RESEARCH ARTICLE

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Impact of [18]FDG PET/CT on Clinical Management, Cost Effectiveness, and Radiation Exposure in Newly Diagnosed Breast Cancer Patients

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Abstract

Background: For the initial staging of breast cancer (BC), [18]FDG PET/CT is recommended by professional guidelines in stage III (except T3N1) and inflammatory BC (T4d) and optional when conventional imaging is equivocal or suspicious. However, growing evidence also supports its role in the staging of intermediate-risk groups (IIA, IIB, T3N1 of IA). This study aimed to compare the impact of [18]FDG PET/CT with conventional imaging (CT-chest+abdomen+pelvis and bone scan; CT-CAP+BS) in staging, cost-effectiveness, and radiation exposure in the initial staging of BC. **Material and Method:** A retrospective study (April 2020 2024) included 115 biopsy-proven BC patients who had CT-CAP+BS and [18]FDG PET/CT for initial staging. Data were analyzed to see the impact of [18]FDG PET/CT on change in staging, cost-effectiveness, and radiation exposure compared to CA-CAP+BS. **Results:** Out of 115 patients (113 female and 02 male), 110 had unilateral and 5 had bilateral BC (Invasive Ductal Ca. 107; Non-IDC: 08) with non-significant laterality. The overall upstaging rate for regional nodal and/or distant metastases was 36% (24/66; excluded 49 with stage IV). The overall upstaging rate due to unsuspected higher nodal metastases was 20% (predominantly stage IIA, and IIB). Upstaging rate to stage IV was seen in 17% (11/66; predominantly in IIIA-C). The overall concordance (no change in staging) was seen in 64% (42/66) while no downstaging was found in any patient. In patients with stage-IV disease (n = 49), [18]FDG PET/CT identified a higher number of hypermetabolic lesions in 18 (37%), lesser in 07 (14%), and similar in 24 (49%) cases. The estimated cost in Pak rupees for CT-CAP+BS and PET/CT was 139000 and 106000 respectively. The mean effective dose imparted by [18]FDG PET/CT was 8.85 mSv compared to the reported 26.6 mSv by CT-CAP+BS. **Conclusion:** We conclude that in the initial staging of BC, [18]FDG PET/CT compared with CT-CAP+BS has a significant impact on decision-making by upstaging the disease in stage II and III and detecting more metastatic lesions in stage-IV disease. Furthermore, [18]FDG PET/CT is more cost-effective and imparts significantly lower radiation exposure as compared with CT+CAP+BS. These findings support the inclusion of [18]FDG PET/CT in the initial staging of stage II-IV BC.

Keywords: Breast cancer- Staging- Upstaging- [18]FDG PET/CT- Cost effective- Radiation exposure

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Introduction

Breast cancer (BC) is the most common cancer and the second leading cause of cancer related mortality in women with 01 million new cases every year [1]. One in nine Pakistani females has a lifetime chance to have BC and in Asia, Pakistan has the highest rate of BC [2]. In developed countries like United States, disease is localized to breast in 62% and to breast and regional nodes in 30% of patients (www.cancer.or/content/). However, in Pakistan due to lack of awareness and screening mammogram especially in rural areas, women usually present with locally advanced breast cancer (LABC) and higher incidence of distant metastasis with smaller primary tumors [2, 3]. National Cancer Comprehensive Network (NCCN) guidelines for breast cancer 2022 recommend contrast enhanced CT of chest, abdomen, pelvis (CT-CAP) with radionuclide bone scan (BS) for patients with cT0-4N1-3 or T2-4N0 [4]. 18F-fluorodeoxyglucose ([18]F-FDG) PET/CT is considered optional in circumstances in which CT-CAP and BS are equivocal or suspicious [4]. The NCCN guidelines do not recommend [18]FDG PET/CT in the staging of clinical stage I, II, or operable III (T3 N1) BC, due to its high false-negative rate for lesions <1 cm and high false-positive scans in patients without locally advanced disease [4]. However, in LABC (III-A

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except T3N1, IIIB and IIIC) and inflammatory BC (T4d), ^{18}FDG PET/CT has an established role in staging [5]. Recent studies have shown that 18FDG-PET/CT may also be useful in intermediate risk group including IIA, IIB and T3N1 disease of stage IIIA [5]. Due to higher incidence and aggressive behavior of BC in Pakistani population, we compared role of CT-CAP+BS and ^{18}FDG PET/CT in upstaging, cost effectiveness and radiation exposure in newly diagnosed BC patients.

