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OUTCOMES OF CT FLUOROSCOPY GUIDED FINE-NEEDLE ASPIRATION CYTOLOGY AND CORE NEEDLE BIOPSIES IN SOLITARY LUNG LESIONS

Radiology

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ABSTRACT

Introduction: The frequent and widespread use of imaging in clinical practice, particularly CT, has led to a steep increase in incidental findings of asymptomatic solitary pulmonary nodules. In this situation, histocytopathological analysis is needed to confirm the diagnosis by CT guided biopsy / FNAC. So, the researcher purposively, designed this study. The aim of this study was to assess the outcomes of CT-Guided Fine-Needle Aspiration Cytology and Core Needle Biopsies of Solitary Lung Lesions. CT-fluoroscopy guidance helps in this process by accurate needle positioning thus increase the success rate. **Materials and Methods:** This was a retrospective study conducted at the Department of Radiology & Imaging in Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, during January 2017 to January 2019.A total of 270 patients who were referred to the Department of Radiology& Imaging for the evaluation of suspicious solitary lung lesions after the detection of a solitary pulmonary nodule in X-ray or CT scan, were included in this study. The results of CT fluoroscopy–guided biopsy and FNAC for the included patients were analyzed to determine the diagnostic accuracy, complication rates, and independent risk factors for diagnostic failure and severe pneumothorax in this study. The factors related to the patients' solitary lesions, and procedures were evaluated by univariate analyses using the two-sided Student t test for numeric values and Chi-squared test for categorical values where $p<0.05$ considered as significant. Statistical analysis were performed using SPSS, version-23.0.**Results:** Diagnostic accuracy rate was 95.86%, failure was 4.14%, the overall sensitivity was 92.96%, specificity was 85.23% and the statistically significant risk factors wereage (p=0.001), sex(p=0.001), smoking stats(p=0.001) emphysema(p=0.001),benign lesions(p=0.001),positioning of the patient for the procedure(p=0.001),location of the lesion(p=0.001) lesion size(p=0.001) pneumothorax (p=0.001) and length from the pleura to the lesion of 1.5 cm or greater,(p=0.001).Pneumothorax requiring drainage occurred in 1.48% of patients. The potential risk factors for pneumothorax requiring drainage were age of 73 years, the presence of emphysema, lesion size $\leq$ 2.0 cm and length from pleura to lesion of $\geq$ 1.5 cm. The major complications were being observed pneumothorax 15(5.63%), haemoptysis16 (6.01%), and hemothorax 03(1.12%).**Conclusion:** CT-Fluoroscopy Guided Fine-Needle Aspiration Cytology and biopsy has a high diagnostic accuracy; complication rates were acceptable and comparable to those of previous studies.

KEYWORDS

CT- Fluoroscopy, Fine-Needle Aspiration Cytology (FNCA), Core Needle Biopsies, Pulmonary Nodule.

I. INTRODUCTION

The frequent and widespread use of imaging in clinical practice, particularly CT, has led to a sharp increase in incidental findings of asymptomatic solitary pulmonary nodules. Cytopathological / histopathological analysis is needed to confirm the diagnosis of these lesions. The usefulness of CT screening is an important public health issue. The detection of indeterminate nodules on CT scans indicates the need for further clinical evaluations, including follow-up CT, percutaneous FNAC / biopsy, and even thoracotomy.According to the World Health Organization (WHO), lung cancer is one of the leading causes of mortality all over the world. As of 2018, among the total cancer patients in Bangladesh, lung cancer patients were 8.2% and lung cancer was in the second position among all other types of cancers in Bangladesh[1].Although various randomized controlled trials, such as the National Lung Screening Trial[2] and the Danish Lung Cancer Screening Trial[3] have been reported, the usefulness of CT screening is an important public health issue. The detection of indeterminate nodules on CT scans indicates the need for further clinical evaluations, including follow-up CT, percutaneous biopsy, and even thoracotomy. Percutaneousbiopsy of lung nodules has been established as a safe and very useful diagnostic procedure, with high diagnostic performance and a diagnostic accuracy as high as 90%[4-9]. However, the diagnostic performance of percutaneous biopsy of indeterminate small nodules, which are usually detected on CT, has not been fully evaluated. In a few previous studies, the diagnostic performance of biopsy was analyzed after taking nodule size into account, including nodules smaller than 1 cm[10,11]. Moreover, there are very few studies and limited data in the national level of Bangladesh regarding outcomes of CT-Guided Fine-Needle Cytology Aspiration and Core Needle Biopsies of lung lesions. Hence, the researcher purposively designed this study. The aim of this study was to assess the outcomes of CT-Fluoroscopy Guided Fine-Needle Cytology Aspiration and Core Needle Biopsies of Lung Lesions.

