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18F-FDG-PET/CT Value in Discriminating between Benign and Malignant Solitary Pulmonary Nodules

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Abstract

Background: Solitary pulmonary nodule (SPN) is a common radiographic finding, which is frequently detected incidentally. Investigation of this entity is challenging, since characteristics of benign and malignant processes may overlap in the differential diagnosis.

Aim of Study: The aim of our study was to estimate the value of positron emission tomography (PET)/computerized tomography (CT) in discriminating between benign and malignant SPNs by detecting their FDG uptake using SUVmax as well as follow-up their course regrading nodule size & metabolic activity.

Patients and Methods: This was a prospective study for 60 patients having SPNs detected by a previous CT and followed by PET/CT examination. Fifty two out of 60 patients gave consent for diagnostic interventional procedures for further histopathological examination. Among them, biopsy was done for nodules that progressed in size or showed progression in their PET uptake (standardized uptake value; SUVmax).

Results: 36 nodules (60%) of the SPNs were benign and 24 (40%) were malignant. The mean SUVmax value for the benign nodules was 2.1±2.2 and 6.9±5.2 for the malignant lesions (p=0.001). The highest sensitivity and specificity were encountered with a 3.5 SUVmax value.

Conclusion: PET/CT can be a practically useful tool in the discriminating benign from malignant SPNs giving a high diagnostic probability for malignant lesions.

Key Words: *Solitary pulmonary nodule – PET/CT – Malignant lesions.*

Introduction

SOLITARY pulmonary nodule (SPN) is a common radiographic finding, which is detected frequently incidentally. Investigation of this entity is challenging, since characteristics of benign and malignant processes may overlap in the differential diagnosis [1].

Many studies are now available to evaluate solitary pulmonary nodules with the main objective of characterizing benign lesions as best as possible, avoiding patients exposure to the risk of invasive techniques, besides early detection of malignant nodules aids to start treatment measures early with good prognostic outcome [1].

Solitary pulmonary nodule (SPN) is a solid globular or ovoid lesion with a clear margin and a less than 3cm diameter with no associated consolidation, atelectasis, chest wall lesions, or lymphadenopathy [2].

The term "pulmonary mass" is u for pulmonary used for pulmonary lesions >3cm in diameter, whose likelihood of malignancy is considerably increased [3].

In chest X-ray, the prevalence of SPN is about 0.09-0.2% and according to their nature (being benign or malignant), their significance differs. In patients above 50 years, when SPNs are detected, more than 50% can be carcinomas [2]. Using fluorodeoxyglucose (FDG), the prevalence of the newly discovered SPN cases in the USA is about 52/100,000 each year as PET has been one of the most beneficial modalities used in oncology in the last 10 years with Fluor-18 (18F) is the commonly used agent [4].

Abbreviations:

18-f FDG	: Fluorodeoxyglucose (18f).
CT	: Computed Tomography.
HRCT	: High resolution computed tomography.
MBq/kg	: Megabecquerel/kilogram.
PET	: Positron emission tomography.
SPN	: Solitary pulmonary nodule.
SUV max	: Maximum standardized uptake value.

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Depending on the assumption that tumor cells consume high level of glucose compared to normal cells, FDG being a glucose analog is used in PET for detection of such tumour cells [5].

With 18F-FDG-PET, differentiation between benign and malignant lesions is possible.

However, false negative results can occur with PET in the bronchoalveolar carcinoma and carcinoid tumor. Additionally, a false positive result in PET imaging can be encountered in some pulmonary granulomatous diseases like active tuberculosis and sarcoidosis [6].

A previous meta-analysis found that PET sensitivity and specificity for malignant pulmonary nodules is 96.8 and 77.8%, respectively, with the sensitivity and specificity for benign nodules is 96% of 88% rendering PET of high efficacy in discriminating between benign and malignant solitary pulmonary modules [7-10].

The aim of our study was to estimate the value of 18F-FDG-PET/CT in discriminating between benign and malignant SPNs.

Patients and Methods

1- Patients:

The study involved 60 patients, 35 females (58.4%) and 25 males (41.6%). Their age ranged from 20-70 years with a mean age of 55 years.

This study was enrolled in Cairo, Egypt along 24 months period from April 2017 till April 2019. All patients provided written informed consent and the study was approved by the Ethical Research Committee of Faculty of Medicine Cairo University.

Inclusion criteria: Patients having a SPN <3cm detected by a pervious chest CT examination, followed by 18F-FDG-PET/CT examination protocol as well as biopsy procedures when needed.

