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PERCUTANEOUS CT-GUIDED CORE BIOPSY OF PULMONARY LESIONS PERFORMED BY RESPIRATORY PHYSICIANS IS SAFE WITH GOOD DIAGNOSTIC YIELD.

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ABSTRACT

Aims: To evaluate the rate and associating factors of diagnostic yield and complications of percutaneous CT-guided core biopsy performed by respiratory physicians and fellows in respiratory training. **Methods**: A retrospective analysis was performed on 99 consecutive patients who underwent percutaneous CT-guided core biopsies performed by respiratory team between 01 January 2016 and 31 August 2018. Diagnostic yield and complication rate were calculated. Demographic and clinical data, pathology results and outcomes were analysed to evaluate the factors associated with diagnostic yield and occurrence of complications. **Results**: The diagnostic yield was 82.8% (82/99) and the complication rate was 28.3% (28/99), of which only 3 cases out of the 28 were classed as major complications requiring interventional procedures. There was no cases of mortality. Using multivariate analysis, only operator's experience (more than 6 years) was associated with diagnostic yield and occurrence of complications was associated with number of needle passes, length of needle path and if needle passing through aerated lung. **Conclusion**: Percutaneous CT-guided core biopsy of intrathoracic lesions performed by respiratory physicians with minimal 6 years of experience, in our centre is safe and feasible, with good diagnostic yield.

Keywords: **Complications, Image-guided biopsy, Lung Neoplasms, Pulmonary nodules, Pulmonologists.**

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Keywords: **Complications, Image-guided biopsy, Lung Neoplasms, Pulmonary nodules, Pulmonologists.**

INTRODUCTION

In the diagnostic work-up for peripheral and mediastinal intrathoracic lesions, tissue biopsy is mandatory. It can be obtained via surgical biopsy or less invasively, by percutaneous Computed tomograph (CT)-guided biopsy or by advanced bronchoscopic techniques such as endobronchial ultrasound (EBUS) guided biopsy and navigation biopsy.[1-6]

Percutaneous CT-guided biopsy has been widely used since first described in 1976 and has well documented excellent diagnostic yield and acceptable complication rate.[7-8] It is usually performed by interventional radiologists but for centres without such speciality, respiratory physicians can be trained to perform the procedure. However, the feasibility and safety of the procedure being conducted by respiratory physicians are not well documented especially in Malaysia. Hence, the present study was aimed at determining the diagnostic yield and rate of complications of the procedure performed by respiratory physicians in routine clinical practice in our centre.

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MATERIAL AND METHODS

This is a retrospective study of 99 patients who underwent percutaneous CT-guided core

biopsy at Penang General Hospital (a tertiary referral hospital in Penang, Malaysia with over 1000 beds) between January 2016 and August 2018. The study was conducted in accordance with the Declaration of Helsinki and was reviewed and approved by the Medical Research Ethics Committee (NMRR-19-404-47003).

Respiratory physicians had been performing percutaneous CT-guided biopsy since the year 2006 in this centre. During the study period, all the procedures were performed by one of the four consultant respiratory physicians who had been trained to perform the procedures and two fellow trainees under supervision.

All procedures were conducted under CT guidance (Siemens SOMATOM Definition AS 64-slice computed tomography system, Siemens Healthcare, Erlangen, Germany). Before the procedure, all patients were fasted for at least 6 hours. After instructions regarding the need for a breath-hold during inspiration or expiration were given, patients were positioned in supine, prone, or decubitus, depending on the location of the lesions. CT scanning was performed with a slice thickness of 2.4 mm to determine the best needle trajectory to target the lesion, considering both the need for diagnostic accuracy and complications. After sterilization of the target site using betadine, local anaesthesia was administered at the needle entry site. Depending on the judgement and preference of the operator, biopsy needle of size 16, 18 or 20-gauge (Unicore; Medax Medical Device, San Possidonio, Italy) was inserted into the target lesion, and then a CT scan was performed to identify the exact location of the needle tip within the target lesion. The length of all needle sets was 10cm. The core biopsy specimens obtained were placed in 10% formalin for pathologic examination. An immediate post-procedural CT scan was performed to identify biopsy-related complications. Patients were observed in wards for 4 to 6 hours before discharged.

