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Research Article

IDENTIFYING FACTORS THAT TEND TO INFLUENCE DIAGNOSTIC YIELD AND COMPLICATION RATES OF COMPUTED TOMOGRAPHY GUIDED FINE NEEDLE ASPIRATION CYTOLOGY FOR DIAGNOSING MEDIASTINAL AND PULMONARY LESIONS

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A B S T R A C T

Computed Tomography (CT) guided Fine Needle Aspiration Cytology (FNAC) for diagnosing mediastinal and pulmonary lesions is a procedure in which CT images are employed to precisely locate the lesion, measure its size, assess its distance from the skin surface and finally to decide the positioning of the patient and type of the needle to be used for the procedure. It is an advanced investigation modality employed for obtaining aspirates pulmonary lesions, either as a first-line diagnostic procedure, or following non-diagnostic bronchoscopy or sputum cytology. CT guidance allows performance of fine needle aspiration cytology in all such situations where ultrasound or conventional X-rays cannot correctly visualise the lesion or the needle tract.

Obtaining a detailed cytopathological analysis report of the aspirate obtained upon FNAC is thus considered to be a dependable approach. Literature is replete with studies that have established the diagnostic accuracy of this procedure. the sensitivity reported to be as high as 76% to 97% while complication rates range from 5% to 61%. While it has been reported that sensitivity and specificity falls significantly if the lesion size is <2 cm and distance of the lesion from skin surface >5 cm. Other reports show that lesions 1.0 cm or smaller can yield good diagnostic accuracy rates as well. Pneumothorax and hemoptysis or pulmonary hemorrhage are reported to be the most common post-procedural complications encountered. Biopsy of central lesions, especially those in the mediastinum, have been found to be more often associated with pneumothorax, while lesions near the hilar region with hemorrhagic complications.

The present study was carried out with an aim to identify the factors that tend to influence the diagnostic yield and complication rates of this procedure as performed at our hospital, to compare the diagnostic accuracy and complication rates of this procedure with previously documented studies and to assess the feasibility of carrying out this procedure in our hospital setting. This single-centre study on 200 patients incorporated a combined retrospective analysis of hospital records of 150 patients subjected to CT-guided FNAC for mediastinal or pulmonary lesions; and a prospective analysis on 50 patients over the period of 2 years.

The overall accuracy of the procedure was found to be 92.5%. The overall sensitivity was found to be 94.03% while specificity was found to be 100% as there were no false positives. Out of the 200 patients who were evaluated in this study, 22 developed post-procedural complications. Thus, the complication rate as found in our study was 11%.

From the results of the study we can conclude that advancing age, female sex, left sidedness of the lesion, prone positioning of the patient during procedure, do not lead to any increase in complication rates of CT guided FNAC All complications developed as a result of the procedure are not life threatening and can be easily managed on an in-patient basis. CT FNAC is a very safe and accurate procedure, thus it is totally feasible to carry it out on a regular basis in tertiary care hospital setting.

INTRODUCTION

Trans-thoracic needle biopsy of lung, mediastinal, pleural and chest wall masses has evolved as a result of advancement in image intensifiers and cross-sectional imaging modalities. Fine needle aspiration for diagnosing lung carcinoma was used for the first time by Menetrier while Haaga and Alfidi reported the first CT-guided biopsy in 1976 [1].

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It has been established that with CT, mediastinal masses can be recognised more easily and their localisation as well as relationship to other organs or their extension can be revealed to a good extent, especially in cases where conventional modalities like X-ray, fluoroscopy, ultrasonography are less accurate [2-5]. Clues to the type of tissue may also be obtained upon CT evaluation itself to some extent, but specific diagnosis usually remains unclear till definite cyto-pathological evaluation [6].

Even though studies mention the efficacy of alternate procedures such as biopsy through suprasternal route or trans-

sternal route [7] for lesions in pre-tracheal, right paratracheal and pre-vascular compartments of superior mediastinum. Over the years, percutaneous CT-FNAC has carved a niche for itself, well above other modalities and has almost replaced open biopsy and mediastinoscopy [8-11]. Needle biopsies employing the use of fine 20, 22 gauge or Chiba needles are a well- established investigation modality for diagnosing palpable and non-palpable masses or lesions anywhere in the body. For deep seated lesions imaging modalities become an absolute necessity in order to guide the diagnostic procedures [1-5,12-14].