Exclusion criteria: Patients having SPN associated with pneumonia, atelectasis, chest wall pathology or with associated lymph node sized >1 cm, poor general health, history of lung cancer, iodine hypersensitivity, poor renal function and old age over 80 years, as well as those who did not consent to be followed-up & to undergo interventional biopsy procedures when needed, were excluded from the study.

2- Methods:

Each patient underwent 18F-FDG-PET/CT examination just after being enrolled in the study to determine the site, size and SUVmax of the nodule. SPN having a diameter more than 2cm with a SUVmax (standardized uptake value) more than 2.5 were classified to be highly suspicious lesion for malignancy that passes directly to biopsy procedures. Other patients were followed-up every 6 months interval, using 18F-FDG-PET/CT to determine the nodule size and metabolic change:

1- Patients with progressive nodule course regarding nodule size and/or SUVmax were investigated by biopsy.
2- Patients with regressive nodule course regarding nodule size and/or SUVmax were followed-up for another 6 months to confirm its regression, and they were considered as benign.
3- Patients with stationery nodule course were followed after another 6 months till 24 monthsperiod.
4- Patients with progressive nodule course after being regressive or stationery were planned to be biopsied, but this was not encountered.

A benign SPN was determined by being histologically confirmed, or being of stationery or regressive size in serial PET/CT exams at 6 months intervals along the follow-up period

PET/CT imaging: Biograph 16 machine was used for all the examinations, that involved a PET system equipped with lutetium orthosilicate detector and a sixteen-slice CT machine.

After assessment for the blood glucose level, 18F-FDG was intravenously given using 3.7 MBq/kg, with blood sugar should be less than 200mg/dl followed by a 1 hour rest period.

The study starts with CT data acquisition, using 16mm°-0.75mm collimation and 1.5 increase factor. The examination field starts at the range from the skull base down to the mid-thigh levels. Then CT data were reconstructed using 700-mm field of view for subsequent attenuation correction of PET images with a 5mm wide soft-tissue reconstruction algorithm.

The study was started after the intravenous administration of 100ml of iodinated contrast medium (concentration of 300mgI/ml) using a power injector at flow rate of 3-4ml/s. Then, CT data were obtained in the arterial phase which starts 20-30s after the intravenous contrast medium injection. Then CT data were reconstructed using 700-mm field of view with a 5mm soft-tissue reconstruction algorithm.

Image analysis: Acquired data were reconstructed to obtain 5mm images thickness with 0.7mm reconstruction increment, using a HRCT soft tissue algorithm resulting in excellent spatial resolution. Axial, sagittal, and coronal images were evaluated to determine the site, shape and size of the nodule with its maximum standard uptake value (SUVmax).

Histo -pathological assessment: All patients were advised to undergo interventional diagnostic procedures with only 8 patients did not consent to those interventional procedures. The diagnosis of the rest of the patients was aided by biopsy and histocytological examination when needed like: via bronchoscopic, endobronchial, transbronchial, transthoracic needle biopsy.

Statistical analysis: Using the Statistical Package for the Social Sciences (SPSS) version 24, all patients' data were entered. *t*-test was used for the quantitative data parametric analysis. Mann-Whitney-U test was used for the non-parametric quantitative analysis.

Qualitative data was compared using Chi-square test. All data were analyzed for assessment of the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy rates. A $p<0.05$ was determined as statistically significant.

Results

The study involved 60 patients, 35 females (58.4%) and 25 males (41.6%). Their age ranged from 20-70 years with a mean age of 55 years.

We found that thirty six (36) patients (60%) had benign SPNs and twenty four (24) patients (40%) had malignant SPNs . For those 36 patients with benign nodules, the SPN SUVmax mean value was 2.1±2.2. For those 24 patients with malignant nodules, the average SUVmax value was 6.9±5.2. The lesion diameter ranges between 6 and 30mm (mean 19±6.5).

It was found that the SUVmax mean value was higher in patients with malignant SPN than those patients with benign lesions which was statistically significantly (p=0.001).

Regarding our study, the SUVmax values ranged between 0.5 and 15.00, with 3.9±2.3 mean value. We found that the diameter of the benign lesions was less than 20mm (mean diameter 15.7±6), while all malignant nodules had a diameter above 20mm (mean 22±7.6). This difference in the lesion diameter was statistically significant (p=0.05).

Additionally, a statistically significant correlation was found between the malignant nodule diameter and its SUVmax value. That correlation was statistically significant (r=0.565, $p<0.05$) (Table 1).

Table (1): Different SUVmax cut-off values with the corresponding sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy for discriminating malignant SPNs.