The study primary outcome was diagnostic yield of the core biopsy and was considered positive if the pathologists reported satisfactory specimen with definite pathologic diagnoses. It was considered non-diagnostic yield if non-specific findings such as fibrocartilaginous lesions, inconclusive or sub-optimal tissue were reported.

Secondary outcome of interest for the study were procedural complications such as pneumothorax and pulmonary haemorrhage. Pulmonary hemorrahage was defined as perilesional or peri-needle-path ground glass opacity or patchy opacity on post procedure CT scan that was not seen prior to the procedure. A complication was considered as minor if patient was asymptomatic and only required conservative management. If a complication required active management such as intubation, chest tube insertion, or blood transfusion, it was classified as major.

Data analysis was performed using SPSS software (version 21.0; SPSS Inc., Chicago, IL, USA). Overall diagnostic yield and complication rates were calculated by dividing the number of procedures that resulted in a diagnostic yield and number of patients with complications divided by the total number of procedures.

The clinical and procedural factors such age and gender of patient, size and site of the lesion (lower lobe or others), operator experience (more or less than 6 years), needle size (16, 18 or 20-gauge), length of needle path and number of needle passes were collected and analysed with regard to the diagnostic yield using simple and multiple logistic regression. For analysis of occurrence of complications, factors of needle passing through aerated lung and concomitant presence of bullae/emphysema were also added.

RESULTS

The demographics of the patients, characteristics of lung lesions and procedural factors are summarized in Table I (n = 99). The mean age of the patients was 62.5 ± 11.9 years and 73.7% (n = 73) were male. Most of the lesions were located in the upper lobe (62.6%) and the mean size of the lesions was 5.94 ± 2.72 cm. There were nine patients (9.1%) with concomitant bullae. The needle pathway for biopsy from skin to lesion had a mean length of 3.46 ± 1.442 cm and 24 cases had needle passing through aerated lung. In terms of needle size, 16 Gauge needles were used in 12 patients (12.1%), 18 Gauge needles were used in 75 cases (75.8%), and remaining 12 patients (12.1%) used the 20-Gauge needles.

Diagnostic yield were achieved in 82 patients (82.8%) and non-diagnostic yield were reported in 17 patients (17.2%). Primary lung carcinoma was the most common diagnosis (60.6%) followed by secondary metastases (13.1%) and granulomatous lesions (tuberculosis) at 5.1% (Table II).

There were 28 patients with procedural complications (Table I: 28.3%; 9 pneumothoraces, 18 pulmonary haemorrhages and 1 with both pneumothorax and pulmonary haemorrhages), but only three patients (3.0%) required post-procedural interventions consisting of chest tube insertion in 2 patients with pneumothorax and one patient requiring blood transfusion and close monitoring for pulmonary haemorrhage. There were no mortalities.

Only operator's experience of more than 6 years (p=0.035) was found to be significant factor associated with a positive diagnostic yield outcome on both simple logistic regression (Table IIIa) and on multiple logistic regression (Table IVa: OR 3.39; 95% CI, 1.09 to 10.51 ; p=0.035).

Table I: Characteristics of Patients undergone Percutaneous CT guided Biopsy.

Characteristics of patients (n=99)	mean (SD)	n(%)
Age (in years)	62.5 (11.93)	
Male gender		73 (73.7)
Ethnicity		
Malay		23 (23.2)
Chinese		65 (65.7)
Indian and others		11 (11.1)
Site of the lesion		
Upper Lobe		62 (62.6)
Lower Lobe		24 (24.2)
Mediastinum		5 (5.1)
Lingula		4 (4.1)
Middle Lobe		4 (4.1)
Size of the lesion in cm	5.94 (2.722)	
Needle Path length in cm	3.46 (1.442)	
Number of Passes Made	3.4 (0.91)	
Needle Size used		
16 G		12 (12.1)
18 G		75 (75.8)
20 G		12 12.1)
Needle pass through Aerated Lung		24 (24.2)
Presence of emphysema/ bullae		9 (9.1)
Optimal Diagnostic Yield		82 (82.8)
Total Complications		28 (28.3)
Minor complications (no intervention)		
Pneumothorax		7 (7.1)
Pulmonary haemorrhages		17 (17.2)
Both pneumothorax and pulmonary haemorrhages		1 (1.0)
Major complications (blood transfusion or chest drain insertion)		
Pneumothorax		2 (2.0)
Pulmonary haemorrhages		1 (1.0)