Pulmonary lesions, either solitary or multiple, are an example of such non-palpable, deep-seated lesions located in the thoracic cavity.The differential diagnosis for these lesions is broad, including tuberculosis, benign cysts, adenocarcinoma, small cell carcinoma, non small cell carcinoma, squamous cell carcinoma etc. [3,15-17]. It is thus essential for a clinician to have an accurate confirmatory diagnosis of the lesion before outlining the course of treatment.This is of utmost importance in cases where the lesion is found to be malignant [18-20], as the prognostic and treatment outcomes of the two most predominant lung cancers i.e. small cell carcinoma and non small cell carcinoma are entirely different. In such cases, even if the exact histology or cell type of the lesion cannot be established, it is sufficient enough to differentiate small cell carcinoma from non small cell carcinoma, in order to decide the treatment regimen. Obtaining a detailed cyto-pathological analysis report of a lesion is thus considered to be a dependable approach [1-5, 21].

Core biopsy is effective in the diagnosis of pulmonary and pleural diseases but its diagnostic yield in mediastinal masses is rather low [22-24]. Fine needle aspiration under local anesthesia is found to be more effective in evaluating anterior mediastinal masses as reported [18]. Computed Tomography (CT) guided Fine Needle Aspiration Cytology (FNAC) is an advanced investigation modality employed for obtaining aspirates from pulmonary lesions, either as a first-line diagnostic procedure, or following non-diagnostic bronchoscopy or inconclusive sputum cytology [25, 26].

CT- FNAC for diagnosing pulmonary lesions is a procedure in which CT images are employed to precisely locate the pulmonary lesion in question, measure its size in terms of maximum horizontal and vertical diameters, assess its distance from the skin surface and finally to decide the positioning of the patient and type of the needle to be used for the procedure. [1-5, 27]. Needle path and its insertion point in the lesion, can be accurately determined by CT guidance, and thus, adjacent vascular structures can be safely avoided [3,28]. CT guidance allows performance of fine needle aspiration cytology in all such situations where ultrasound or conventional X-rays cannot correctly visualise the lesion or needle tract. As compared to trucut biopsies in which a core of tissue about 2 mm thick is taken from a lesion or lump, this is a lesser invasive method, to obtain aspirates from lesions that are otherwise difficult to approach [1,29].

Owing to a high prevalence of smoking (an etiological factor for most lung cancers) and tuberculosis (which is found to be endemic) amongst populations of North India, a large number of patients reporting to the out patients department of chest and respiratory diseases in our hospital, on preliminary investigations i.e. X-ray chest and chest CT, are found to have pulmonary lesions. Also, at times incidental detection of pulmonary lesions in patients undergoing treatment for some other cause makes it necessary to clearly investigate the suspected lung involvement [1,8].

Numerous studies have evaluated the diagnostic accuracy and complication rates of this procedure and found it to be safe and effective [1-5]. The diagnostic sensitivity of this procedure has been reported to range from 76% to 97% while complication rates have been reported to range from 5 to 61% with a mean of 20%. While it has been reported that sensitivity and specificity fall significantly if lesion size is <2 cm and distance of lesion from skin surface >5cm [1-4], it has also been reported that lesions 1.0 cm or smaller can yield good diagnostic accuracy rates as well [5].

Most studies reveal that adequacy of aspirate depends more on the lesion parameters of distance from skin surface, size and location and not much on demographic profile of patients [1-5, 26-30]. However, risk of complications are influenced to some extent by the overall health status of the patient. The most commonly encountered complications associated with this procedure are pneumothorax, hemoptysis, haemorrhage at the puncture site and chest pain [3,5]. Biopsy of central lesions, especially those in the mediastinum have been found to be more often associated with pneumothorax, while lesions near the hilar region with haemorrhagic complications. Also, reportedly fewer complications occur with biopsy of lesions along the pleural surface and in lesions in periphery of lungs. While some studies suggest that pneumothorax rates are significantly influenced by the number of samples obtained and not merely by the number of pleural punctures, there are others which report that pneumothorax rates are significantly influenced by the number of punctures [4,19].

An increased rate of pneumothorax has been correlated with smaller lesion size and presence of emphysema. Pneumothorax rates are also reported to increase significantly if an aerated lung is penetrated as compared with a non-aerated lung. Not only in adults, the safety and efficacy of this procedure has also been reported in the paediatric age group, more so in patients harbouring solid tumors [4,16].