SUVmax	Sensitivity%	Specificity%	PPV%	NPV%	Accuracy%
2.5	79	58.2	79.7	79.1	80.6
3	83	63.2	66.2	85.0	71.0
3.5	91.0	75.0	70.8	93.0	81.4
4	81.1	66.2	63.6	88.2	75.5
7	84.1	69.7	65.0	89.1	76.4

SUVmax: Maximum standard uptake value.

SPNs were found on the right lung in 70% (42 patients) and in the left lung in 30% (18 patients) of the study cases. Benign nodules were seen within the right lung in 57.6% and within the left-lung in 42.4% of cases, meanwhile malignant nodules were right sided in 50.2% and in the left sided in 49.8% of patients. Regarding nodule side whether right or left sided, there was no statistical significance between benign and malignant SPNs localization (p=0.210). Also, we found no statistically significant difference between benign and malignant lesions regarding its site in the lung whether in the superior, middle, or in the inferior lobe (p=0.700).

Among those thirty six (36) patients with benign SPN, eleven (11) nodules (30.5%) of them showed regression in the nodule size by CT along the 24 months follow-up period (Fig. 1) with nine (9) patients (25%), showed stationery size (Fig. 2) along the same period without detection of another malignancy. The rest of those 36 benign SPN patients, who were sixteen (16) patients (44.5%) showed progression in size with no other body malignancies were shown up along the follow-up period so, they underwent biopsy and histopathologic examination that revealed: 7 aspergilloma, 4 tuberculous granuloma, and 3 rheumatoid granuloma and 2 non-specific granuloma (Table 2).

Twenty four patients (24) had malignant SPNs, 16 of 24 patients (66.7%) had histopathologic confirmation using transthoracic needle biopsy/ trans-bronchial biopsy.

Among those 16 patients with pathologically proven malignant SPN, 8 patients (50%) had non-small cell lung cancer (Fig. 3), 1 patient (6.3%) had small cell lung cancer, and 7 patients (43.7%) had metastatic SPNs (Table 2).

The rest of the twenty four patients who were 8 patients (33.4%), had no consent for interventional procedures so, they had been diagnosed based on the PET/CT findings, putting in consideration the patient clinical data, like history of a primary neoplasm, to put the metastatic possibly (Fig. 4). We found that the nodules progressed in size in 6 patients (75%) with the existence of other body malignancy, so they were diagnosed as metastatic nodules. The residual 2 patients showed progression in the nodule size with starting infiltration of the mediastinum and enlargement of the mediastinal LNs and they were considered as 1ry malignant lung lesions (Table 2).

Table (2): Distribution of the study patients.

Total study patients:	36 Benign nodules (60%)	11 nodules (30.5%): Regressed in size along the 24month period	
		9 nodules (25%): Showed stationery size along the 24month period	
		16 nodules (44.5%): Progressed in size then biopsied for histo-pathological examination: 7 aspergilloma, 4 tuberculous granuloma & 3 rheumatoid granuloma and 2 non-specific granuloma.	
60 patients With 60 SPNs	24 malignant Nodules (40%)	16 nodules (66.7%) were biopsied & pathologically proven	9 nodules (56.3%): Bronchogenic carcinoma
			7 nodules (43.7%): Metastatic.
		8 nodules (33.3%) were followed-up	6 nodules (75%): - Progressed in size with a known 1ry neoplasm 2 nodules (25%) Progressed in size with starting mediastinal infiltration & development of mediastinal lymphadenopathy without appearance of other body malignancy, suggesting being 1ry lung malignancy.

