكبيرة، ولا بين الأورام الصلبة والأورام الصلبة جزئياً. تم الحصول على عينة كافية لاختبار تسلسل الجيل التالي NGS في 135 من الخزعات الأساسية (79.4%). كانت المضاعفة الأكثر شيوعاً هي نزيف حول الورم في الرئة، وكانت المضاعفة الثانية الأكثر شيوعاً هي الاسترواح الصدري؛ وكانت بمعدل 26.0% و 15.2% على التوالي. حدث لدى مريض واحد (1.1%) استرواح صدري مضاعف تطلب وضع أنبوب صدري في مريض واحد. تم اكتشاف معظم المضاعفات (98.9%) في الساعة الأولى من الخزعة، وتم علاج اثنين فقط من المرضى الذين تم عرضهم على قسم الطوارئ بعد ساعة من الخزعة، وتم علاجهما بشكل متحفظ.

الخلاصة:

لم تتأثر الدقة التشخيصية بسمات الأورام أو عدد العينات. تبين أن الإبر ذات القطر الأكبر والأورام الصغيرة والعميقة ارتبطت بمعدلات مضاعفات أعلى، مقارنة بالأورام ذات الحجم الأكبر والأورام الصلبة والأورام الواقعة في أطراف الرئة. نتج عن الخروج المبكر بعد الخزعة الرئوية الموجهة بواسطة الحاسوب المقطعي بنسب قليلة من المضاعفات وعدم وفاة أي مريض.

Keywords: Lung neoplasms, CT-guided percutaneous core needle biopsy, Computed Tomography.

1. INTRODUCTION

The increasing use of CT in clinical practice has led to increased detection of pulmonary masses and nodules. A pulmonary nodule is typically defined as a lung lesion that's less than or equal to three centimeters in diameter. On the other hand, a lung mass is regarded as a larger one that's over three centimeters in diameter [1].

The identification of malignant and benign pulmonary lesions is very important in order to reduce the likelihood of unnecessary surgical interventions, thus the next step is to get the tissue proof if lung lesion is suspected to be malignant. Percutaneous computed

tomography guided transthoracic lung biopsy (CT-TTLB) is a well-known and proven method for the evaluation of various pulmonary lesions [2]. It has been used for a long time to guide the treatment of these conditions. Its simplicity, minimal invasiveness and accuracy make it an ideal method for the evaluation of lung masses and nodules [3].

However, there are a number of potential complications with CT-TTLB that could raise the morbidity of patients. These complications include pulmonary parenchymal hemorrhage, with reported rates ranging from 1.3 to 62.1% [4–8], pneumothorax, which can occur in a wide range of 12.1–38.4% of patients [4–7, 9, 10], and haemothorax which is extremely uncommon and can occur in a range of 0.092 to 1.5% [5, 11, 12].

According to some previous studies reports, lesion size has a substantial impact on both the likelihood of complications and the accuracy of diagnosis. However, in other published data, lesion's diameter > 3.1 cm is also identified as a factor that decreases the diagnostic accuracy, primarily due to the higher rates of necrosis. On other hand, small lesion size is reported as a significant risk factor decreasing diagnostic accuracy and increasing incidence of complications [4, 13–16].

Along with lesion size, additional variables reported to affect diagnostic accuracy and complication incidence, including the lesion's nature and the radiologist's experience [4]. Solid and partially solid are common descriptions of lung lesions. Lesions that are partially solid are made up of both ground-glass and solid soft-tissue attenuation components [1].

Previous study stated that part-solid lesions had a much greater incidence of hemorrhage on the post-biopsy follow-up CT scan than solid lesions did, whereas pneumothorax and symptomatic major hemorrhage did not differ significantly between the two [16].

To our knowledge, most health care institutions reported observation periods for post CT-TTLB is to discharge stable and asymptomatic patients without complications in an average of 4 hours.

According to Carole and colleagues' study [17], there is no mortality and minor morbidity 30 minutes following outpatient CT-TTLB of the lung. Stevens and Jackman [18] reported that a pneumothorax rarely occurred during a one-hour chest radiograph.

