

Role of ^{18}F - FDG PET-CT and MRI for Predicting Pathological Response to Neoadjuvant Chemotherapy in Breast Cancer Management

¹Shahnaj Hossain Dinu, ²Pupree Mutsuddy, ²Tapati Mandal, ²Khokon Kumar Nath, ²Md. Abu Bakker Siddique and ³Shamim M F Begum

¹Directorate General of Health Services (DGHS), Mohakhali, Dhaka, ²National Institute of Nuclear Medicine & Allied Sciences (NINMAS),
³Bangladesh Atomic Energy Commission, Dhaka

Correspondence Address : Dr. Shahnaj Hossain Dinu, MD (Nuclear Medicine), Directorate General of Health Services (DGHS), Mohakhali, Dhaka. Email: drshahnajhossaindinu@gmail.com

ABSTRACT

Background: Neoadjuvant chemotherapy is used in breast cancer patients to reduce tumor size and prevent micrometastasis, with accurate assessment through ^{18}F -FDG PET-CT and DCE-MRI providing operation guidelines.

Objective: To establish the diagnostic accuracy of ^{18}F -FDG PET-CT scans and MRI compared to pathological response for NAC assessment in BC management.

Patients and Methods: This cross-sectional comparative study was conducted at NINMAS, Shahbag, Dhaka, under a Coordinated Research Project (CRP)-E1.30.44 of IAEA. The study spanned from September 2022 to February 2024, examining 17 stage II and stage III BC patients who had received NAC before surgery and had prior ^{18}F -FDG PET-CT and DCE-MRI studies. For therapy response of NAC, ^{18}F -FDG PET-CT and MRI were performed after completion of NAC. Parameters of ^{18}F -FDG PET-CT and MRI were obtained and evaluated by using PET Response Criteria in solid tumors (PERCIST) 1.0 based on SUV normalized by lean body mass (SULpeak) in PET-CT and Response Evaluation Criteria in solid tumors (RECIST) 1.1 based on the longest diameter in MRI of primary tumors and axillary lymph nodes, respectively. Descriptive and analytical analyses were performed to examine ^{18}F -FDG PET-CT and MRI to compare pathological response after surgery, and diagnostic accuracies were compared.

Result: The study patients were divided into responder 12 (70.5%) and non-responder five (29.4%) groups according to overall pathological response to NAC after surgery. Both RECIST 1.1 and PERCIST 1.0 with post-surgical pathological response to NAC of BC patients were compared.

The sensitivity of PET-CT with pathological response to NAC of the study population was 80%, followed by specificity 100%, positive predictive value (PPV) 100%, and negative predictive value (NPV) 92.31%. The sensitivity of MRI with pathological response to NAC of study patients was 100%, followed by specificity at 83.33%, PPV at 71.43%, and NPV at 100%. The accuracy levels of PET-CT and MRI were 94.12% and 88.24%, respectively. PPV and accuracy compared to RECIST 1.1; PERCIST 1.0 was more accurate in predicting pathological response to NAC of BC patients.

Conclusion: PET-CT accurately predicts pathological response in breast cancer patients following NAC, reducing surgical intervention and chemo radiation burden, thereby reducing the need for chemo radiation.

Keywords: Neoadjuvant Chemotherapy, Response Evaluation Criteria in Solid Tumors, PET Response Criteria in Solid Tumors, Pathological Response

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INTRODUCTION

Female breast cancer (BC) is responsible for 6.9% of deaths for cancer-related mortality globally. BC in women has overtaken lung cancer to become the most common type of cancer (11.7%), with lung cancer following closely behind at 11.4%. BC is affecting 1 in 8 women worldwide. In 2020, GLOBOCAN estimated 2.3 million cases and 685 thousand deaths from female BC globally (1).

In Bangladesh, approximately 7,000 women die from BC annually, and 13,000 are diagnosed, according to the International Agency for Research on Cancer (2).

As per the Bangladesh Maternal Mortality Survey conducted in 2010, BC contributes to a significant proportion of female mortalities within the age of 15 to 44 years. Incidence is higher in developed countries, but mortality rates are similar due to limited resources in developing countries. Early diagnosis and management could not be done properly due to a lack of screening and imaging. Nowadays, neoadjuvant chemotherapy (NAC) is increasingly used to treat BC in Bangladesh (3).

NAC is a pre-surgery treatment for 4-6 months to reduce tumor size. It may prevent unnecessary surgery, lower complications, help with breast-conserving surgery (BCS), and guide post-surgery treatment. Malignancy negative margin is crucial during surgery (4).