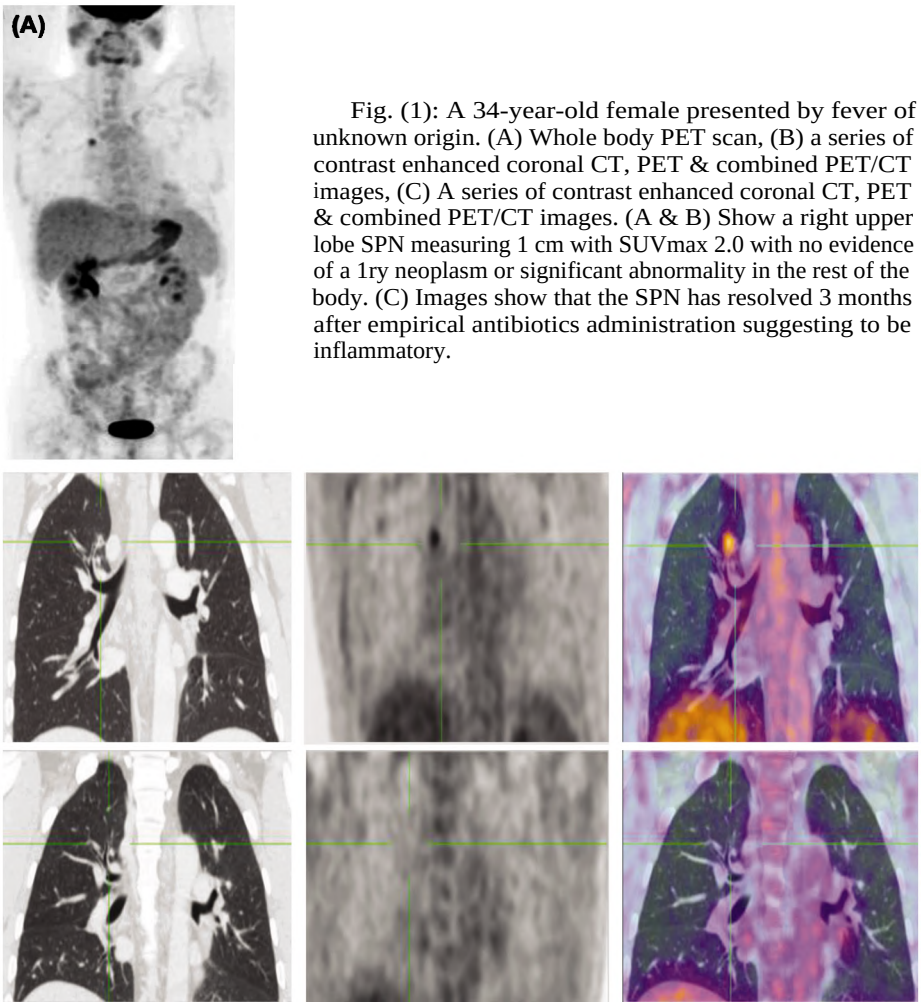

Fig. (1): A 34-year-old female presented by fever of unknown origin. (A) Whole body PET scan, (B) a series of contrast enhanced coronal CT, PET & combined PET/CT images, (C) A series of contrast enhanced coronal CT, PET & combined PET/CT images. (A & B) Show a right upper lobe SPN measuring 1 cm with SUVmax 2.0 with no evidence of a 1ry neoplasm or significant abnormality in the rest of the body. (C) Images show that the SPN has resolved 3 months after empirical antibiotics administration suggesting to be inflammatory.