In our institution, we perform 3 to 4 transthoracic trucut biopsy procedures per week. The procedure lasts around 15 to 30 minutes. The patient stays under observation for 60 minutes after the procedure, monitoring vital signs and patients' symptoms. A post procedure chest x-ray is obtained to evaluate for pneumothorax. If negative, the patient is discharged with routine post procedure instructions. On the other hand, if a small pneumothorax is encountered, a second radiograph 2 hours post procedure after asking the patient to ambulate under supervision to assess for hypoxia, shortness of breath or chest pain. If the pneumothorax is stable and the patient remains asymptomatic, discharge with

routine post procedure instructions is given. If the initial radiograph reveals a large pneumothorax or the patient is symptomatic a chest tube will be inserted. The current study aims to retrospectively analyze the diagnostic accuracy and risk factors of complications of percutaneous CT-guided core needle biopsy (CT-TTLB) by stratifying pulmonary lesions by their size and consistency, in addition to assess the feasibility and safety of 1 hour patient discharge after (CT-TTLB).

2. METHODOLOGY

Study design

- It's an observational descriptive cross-sectional study conducted at a single tertiary care hospital, King Fahad Specialist Hospital – Dammam. This study comprised 220 lung biopsies performed between June 1, 2015 and May 1, 2022. It is based on a review of histopathology records of patients who had CT-TTLB in our unit. All adult patients who had CT-TTLB during the study period were eligible for the study. 50 out of 220 patients were excluded. The exclusion criteria were extra pulmonary biopsies (mediastinum, pleura and chest wall), lung biopsies with no available histopathology reports and lung biopsies with no available CT-guided Biopsy images in PACS.
- Age, Gender, smoking status, Pre-existing lung disease, lung lesions characteristics, biopsy complications and pathology report results were collected from subjects' hospital records, radiology and pathology reports.

Ethical considerations

- The study was approved by King Khalid medical city IRB committee. The ethical review board did not require informed consent from the participants because the study was retrospective in nature. There was no specific grant for this research from any funding organization in the public, private, or nonprofit sectors.

Definitions:

- Diagnostic accuracy is defined as reaching cancer diagnosis whereas biopsy adequacy was defined as reaching a pathological diagnosis enough for Next-Generation Sequencing NGS testing.

Statistical analysis

- SPSS was used for all statistical analysis (Statistical Package for social sciences version 24.0). For all quantitative variables (such as age), descriptive findings are reported as mean \pm standard deviation, whereas number (percentage) is reported for all categorical variables (such as gender). All statistical analysis was done using two-tailed tests and an alpha error of 0.05. A P-value less than 0.05 was considered to be statistically significant. Chi-squared analyses were used as appropriate to evaluate the relationships between participants' characteristics and procedure and Fisher's exact test was used in case of the conditions were not fulfilled (when more than 20% of cells have expected frequencies $<$ 5). Independent Student T test was used to test the association between continuous variables and Independent Sample T Test correction was used if the equal variances were not assumed.

3. RESULTS

Table 1 shows that the study included 170 patients with an age range between 19 and 91 years with a mean of 60.9 years. More than half were male (68.2%). A total of 63 (37%) patients had underlying disease such as (57 emphysema, 2 fibrosis and 4 Combined pulmonary fibrosis and emphysema (CPFE)). The majority of the lesions were solid (87.6%) with necrosis (68.8%) (Table 2). For biopsy procedures, lesion longest diameter mean was 6.08 cm whereas the mean of needle path length between the pleura and target lesion was 1.12 cm. Only 4 (0.02%) patients returned to the ER within 2 weeks after discharge for biopsy related complications such as chest pain which was treated conservatively (Table 3). Figure 1 related the distribution of overall complications distribution, 101 (53%) patients had no early complications, 49 (26%) patients had early regional pulmonary hemorrhage, 26 (15%) had pneumothorax which did not require intervention (24 patients had early small pneumothorax and 2 delayed pneumothorax), only one patient (0.005%) needed chest tube insertion which was seen on the 1 hour post procedure radiograph, 13 (7%) patients had self-limiting mild to moderate hemoptysis and 4 (0.02%) patients suffered from other minor complications (3 chest pain and 1 shortness of breath). No significant difference in the complication rate was found when comparing solid and part-solid lesions in Table 5. Table 6 compare diagnostic accuracy and adequacy, and neither lesion nor patient characteristics showed a significant difference. Furthermore, the number of biopsy samples and complication were neither associated with accuracy nor adequacy.