The gold standard for evaluating therapeutic response is post-operative histopathology analysis, which determines

whether pathological response is achieved or not. Preoperative evaluation after NAC can help guide surgical resection and ensure removal of active tumor. This information is essential since it is believed that patients who receive a response after NAC would do better in treatment outcomes than those who do not. It can be difficult to assess the pathological response before surgery and without doing histology. For the initial evaluation of BC, conventional imaging techniques like mammography and ultrasound are frequently used as diagnostic imaging modalities. Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) is used to establish the extent of the disease and also for the assessment of NAC response to BC. The lack of ability of MRI to differentiate between viable tissue and fibrotic scar tissue, however, may be a drawback. So there is a necessity to find out the accurate imaging method for predicting pathological response evaluation after NAC treatment. ^{18}F -FDG PET-CT may be a better predictor of response than MRI due to its ability to detect metabolic changes earlier. It's also useful for whole-body staging and re-staging. The study aims to assess the accuracy of ^{18}F -FDG PET-CT and MRI for predicting pathological response in patients with BC (5).

The MRI measurements may not always assess these metabolic changes and also blood flow and microvascular permeability. Changes in the standardized uptake value (SUV) assessment on ^{18}F -FDG PET-CT scan are a reasonably reliable predictor of the pathologic response to NAC in BC patients. ^{18}F -FDG PET-CT scan is also useful in the management of BC patients over traditional imaging modalities for not only evaluating treatment response but also whole-body staging and re-staging.

For NAC response prediction, the most accurate imaging modality must be chosen. The aim of this study is to assess the diagnostic accuracy of ^{18}F -FDG PET-CT and MRI breast as well as pathological response prediction for patients with BC. The findings of this investigation may give clinicians new information about the value of ^{18}F -FDG PET-CT and MRI imaging in assessing patients' responses to NAC.

The results obtained from the research conducted in this study could potentially provide healthcare professionals with a fresh perspective on the significance of utilizing ^{18}F -FDG

PET-CT and MRI imaging techniques for evaluating patients' response to NAC. These findings may offer valuable insight into the efficacy of these diagnostic tools, which can ultimately aid clinicians in making informed decisions regarding patient care and treatment plans.

PATIENTS AND METHODS

This cross-sectional comparative study was conducted at the 'PET-CT division and Cyclotron Center' of the National Institute of Nuclear Medicine and Allied Sciences (NINMAS), Bangabandhu Sheikh Mujib Medical University (BSMMU) campus, Shahbag, Dhaka. This study was approved by the Medical Research Ethics Committee (MREC) under a Co-ordinated Research Project (CRP)-E1.30.44 of the International Atomic Energy Agency (IAEA).

The study period was from September 2022 to February 2024 and was conducted among 17 stage II and stage III BC patients who were given NAC before surgery with a history of previous baseline ^{18}F -FDG PET-CT and DCE-MRI study. For therapy response of NAC. ^{18}F -FDG PET-CT and MRI were performed. Parameters of ^{18}F -FDG PET-CT and MRI were obtained and evaluated before and after NAC by using PET Response Criteria in solid tumors (PERCIST) 1.0 based on SUV normalized by lean body mass (SULpeak) in PET-CT and Response Evaluation Criteria in solid tumors (RECIST) 1.1 based on the longest diameter in MRI of primary tumors and axillary lymph nodes, respectively. Informed written consent was obtained from all patients. Descriptive and analytical analyses were performed to examine ^{18}F -FDG PET-CT and MRI to compare pathological response after surgery, and diagnostic accuracies were compared.

INTERPRETATION CRITERIA

The present study's reference for tumoral response was the pathology that existed after surgery. Tumoral response was categorized into responder and non-responder groups based on postoperative pathology. The pathological response for NAC was examined following surgical excision of the residual tumor in the breast (6). The pathological response was defined by tumor necrosis or fibrosis of more than 50% on pathology and nonresponse by necrosis or fibrosis of less than 50%, regardless of the presence of in situ or invasive

carcinomas. The complete pathological response was defined as the absence of invasive or in situ carcinomas in the breast (7).

According to RECIST 1.1 and PERCIST 1.0, patients were split into two groups: responders and non-responders for each modality. Patients were classified as responder groups, including those with CR or PR (as determined by RECIST 1.1) (8) and those with CMR or PMR (as determined by PERCIST 1.0 criteria) (9). Patients were classified as non-responder groups: those with SD or PD (as determined by RECIST 1.1) or those with SMD or PMD (as determined by PERCIST 1.0 criteria).

Data processing and statistical analysis: The study used SPSS for statistical analysis, using descriptive tools for quantitative

and qualitative variables. Cross-tabulation was conducted, with P-values <0.01 and <0.05 considered significant. Validity tests were conducted, and tests were conducted for sensitivity, specificity, positive predictive value, negative predictive value, and accuracy.