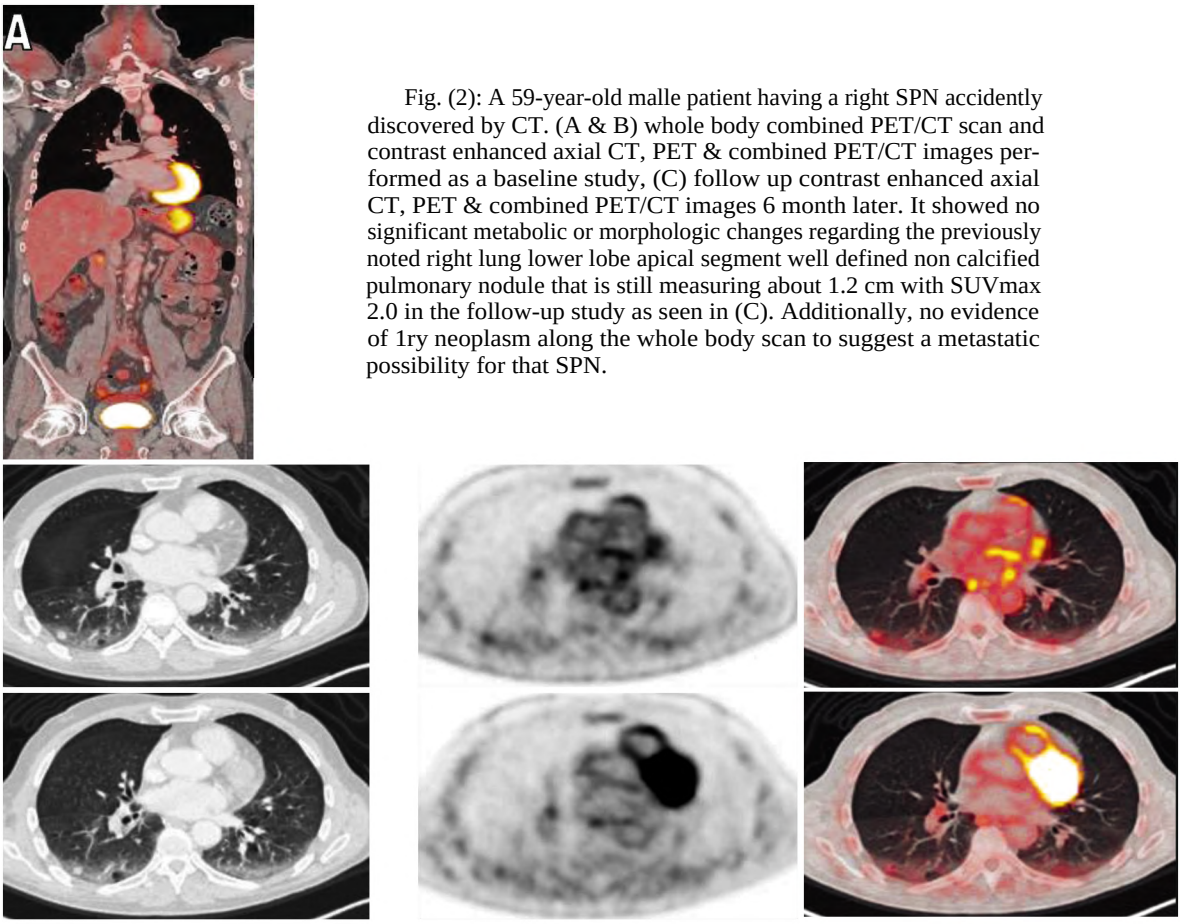

Fig. (2): A 59-year-old malle patient having a right SPN accidently discovered by CT. (A & B) whole body combined PET/CT scan and contrast enhanced axial CT, PET & combined PET/CT images performed as a baseline study, (C) follow up contrast enhanced axial CT, PET & combined PET/CT images 6 month later. It showed no significant metabolic or morphologic changes regarding the previously noted right lung lower lobe apical segment well defined non calcified pulmonary nodule that is still measuring about 1.2 cm with SUVmax 2.0 in the follow-up study as seen in (C). Additionally, no evidence of 1ry neoplasm along the whole body scan to suggest a metastatic possibility for that SPN.