II. OBJECTIVES

To assess the outcomes of CT-Fluoroscopy Guided Fine-Needle Cytology Aspiration and Core Needle Biopsies of Lung Lesions.

III. METHODOLOGY AND MATERIALS

This was a retrospective analysis conducted at the Department of Radiology in Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, during January 2017 to January 2019. The ethical clearance of this study was obtained from the IRB of BSMMU. A total of 270 patients who were referred to the Department of Radiology& Imaging for the evaluation of suspicious solitary lung lesions after detection of the pulmonary nodule by X-ray or CT scan were included in this study. Pathological (cyto/ histo) results of CT-Fluoroscopy guided lung FNA / biopsies were analyzed. All examinations were performed on the basis of clinician's advice.Normal platelet counts and coagulation parameters (e.g.

prothrombin time or activated partial thromboplastin time) were confirmed by recent hematological reports and it was ensured that patients had not taken any anticoagulants within 3 days before the procedure. Informed consent was obtained from all patients before all procedures.Before lung biopsy, all lesions were scanned using routine CT performed at a thickness of 2 mm (Toshiba Scanner, Prime Aquilion, Model TSX-303A). The maximum diameters of the lesions were measured on lung window settings. All FNAC &biopsies were performed by interventional radiologist. All procedures were performed percutaneously under CT fluoroscopy guidance. Fine needle aspirations were done with 23G Chiba needle and biopsies were done with 18G semiautomatic biopsy needle &coaxial system. Patients were placed in the prone or supine position, depending on the position of the, to provide the shortest route. The patient was instructed to stop breathing after normal inspiration at functional residual capacity before the procedure. The center of the lesion was positioned at the CT landmark using a radiopaque skin grid on the patient's skin. CT images were obtained again, and the puncture point was determined after measuring the distance from the skin surface to the lesion, the needle path length, and the smallest angle between the vertical line and the needle. At the needle puncture site, 5 mL of 2% lidocaine hydrochloride (Jasocaine, Jayson Pharma Ltd.) was administered subcutaneously and needle advanced upto the parietal pleura and sufficient local anesthesia were given to reduce pain. FNACs were done without any skin incision and needle advanced through puncturing the skin. After small skin incision, all biopsies were performed with a coaxial needle system consisting of a 17-gauge coaxial introducer needle (Mission Disposable Core Biopsy Instrument, BARD Biopsy Devices). The initial puncture was performed without penetrating the pleura. CT images were obtained to check the needle position, and needle tracks were chosen after carefully avoiding ribs, bullae, vessels and fissures. If the lesion was on the extended course of the needle track, the FNAC / biopsy procedure was continued; otherwise, the course or puncture site was changed. Then needle was gradually advanced under CT fluoroscopy guidance. After the lesion was penetrated, the needle tip was checked, and the biopsy was repeated multiple times by changing the direction of the coaxial needle within the lesion in the same session and specimens were immediately immersed in 10% formalin solution and were sent to the pathologist for examination. FNAs were done multiple fast jabbing movements of needle tip within the lesion. After the procedure, chest CT was routinely performed to detect pneumothorax or intrapulmonary hemorrhage. Patients with asymptomatic pneumothorax or intrapulmonary small hemorrhage were treated conservatively by monitoring vital signs, and follow up chest radiographs were obtained 2 and 5 hours after the procedure and again the next morning to confirm stability. We inserted a temporary drainage or indwelling chest tube in patients who had pneumothorax with signs of respiratory distress or shortness of breath. All patients were admitted to the hospital and discharged the day after an uneventful course. To determine the diagnostic accuracy, we classified biopsy diagnoses as malignant, benign, or nondiagnostic. Results were considered nondiagnostic if the procedure was terminated before specimen acquisition because of complications during the procedure. Diagnoses of malignant and benign disease were considered positive and negative results, respectively. A final diagnosis of benign disease was classified as a true-negative result if it was confirmed in the surgical specimen or the lesion regressed without anticancer therapy, or the lesion was stable in size for at least 12 months. Follow-up CT for patients with benign disease was scheduled 3, 6, and 12 months after the biopsy / FNAC to access the size of the lesion and compare with previous report whether size is increasing or stable. A final diagnosis of malignant disease was classified as a true- positive result. These malignant diagnoses were confirmed by the surgical specimen, similarities between the histology of the biopsy specimen and the patient's known malignancy of other organs, or postprocedural malignant processes. A typical adenomatous hyperplasia was included in the final diagnosis of malignant disease. A positive biopsy result was considered to be false-positive if surgical resection yielded a benign diagnosis,the lesion subsequently disappeared or decreased in size before surgical resection, or the lesion remained stable on follow-up CT for at least 12 months for cases in which the patient did not agree to surgical resection. A negative biopsy result was considered to be false-negative if surgical resection yielded a malignant diagnosis; the lesion increased in size; or other proven metastases were diagnosed on CT, MRI, or bone scintigraphy. True-positive and true-negative cases were considered diagnosed cases. The overall diagnostic accuracy was calculated using the following formula: diagnostic accuracy (%) = number of cases accurately diagnosed (true- positive + true-negative) / total number of cases (excluding nondiagnostic cases). We calculated the overall sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the diagnosis of malignancy. The factors related to the patients, lesions, and procedures were evaluated by univariate analyses using the two-sided Student t test for numeric values and chi-square test for categorical values where $p<0.05$ considered as significant.Statistical analyses were performed using SPSS, version-23.0. The inclusion and exclusion criteria of the enrolled patients were as follows:

- **Inclusion Criteria:** The patients having suspicious solitary lung lesions after the detection of a solitary pulmonary nodule in X-ray or CT scan
- **Exclusion Criteria:** The patients having lesions size <1 cm

IV. RESULTS

In this retrospective analysis a total of 270 consecutive patients who under went CT-Fluoroscopy Guided Fine-Needle Cytology Aspiration and Core Needle Biopsies of Lung Lesions were included between January 2017to January 2019 Among them 110 patient underwent biopsy while 160 patient underwent FNAC. (Table: I) shows the baseline characteristics of the studied patients. The mean age of the studied patients was 57.22±14.03. Among the patients, male were 199 (73.70%) and female were71 (26.29%).The meanlesion size (cm) was 2.3±1.6. The mean length of lesion from pleura (cm) was 2.5±1.1. The location of lesion was in upper lobe 152(56.29%), and followed by middle lobe 41 (15.18%), lower lobe 77 (28.51%).Nondiagnostic results were obtained in 04(1.48%) of 270 patients because the procedure was terminated before specimen acquisition due to progressive pneumothorax during the procedure. Of the remaining 266 patients , the diagnostic success rate was 255(95.86%) consisted of 180 true-positive results and 75 true-negative results and the diagnostic failure rate was 11(4.14%) consisted of 03 false-negative results, 04 non diagnostic results, and 4 false-positive result(Table II).(Table: III) shows the results of the univariate analysis to identify potential risk factors for diagnostic failure.The mean age of the success group was 59.0 ± 1.70 and the mean age of the failure group was58.5 ± 1.61($p=0.001$). The male patients in success group were 160(62.74%),and female were 95(37.25%) while in failure group, male patientswere 9(81.81%) and female were 2(18.18%) ($p=0.001$). In success group, non smokers were 85(33.33%) and smokers were 170(66.66%), while in failure group nonsmokers were 6(54.54%), and smokers were 5(45.45%)($p=0.001$). In success group, Emphysema, (Yes) were 55(21.56%) and (No) were 200(78.43%) while in failure group,(Yes) were 2(18.18%) and (No) were 9(81.81%)($p=0.001$). In success group, final diagnosis: benign was 55(21.56%) and malignant was 200(78.43%) while in failure group benign was 1(9.09%) and malignant was 10(90.90%)($p=0.001$). In success group, the mean lesion size (cm) was 2.40 ± 0.10 while in failure group, the mean lesion size (cm) was 2.40 ± 0.101.94 ± 0.36.($p=0.001$) In success group,lesion size cutoff,≤ 2.0 cm were128(50.19%) and >2.0 cm were 127(49.80%) while in failure group,≤ 2.0 cm were 9(81.81%) and > 2.0 cm were 2(18.18%)($p=0.001$). In success group,location of lesion in upper lobe were 98(38.43%), middle lobe were 98(38.43%) and lower lobe were 96(37.64%) while in failure grouplocation of lesion in upper lobe were 7(63.63%), middle lobe were 1(9.09%)and lower lobe were3(27.27%)($p=0.001$). The patients positioning for procedure, in success group, supine were 85(33.33%) and prone were 170(66.66%)while in failure group,supine were 4(36.36%) and prone were 7(63.63%)($p=0.001$). The mean length from pleura to lesion (cm), in success group was 1.71 ± 0.80, and in failure group was 15.6 ± 0.50($p=0.001$). The length from pleura to lesion cutoff,<1.5 cm in success group were 125(49.01%) and ≥ 1.5 cm were 130(50.98%) while in failure group,<1.5 cm were 8(72.72%) and ≥ 1.5 cm were 3(27.27%)($p=0.001$).Pneumothorax during procedure in success group, absent were 240(94.11%) and present were 15(5.88%), of them, mild were 08(53.33%), moderate were 03(20%) and severe were 04(26.66%), while in failure group, absent were 5(45.45%) and present were 6(54.54%)($p=0.001$). (Table: IV) shows the potential risk factors for pneumothorax requiring drainage. The potential risk factors for pneumothorax requiring drainage were male, age ≥ 73 years, emphysema 04 with lungs, lesion size ≤ 2.0 cm, length from pleura to lesion of ≥ 1.5cm. (Table-V) shows the complications of the studied patients. Among the observed complications, pneumothorax was 15(5.63%), haemoptysis were 16(6.01%), and hemothorax were 03(1.12%).Insertion of chest tube,(Yes) were 04(1.50%) and (No) were 262(98.50%). The overall sensitivity was (92.96%) and specificity was (85.23%).

Table-I: Baseline characteristics of the studied patients (n=270).

Characteristics	Value
Age (Years) mean ± SD	57.22±14.03

Sex:	
Male	199 (73.70%))
Female	71 (26.29%)
Lesion size (cm), mean ± SD	2.3 ± 1.6
Length of lesion frompleura(cm), mean ± SD	2.5 ± 1.1
Location of lesion:	
Upper lobe	152 (56.29%)
Middle lobe	41 (15.18%)
Lowerlobe	77 (28.51%)
Nondiagnostic	04(1.48%)

Table II: **Final diagnostic success and failure according to biopsy results (n=266).**

Diagnostic Success = (True-positive + true-negative results) = (180+75) =255(95.86%)
Diagnostic Failure = (Nondiagnostic + false-positive +false-negative results) = (04+04+03) =11(4.14%)

Table III: Results of Univariate Analysis to Identify Risk Factors for Diagnostic Failure (n=266).