RESULT

Among 17 patients, the majority (70.6%) belonged to the age group 41 to 60 years, and the mean age was 48.2 ± 8.88 years at the time of diagnosis of BC. 7 (41.2%) patients had a positive family history of BC, and a maximum of 15 (88.2%) were in stage III. About 10 (58.8%) of the study population were ER positive and PR positive. Maximum 13 (76.5%) were HER2 negative, and 17 (100%) were ductal type histopathologically.

Table 1: Demographic distribution and IHC with histopathological type of BC of the study patients (n=17)

Patient Demography	Number (Frequency)	Percentage (%)
Age group (years)		
20-40	4	23.5
41-60	12	70.6
> 60	1	5.9
Mean±SD		48.2±8.88
Range (min – max)		(32-65) years
Clinical Stage		
Stage II	2	11.8
Stage III	15	88.2
Family History of BC		
Positive	7	41.2
Negative	10	58.8
Immunohistochemistry Status		
ER		
Positive	10	58.8
Negative	7	41.2
PR		
Positive	10	58.8
Negative	7	41.2
HER2		
Positive	4	23.5
Negative	13	76.5
Luminal A	7	41.2
Luminal B	4	23.5
Tripple negative breast cancer (TNBC)	6	35.3
Histopathological Type		
Ductal cell carcinoma	17	100
Lobular cell carcinoma	0	0

(Within parenthesis are percentages over column total)

Data were expressed as frequency, percentages, and mean \pm SD. SD = Standard Deviation; n = number of study patients; BC = Breast Cancer

The responder group had a total of 12 (70.6%) patients, and the non-responder group had a total of five (29.4%) patients, according to post-operative histopathology after NAC. According to PERCIST 1.0, 13 (76.5%) patients were in the responder group and four (23.5%) were in the non-responder group according to the decrease or

increase in metabolic activity, respectively, in the target lesion following NAC. The responder group had a total of 13 patients who had complete (41.1%) and partial responses (35.3%), respectively. The non-responder group had a total of four patients with stable disease (11.8%) and progressive disease (11.8%), respectively.

Table 2: Responder and Non-responder Group of the Study Patients According to Response of Target Lesion by PERCIST 1.0

Variables	Responder group		Non-responder group	
Category of target lesion response as per PERCIST 1.0	Complete metabolic response	Partial metabolic response	Stable metabolic disease	Progressive metabolic disease
Characteristics of category	Reduction of metabolic activity in all FDG avid tumor lesions below background	≥30% along with at least 0.8 unit reduction of SUL peak value of target lesion	Neither complete or partial nor progressive metabolic disease	>30% along with at least 0.8 unit increase in SUL peak value of target lesion
Frequency (%)	07 (41.1%)	06 (35.3%)	02 (11.8%)	02 (11.8%)
Total	13 (76.5%)		4 (23.5%)	

Data were expressed as frequency.

PERCIST 1.0= Positron Emission Tomography Response Criteria in Solid Tumors version 1.0

¹⁸F FDG PET =Fluorine 18 fluorodeoxyglucose positron emission tomography

10 (58.8%) patients having complete and partial response were in the responder group, and seven (41.2%) patients with stable as well as progressive disease were in the non-responder group according to RECIST 1.1. The

responder group had a total of 10 patients who had complete (5.8%) and partial responses (52.9%), respectively. The non-responder group had a total of seven patients with stable disease (35.2%) and progressive disease (5.8%), respectively.

Table 3: Responder and Non-responder Group of Study Patients According to Response of Target Lesion by RECIST 1.1

Variables	Responder group		Non-responder group	
Category of target lesion response as per RECIST 1.1	Complete Response	Partial Response	Stable Disease	Progressive Disease
Characteristic of category	Disappearance of all target lesions	≥30% reduction in size of target lesions	Not classified as PR or PD	≥20% increase in size of target lesions
Frequency (%)	01 (5.8%)	09 (52.9%)	06 (35.2%)	01 (5.8%)
Total	10 (58.8%)		7 (41.2%)	

(Within parenthesis are percentages over columns total)

Data were expressed as frequency and percentages.