The size of lesion (*p=0.001*), number of needle passes (*p=0.001*), length of needle path (*0.001*) and route of needle pass through aerated lung (p<0.001) were significant risk factors for pulmonary complications

Table II: Summary of CT guided Biopsy Results

Diagnosis	n(%)
Primary Lung Malignancy	60 (60.6)
Lung Metastasis	13 (13.1)
Granulomatous Lesion (Tuberculosis)	5 (5.1)
Thymoma	2 (2.0)
Lymphoma	1 (1)
Aspergilloma	1 (1)
Non-diagnostic	17 (17.2)

on univariate analysis (Table IIIb). However, on multivariate analysis, only the number of needle passes (OR, 0.33; 95% CI, 0.14 to 0.78 ; p=0.011), and route of needle pass through aerated lung (OR, 39.00; 95% CI, 8.60 to 176.79 ; p<0.001) remained as significant predictive factors for pulmonary complications (Table IVb).

Table III: (a) Factors Associated with Diagnostic Yield and (b) with Procedural Complications of the CT-guided Core Biopsy (using simple logistic regression).

Factors		Crude OR	(95% CI OR)	X^2 stat. (df)[a]	P value[a]
(a) Factors Associated with Diagnostic Yield of the CT-guided Core Biopsy					
Age (year)		1.06	(1.01, 1.11)	7.16 (1)	***0.010***
Gender	**Female**	1.19	(0.35, 4.05)	0.08 (1)	0.770
	Male	1.00			
Site of Lesion	**Others**	2.68	(0.89, 8.07)	2.93 (1)	0.080
	Lower Lobe	1.00			
Size of lesion (cm)		1.12	(0.91, 1.38)	1.14 (1)	0.300
Operator's Experience	**> 6 years**	3.38	(1.09, 10.51)	4.88 (1)	***0.035***
	< 6 years	1.00			
Number of needle passes		1.00	(0.56, 1.79)	0.00 (1)	0.998
Length of the needle path (cm)		0.915	(0.64, 1.31)	0.24 (1)	0.623
Needle Size	**20 Gauge**	0.48	(0.06, 4.05)		
	18 Gauge	0.18	(0.02, 1.95)	2.69 (2)	0.256
	16 Gauge	1.00			
(b) Factors Associated with Procedural Complications of the CT-guided Core Biopsy					
Age (year)		1.01	(0.97, 1.05)	0.28 (1)	0.601
Gender	**Female**	0.92	(0.33, 2.49)	0.03 (1)	0.858
	Male	1.00			
Site of Lesion	**Others**	0.44	(0.17, 1.17)	2.67 (1)	0.099
	Lower Lobe	1.00			
Size of lesion (cm)		0.67	(0.53, 0.84)	15.97 (1)	***0.001***
Operator's Experience	**> 6 years**	0.55	(0.23, 1.33)	1.79 (1)	0.184
	< 6 years	1.00			
Number of needle passes		0.36	(0.20, 0.67)	12.96 (1)	***0.001***
Length of the needle path (cm)		1.87	(1.31, 2.66)	14.46 (1)	***0.001***
Needle Size	**20 Gauge**	4.28	(0.52, 35.22)		
	18 Gauge	11.0	(1.06, 114.09)	5.47 (2)	0.106
	16 Gauge	1.00			
Presence of Aerated Lung	**Yes**	41.88	(11.41, 153.65)	45.38 (1)	***<0.001***
	No	1.00			
Presence of Bullae	**Yes**	0.275	(0.07, 1.11)	3.26 (1)	0.07
	No	1.00			

Footnote: Crude OR = Crude Odds Ratio

Table IV: (a) Factors Associated with Optimal Diagnostic Yield and (b) with Procedural Complication of CT-guided Core Biopsy (using multiple logistic regression).