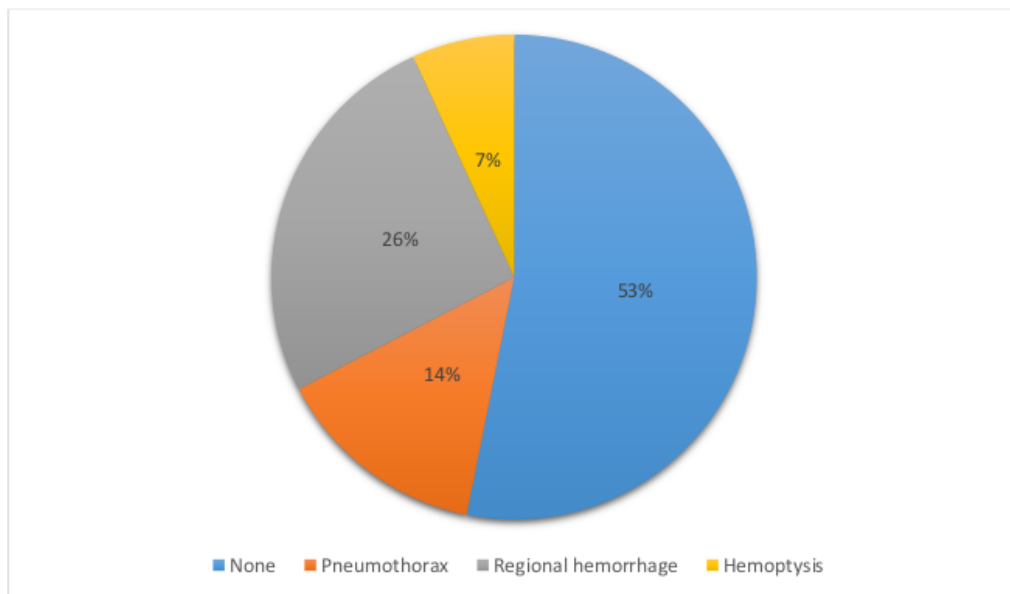


Figure 1 Post biopsy complication distribution

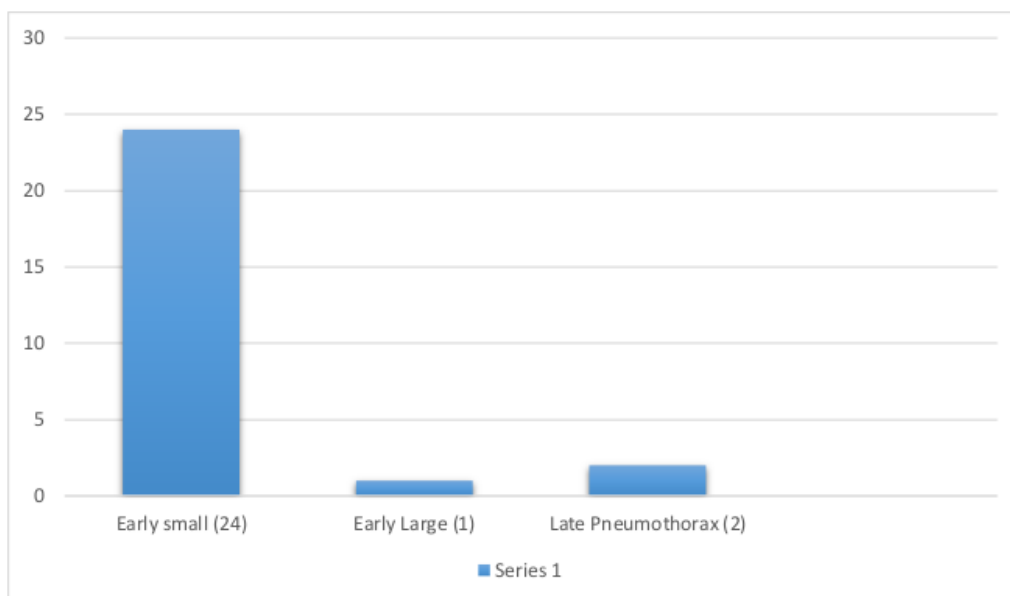


Figure 2 Pneumothorax distribution

Table 1 Patients' Demographics (N=170).

	Frequency
Male	116 (68%)
Female	54 (31.8%)
Age mean \pm SD	60.9 \pm 14.24 (Min:19 Max:91)
Pre-existing lung disease	63 (37.1%)
Emphysema	57 (33.5%)
CPFE	4 (2.4%)
Fibrosis	2 (1.2%)

Table 2 Lesion characteristics (N=170)

Part solid	21 (12.4%)
Solid	149 (87.6%)
Necrosis	117 (68%)
Lesion long axis (cm) mean \pm SD	6.08 \pm 3.33 (Min:1 Max:18)

Table 3 Biopsy details (N=170)

	Frequency
Needle Gauge	
18.0	4 (2.4%)
19.0	1 (0.6%)
20.0	164 (96.5%)
22.0	1 (0.6%)
Needle path length mean \pmSD	1.12 \pm 1.5 (Min:0 Max:8)

Table 4 Biopsy results (N=170)

Diagnostic accuracy	
Non-diagnostic sample	33 (19.4%)
Diagnostic sample	137 (80.6%)
Sample adequacy	
Not adequate for NGS testing	35 (20.6%)
Adequate	135 (79.4%)

4. DISCUSSION

Percutaneous CT-guided transthoracic lung core needle biopsy (CT-TTLB) is a widely accepted method for the evaluation of pulmonary lesions. Accuracy rates for lung lesions varied from 67.6% to 95.4%, according to some studies [4, 13–16]. The considerable variability may be linked to a number of variables, including the patient's characteristics, the performer's experience, the presence or absence of a bedside pathologist, and the choice of