Factors	DiagnosticSuccess n = 255(95.86%)	Diagnostic Failure n = 11(4.14%)	p-value
Age (years):			P<0.0001
Mean ± SD	59.0 ± 1.70	58.5 ± 1.61	
Sex:			P<0.0001
Male	160(62.74%)	9(81.81%)	
Female	95(37.25%)	2(18.18%)	
Smoking status:			P<0.0001
Nonsmoker	85(33.33%)	6(54.54%)	
Smoker	170(66.66%)	5(45.45%)	
Emphysema:			P<0.0001
Yes	55(21.56%)	2(18.18%)	
No	200(78.43%)	9(81.81%)	
Final diagnosis:			P<0.0001
Benign	55(21.56%)	1(9.09%)	
Malignant	200(78.43%)	10(90.90%)	
Lesion size (cm):			P<0.0001
Mean ± SD	2.40 ± 0.10	1.94 ± 0.36	
Lesion size cutoff:			P<0.0001
≤ 2.0 cm	128(50.19%)	9(81.81%)	
> 2.0 cm	127(49.80%)	2(18.18%)	
Location of lesion:			P<0.0001
Upper lobe	98(38.43%)	7(63.63%)	
Middle lobe or lingula of left lung	61(23.92%)	1(9.09%)	
Lower lobe	96(37.64%)	3(27.27%)	
Patient positioning for procedure:			P<0.0001
Supine	85(33.33%)	4(36.36%)	
Prone	170(66.66%)	7(63.63%)	
Length from pleura to lesion (cm):			P<0.0001
Mean ± SD	1.71 ± 0.80	15.6 ± 0.50	
Length from pleura to lesion cutoff:			P<0.0001
< 1.5 cm	125(49.01%)	8(72.72%)	
≥ 1.5 cm	130(50.98%)	3(27.27%)	
Pneumothorax during procedure:			P<0.0004
Absent	240(94.11%)	5(45.45%)	
Present: Mild Moderate Severe(sealed water)	15(5.88%) 08(53.33%) 03(20%) 04(26.66%)	6(54.54%)	

Table IV: Potential risk factors for pneumothorax requiring drainage(n=4)

- Sex, Male
- Age ≥ 73 y
- Emphysema 04 with lungs
- Lesion size ≤ 2.0 cm
- Length from pleura to lesion of ≥ 1.5 cm

Table-V: Complications of the studied patients. (n=266).

Variables	Frequency	%
Complication		
Pneumothorax	15	5.63
Haemoptysis	16	6.01
Haemothorax	03	1.12
Insertion of chest tube		
Yes	04	1.50
No	262	98.50