Percutaneous trans-thoracic CT-guided FNAC, has been carried out in our tertiary care hospital for more than half a decade. In the present study we attempted to identify the factors that influence the diagnostic yield and complication rates of this procedure, to compare the diagnostic accuracy of this procedure with previously documented studies, and also to assess the feasibility of carrying out this procedure on a day-to-day basis in our hospital setting. Secondarily, the study was also aimed at finding out the incidence of benign and malignant pulmonary lesions, and the histological preponderance in the predominantly agrarian North Indian population.

For adequacy of aspirate, it was hypothesised that CT-FNAC done on patients in the age groups of 30-60 years is more likely to result in an adequate amount of aspirate than in extremes of ages. Similarly it was hypothesised that male patients, lesions on the right lung or in right side of the mediastinum, supine positioning during the procedure, relatively superficial lesions, lesion size more than 3 cm, and more number of passes encourage obtaining an adequate amount of aspirate. For complication rates, it was hypothesised that advancing age, female gender, left sided lesions, prone

positioning, lesions distant from skin surface, smaller lesions and more required passes predispose the patients to developing complications.

MATERIALS & METHODS

Study design

This single-centre study on 200 patients was conducted in a tertiary care centre of North India over a period of two years. The study incorporated a combined retrospective analysis of hospital records of 150 patients, and a prospective analysis of 50 patients subjected to CT-guided FNAC for mediastinal or pulmonary lesions. Confidentiality of all patients was maintained and only anonymised clinical information was analysed.

Inclusion Criteria

CT-guided FNAC was performed on patients in whom a routine X-ray chest and then a CT scan identified a possible lesion, sputum cytology and bronchoscopy reports were found to be inconclusive, the radiologist declared the lesion unapproachable ultrasonographically, and an informed consent had been attained in each case undergoing CT-guided FNAC.

Exclusion Criteria

CT-guided FNAC was considered a relative contra-indication in patients having bleeding disorders, severe Chronic Obstructive Pulmonary Disease (COPD), contralateral pneumonectomy, Pulmonary Arterial Hypertension.

Procedure

Patients underwent a CT scan without contrast material enhancement in either a prone or supine position, the positioning being decided on the basis of the shortest distance of lesion from the skin surface. Images were obtained through the region of interest by using a section thickness of 3-5 mm and were viewed using lung window settings. Point of needle insertion was then determined by placing metallic needles (pasted between two layers of leucoplast) on the chest wall and taking CT images. The chosen entry site was prepared in a sterile manner and 2% xylocaine® was administered for local anaesthesia. FNAC was performed using 20-22 gauge spinal or Chiba needles, and appropriate needle was chosen depending upon distance of the lesion from the skin surface.

The needle was first inserted only 2-3 cm deep, and CT images were taken to ensure that the needle was moving in the right direction. The needle was then inserted to the desired depth, and position of the needle tip was again confirmed using CT images. Samples were obtained by using aspiration techniques. From each needle pass, smears were prepared in sets viz. air drying (which yield excellent nuclear details) or fixing in 95% ethanol (which yield excellent cytoplasmic details.)

Patients were closely observed for two hours. An expiratory chest radiograph was obtained to ascertain the development of complications if any. Samples obtained upon CT-guided FNAC on eligible patients, were subjected to cytopathological examination. A final diagnosis of the lesions was thus made, based upon detailed cytopathological analysis of the aspirate.

Variables Analysed

Efficacy of the procedure was analysed in terms of diagnostic accuracy, sensitivity and specificity. Safety was analysed in terms of complications developed if any. Feasibility was analysed in terms of number of passes/ attempts required and post-procedural hospital stay.

The various variables chosen for the study were stratified as patient related variables, i.e. age and gender, lesion related variables i.e. distance from the skin surface in cm, maximum horizontal diameter in cm, maximum vertical diameter in cm and lung involved-right or left, and procedure related variables i.e. positioning of the patient during procedure- prone or supine and number of passes/ attempts required to obtain adequate amount of aspirate,

Statistical Analysis

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, version 16.0 for Windows). For all quantitative variables mean, median and standard deviation were calculated. Means were compared using Mann Whitney test and proportions were compared using Chi square or Fisher's exact test wherever applicable. Statistical tests were performed at a significance level of α=.05

RESULTS

Out of the 200 patients evaluated as part of our study, an amount of aspirate adequate enough for cyto-pathological analysis was obtained in 185 patients while the remaining 15 patients were advised a repeat FNAC. Thus, the overall accuracy of the procedure was found to be 92.5%. The overall sensitivity was found to be 94.03% while specificity was found to be 100% as there were no false positives.

