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Role of ^{18}F-FDG PET/CT in evaluation of recently diagnosed breast cancer patients

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Abstract

Background: Breast cancer is the most frequent malignant disease in women and usually affects people of all ages, races, socioeconomic classes, and geographic locations. Once breast cancer is diagnosed, tumor staging should be assessed precisely before treatment and prognosis could be determined. The purpose of this study was to determine the diagnostic usefulness of PET/CT in the initial assessment of patients with newly diagnosed breast cancer who were referred for tumor staging, pre-therapeutic or preoperative evaluation.

Results: In the examined 50 patients, PET/CT has higher sensitivity and accuracy compared to CT alone (reaching 100% for PET/CT and 96% for CT) in detecting malignant breast lesions, regional and distant nodal deposits as well as distant deposits, with subsequent upstaging in two patients.

Conclusions: ^{18}F-FDG PET/CT is a single valuable technique that detects metastatic illness in newly diagnosed breast cancer patients in an efficient, accurate, and noninvasive manner, resulting in modification of the initial staging, which in turn reflected on the patients' therapeutic plans.

Keywords: Breast cancer, Positron emission tomography, Computed tomography

Background

Breast cancer is the most frequent malignancy in women and the second cause of cancer-related deaths among them [1]. Accurate staging of breast cancer is critical for planning the optimal therapeutic option for each patient as well as determining the prognosis [2]. Except in some circumstances, such as patients with dense breast parenchyma, having extensive scarring from previous biopsies, or substantial architectural abnormalities, mammography has been found to be accurate for breast cancer screening. Precise information regarding the size and extent of breast masses can be provided by contrast-enhanced magnetic resonance imaging (MRI), and it is especially useful for assessing multifocal and multicentric breast tumors, yet traditional imaging methods are incapable of precisely detecting nodal involvement or presence of distant metastasis, which fundamentally alter the therapeutic management of these patients. Whole-body ^{18}F-fluorodeoxyglucose positron emission tomography–computed tomography (^{18}F-FDG PET/CT) has been shown to be an efficient imaging technique for the identification, staging, and post-treatment follow-up of malignant tumors [3–5]. Furthermore, combined PET/CT is able to partially overcome the limited specificity of positron emission tomography (PET) caused by the increased metabolic activity of some benign tumors and inflammatory tissue. As a result, the ^{18}F-FDG PET/CT would be more beneficial for pre-therapeutic staging of the whole body in a single study [6, 7]. The ability of ^{18}F-FDG PET/CT to incorporate functional and morphologic information makes it a valuable imaging tool for the diagnosis and staging of many malignant tumors, including breast cancer [8]. The goal of this study was to investigate the role of ^{18}F-FDG PET/CT in staging and pre-therapeutic metastatic workup of newly diagnosed patients with breast cancer which subsequently affects their management.

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Methods

Patients

From October 2019 to September 2021, this cross-sectional study comprised 50 female patients who had just been diagnosed with breast cancer (biopsy proven) and were referred for initial PET/CT scans for staging, preoperative or pre-therapeutic assessment. Before the study began, the institutional research ethical committee approved it, and all patients provided signed informed consent.

Inclusion criteria

Female patients with a histologically confirmed diagnosis of breast carcinoma, who did not receive any therapy, with no age predilection.

Exclusion criteria

Patients with high blood glucose levels > 200 mg/dl, high serum creatinine > 1.3 mg/dl, and bad general condition at the time of the study were excluded.

Patient preparation

All patients were instructed to fast for at least 6 h and stay hydrated. All metallic objects were removed, including zippered pants, bras, belts, wristbands, and so on, and the patient wore gowns. Prior to ^{18}F-FDG injection, serum glucose was routinely evaluated and should be less than 200 mg/dl (including those with diabetes who were instructed to control their blood glucose level properly before the examination). Intravenous (I.V) cannulas were inserted in order to administer ^{18}F-FDG and the IV contrast. To avoid physiologic muscle uptake of FDG, the patients were instructed to remain calm and avoid any intense exercise prior to the examination (for at least 24 h) and following the radiotracer administration. A warm environment with controlled temperature should be provided for the patients before the ^{18}F-FDG injection to reduce brown fat uptake. The patients were advised to have a low carbohydrate, high fat, and protein diet before the examination.

Technique of ^{18}F-FDG PET/CT scan

The dose of the intravenous radioactive tracer (^{18}F-FDG) was about 0.1 mCi/kg body weight. The patients were stayed in complete physical rest in warm rooms and instructed to void immediately before scanning. A hybrid PET/CT scanner (PHILIPS; Ingenuity TF PET/128 computed tomography (CT) scanner, USA) was used to scan the patients 60 min after injection. The patients were lying supine on the table and arms lifted above their heads. We started with a low-dose non-enhanced CT scan and then performed whole-body PET scanning. Following that, an enhanced diagnostic whole-body CT scanning was done. The entire study took about 20–25 min. The typical whole-body PET/CT scanning began from the base of the skull down to mid-thighs. The CT coverage was determined by the number of bed positions scanned during PET (approximately 5–7 bed positions by 3D acquisition mode with 2–4 min for each bed position). The studies were carried out while the patients were breathing gently. The scanning parameters for low-dose attenuation correction CT were 120 kV, 100 MA, 64×0.625 mm collimator width, 0.8 pitch, 0.5 s gantry rotation time, and 50 cm field of view. The scanning parameters for high-dose diagnostic CT were 120 kV, 300MA, 64×0.625 mm collimator width, 0.8 pitch, 0.5 s gantry rotation time, and 50 cm field of view. The helical data were reconstructed retrospectively at 1-mm intervals. The patient was injected with 100 ml of non-ionic iodinated contrast material using a dual syringe Medrad (Stellant) automated injector at a rate of 2.5 ml/sec, followed by a CT scan 40 s later.