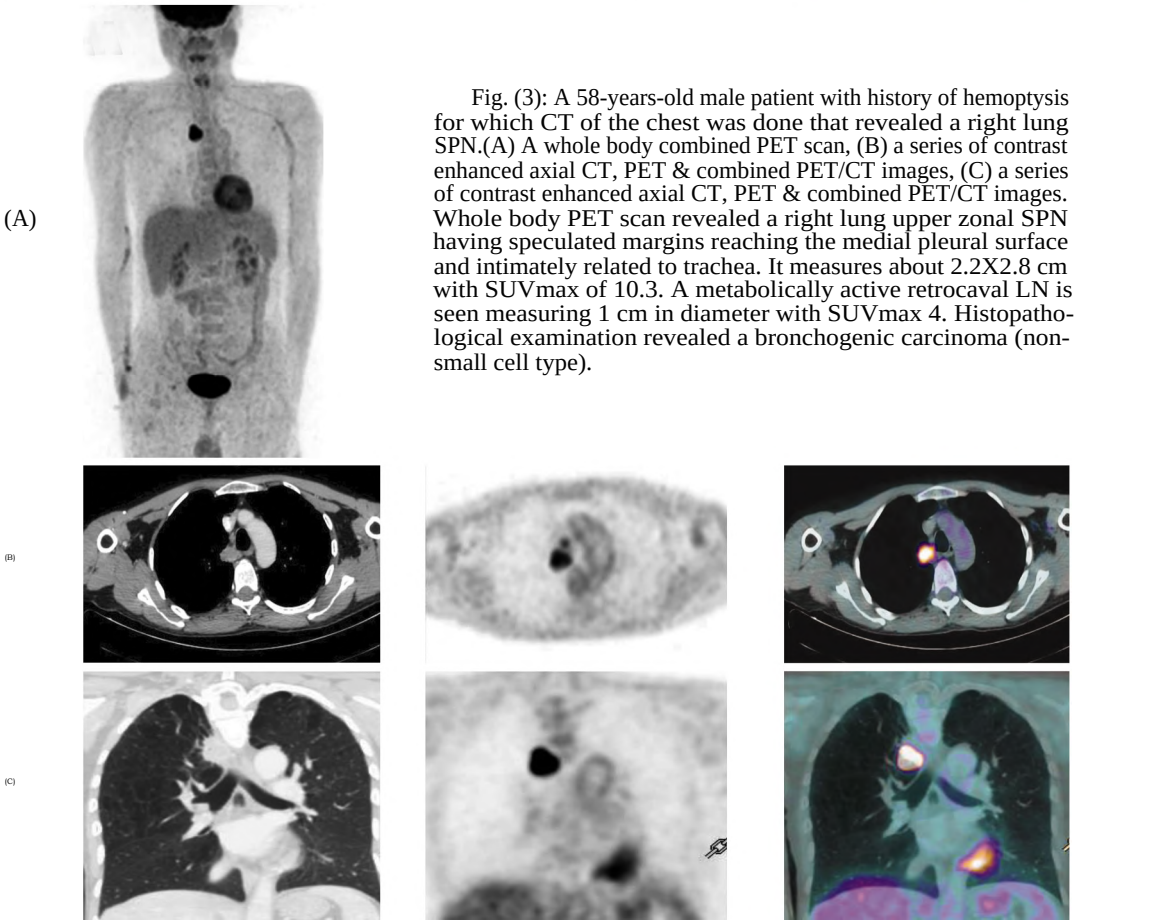

Fig. (3): A 58-years-old male patient with history of hemoptysis for which CT of the chest was done that revealed a right lung SPN.(A) A whole body combined PET scan, (B) a series of contrast enhanced axial CT, PET & combined PET/CT images, (C) a series of contrast enhanced axial CT, PET & combined PET/CT images. Whole body PET scan revealed a right lung upper zonal SPN having speculated margins reaching the medial pleural surface and intimately related to trachea. It measures about 2.2X2.8 cm with SUVmax of 10.3. A metabolically active retrocaval LN is seen measuring 1 cm in diameter with SUVmax 4. Histopathological examination revealed a bronchogenic carcinoma (non-small cell type).