Cyto-pathological analysis of the aspirate obtained from 185 patients provided us with various infectious, benign and malignant pathologies in these 185 patients as shown in Table *1*

Table 1 Frequency distribution of diagnosed lesions.

Diagnosis	Frequency	Percentage
Squamous cell carcinoma	31	16.8%
Adeno carcinoma	30	16.2%
Small cell carcinoma	15	8.1%
Poorly differentiated carcinoma	9	4.9%
Non-small cell carcinoma	7	3.8%
Non Hodgkin's Lymphoma	5	2.7%
Aspergilloma	5	2.7%
Ewing's scarcoma	1	0.5%
Others (ALL, carcinoid tumor, bronchoalveolar carcinoma, osteosarcoma, chondroid hematoma)	28	15.1%
Inflammatory pathology	27	14.6%
Tuberculosis	26	14.1%
No abnormality detected	1	0.5%
TOTAL	185	100%

The influence of patient, lesion and procedure related variables on adequacy of aspirate was analysed in the 185 patients in whom adequate material was aspirated.

An adequate amount of aspirate was obtained in patients as young as 10 years and as old as 95 years of age, the mean age being 55 years (standard deviation=16.74.)

As shown in figure *1*, it was found that majority (114 i.e. 61.6%) of the patients in whom an adequate amount of aspirate was obtained; were those with right sided lesions as against only 71 i.e. 38.4% with left.

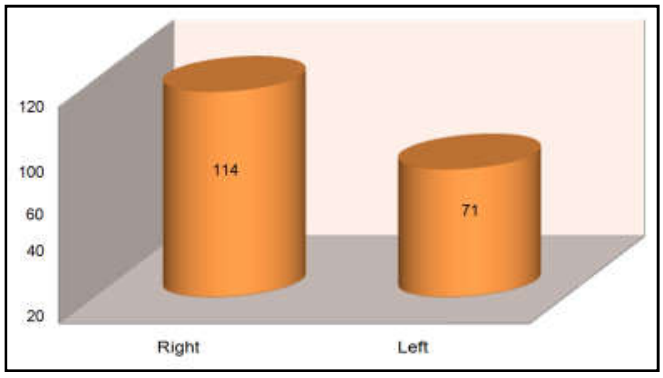

Figure 1 side distribution of lesions in patients with adequate aspirate

As shown in figure *2*, it was found that majority (111 i.e. 60%) of the patients in whom adequate aspirate was obtained were positioned supine during the procedure as against 73 i.e. 39.5% prone and only one i.e 0.5% lateral.

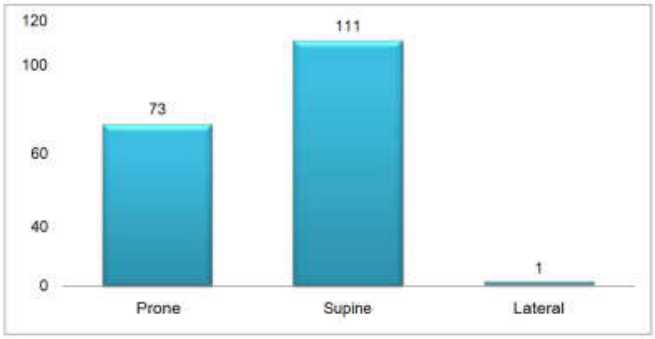

Figure 2 positioning as found in patients with adequate aspirate

The majority (80.61%) of lesions yielding adequate aspirate were those which were relatively superficial i.e. <7 cm from the skin surface as against only 19.39% which were deeper than 7 cm. The mean depth was found to be 5.82±1.78 cm. Figure *3* shows the depth distribution of lesions in the patients in whom adequate amount of aspirate was obtained.

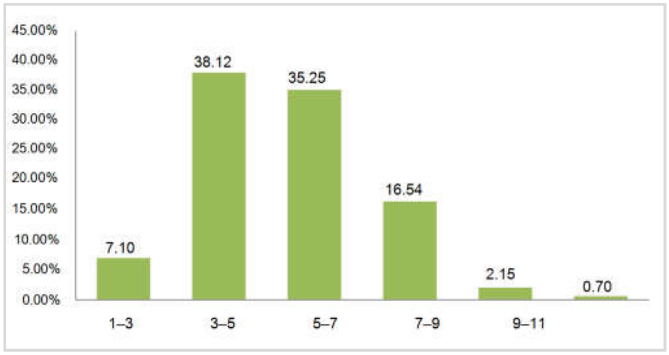

Figure 3 depth distribution (in cm) of lesions inpatients with adequate amount of aspirate

The mean horizontal and vertical diameters were found to be 5.13±2.31 cm and 5.13±2.58 cm respectively. It was found that majority (82.1%) of lesions had a horizontal diameter >3cm and majority (80%) had a vertical diameter >3 cm. Figure *4* and figure *5* show the size distribution of these lesions in terms of horizontal diameter and vertical diameter respectively.