The trans-axial CT and PET images were transmitted to a dedicated workstation, for reconstruction and reformation into coronal and sagittal views facilitating their interpretation. Also, the fusion of corresponding CT and PET images was done integrating the two types of data.

Interpretation of images

All PET/CT studies were reviewed separately by two experienced nuclear medicine physicians and radiologists (with 7 and 10 years of experience, respectively). The breast tumors as well as the nodal and distant metastases were assessed using both CT and fused PET/CT images. The lesions with elevated glucose uptake greater than that of the surrounding tissue, more than the chest mediastinal blood, the background activity in the rest of the body (qualitative analysis), or having a standard glucose uptake value (SUV) of more than 2.5 (quantitative analysis) were considered to be pathological. The SUV was determined by manually drawing a 5–10 mm region of interest (ROI) over the area of greatest activity of the lesion.

The nodal tumor infiltration should be evaluated as positive or negative for the ipsilateral axillary, contralateral axillary, internal mammary, hilar and mediastinal, and pelvi-abdominal lymph node groups. Any lymph node with a short-axis diameter of more than 10 mm or any necrotic lymph node regardless of its size in CT scans was classified as malignant, while any lymph node with retained fatty hilum regardless of its size was considered benign. Lymph nodes with enhanced glucose concentration in PET scans were classified positive for metastatic dissemination even if their short-axis diameter was less than 1 cm. Non-FDG avid lymph nodes in PET images

were considered benign (negative for metastatic dissemination) even if they measured more than 1 cm in short-axis diameter.

The lung, visceral organs (liver, spleen, and adrenal glands), brain, and bone were all checked for distant metastases, and the tumor infiltration findings for each of these locations were evaluated as positive or negative. Patients with 5-mm lung nodules should be deemed positive if FDG uptake exceeds the mediastinal blood pool. If the size of the nodule exceeds 5 mm, metastatic lung deposit cannot be ruled out. Positive hepatic or splenic lesions are those whose uptake is more than that of the liver or spleen. Regarding adrenal gland lesions, they were considered benign if the density of the lesion was less than 10 HU, but if it was greater than 10HU, the SUVmax of the lesion should be evaluated, then they were classified as benign if the SUV maximum was less than 3.1 and malignant if it was greater than 3.1. Positive patients for osseous deposits were considered if they have focal bone marrow lesions with increased FDG uptake.

Statistical analysis

The collected data were revised and coded with input into RStudio version 2.3.2 of the Statistical Package for Social Science. The qualitative data were presented as numbers and percentages, while the quantitative data with parametric distribution were presented as mean, standard deviations, and ranges, and the quantitative data with nonparametric distribution as median with interquartile range (IQR). As a normality test, the Shapiro test was utilized. When comparing two groups with qualitative data, the chi-square test was utilized, while the Fisher's exact test was used instead of the chi-square test when the expected count in any cell was less than 5. The confidence interval was set at 95%, while the acceptable margin of error was set at 5%. The *P* value was considered nonsignificant (NS) if $P > 0.05$, significant (*S*) if $P < 0.05$, and highly significant (HS) if $P < 0.01$.

Results

This study was carried out over 24 months on 50 females with biopsy-proven breast cancer lesions. The age of all patients ranged between 24 and 78 years, with a mean age of about 56.8 ± 14.8 years. Among the 50 patients, 16 patients (32%) were more than 60 years, 20 patients (40%) were ranged between 51 and 60 years, 10 patients (20%) were ranged between 35 and 50 years, while only 4 patients (8%) were less than 35 years (Fig. 1).

Regarding detection of breast lesions, it was found that 52 breast lesions in 50 females (96.3%) were detected by CT only, while 54 breast lesions (100%) were detected by PET/CT (*P* value 0.495 by Fisher's exact test).

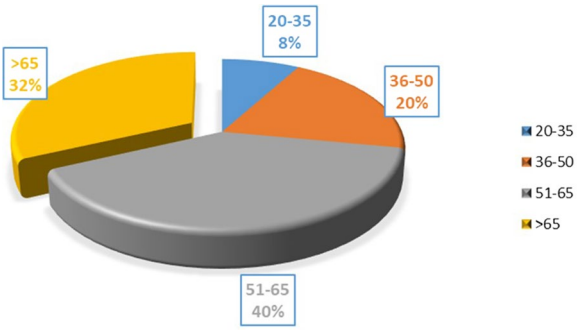

Fig. 1 Distribution of all patients according to age range

PET/CT revealed lesions in the right breast in 26 patients (52%), the left breast in 20 patients (40%), and bilaterally in 4 individuals (8%). In 14 cases (28%), combined PET/CT detected skin and nipple involvement. The SUV of breast cancer lesions ranged between 3.4 and 26.5, with a mean value ± SD was 9.92 ± 6.06. Among the 54 breast cancer lesions, the size of 34 lesions (63%) was less than or equal to 2 cm, 18 lesions (33.3%) were more than 5 cm, and 2 lesions (3.7%) were between more than 2 cm and less than or equal 5 cm (Figs. 2, 3, 4, 5, 6).