V. DISCUSSION

In this retrospective analysis of CT-Fluoroscopy guided lung FNAC & biopsies of 270patients.Inthis study, we evaluated diagnostic accuracy, complication rates, and risk factors for diagnostic failure and severe pneumothorax. In our study, we found the mean age of the patients was 57.22±14.03 years. Among the patients, male were 199 (73.70%) and female were 71 (26.29%). The mean lesion size (cm) was 2.3±1.6. The mean length of lesion from pleura (cm) was 2.5±1.1. The location of lesion was in upper lobe 152(56.29%), and followed by middle lobe 41 (15.18%), lower lobe 77 (28.51%). These findings of our studies were comparable to those of previous studies evaluating the diagnostic outcomes of conventional CT–guided lung biopsy[12-14]. In our study, we found the final diagnostic accuracy rate was 95.86%, the diagnostic failure rate was 4.14%.the overall sensitivity was 92.96% and specificity was 85.23%. We also observed the statistically significant risk factors were age, sex, smoking status, emphysema, benign lesions, positioning of the patient for the procedure, location of the lesion, lesion size, pneumothorax and length from the pleura to the lesion of 1.5 cm or greater,($p<0.05$). In our study,the potential risk factors for pneumothorax requiring drainage were male, age ≥ 73 years, emphysema 04 with lungs, lesion size ≤ 2.0 cm, length from pleura to lesion of ≥ 1.5 cm and length from pleura to lesion of ≥1.5 cm. The similar observation was found in some other previous studies[15-17]. In this present study, the major complications were being observed pneumothorax15 (5.63%), haemoptysis16 (6.01%), and hemothorax 03(1.12%). Insertion of chest tube,(Yes) were 04(1.50%) and (No) were 262(98.50%). The similar complications were observed in the study Ohbayashi C, et al and Ziakas PD, et al [18,19]. In our study, we found that lesion size (≤ 2.0 cm) is one of the risk factorsfor diagnostic failure. Tsukada et al.[18]reported diagnostic accuracies of 67% for lesions measuring 1.0 cm or smaller and 79% for lesions measuring 1.1–2.0 cm, and Hiraki et al.[17] reported diagnostic accuracies of 92.7% for lesions measuring 1.0 cm or smaller and 96.1% for lesions measuring 1.1–2.0 cm. In our study, diagnostic accuracies were 95.86.3% for lesions measuring 2.0 cm or smaller which were considerably higher than those of Tsukada et al,[18] who evaluated the results of conventional CT–guided needle biopsy, but are lower than those of Hiraki et al. [17] who evaluated the results of CT fluoroscopy–guided biopsy. CT fluoroscopy–guided biopsy can provide real-time visualization of the needle tip or lesion site; however, a major drawback of this technique is the high radiation exposure to the operator's hand[19,20]. We assume that our use ofCT Fluoroscopy, which shortens procedure time and minimizes the effect of patient movement due to breathing, contributed to the relatively high diagnostic accuracy for conventional CT–guided needle biopsy. The diagnostic failure group consisted