Materials and Methods

This retrospective study was conducted at PET/CT imaging facility of Department of Radiology, Aga Khan University Hospital, Karachi Pakistan. The study was approved by the institutional Ethical Review Committee (ERC: 2024-10043-28834). The study included 115 patients with BC who underwent ^{18}FDG PET/CT scans between April 2020 and February 2024. Inclusion criteria were treatment naïve newly diagnosed BC patients who were referred for ^{18}FDG PET/CT within 4 weeks of CT-CAP and BS. ^{18}FDG PET/CT indications included suspicious findings on prior imaging and/or to assess tumor burden in known clinical stage IV disease (due to late arrival and/or late disclosure of disease primarily due to social taboos). Patients with history of prior treatment (like surgery / chemo / endocrine) or not having CT-CAP+BS within 4 weeks of ^{18}FDG PET/CT were excluded. Age at diagnosis, tumor histology, receptor status (estrogen receptor, progesterone receptor, HER2 expression) and initial clinical stage (cTcN) were recorded for each patient. ^{18}FDG PET/CT findings were then evaluated to see impact upon change in clinical stage, cost effectiveness and radiation exposure.

^{18}FDG PET/CT Imaging

^{18}FDG PET/CT was performed as per institutional protocol adopted from European Association of Nuclear Medicine (EANM) guidelines [6]. All patients had 4-6 hours of fasting (only plain water was allowed) and a fasting blood sugar less than 200 mg% before receiving an intravenous 18FDG dose of 3 MBq/Kg in the uptake room. During uptake period (55 -75 minute) patients were requested to laydown comfortably and allowed to take about 500-1000 ml of plain water. Bladder was emptied prior to call the patient in PET/CT imaging suite equipped with Celesteion, Toshiba, Japan. A low dose CT examination (mid brain to mid-thigh) without intravenous contrast from head to toe followed by acquisition of PET imaging using 3 minute/bed position from toe to head in all patients.

Image Interpretation

All PET/CT studies were jointly reported by a team of 02 nuclear physicians and 01 radiologist (all having at least 10-years' experience). PET/CT was read in context with other imaging studies available to ensure best practices. We analyzed the data based on nuclear physicians' and radiologist interpretations. An abnormal 18FDG uptake was defined as non-physiologic, non-inflammatory, and focal uptake above the local background activity. An imaging finding was considered positive for radiographic evidence of unsuspected regional nodal metastases when the radiologist reported a malignancy found outside of the N1 axillary region, such as subpectoral, internal mammary, or supraclavicular; imaging was considered positive for distant metastases when the radiologist reported disease in other organs besides the breasts. In suspicious PET/CT findings, histology was the preferred method of confirmation for malignancy or correlation with MRI or CT was used to confirm the distant metastases.

Cost Estimate

At our university the estimated cost of contrast enhanced CT (chest, abdomen and pelvis) and radionuclide bone scan was 139000 (Pak Rupees). While the cost of non-contrast enhanced ^{18}FDG PET/CT was 106000 (Pak rupees). Worth to mention to consider the travelling cost incurred in those patients who used to travel from outside Karachi on each visit.

Statistical Analysis

Commercially available packages including Microsoft Excel 2016, Medcalc® 2024 version 22.019, and the Statistical Package for Social Sciences (SPSS 19® Armonk, New York, US) were utilized for the study. Statistical significance was established as $P < 0.05$ (where applicable using Two-sample T-test). For continuous variables, the mean difference and standard deviation were computed for each parameter. We did not apply correction for multiple comparison as it would increase the number of false negatives.

Results

The study group included 115 newly diagnosed BC patients (113 female and 02 male; median age: 58 years [range: 25 – 88 years]). No significant gender-based difference was found for diabetes and body mass index (BMI). Unilateral cancer was found in 110 patients (Right: 52 [45%] and Left: 58 [51%]) while 05 (04%) had bilateral disease. Of 115 patients, 107 (93%) had invasive ductal carcinoma (IDC), 02 (02%) had invasive lobular carcinoma (ILC), 04 (03%) had ductal carcinoma in-situ (DCIS) while lobular carcinoma in-situ (LCIS) was reported in 02 (02%) patients (Table 1).