In 35 patients (70%), CT identified the involvement of axillary lymph nodes while detected by combined PET/CT in 38 patients (76%) with a *P* value of 0.65 (by chi-square test). The size of axillary lymph nodes detected by PET/CT ranged between 6 and 36 mm with a mean size of 12.5 ± 21.1 mm, and the SUV ranged between 3.1 and 33.2 with a mean SUV of 12.65 ± 10.89.

Internal mammary lymph node metastases were discovered in four cases using combined PET/CT (8%). The metastases of contralateral axillary lymph nodes were found by CT in 3 cases (6%) and by combined PET/CT in 5 patients (10%), with a *P* value of 0.72 (by Fisher's exact test).

Other extra-axillary lymph node metastases were found using CT in 11 patients (22%) and combined PET/CT in 14 patients (28%), with a *P* value of 0.64 (by chi-square test).

Among 50 patients, pulmonary and visceral metastasis was detected by CT in 7 patients (14%) and by combined PET/CT in 8 patients (16%) with a *P* value of 0.99 (by chi-square test).

Among 50 patients, bony metastasis was detected by CT in 14 patients (28%) and by combined PET/CT in 16 patients (32%) with a *P* value of 0.83 by chi-square test.

As regards T staging (local tumor staging) by both CT and PET/CT, 7 patients (14%) were staged as T1, 37

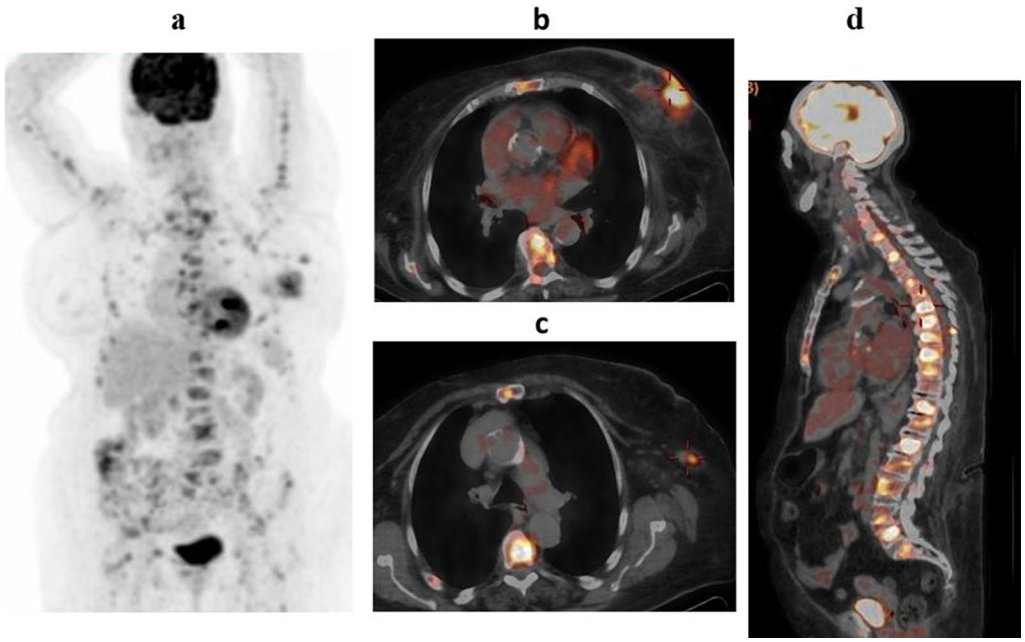

Fig. 2 A female patient aged 84 arrived with newly diagnosed left breast cancer (IDC grade III). **a** Whole-body PET MIP image revealed active left breast and left axillary lesions with other innumerable skeletal active lesions. **b** Axial fused PET/CT picture revealed an ill-defined irregular metabolically active left breast retroareolar soft tissue mass lesion with maximal axial dimensions of 43 × 25 mm and SUVmax of up to 7.33, coupled with modest overlaying skin thickening and surrounding architectural distortion. **c** Axial fused PET/CT image revealed enlarged metabolically active left axillary lymph node, measuring 11 × 7.5 mm and achieving up to 5.19 SUVmax. **d** Sagittal fused PET/CT image revealed innumerable hypermetabolic osseous lesions at the spine, achieving up to 10.41 SUVmax

patients (74%) were staged as T2, 4 patients (8%) were staged as T3, and 2 patients (4%) were staged as T4 stage (*P* value 1 by Fisher's exact test).