RECIST1.1= Revised Response Evaluation Criteria in Solid Tumors version 1.1

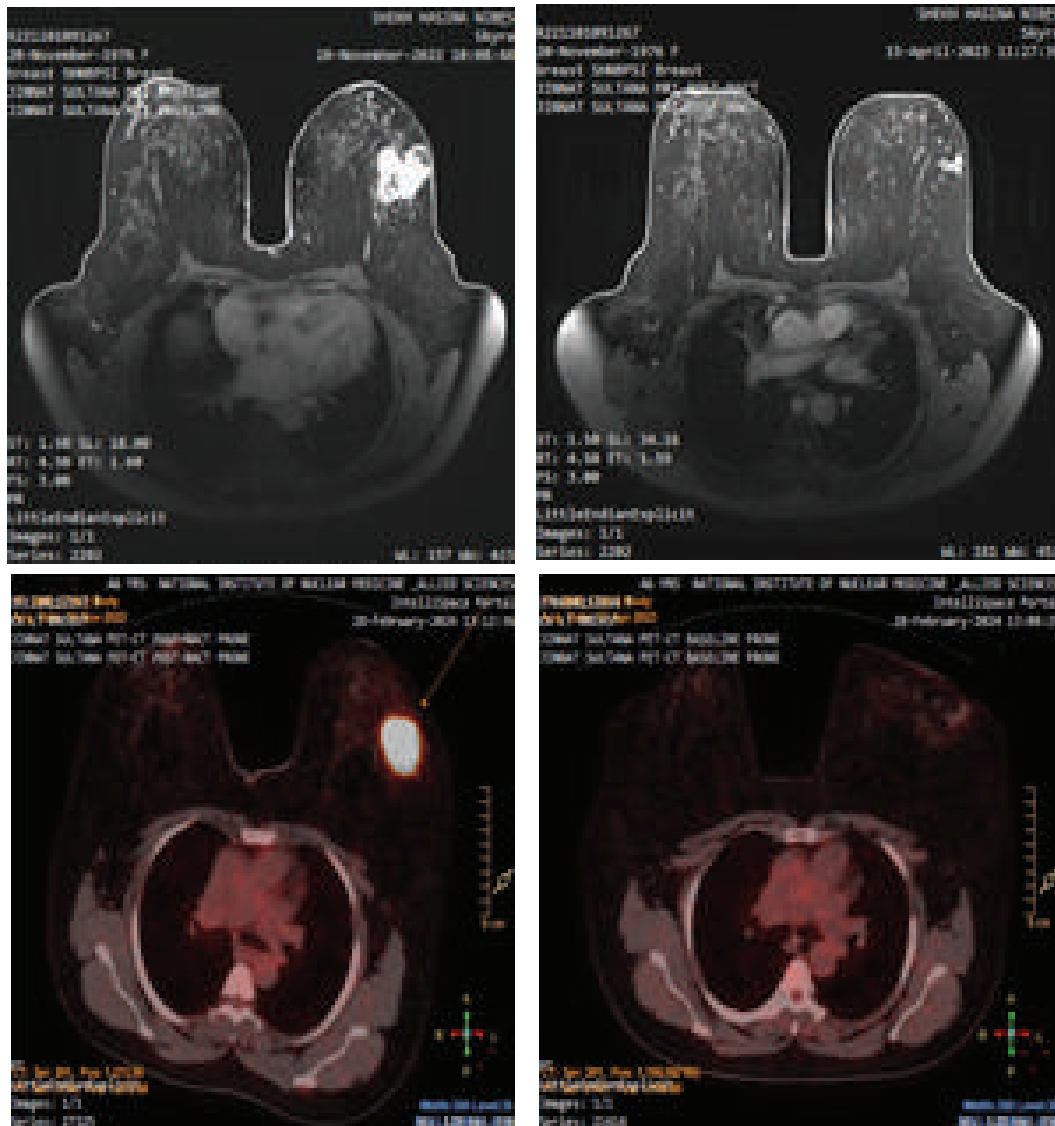


Figure 1: ^{18}F FDG PET-CT and MRI of both breast image baseline and after NAC of a study patient: A 46-year-old woman having (a) gadolinium-enhanced MR image at baseline showed a 5.6 cm enhancing mass in the left breast. (b) After neoadjuvant chemotherapy, the enhancing mass in the left breast was seen as a partial response in comparison to the baseline MRI study. (c) Fused PET-CT images at baseline showed an SUV max of 14.4 of the primary tumor in the left breast. (d) After NAC, fused PET-CT images showed no perceptible FDG uptake in the left breast. This case was classified as a responder according to both RECIST and PERCIST. Histopathological findings from the mastectomy after NAC showed a complete response, which is under the responder group.

When comparing treatment response assessments between pathological response and either RECIST 1.1 or PERCIST 1.0, almost perfect agreement was found between pathological response and PERCIST 1.0 (Kappa = 0.850, $p = 0.002$), indicating strong concordance. However, the agreement between pathological response and RECIST 1.1 was slightly lower but still substantial (Kappa = 0.746, $p = 0.003$), indicating moderate concordance. PERCIST 1.0 showed

higher agreement with pathological resp compared to RECIST 1.1.