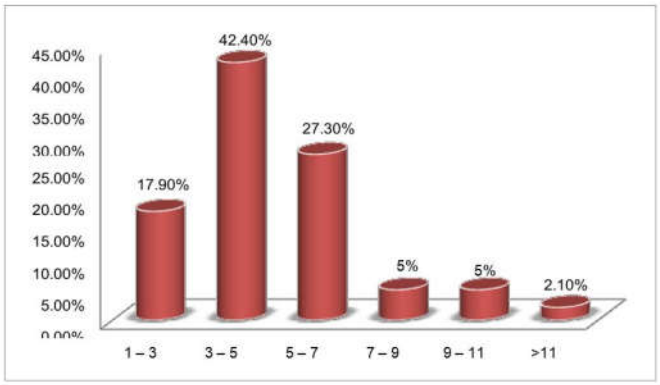

Figure 4 maximum horizontal diameter of lesions (cm)

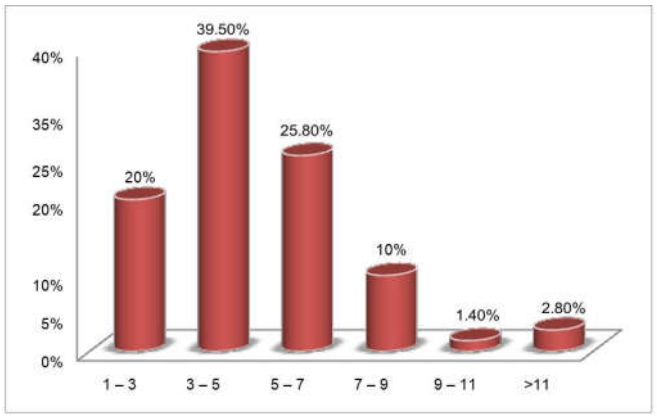

Figure 5 maximum vertical diameter of lesions (cm)

The maximum number of patients in whom adequate amount of aspirate was obtained required two or more passes. Figure 6 shows the frequency distribution of passes required in these 185 patients.

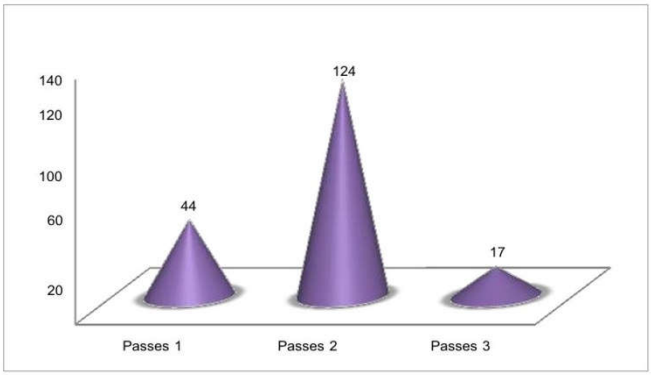

Figure 6 frequency distribution of passes require

Out of the 200 patients who were evaluated in this study, 22 developed post-procedural complications. Thus, the complication rates as found in our study were just about 11%. Figure *7* shows the relative incidence of various complications as found in our study.

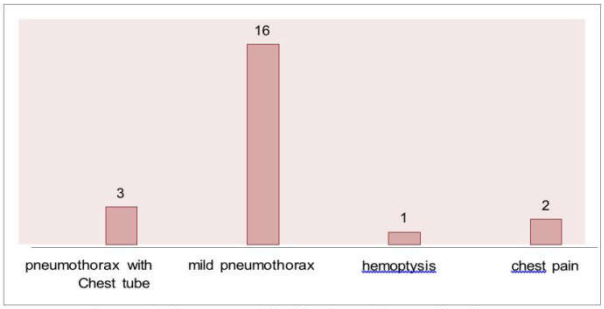

Figure 7 frequency distribution of complications

The various factors studied for influence on adequacy were similarly also studied for their influence on complication rates. It was found that majority (86.4%) of patients developing complications were aged more than 45 years of age.
Figure *8* shows the age distribution of these patients.