As regards N staging (nodal staging) by CT, 15 patients (30%) were staged as N0, 31 patients (62%) were staged as N1, 1 patient (2%) was staged as N2, and 3 patients (6%) were staged as N3. By PET/CT, 12 patients (24%) were staged as N0, 34 patients (68%) were staged as N1, 1 patient (2%) was staged as N2, and 3 patients (6%) were staged as N3 (*P* value of 0.94 by Fisher's exact test).

As regards M staging (distant metastasis staging), 30 patients (60%) were staged as M0 and 20 patients (40%) were staged as M1 by CT, while 28 patients (56%) were staged as M0 and 22 patients (44%) were staged as M1 by PET/CT (*P* value 0.84 by chi-square test).

According to the overall staging of all patients, CT staged 21 patients (42%) as stage IV, 14 patients (28%) as stage IIB, 5 patients (10%) as stage IIA, 4 patients (8%) as stage IIIA, 3 patients (6%) as stage IIIC, 2 patients (4%) as stage I, and 1 patient (2%) as stage IIIB, while fused PET/CT staged 23 patients (46%) as stage IV, 13 patients (26%) as stage IIB, 5 patients (10%) as stage IIA, 3 patients (6%) as stage IIIA, and 3 patients (6%) as stage IIIC. So, PET/CT upstaged 2 patients (with a *P* value of 0.99 by Fisher's exact test), as shown in Fig. 7.

Regarding lesion-based analysis, the diagnostic performance of PET/CT is higher than CT for breast cancer detection, with 100% sensitivity, PPV, and accuracy for PET/CT compared to 96%, 100%, and 96%, respectively, for CT.

Discussion

Breast cancer is the most frequent cancer and the main cause of cancer-related mortality worldwide in women, affecting both elderly and young patients. Once breast cancer has been detected, the tumor stage must be precisely evaluated before therapy and prognosis can be determined [9].

Clinical examination of cancer patients is essential for initiating and monitoring treatment. The findings of CT can be improved by using the extra functional information offered by FDG PET, especially in the follow-up of cancer patients following surgery, radiation treatment, or chemotherapy [10, 11].

FDG PET is superior to conventional CT in the aspects of initial cancer assessment and progression. Mild metabolic activity in FDG PET may lead to misleading results, which may be confused with natural physiological activity. Added CT scans may help the detection of pathological sites for FDG accumulation [12].