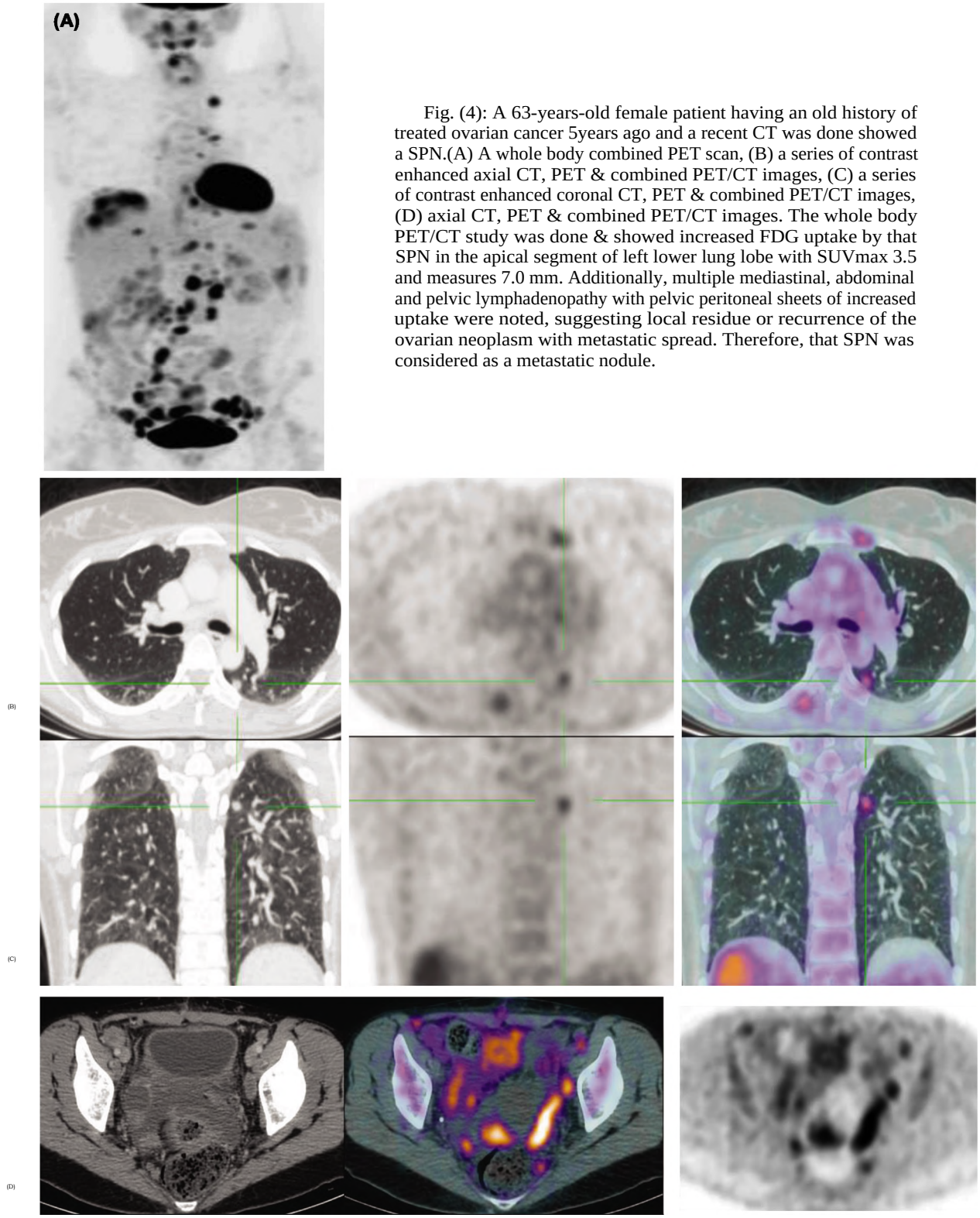

Fig. (4): A 63-years-old female patient having an old history of treated ovarian cancer 5years ago and a recent CT was done showed a SPN.(A) A whole body combined PET scan, (B) a series of contrast enhanced axial CT, PET & combined PET/CT images, (C) a series of contrast enhanced coronal CT, PET & combined PET/CT images, (D) axial CT, PET & combined PET/CT images. The whole body PET/CT study was done & showed increased FDG uptake by that SPN in the apical segment of left lower lung lobe with SUVmax 3.5 and measures 7.0 mm. Additionally, multiple mediastinal, abdominal and pelvic lymphadenopathy with pelvic peritoneal sheets of increased uptake were noted, suggesting local residue or recurrence of the ovarian neoplasm with metastatic spread. Therefore, that SPN was considered as a metastatic nodule.

Discussion

Being the most common type of cancer worldwide, lung malignancy is considered an important health problem and one of the mortality causes in the USA, accounting for 12.3% of diagnosed cancer cases per year **[11]**. It can be lately discovered, making most of patients diagnosed in locally advanced stage (stage III) or a more late metastatic stage. This results in a poor patient prognosis and short life expectancy with about 5-year survival rate in less than 9% of patients. The 5-year survival rate is about 14% when all the disease stages were included **[12]**.

In routine radiological imaging, 5% of the detected SPNs are found to be carcinomas, with more than 50% of the SPNs detected in old patients above 50 years age are carcinoma [3]. In the current study, 24 (40%) of those 60 SPNs patients were diagnosed as malignant lung lesions and 75% of those patients with malignancy were older than 50 years (p=0.04).

A recent study has reported that complication rate can be high up to 23.8% from invasive tests for pulmonary nodules, so rather than increasing investigation cost, selective use of FDG PET/CT may result in significant cost saving by avoiding unnecessary biopsy and possible complications in those patients [13].

PET scan can give a valuable data about the characteristics of the SPNs and the probability of being malignant [8] based on the fact that metabolically active rapidly growing lesions show higher tracer uptake than slow-growing, well differentiated lesions [14].

Additionally, combined PET/CT was reported as an important modality in the discrimination between the natures of SPNs. As evident by [15], the CT, PET, and PET/CT sensitivity was 93, 69, and 97%, respectively, whereas its specificity was 31, 85, and 85%, respectively.

Hickeson et al. [16] showed that the sensitivity, specificity and accuracy parameters for FDG-PET/CT in assessment of SPNs were 82-100%, 60-100%, and 79-100%, respectively.

A previous study by Quint et al. [17], showed that 76% of the examined SPNs were primary lung neoplasm, 9% were solitary metastases, and 15% were different benign lesions. In the current study, among those 24 patients having malignant SPNs, 13 (54.2%) were metastatic and 11 (45.8%) were primary lung neoplasm.

According to [18], with a SUVmax value of 0-2.5, the probability of malignancy was 25%. Additionally, with a 2.5-4.0 SUVmax value, the probability of malignancy was 80% and with SUVmax values above 4.1 the probability of malignancy was a 96%. In our study, the SUVmax mean value was 6.9±5.2 for malignant nodules and 2.1±2.2 for benign nodules. In general, high FDG uptake is seen with malignant lesions however, exceptions may exist giving a false positive results.

The current study encountered false positive results that was induced by granulomatous lesions like tuberculosis and aspergillosis. With a SUVmax threshold of 3.5, we found that 9 (25%) of the 36 benign SPNs showed a SUVmax value of more than 3.5 giving a false positive result. Five of them spontaneously regressed (Fig. 1) or with treatment in the follow-up period & four were biopsied and confirmed to be a granuloma. On the other hand, with a threshold value of 3.5 for SUVmax, 2 patients (8.3%) showed a SUVmax value below 3.5 giving false negative result and they were metastatic in nature.

It was found that patients coming with a small SPN and having history of other organ malignancy, even with low or no nodules FDG uptake were more likely to be of metastatic nature [19].