Table 5 Comparison of solid and part-solid lesions in lung biopsies (N=170)

	Part-solid lesions N=21	Solid lesions N=149	P-value
Complications			
No	9(8.9%)	92 (91.1%)	0.099
Yes	12(17.4%)	57(82.6%)	
Diagnostic accuracy			
Non-diagnostic sample	4(12.1%)	29(87.9%)	1*
diagnostic sample	17(12.4%)	120(87.6%)	
Sample adequacy			
Not adequate for NGS testing	5(14.3%)	30(85.7%)	0.773*
Adequate	16(11.9%)	119(88.1%)	

*Fisher's exact test was used

Table 6 Comparison between diagnostic and non-diagnostic biopsy groups (N=170)

	Diagnostic N=137	Non-Diagnostic N=33	P-value
Pre-biopsy PETCT			
No	63(46%)	13(39.4%)	0.494
Yes	74(54%)	20(60.6%)	
Necrosis			
No	44(32.1%)	9(27.3%)	0.59
Yes	93(67.9%)	24(72.7%)	
Lesion character			
Part solid	17(12.4%)	4(12.1%)	1*
Solid	120(87.6%)	29(87.9%)	
Number of biopsy samples			
1-2	29(21.2%)	11(33.3%)	0.2
3-4	82(59.8%)	19(57.6%)	
>5	26(19%)	3(9.1%)	

*Fisher's exact test was used **Independent Sample T Test correction was used

biopsy tools. In our study, the overall biopsies' accuracy was 80.6% which was comparable to the results of earlier studies. Although not particularly high, this accuracy is sufficient considering the absence of a pathologist on site.