TNM staging based on CT-CAP+BS prior to ^{18}FDG PET/CT studies were the following: stage IA (n=08, 07%), stage IB (n = 0), stage IIA (n = 18, 16%), stage IIB (n = 13, 11%), stage IIIA (n = 03, 03%), stage IIIB (n = 15, 13%), stage IIIC ((n = 09, 08%) and stage IV (n = 49, 42%) (Table 2). Taking the ^{18}FDG PET/CT findings into consideration the disease stages were as follows: : stage IA (n=07, 06%), stage IB (n = 01, 01%), stage IIA (n = 11, 10%), stage IIB (n = 10, 09%), stage IIIA (n = 06, 05%), stage IIIB (n = 12, 10%), stage IIIC ((n = 08, 07%) and stage IV (n = 60, 52%) [Table 2]. Impact of ^{18}FDG PET/CT upon CT-CAP+BS based staging in terms of upstaging or same staging were as follow: stage IA (n = 01 : 07, 012% : 88%), stage IIA (n = 07 : 11, 39% : 61%), stage IIB (n = 05 : 08, 38% : 62%), stage IIIA (n = 01 : 02, 33% : 67%), stage IIIB (n = 06 : 09, 40% : 60%) and stage IIIC

Table 1. Study Demographics of Breast Cancer Patients for Initial Staging

Variables	N=115
Age in years	58
Median (range)	(25-88 years)
Gender (Male: Female)	02: 113 (02%: 98%)
DM: Non-DM	20: 95 (17: 83%)
BMI (Kg/m^2) Mean ± SD	29.766 ± 5.795
Breast Cancer laterality	52:58:05
Right: Left: Bilateral	(45%: 51%: 04%)
Tumor Type	107: 02 : 04: 02
IDC: ILC: DCIS :LCIS	(93%: 02%: 03%: 02%)
TNM Staging based on (CTBS)	
IA	08 (07%)
IIA	18 (16%)
IIB	13 (11%)
IIIA	03 (03%)
IIIB	15 (13%)
IIIC	09 (08%)
IV	49 (42%)

SD, Standard Deviation; DM, Diabetes Mellitus; IDC, Infiltrating Ductal Carcinoma; ILC, Infiltrating Lobular Carcinoma; DCIS, Ductal Carcinoma in Situ; LCIS, lobular Carcinoma in Situ; CTBS, Computed Tomography and Bone Scintigraphy

(n = 04 :05, 44% : 56%). The overall upstaging rate for regional nodal metastases and/or distant metastases was 36% (24/66; excluded 49 patients with stage IV disease). The overall upstaging rate due to unsuspected higher nodal metastases (including supraclavicular, infraclavicular or internal mammary nodes) was 20% (13/66), including 12% for stage IA (01/08), 33% for stage IIA (6/18), 31% for stage IIB (4/13), 13% for stage IIIB (02/15) and 0% for stage IIIA (0/03) and IIIC (0/09). The overall upstaging rate to stage IV based on unsuspected distant metastases was 17% (11/66), including 0% for stage IA (0/66), 06% for stage IIA (01/18), 08% for stage IIB (01/13), 33% for stage IIIA (01/03), 27% for stage IIIB (04/15), and 44% for stage IIIC (04/09). The overall concordance (no change in staging) was seen in 64% (42/66) and no downstaging was seen in any patient. In patients with stage IV disease (n = 49), [18]FDG PET/CT identified higher number of hypermetabolic lesions in 18 (37%), lesser in 07 (14%) and same numbers of lesions in 24 (49%) cases (Table 2).

Cost Estimate

The estimated cost of contrast enhanced CT-CAP+BS was 139000 (Pak Rupees) and for [18]FDG PET/CT was 106000 (Pak rupees). This difference would remain same if CT-CAP+BS and [18]FDG PET/CT continue to use for follow-up and response assessment. We see cost effectiveness in patients in whom [18]FDG PET/CT rather CT-CAP+BS is selected for follow-up the disease course.

Radiation Exposure

Radiation exposure imparted by low dose [18]FDG PET/CT was measured as we have reported in a prior study with similar acquisition parameters adopted from EANM guidelines [7] (CT: Tube Potential =120 kVp; Tube Current = up to 120 mAs; Rotation Time = 0.58 sec/rotation; Slice Thickness = 1mm; 18FDG Dose: 3 MBq/Kg) [7]. The mean effective dose by using these acquisition parameters was reported as 8.85 mSv per [18]FDG PET/CT study [7].