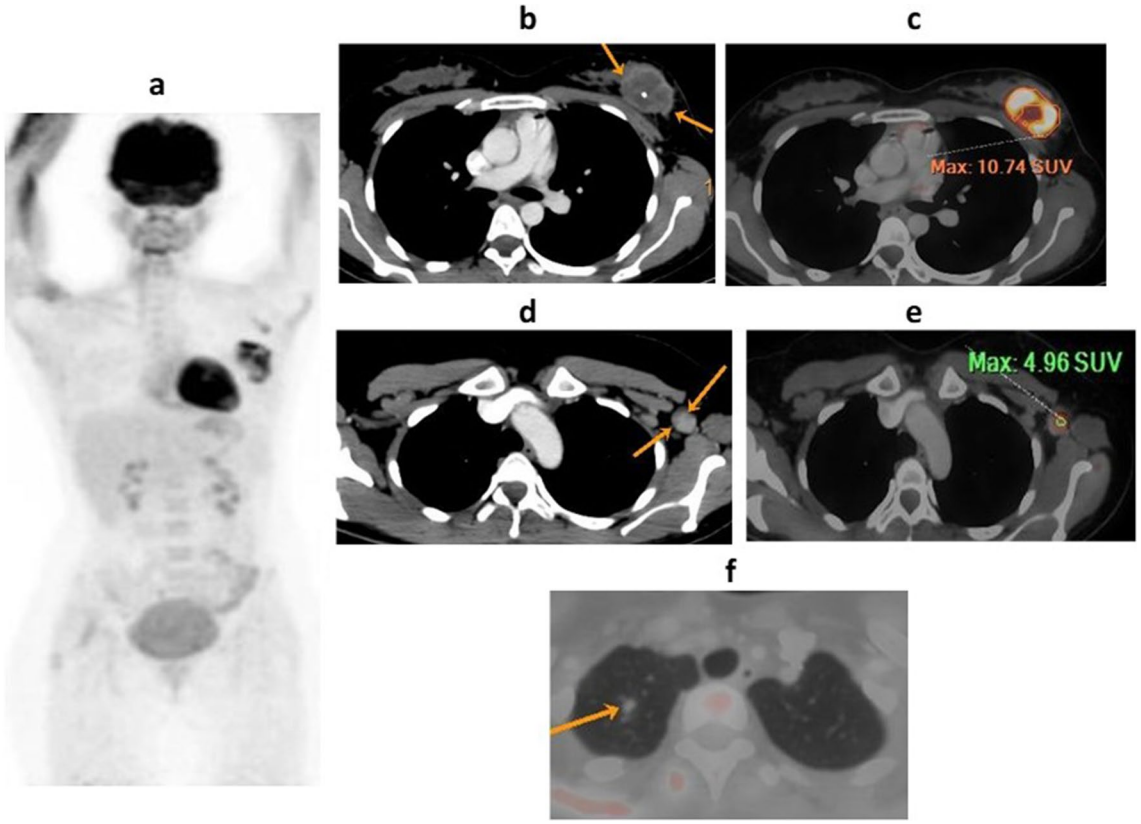

Fig. 3 A 27-year-old female patient arrived with newly diagnosed left breast cancer (IDC grade II). **a** A whole-body PET MIP picture indicated active lesions in the left breast and axilla. **b**, **c** Axial CECT and fused PET/CT scans indicated an active heterogeneously enhancing soft tissue mass lesion in the upper outer quadrant of the left breast, with central inactive patches of necrosis and a minor calcific focus, measuring approximately 30 × 41 × 59 mm and attaining a maximum SUVmax of 10.74. **d**, **e** Axial CECT and fused PET/CT images revealed few left axillary and subpectoral lymph nodes, measuring up to 15 × 17 mm and achieving up to 4.96 SUVmax. **f** Axial fused PET/CT image revealed small non-FDG avid pulmonary nodule at the right lung apex, measuring 6 mm

Axillary lymph node involvement and/or the existence of distant metastases cannot be detected accurately by conventional imaging, which changes the therapeutic treatment of these patients dramatically. Whole-body ^{18}F-FDG PET/CT has shown to be a useful imaging tool for malignant tumor staging. Furthermore, PET/CT can somewhat overcome the poor specificity of PET caused by the elevated glucose metabolic activities of benign tumors and inflammatory tissues [13].

The combination of PET and CT images enables integrated morphologic and functional imaging with a single scanner. The added functional information by FDG PET improves the evaluation of ambiguous CT finding, particularly in the follow-up of cancer patients who have had surgery, radiation therapy, or chemotherapy [14–16].

In general, FDG PET scans evaluated the pathologically elevated radiotracer uptake both quantitatively and quantitatively [17]. The SUV is elevated in malignant tumors than in benign lesions [18].

The mismatch between CT and PET images caused by patient breathing has serious consequences in evaluating areas near the heart, diaphragm, and lung bases, which may interfere with the interpretation of lung nodules [19]. To reduce misregistration, CT and PET scans were performed during shallow breathing in our studies, as Townsendetal et al. did [20].

Problems were frequently seen in diabetes patients because hyperglycemia inhibits ^{18}F-FDG absorption into the cells; therefore, blood glucose levels above 200 mg/dl result in considerable alterations in ^{18}F-FDG distribution. All of the participants in this research are within the suitable range of blood glucose level for injection.

The use of CECT in PET/CT assisted in improved characterization and anatomic localization of lesions, although contrast-enhanced pixel scan has the potential to cause focal artifacts in PET images, which is undesirable for tumor imaging [21].

In our study, we did PET with low-dose CT for attenuation correction, followed by contrast-enhanced CT for

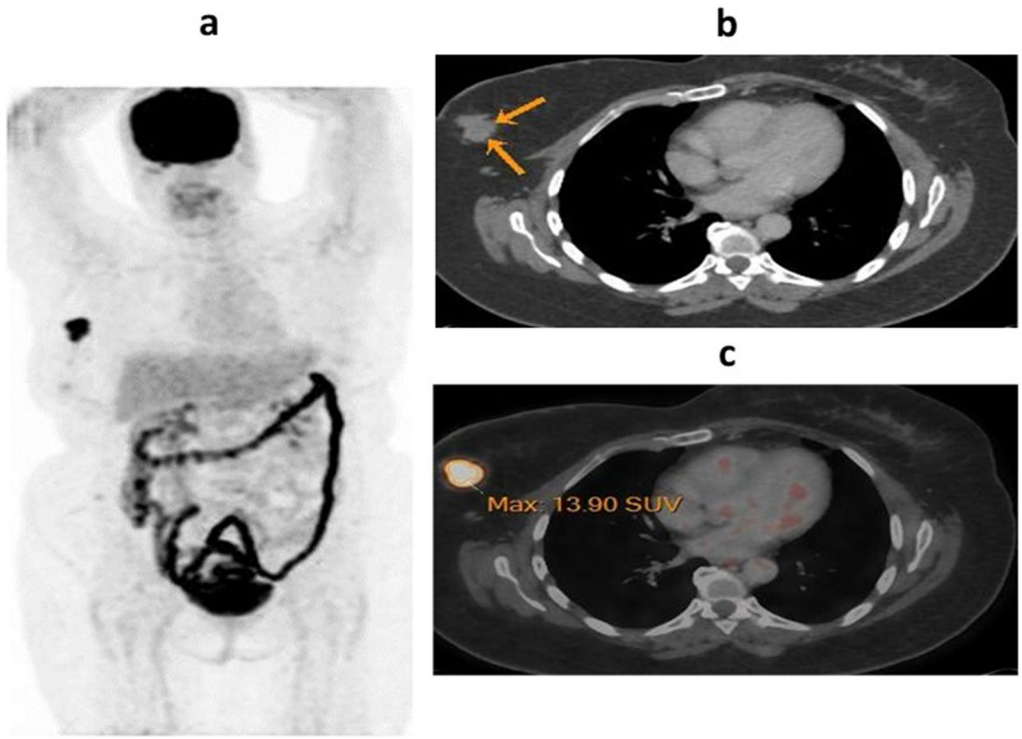

Fig. 4 A 55-year-old female patient arrived with newly diagnosed right breast cancer (adenoid cystic carcinoma). **a** A whole-body PET MIP picture indicated an active right breast lesion with no additional hypermetabolic lesions found anywhere else on the body. **b**, **c** Axial CECT and fused PET/CT images revealed speculated hypermetabolic soft tissue lesion at upper outer quadrant of the right breast, measuring about 23 × 27 mm and achieving up to 13.9 SUVmax

fused images. According to Bernsdorf et al., CECT is not used for attenuation correction; therefore, we did not have to deal with quantitative overestimation of ^{18}F-FDG activity or artifactual hot spots in the attenuation-corrected images [22].