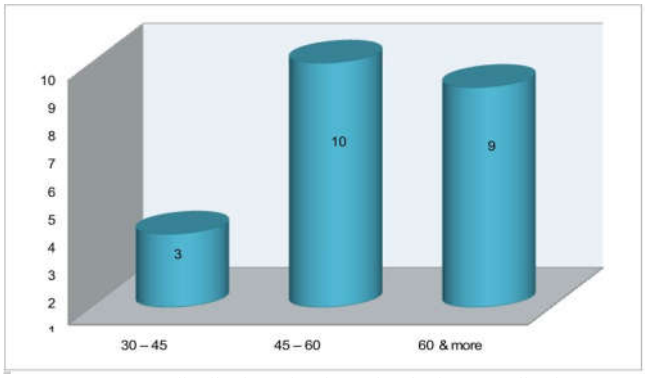

Figure 8 age distribution of patients developing complications

It was found that majority of the patients (15 i.e. about 68%) developing complications were males as against only 7 i.e. about 32% females. Figure *9* shows the gender distribution of patients developing complications.

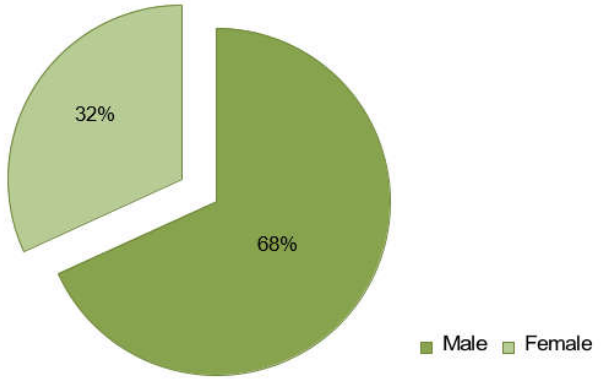

Figure 9 gender distribution of patients developing complications

It was found that majority of patients developing complications had right sided lesions. Figure *10* shows the side distribution of lesions in these 22 patients.

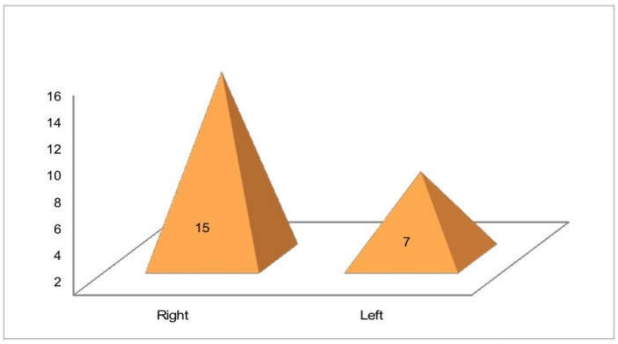

Figure 10 side distribution of lesions in patients with complications

The majority of patients (17 i.e. 77.3%) developing complications were positioned supine during the procedure as against only 5 i.e. 22.7% prone and 0 lateral. Figure *11* shows the relative positioning in these 22 patients.

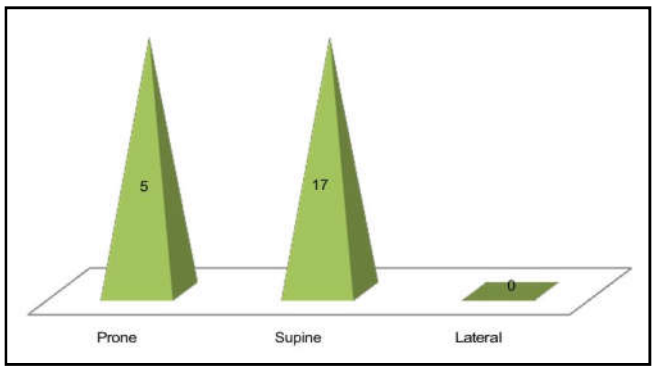

Figure 11 positioning in the patients developing complications

It was found that majority (14 i.e. 63.7%) of patients developing complications had lesions >5 cm deep from the skin surface. Figure *12* shows the depth distribution in these 22 patients.