Discussion

[18]FDG PET/CT is a useful imaging modality having an established role in staging LABC while futile in T1N0 disease. However, recent data have shown its evolving role in intermediate risk groups including stage IIA, IIB and T3N1 of stage IIIA. In this study we have primarily evaluated the role of [18]FDG PET/CT in staging newly diagnosed treatment naïve BC patients in Pakistani women. In addition, we also evaluated the cost effectiveness and radiation exposure associated with [18]FDG PET/CT compared with CT-CAP+BS.

We have observed that [18]FDG PET/CT has an overall upstaging rate of 36% in patients with stage I-III disease which is comparable with study published in 2018 [8]. In our study, the highest upstaging rate of 44% was observed in stage IIIC compared to 68.8% in stage IIIB in a published study [8]. This is significantly high and

Table 2. Summary of [18]FDG PET/CT based Upstaging Categorized by Initial TNM Staging based on Conventional Imaging (CT-CAP+BS).

TNM staging based on CT-CAP+BS	TNM staging based on [18]FDG PET/CT											
	N	IA	IB	IIA	IIB	IIIA	IIIB	IIIC	IV	Up-staging	Same-Staging	Down-staging
IA	8	7	1	0	0	0	0	0	0	(01) 12%	(07) 88%	0%
IIA	18	0	0	11	2	2	2	0	1	(07) 39%	(11) 61%	0%
IIB	13	0	0	0	8	2	1	1	1	(05) 38%	(08) 62%	0%
IIIA	3	0	0	0	0	2	0	0	1	(01) 33%	(02) 67%	0%
IIIB	15	0	0	0	0	0	9	2	4	(06) 40%	(09) 60%	0%
IIIC	9	0	0	0	0	0	0	5	4	(04) 44%	(05) 56%	0%
IV	49	0	0	0	0	0	0	0	49	Based on FDG avid sites		
										(18) 37%	(24) 49%	(07) 14%
Overall	115	7	1	11	10	6	12	8	60	(42) 37%	(66) 57%	(07) 06%

CT-CAP+BS = Computed Tomography – Chest, Abdomen, Pelvis+Bone Scintigraphy

plausible reason could be the numerical difference in patients' number in individual groups in two studies (stage IIIB: 15 Vs 16; stage IIIC: 09 Vs 24). Our findings are also in concordance with another published study which reported an upstaging rate of 37% in patients with stage IIA-IIIC BC [9]. On contrary, another published study reported a significantly higher upstaging rate of 66.6% caused by ^{18}FDG PET/CT in primary staging group [10]. This could be due to smaller sample size (only 15 patients in primary staging group), although the major upstaging was seen in Stage II and III (33.3% Vs 44% in stage III in our study) and downstaging from stage IV (53.3%) to lower stage(s) in 13.3% (no downstaging seen in our study). Overall upstaging due to unsuspected higher nodal metastasis in our study was 20% which is comparable to a published study having an overall rate of 24% [9]. However, in that study significant change was observed in stage IIIA (44%) while in our study stage IIA and IIB had a significant impact (33% and 31% respectively). The reason for predilection towards relatively early stage in our study, could be an aggressive phenotype in Pakistani women [3] with relatively extensive metastasis in normal sized nodes [2]. Another prospective study has shown an upstaging rate from N1 to N3 in 20% which is like our finding [11]. However, a published prospective study has shown upstaging from N1 to N3 in 57% cases [12]. But this study had included tumor ≥T2 cm or positive regional nodes which could be the reason for higher upstaging rate. Overall upstaging rate for distant metastasis in our study was 17% with higher incidence in stage III (highest 44% in stage IIIC). This is comparable to a published study having an upstaging rate of 14% for distant metastasis with highest incidence in stage III (highest 37% in stage IIIC). This is explained by the fact that axillary nodal metastasis is the most important predictor of overall recurrence, survival, and higher rate of distant metastasis in patients with breast cancer [13, 14]. In stage IV patients of our study, ^{18}FDG PET/CT compared with CT-CAP+BS has detected higher number of hypermetabolic metastases in 37% and excluded equivocal lesions due to lack of metabolic activity (14% cases; predominantly hypodense hepatic and adrenal lesions showing no 18FDG avidity). ^{18}FDG PET/CT has an established higher diagnostic accuracy for detecting occult distant metastasis [5]. ^{18}FDG PET/CT is more sensitive and specific than CT-CAP+BS for diagnosing osteolytic or mixed bone metastasis or marrow deposit; however, its diagnostic accuracy is lower for osteoblastic lesions due to variable metabolic activity [15]. Similarly, ^{18}FDG PET/CT has limited diagnostic accuracy for brain metastasis (due to intense 18FDG uptake in normal brain) and smaller lung nodules (sensitivity 85.7% Vs 100%; similar specificity of 98.2% due to partial volume effect and respiratory movement) [16]. However, it is important to be cognizant about false positive rate of ^{18}FDG PET/CT which is reported as high as 16% in an early study and results in unjustified further examinations [17]. For this reason, ^{18}FDG PET/CT is not recommended in clinical stage I (T1N0) [5].