Numerous studies [5, 13, 14, 19] have reported that small lesion size is a risk factor that affects the diagnostic accuracy of CT-TTLB. No discernible difference in accuracy between small and large lesions was seen in our study. This has also been observed in a few earlier investigations [20, 21]. Nodules equal to or less than 20 mm were compared with nodules greater than 20 mm by Laurent et al. [20]. The diagnosis accuracy for small and bigger nodules, respectively, was 91% and 96.2%. No discernible difference was discovered. However, the skilled and experienced performers and on-site pathologists may be held responsible

Table 7 Comparison between adequate and non-adequate for NGS testing groups (N=170)

	Adequate N=135	Not adequate N=35	P-value
Pre-biopsy PET-CT			
No	63(46.7%)	13(37.1%)	0.313
Yes	72(53.3%)	22(62.9%)	
Necrosis			
No	43(31.9%)	10(28.6%)	0.709
Yes	92(68.1%)	25(71.4%)	
Lesion character			
Part solid	16(11.9%)	5(14.3%)	0.773
Solid	30(85.7%)	119(88.1%)	
Number of biopsy samples			
1-2	28(20.7%)	12(34.3%)	0.131
3-4	81(60%)	20(57.1%)	
>5	26(19.3%)	3(8.6%)	

*Fisher's exact test was used **Independent Sample T Test correction was used

Table 8 Rate of pneumothorax (N=170)

	No N=145	pneumothorax Post biopsy pneumothorax N=25	P-value
Pre-existing lung disease			
No	92(63.4%)	15(60%)	0.742
Yes	53(36.6%)	10(40%)	
Lesion composition			
Part solid	16(11%)	5(20%)	0.319*
Solid	129(89%)	20(80%)	
Longest diameter (cm) mean±SD	6.36±3.38	4.42±2.45	0.001**
Needle size			
18	2(1.4%)	2(8%)	0.005*
19	0(0%)	1(4%)	
20	143(98.6%)	21(84%)	
22	0(0%)	1(4%)	
Needle Pathway length	1.039±1.52	1.6±1.31	0.084

*Fisher's exact test was used **Independent Sample T Test correction was used

for the high accuracy outcomes and negligible accuracy difference between smaller and bigger nodules.

The differences in the diagnostic efficacy of CT-TTLB according to the presence of ground-glass opacity (GGO) part have been studied in several researches [22–24]. The diagnostic yields of CT-guided biopsy for part-solid lesions are much lower than solid lesions, according to Lee et al. [24]. However, Yun et al. observed contradictory findings,

notably that the diagnostic efficacy of CT-TTLB is unaffected by the GGO component proportion [25].

The diagnostic accuracy of solid and part-solid lesions was examined in this study, and there was no appreciable difference. Additionally, there was no discernible difference between solid and part-solid lesions in the frequency of inadequate NGS testing results.

For achieving the highest diagnostic accuracy, our typical practice is to obtain ≥ 3 samples. The overall biopsy sample results were non-diagnostic in 33 patients (19%) and insufficient for NGS testing in 35 patients (21%), while specific diagnosis was confirmed in 137 patients (81%) and adequate samples for NGS testing seen in 135 patients (79%).

Furthermore, the number of biopsy samples was not associated with accuracy nor adequacy. Our results are similar to AN, et al. study [26] that number of biopsy samples has no significant rule in diagnostic accuracy or adequacy.

In the Society of Interventional Radiology (SIR) Guidelines [22], complications are divided into minor and major. Pneumothorax without the need for intervention, pulmonary bleeding near the target, and hemoptysis with spontaneous hemostasis are examples of minor complications. Pneumothorax requiring medical attention, hemothorax, seeding of the needle tract, air embolism, and death are examples of major complications.