Factors		Crude OR	(95% CI OR)	X^2 stat. (df)[a]	P value[a]
(a) Factors Associated with Optimal Diagnostic Yield of the CT-guided Core Biopsy					
Age (year)		1.13	(1.05, 1.21)	17.60 (1)	***0.001***
Site of Lesion	**Others**	6.34	(1.46, 27.66)	6.55 (1)	***0.014***
	Lower Lobe	1.00			
Operator's Experience	**> 6 years**	10.82	(2.17, 53.91)	11.21 (1)	***0.004***
	< 6 years	1.00			
(b) Factors Associated with Procedural Complications of the CT-guided Core Biopsy					
Number of needle passes		0.33	(0.14, 0.78)	7.86 (1)	***0.011***
Length of the needle path (cm)		1.62	(1.00, 2.64)	4.00 (1)	0.050
Presence of Aerated Lung	**Yes**	39.00	(8.60, 176.79)	31.67 (1)	***<0.001***
	No	1.00			

Footnote: Adj. OR = Adjusted odds ratio [a] = Likelihood Ratio (LR) test

DISCUSSION

The present study showed that percutaneous CT-guided core biopsy performed by respiratory team in our centre had an acceptable diagnostic yield and complication rates. Our diagnostic yield is above the suggested threshold yield of 75% and occurrence of pneumothorax complication rates were within the estimated rates of 12% to 45% set by the Society of Inteventional Radiology Guidelines.[9]

Most published data of percutaneous CT-guided core biopsy were those performed by interventional radiologists and they reported diagnostic yield ranging from 80.7% to 96.9% and complication rates between 5.7% and 64%.[8,10-15] It is notable that there are many centres that performed better and safer compared to us. It may not just due to the fact that the interventional radiologists are performing the procedures, but it may also be due to patient type, experience of the operator, availability of advanced equipment such as fluoroscopy and PET/CT machine, better tools (co-axial needles) and availability of on-site pathologist.[10-18] Procedures performed by a respiratory physician in a centre in Korea had reported a very high yield of 96.9% but the complication rates were higher than us at 33.1%.[8]

As expectedly, we found that operator's experience to be a significant independent factor for diagnostic yield, in agreement with previously reported study.[13] Other studies had also reported site of the lesion as a significant predictor to diagnostic yield. Lesions in lower lobe pose a greater challenge to achieve diagnostic yield.[12,13] However, we did not find statistical significance in our analysis. A further prospective study to investigate this relationship is indicated.

Also, the size of the lesion was not found to be independent risk factor in our study in contrary to other analysis.[19] This can be explained by our patient selection as patients with smaller lesions (less than 2 cm) who are technically more challenging are excluded as they are referred to interventional radiologist.

The most common complications of the procedure were pneumothorax and pulmonary haemorrhage. Pneumothorax was only reported in nine patients (10.1%), which was much lower than previously reported rates of 17.7% to 49.3%.[8-16] In terms of pulmonary hemorrhage, we reported 19.2% of cases but only one case required treatment in the form of blood transfusion and close monitoring. The rate of pulmonary haemorrhage

reported in the literature varied widely from 30% to 65.6% but it is not an indication of poorer outcome and rarely requires intervention.[20,21]

Greater number of needle passes, longer length of needle pathway and needle passing aerated lung were significant risk factors of the occurrence of overall complications in keeping with many other studies.[19,20,22] This is usually due to displacement of biopsy needles to adjacent tissues or structures during spontaneous breathing.[23] Many authors had advocated for the usage of co-axial needles to address this but this is not availabled in our practice.[24,25]

This study has several limitations. The study is limited to patients who had been preselected by the respiratory physicians taking into account the technical difficulties and hence may introduced some degree of selection bias. We did not perform a sample size calculation prior to the study as we have included all cohort included in the 2.5 years study period. However, sample size of 99 may still be considered a small sample size and extending the study period may alleviate this limitation. It is quite evident that there are many other important factors such as smoking history, position of patients, angle of needle and final tissue diagnosis were not included. A further study to explore the specific factors associated with good diagnostic outcome and complication rates is indicated.

In our multiple logistic regression analysis, the age variable was found to be non-linear hence categorization has been done. We had decided for cut off at 65 years old as it correlates with the categorization of elderly person in Malaysia.[26]

CONCLUSION

In conclusion, the study found that in a group of well selected patients, percutaneous CT-guided core biopsy performed by respiratory physicians with at least a minimum of 6 years experience can achieve good diagnostic yield and acceptable safety profile. This can have implications on privileging of doctors to perform invasive procedure in our centre.

DISCLOSURE

All authors have contributed to the manuscript equally. None of the authors have direct or financial conflicts of interest with this paper and material contained herein.

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