The main goal of this study is to evaluate the diagnostic performance of ^{18}F-FDG PET/CT as a pre-therapeutic and preoperative assessment tool. Many previous studies revealed its superiority compared to other conventional modalities in alteration of initial patient staging. It was accurate in staging, which was crucial for the management of breast cancer patients.

In this study, combined PET/CT was demonstrated to be better than CT alone in detecting primary malignant breast tumors in the examined 50 patients, as PET/CT detected all 54 lesions compared to 52 lesions recognized by CT alone. These two lesions were tiny and could not be distinguished from surrounding glandular breast tissue on CT, although exhibiting significant metabolic activity in corresponding fused PET/CT images.

This agreed with prior research by Bernsdorf et al., who reported 97% sensitivity of PET/CT in detecting the breast tumors [22]. Furthermore, better sensitivity of FDG PET over CT alone was found by Mahner et al., that revealed 93% sensitivity of FDG–PET for detection of breast lesions compared to 88% of CT in patients with recently diagnosed breast cancer [23]. Fuster et al., in a trial on 60 patients, found that combined PET/CT could identify primary tumors in all the patients [4]. Tatsumi et al. [6] demonstrated that PET/CT is superior to PET or CT alone for the diagnosis of breast cancer.

In addition, although there was no statistically significant difference in this trial, combined PET/CT revealed metastatic axillary lymph nodes in 38 patients compared to 35 patients with CT alone.

This study matched with Tatsumi et al., who found that combined PET/CT was preferable to CT alone in detecting metastatic axillary lymph nodes as small lymph nodes usually interpreted negative by CT. As a result, PET/CT may be useful in prediction of patient outcomes, as patients with nodal metastasis have poorer prognosis than patients without nodal affection [6].

Many previous studies have shown that combined PET/CT had high specificity (90–100%), positive predictive value and sensitivity (63–70%) for detecting axillary nodal metastasis and can accurately differentiate reactive from metastatic lymph nodes when multiple enlarged axillary lymph nodes are seen in CT [4, 22, 24, 25].