mainly of false-negative results; therefore, the risk of diagnostic failure was higher for malignant lesions than for benign lesions. The higher risk of diagnostic failure associated with lesions in the upper lobe (63.63%) may be explained by breathing during the procedure. Increased motion of the upper lobe during respiration can cause displacement of the biopsy needle. This motion can be a problem particularly for women older than 65 years and men older than 75 years who have decreased respiratory muscle strength and difficulty holding their breath for long periods[21]. In the patients who developed pneumothorax, diagnostic failure was due to termination of the biopsy procedure. In previous studies[9-11], pneumothorax occurred in 8–69% of patients undergoing CT-guided lung biopsy, and pneumothorax requiring drainage occurred in 7–15% of patients. In our study,5.63%patients developed pneumothorax; however, we included cases of small asymptomatic pneumothorax,which may have overestimated the pneumothorax rate. Pneumothorax requiring drainage occurred in 1.48% of patients in our study, which is similar to

the results of previous studies [9-11]. Several studies have suggested that emphysema and deep lesion location increase the risk of pneumothorax [9-11]. In our study, risk factors for pneumothorax requiring drainage were age (≥ 73 years) and benign lesions. Elderly patients have a more difficult time following the breath-holding directions for our procedure than young and middle-aged patients. Four patients need pneumothorax requiring drainage yielded nondiagnostic results, indicating biopsy of normal lung tissue.

VI LIMITATIONS OF THE STUDY

This was a single center univariate study with a small sample size. So, the real scenario of lung cancer may not prevail in this study. So, multivariate analysis may be done with a large sample size. Moreover, as this study was a retrospective, unknown bias may include the limitations. In addition, multiple testing is associated with an inflated type 1 error rate. The final diagnosis for negative cases could not be established for most patients unless they underwent surgery.

VII CONCLUSION AND RECOMMENDATIONS

CT-Fluoroscopy guided Fine-Needle Aspiration (FNAC) and core needle biopsies have high diagnostic accuracy. The significant risk factors were age (p=0.001), sex (p=0.001), smoking status (p=0.001) emphysema a(p=0.001), benign lesions (p=0.001), positioning of the patient for the procedure (p=0.001), location of the lesion(p=0.001) lesion size (p=0.001) pneumothorax (p=0.001) and distance from the pleura to the lesion of 1.5 cm or greater, (p=0.001). Pneumothorax requiring drainage occurred in 1.48% of patients. The potential risk factors for pneumothorax requiring drainage were age of 73 years, the presence of emphysema, lesion size ≤ 2.0 cm and length from pleura to lesion of ≥ 1.5 cm. The major complications were being observed pneumothorax, hemoptysis and hemothorax.

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