Regarding the nodule diameter, in three previous studies made to evaluate a single pulmonary nodule and with a diameter less than 1cm, those SPNs were found to be benign in 64, 57, and 92%, among those studies [20,21,22]. In this study, a positive correlation was found between the nodule diameter and risk of being malignant. The mean diameter for benign nodules was 16.90±7.50mm with the mean diameter for malignant nodules was 21.99± 6.68mm (p=0.001).

According to Hickeson et al. [16], when the threshold value was set at SUVmax of 2.5, the sensitivity, specificity, and accuracy for detecting malignancy were 47, 80, and 59% respectively; when it was set at 3, it was 35, 100, and 59%, respectively.

In our study, the best sensitivity and specificity for predicting malignancy was achieved when the SUVmax threshold value was set at 3.5. The sensitivity, specificity and accuracy were 91%, 75% and 81.4% (Table 1). Meanwhile the study held by Hadique, S. et al., showed, the sensitivity, specificity as well as positive and negative predictive values of FDG PET/CT were 94%, 82%, 78% and 95% respectively by using biopsy or two-year stability to reach final diagnosis [23].

Regarding nodule side whether right or left sided, there was no statistical significance between benign and malignant SPNs localization (p=0.210). Also, we found no statistically significant difference between benign and malignant lesions regarding its site in the lung whether in the superior, middle, or in-the inferior lobe (p=0.700).

Regarding the nodule location, according to Quint et al. [17], 70% of malignant SPNs have been seen located along the superior lobes, while benign SPNs were found to evenly distribute. In the current study, 34 (42.5%) of the 80 malignant nodules

were seen along the superior lobes, a finding inconsistent with the literature.

A possible disadvantage of PET/CT is the high cost that may be not a problem in the near future because of the progression in its availability. Another concern is the exposure to radiation however, when weighing benefits versus risks, the benefits of PET/CT are remarkable for the patient assessment and future management.

Conclusion:

According to this study, 18-F FDG-PET/CT was found to be a useful and accurate quantitative and qualitative modality in discriminating between benign and malignant SPNs based on the fact that malignant lesions show high FDG uptake. However, other inflammatory lesions can produce a false positive result that should be kept in mind as a possibility. In those patients known to have distant malignancy associated with a SPN, carrying a risk of being malignant lesion even with insignificant FDG uptake. A positive correlation was found between the SPN diameter and the risk of malignancy risk. The SUVmax value with the best sensitivity and specificity was 3.5, according to our study.

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قيمة تصوير الإصدار البوزيترونى فى التمييز بين العقدة الرئوية الانفرادية الحميدة والخبيثة

العقدة الرئوية الانفرادية هى إكتشاف شعاعى شائع، يتم إكتشافه بشكل عرضى فى كثير من الأحيان. لا يزال التحقيق فى هذا الكيان يمثل تحدياً، حيث قد تتداخل خصائص العمليات الحميدة والخبيثة فى التشخيص التفريقى.

اعتماداً على افتراض أن الخلايا السرطانية تستهلك مستوى مرتفعاً من الجلوكوز مقارنة بالخلايا الطبيعية، يتم استخدام فلوريد الجلوكوز منقوص الأكسجين باعتباره نظيراً للجلوكوز فى تصوير الإصدار البوزيترونى للكشف عن هذه الخلايا السرطانية.

مع تصوير الإصدار البوزيترونى، يمكن التمييز بين الآفات الحميدة والخبيثة. ومع ذلك، يمكن أن تحدث نتائج سلبية خاطئة مع تصوير الإصدار البوزيترونى فى سرطان القصبات الهوائية والورم السرطانى. بالإضافة إلى ذلك، يمكن مواجهة نتيجة إيجابية خاطئة فى التصوير المقطعى بالإصدار البوزيترونى فى بعض أمراض الأورام الحبيبية الرئوية مثل السل النشط والساركويد.

وجد دراسة تحليلية سابقة أن حساسية ونوعية تصوير الإصدار البوزيترونى للعقيدات الرئوية الخبيثة هى ٩٦.٨٪ و ٧٧.٨٪ على التوالى، مع حساسية ونوعية العقيدات الحميدة هى ٩٦٪ من ٨٨٪ مما يجعل تصوير الإصدار البوزيترونى ذات فعالية عالية فى التمييز بين الانفرادى الحميدة والخبيثة الوحدات الرئوية.

كان الهدف من دراستنا هو تقدير قيمة تصوير الإصدار البوزيترونى فى التمييز بين العقدة الرئوية الانفرادية الحميدة والخبيثة.