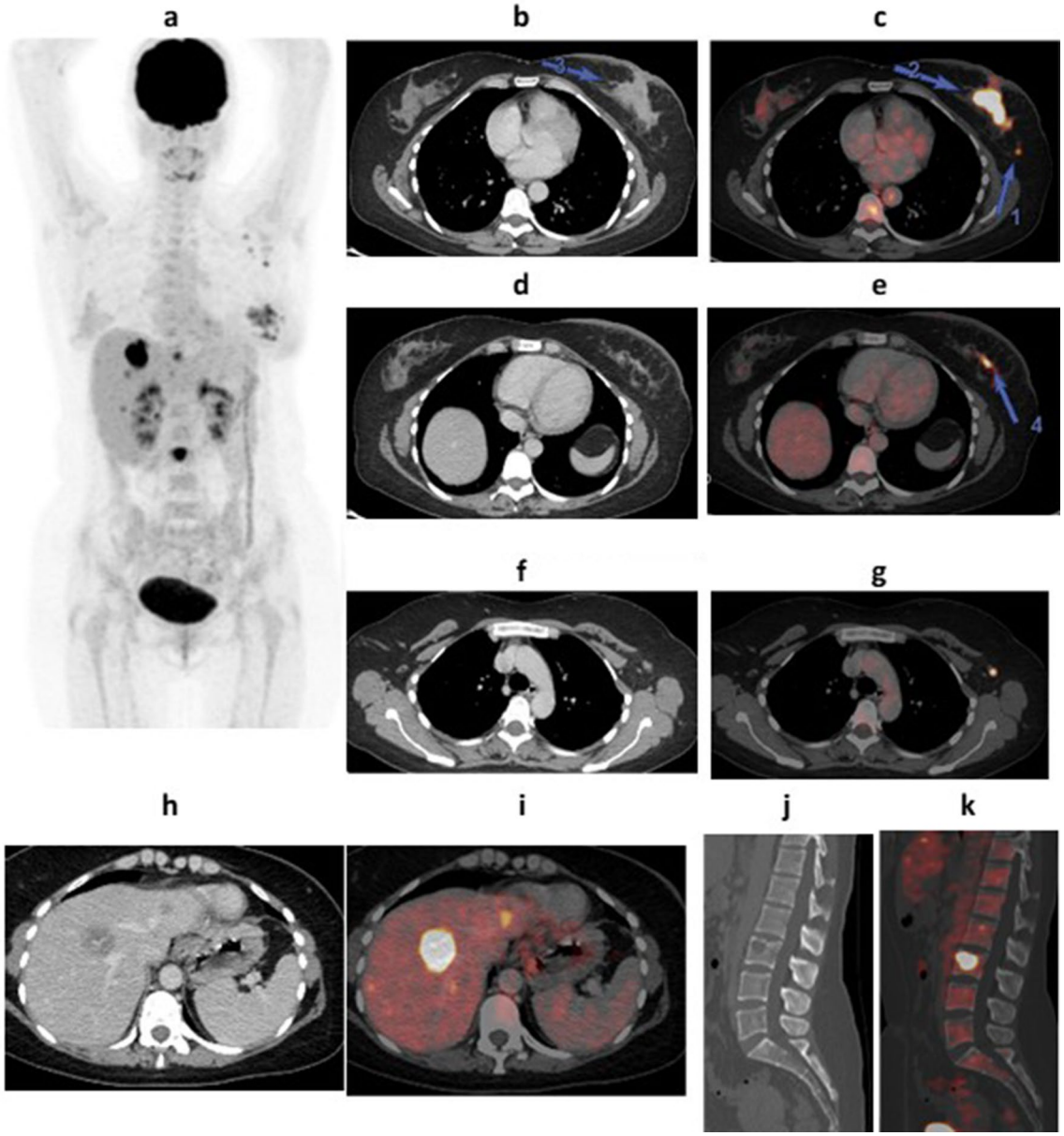

Fig. 5 A 37-year-old female patient arrived with newly diagnosed left breast cancer (IDC grade II). **a** A PET MIP picture of the entire body indicated active left breast, axillary, hepatic, and osseous lesions. **b**, **c**, **d**, **e** Axial CECT and fused PET/CT images revealed large ill-defined mildly enhancing speculated metabolically active left breast retroareolar soft tissue mass focally infiltrating the overlying nipple with retraction, measuring about 29 × 39 × 59 mm and achieving up to 7.9 SUVmax with other adjacent small metabolically active parenchymal lesions at lower outer quadrant, in fused PET/CT images, measuring up to 10 × 15 mm and achieving up to 6.6 SUVmax, not appreciated in CT images alone. **f**, **g** Axial CECT and fused PET/CT images revealed few variable-sized left axillary lymph nodes, measuring up to 11 × 21 mm and achieving up to 6.3 SUVmax. **h**, **i** Axial CECT and fused PET/CT images revealed bilobar hypodense metabolically active hepatic focal lesions, the largest and most active of them is seen at subsegment IVa, measuring about 29 × 31 × 39 mm and achieving 15.2 SUVmax. **j**, **k** Axial CECT and fused PET/CT images revealed hypermetabolic lytic osseous lesion at LV3 body, achieving 12 SUVmax

Our study also revealed that combined PET/CT was better than CT alone in detecting extra-axillary nodal involvement. In 14 patients (28%), combined PET/CT revealed distant nodal metastasis, while CT alone detected them in just 11 patients (22%). Combined PET/CT found contralateral axillary nodal deposits in 5 patients, but only in 3 patients by CT alone. This discrepancy can be explained by the substantial metabolic