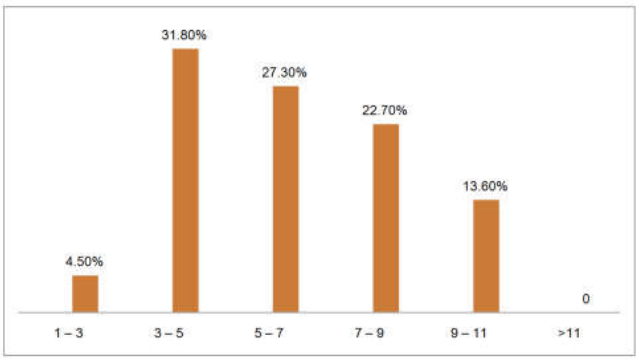

Figure 12 depth distribution of lesions in patients with complications

It was found that maximum complications developed in patients who had <5 cm horizontal (86.4%) and vertical diameters (72.8%) respectively. Figures *13* and figure *14* show the relative distribution of lesions in various size groups respectively.

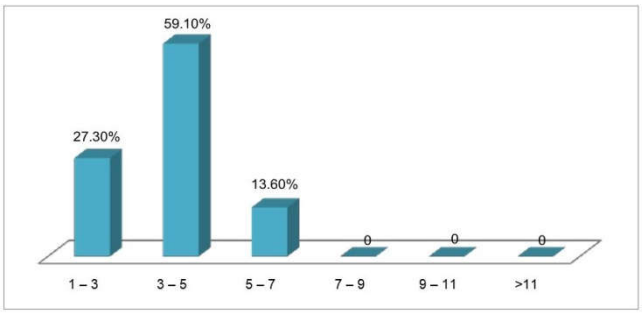

Figure 13 maximum horizontal diameter in patients with complications

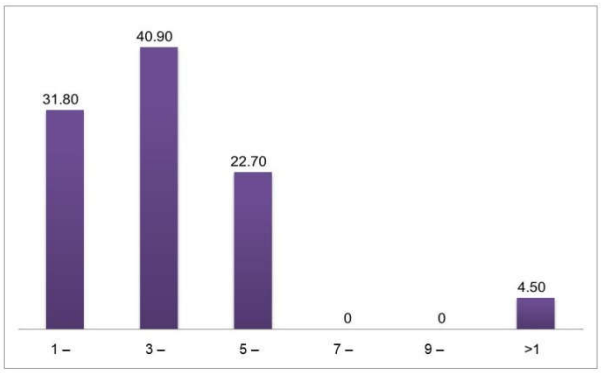

Figure 14 maximum vertical diameter in patients with complications

It was found that majority (81.8%) of patients developing complications were those who required 2 or more passes. Figure *15* shows the frequency distribution of passes in patients developing complications.

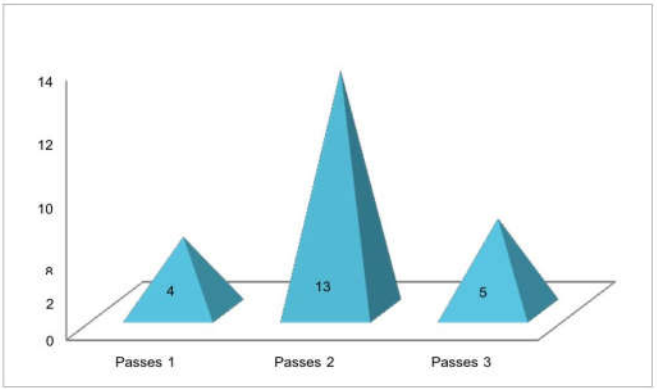

Figure 15 frequency distribution of passes in patients with complications

DISCUSSION

Upon cyto-pathological analysis, 54% lesions were found to be malignant while 46% were benign or inflammatory in nature. Amongst lesions that were reported to be malignant, squamous cell carcinoma and adeno carcinoma were found to be the most predominant histological type. Amongst the inflammatory lesions, tuberculosis was found to be quite frequent in occurrence. In the 185 patients in whom adequate amount of aspirate was obtained, it was found that majority (54.1%) were in the age group of 30-60 years. Smaller thoracic cage in children and increasing fragility in old age, along with other underlying disorders such as Chronic Obstructive Pulmonary Disease tend to influence patient profiles making it slightly difficult to carry out in extremes of ages.