Pulmonary hemorrhage and small pneumothorax were the two complications that occurred most frequently in our study. The rate of pulmonary hemorrhage was 26%, and it was self-limiting and did not require further medical attention. Previous investigations found that the prevalence of pulmonary hemorrhage varied from 1.3% to 62.1% [4, 5, 7, 17, 26]. The high variety may be ascribed to various pulmonary hemorrhages that were accounted for by using various definitions, passing needle gauges, coaxial technique usage or non-usage, performance experience, and patient selection.

Regardless of the existence of hemoptysis, which some other studies used to define and account postprocedural bleeding rate, the current investigation defined pulmonary hemorrhage as perilesional or peri-needle-path ground glass opacity (GGO) or patchy opacity that was not evident in pre-procedure CT scans. Our study shows less pulmonary hemorrhage when compared to 62% in HUANG et al. Study [5] and 55.3% in AN, et al. [26] with the same intrapulmonary hemorrhage definition in present study. This could be explained due to using 18 G needle biopsy in both studies, which was considered as a significant risk factor in the present study.

In earlier studies, the pneumothorax rate varied from 12.1% to 38.4% [4-7, 9, 10]. The wide variety could be related to the varying passing needle gauges, variations in lesions' sizes, the employment of various procedure techniques, and variations in expertise. In our study, the overall pneumothorax rate was 15.8%. We assessed the likelihood of pneumoth-

orax occurrence in relation to the patient's age, sex, underlying preexisting lung disease (emphysema, fibrosis, or both), lesion longest diameter, the distance between the target lesion and the pleura, the number of biopsy samples, and the patient's position. Analysis of the pneumothorax risk factors revealed that smaller lesions (4.42 ± 2.45 cm), longer needle paths from the pleura to the target lesions, more biopsy samples, and larger needle sizes all contributed significantly to an increased risk of pneumothorax following CT-TTLB, which is consistent with findings from previous studies [9, 19, 21, 25, 26].

Preexisting lung diseases were mentioned as risk factors associated with pneumothorax development after CT-guided lung biopsy in some studies [13]. In our study, preexisting lung diseases were not associated with pneumothorax which correlated with the same results seen in other studies [4, 5, 26].

The rate of hemoptysis in our study is 7%, all cases were self-limiting and did not require intervention. Our results within the range of 2.1% to 8.4% seen in the previous studies [10, 13, 19, 23].

Numerous authors have questioned the optimal time to discharge a patient after CT-TTLB. To our knowledge, most health care institutions reported observation periods for post CT-TTLB is to discharge stable and asymptomatic patients without complications on average 4 hours.

According to Carole and colleagues' study [17], there is no mortality and minor morbidity 30 minutes following outpatient CT-TTLB of the lung. Stevens and Jackman [18] reported that a pneumothorax was rarely discovered in a one-hour post CT-TTLB chest radiograph in another trial with 447 biopsies. Early patient release following CT-TTLB reduces costs and provides more scheduling flexibility. Our study shows no significant number of delayed complications post 1 hour discharge, confirming safety of early discharge.

5. STUDY LIMITATIONS

The number of cases in this single-center, retrospective analysis is relatively small. Therefore, additional validation with a larger study population is needed for diagnostic yields and post-biopsy complication rates.

Another limitation of this study is the absence of a control group that would have allowed for a comparison between the conventional 4-hour post-biopsy observation period and the 1-hour observation period

6. CONCLUSION

Percutaneous CT-guided transthoracic lung core needle biopsy (CT-TTLB) are accurate with no significant difference in accuracy between small and large lesions, nor with solid and part-solid lesions. The most common complication is perilesional pulmonary hemorrhage followed by small pneumothorax, in which all patients were treated conservatively.

The smaller lesion size (4.42 ± 2.45 cm), longer needle path length from the pleura to target lesion, more biopsy samples, and larger needle size were the parameters linked to post-biopsy pneumothorax in our study. The results of the current study showed that discharging an outpatient CT-TTLB of the lung after an hour following lung biopsy is safe practice.

CONFLICT OF INTEREST

There is no conflict of interest to declare

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N/A

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