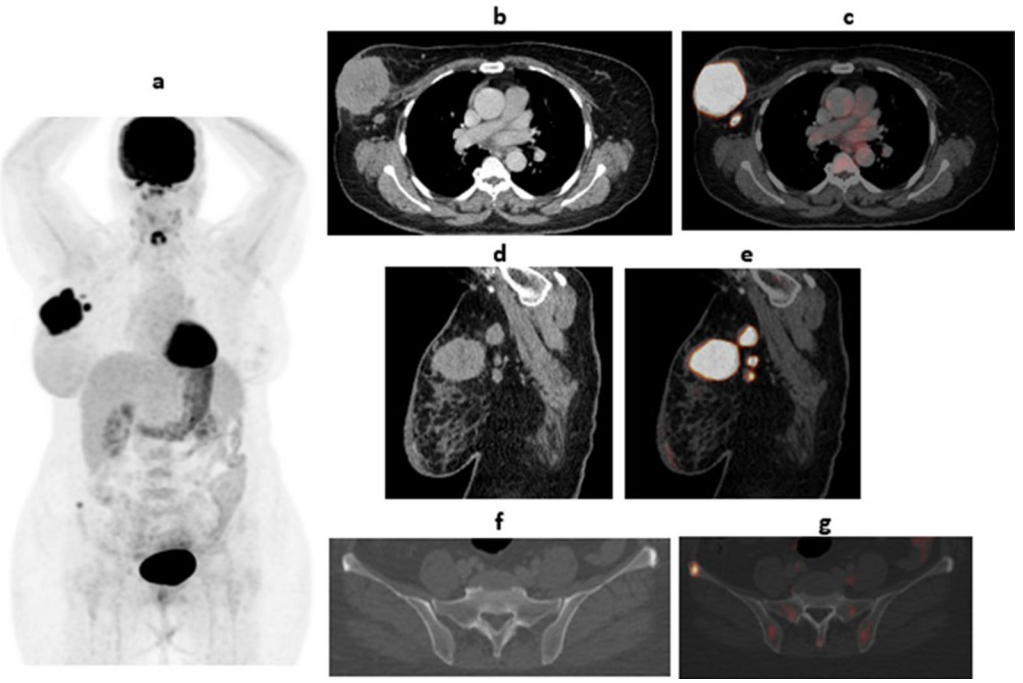

Fig. 6 A 61-year-old female patient presented with recently diagnosed right breast cancer (invasive ductal carcinoma). **a** Whole-body PET MIP image revealed large active right breast mass with multiple active ipsilateral axillary LNs as well as other less active right pelvic bone focus. **b**, **c**, **d**, **e** axial and sagittal CECT and fused PET/CT images revealed large right breast heterogeneously enhancing hypermetabolic upper outer quadrant mass, measuring 77 × 56 × 66 mm and achieving 23 SUVmax as well as multiple enlarged hypermetabolic right axillary lymph nodes, the largest measures 23 × 24 × 26 mm and achieving 20.5 SUVmax. **f**, **g** axial pelvic CT and fused PET/CT images (bone window) revealed small metabolically active right iliac bone deposit in fused PET/CT image, achieving 6 SUVmax, not appreciated in CT image alone

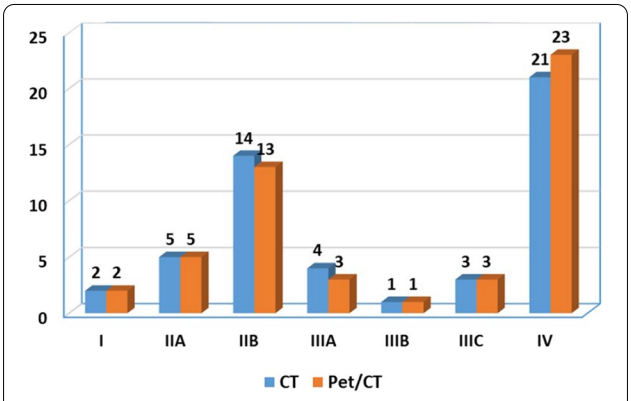

Fig. 7 Comparison between CT and PET/CT according to overall staging

activity by the combined PET/CT in tiny sub-centimetric lymph nodes that were negative on CT.

We also agreed with a study by Choi et al. who revealed that combined PET/CT was more efficient than contrast-enhanced CT in localizing extra-axillary nodal involvement [26]. According to Aukema et al., FDG PET/CT is a beneficial imaging technique to identify extra-axillary lymph node metastases, which may have an influence on adjuvant radiation treatment [27].

Breast cancer distant metastasis is usually seen in the lungs, liver, and bones. The ability to identify metastases at several organs and locations in a single examination is one advantage of whole-body PET/CT imaging compared to other imaging techniques [28].

Out of 50 patients included in the study, fused PET/CT revealed pulmonary and visceral metastases (including the liver, spleen, and suprarenal glands) in 8 patients, while recognized in 7 patients by CT alone. Furthermore, fused PET/CT identified osseous deposits in 16 patients, whereas CT alone showed osseous deposits in 14 patients. This study showed overall better performance of combined PET/CT than CT alone in detecting distant metastases.

Our study matched with Bernsdorf et al. who showed that PET/CT is a useful method for detecting extra-axillary nodal involvement, distant metastases, and other occult primary tumors. They revealed that preoperative FDG PET/CT scanning had a significant influence on staging and subsequent management [22].

This is consistent with the findings of other studies by Choi et al., Groheux et al., and Morris et al., who found

that ^{18}F-FDG PET/CT has higher overall sensitivity and specificity in detecting distant metastases than conventional imaging and is also preferable in evaluating breast cancer lesions [26, 29, 30].

The main limitation of this study was the relatively small sample size; therefore, prospective studies in the future with a larger number of patients will more clearly define the role of PET/CT-based evaluation with more accurate results.

Conclusions

Fused PET/CT is a valuable single imaging modality that provides a whole-body overview evaluation of newly diagnosed breast cancer patients. It is an accurate, efficient, and noninvasive imaging tool for detecting nodal and distant metastasis, which in turn lead to modification of the initial patient staging and subsequently changing the management planes.

Abbreviations

^{18}F-FDG: ^{18}F-Fluorodeoxyglucose; PET/CT: Positron emission tomography/computed tomography; CT: Computed tomography; CECT: Contrast-enhanced computed tomography; SUVmax: Maximum standard uptake value; mg/dL: Milligram per deciliter; mCi: Millicurie; Kg: Kilogram; mL: Milliliter; mA: Milliampere; kV: Kilovolt; s: Second; mm: Millimeter.

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Not applicable

Author contributions

AM carried out the PET/CT studies and collected the data. SA, HM, and OA participated in the design of the study. AM performed the statistical analysis and SA drafted the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analyzed during this study are included in this article.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Research Ethics Committee (REC) of Ain Shams University, Faculty of Medicine (FMASU M D 341/ 2018), and written informed consent was obtained from all patients to participate in the study.

Consent for publication

Written informed consent was obtained from all patients for publication of the study.

Competing interests

The authors declare that they have no competing interests.

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