Out of the 185 patients in whom adequate amount of aspirate was obtained, 131 i.e. 70.8% were found to be males while only 54 i.e. 29.2% were females. A basic difference in the genetic constitution of males and females could be a probable cause for this finding. It was found that majority (114 i.e. 61.6%) of the patients in whom an adequate amount of aspirate was obtained; were those with right sided lesions as against only 71 i.e. 38.4% with left (p value = 0.002). The presence of the heart and the great vessels which are more prominent on the left side of the mediastinum were thought to be the risk factors enhancing the difficulty on left sided lesions. It was found that majority (111 i.e. 60%) of the patients in whom adequate aspirate was obtained were positioned supine during the procedure as against 73 i.e. 39.5% prone and only one i.e 0.5% lateral (p value = 0.00). The difficulty of the needle in traversing through the bulkier back muscles as against the pectoral girdle, could be responsible for the same.

The majority (80.61%) of lesions yielding adequate aspirate were those which were relatively superficial i.e. <7 cm from the skin surface as against only 19.39% which were deeper than 7 cm. The mean depth was found to be 5.82±1.78 cm. These values were found to be significant as in accordance with our hypothesis that superficial lesions yield better amount of aspirate (p value = 0.00). The ease with which a needle can be guided through to superficial lesions, is thought to be the most important cause for the same. It was found that an adequate amount of aspirate was successfully obtained in lesions as small as 1.70 cm in horizontal and 1.50 cm in vertical diameter; and as large as 14.00 cm in horizontal and 19.00 cm in vertical diameter. The mean horizontal and vertical diameters were found to be 5.13±2.31 cm and 5.13±2.58 cm respectively. It was found that majority (82.1%) of lesions had a horizontal diameter >3cm and majority (80%) had a vertical diameter >3 cm. These values were also significant to show that larger lesions yield more adequate aspirate, (p value=0.01 and 0.003 respectively).

It is easier to avoid accidental path deviation of the needle when lesions are larger, thus proving our hypothesis. The maximum number of patients in whom adequate amount of aspirate was obtained required two or more passes. Even though informative, this was not found to be significant in order to support our hypothesis that more passes yield more adequate aspirate(p value = 0.7). Out of the 200 patients who were evaluated in this study, 22 developed post-procedural complications, the most common of which was pneumothorax (detected on chest X-ray), hemoptysis and chest pain. Only three out of those with pneumothorax required chest tube insertion and overnight hospital stay.Thus, the complication rates as found in our study were about 11% which is similar to those reported in previous studies. It was found that majority (86.4%) of patients developing complications were aged more than 45 years of age. The values were however not significant to support our hypothesis that advancing age predisposes to complications (p value = 0.142). It was found that majority of the patients (15 i.e. about 68%) developing complications were males as against only 7 i.e. about 32% females. It may alternatively be stated that 0.11% of the males and 0.12% of the females in whom an adequate amount of aspirate was obtained, developed complications.

It was found that majority of patients developing complications had right sided lesions. This was also not in accordance with our hypothesis that left sided lesions produce more complications. The values were however not significant statistically (p value = 0.084). The majority of patients (17 i.e. 77.3%) developing complications were positioned supine during the procedure as against only 5 i.e. 22.7% prone and 0 lateral. This significantly disproved our hypothesis on the same that prone positioning does not make the procedure more complicated (p value = 0.011). It was found that majority (14 i.e. 63.7%) of patients developing complications had lesions >5 cm deep from the skin surface. This was in support of our hypothesis that deeper lesions predispose to complications. The values were found to be significant (p value = 0.026). It was found that maximum complications developed in patients who had lesions with <5 cm horizontal (86.4%) and vertical diameters (72.8%) respectively.

These results were in accordance with our hypothesis that smaller lesions enhance the risk of complications and the values were found to be statistically significant (p value = 0.012 and 0.036 respectively). It was found that majority (81.8%) of patients developing complications were those who required 2 or more passes. This again significantly supported our hypothesis that complication rates increase with increasing number of passes (p value = 0.036). The more the number of passes, the more the puncture sites and more the possibility of developing haemorrhage and pneumothorax, similar to results that have been found upon studies conducted elsewhere.

CONCLUSIONS

From the results of the study we can conclude that advancing age, female sex, left sidedness of the lesion, prone positioning

of the patient during procedure, do not lead to any increase in complication rates of CT-guided FNAC. All complications developed as a result of the procedure can be easily managed on an in-patient basis.An effort should be made to aspirate as sufficient an amount of material in the least number of attempts as possible as this prevents the risk of developing complications. It is always good to have a favourable demographic profile of patients undergoing such a procedure, but old age, female sex, smaller, deeper, left-sided lesions aren't contraindications in any way. CT-guided FNAC is a very safe and accurate procedure.

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