Cost Estimate

The estimated cost of contrast enhanced CT-CAP+BS was 139,000 (Pak Rupees) and for ^{18}FDG PET/CT was 106,000 (Pak rupees). This difference would remain same if CT-CAP+BS and ^{18}FDG PET/CT continue to use for follow-up and response assessment. We see cost effectiveness in patients in whom ^{18}FDG PET/CT rather CT-CAP+BS is selected for follow-up the disease course. Furthermore, having a single whole-body imaging (^{18}FDG PET/CT) is more convenient and if follow-up ^{18}FDG PET/CT is done without intravenous contrast (which is preferred in most centers), this would further minimize the chances of contrast related side effects as well. We feel that if baseline ^{18}FDG PET/CT is performed with IV contrast but for follow-up a low dose ^{18}FDG PET/CT without IV contrast is used, this could be a viable practice towards a significant cost saving and lowering the contrast related side effects.

Radiation Exposure

In recent years, better survival in some cancers including breast, there is a growing concern for cumulative radiation exposure caused by CT-CAP+BS and ^{18}FDG PET/CT and higher probability for second primary malignancy in future. According to published data, a standard contrast enhanced CT-CAP imparts a mean effective dose of 22.4 ± 5.9 mSv (milli-Sievert) per procedure [18]. The effective dose from a radionuclide bone scan (BS) is about 4.208 ± 0.443 mSv (for an average 20 millicurie injected dose of 99mTc-MDP) [19]. This makes an average effective dose imparted by CT-CAP+BS of 26.6 mSv (22.4 mSv + 4.2 mSv). While a low dose ^{18}FDG PET/CT performed as per EANM imaging guidelines [6] imparts a mean effective dose of 8.85 mSv as published by our group [7]. These figures speak loudly about the significantly low radiation exposure associated with ^{18}FDG PET/CT and draw attention to consider the option as discussed in cost estimate section.

We feel that the strength of this study is the adequate number of treatment naïve patients of all stages of BC who were evaluated for impact of ^{18}FDG PET/CT upon change in staging and management, cost effectiveness and radiation exposure. Interestingly data favor the positive impact of including ^{18}FDG PET/CT in stage IIA, IIB, and T3N1 of stage IIIA. Another strength of this study is that all ^{18}FDG PET/CT were reported by a team of 02 nuclear physicians and 01 radiologist all having more than 10 years' experience.

Our study has several limitations

First, it is a single institutional retrospective study and data collected could have potential of inherent selection biases. Secondly, unsuspected metastatic lesions on ^{18}FDG PET/CT in some patients did not have biopsy but ancillary imaging. Thirdly, we detected 07 (14%) false-positives distant metastases which reduces the specificity and added the cost of biopsy or additional imaging as well. Lastly, since PET/CT was performed only on clinical indication, we cannot exclude a possible clinical bias.

We conclude that in initial staging of BC, ^{18}FDG PET/CT compared with CT-CAP+BS has a significant impact upon

decision making by upstaging the disease in stage II and III and detects more metastatic lesions in stage IV disease. Furthermore, [18]FDG PET/CT is more cost effective and imparts significantly lower radiation exposure as compared with CT+CAP+BS. These findings support the inclusion of [18]FDG PET/CT in initial staging of stage II-IV breast cancers.

Author Contribution Statement

Maseeh uz Zaman: Conception, interpretation, critical revision, final approval. Nosheen Fatima: Conception, Interpretation, statistics, drafting, final approval. Unaiza Zaman: Conception, Design, critical revision. Anwar Ahmad: Interpretation, critical revision. Sidra Zaman: Literature search, drafting, critical revision. Khalil Khan: Data collection, standardization of protocol, methodology

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Institutional Ethical Board Committee

The study was approved by Ethical Review Committee of Aga Khan University Hospital, Karachi Pakistan (#2024-10043-28834).

Consent to participate and publication

The requirement for informed consent was waived.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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