The Kappa values indicate moderate to strong agreement between different assessment methods and pathological response. Among the methods compared, PERCIST 1.0 showed the highest agreement with pathological response in comparison to RECIST 1.1. Therefore, PERCIST 1.0 appears to be a more reliable method for assessing treatment response compared to RECIST 1.1.

Table 4: Comparison of treatment response assessments between pathologic response and either RECIST 1.1 or PERCIST 1.0

Criteria	Pathological Response		Total (n=17)	Kappa value	p-value
	Non-Responder (n=5)	Responder (n=12)			
PERCIST 1.0					
Non-responder	4(80.0%)	0(0.0%)	04(23.5%)	0.850	0.002
Responder	1(20.0%)	12(100.0%)	13(76.5%)		
Total	5(100.0%)	12(100.0%)	17(100.0%)		
RECIST 1.1					
Non-responder	5(100.0%)	02(16.7%)	07(41.2%)	0.746	0.003
Responder	0(0.0%)	10(83.3%)	10(58.8%)		
Total	5(100.0%)	12(100.0%)	17(100.0%)		

P-value obtained by Fisher Exact test, $p < 0.05$ was considered as a level of significant

In the comparison between PERCIST 1.0 and RECIST 1.1, there was moderate agreement (Kappa = 0.611, $p = 0.015$) between PET-CT response (PERCIST 1.0) and MRI response (RECIST 1.1). PERCIST 1.0 demonstrated a higher agreement with pathological response compared to RECIST 1.1.

Table 5: Comparison of treatment response assessments between PERCIST 1.0 and RECIST 1.1

MRI response (RECIST 1.1)	PET CT response (PERCIST 1.0)		Total (n=17)	Kappa value	p-value
	Non-Responder (n=4)	Responder (n=13)			
Non-responder	4(100.0%)	3(23.1%)	7(41.2%)	0.611	0.015
Responder	0(0.0%)	10(76.9%)	10(58.8%)		
Total	4(100.0%)	13(100.0%)	17(100.0%)		

P-value obtained by Fisher Exact test, $p < 0.05$ was considered as a level of significant

According to the diagnostic accuracy test of PET-CT with pathological response to detect breast cancer after NAC, sensitivity was 80%, specificity was 100%, PPV was 100%, and NPV was 92.31%. The accuracy level is 94.12%.

According to the diagnostic accuracy test of MRI with pathological response to detect breast cancer after NAC, sensitivity was 100%, specificity was 83.33%, PPV was 71.43%, and NPV was 100%. The accuracy level is 88.24%.

Table 6: Comparison of predicting pathological response in PERCIST 1.0 and RECIST 1.1 by Diagnostic Validity Test

	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Accuracy
PERCIST 1.0	80.00% (28.36% to 99.49%)	100.00% (73.54% to 100.00%)	100.00% (39.76% to 100.00%)	92.31% (67.52% to 98.58%)	94.12% (71.31% to 99.85%)
RECIST 1.1	100.00% (47.82% to 100.00%)	83.33% (51.59% to 97.91%)	71.43% (41.37% to 89.86%)	100.00% (69.15% to 100.00%)	88.24% (63.56% to 98.54%)

DISCUSSION

Statistics showed that approximately 36% of all cancer patients are diagnosed with BC (10). This high percentage emphasizes the significance of prompt treatment in accordance with accepted guidelines for this kind of cancer and early identification. This is the first investigation to determine the diagnostic precision of MRI and 18F-FDG PET-CT scans in relation to pathological response for NAC assessment in BC management of Bangladesh. NAC is the treatment of choice to reduce the tumor size before surgery for BC patients. Treatment options for BC include surgery, radiation therapy, chemotherapy, and/or hormone therapy, according to staging and re-staging.

In this cross-sectional comparative study, most of the patients, around 70.6%, were 41 and 60 years old. The average age of all the patients at the time of diagnosis was 48.2 years old, with a standard deviation of 8.88 years (Table 1). People in their forties to sixties are more likely to be diagnosed with this condition than younger or older individuals; on average, people are diagnosed when they are around fifty years old in BC. One study was similar to this study regarding the age of the study population. Where they found the mean age was 41.9 years, and the age at diagnosis of BC was ≥ 40 years (11).

Several studies match with the findings of this study regarding positive family history of BC, staging, and type of carcinoma. The majority (41.2%) of the patients had a positive family history; 15 (88.2%) were in stage III, and 100% of patients were diagnosed as having invasive ductal carcinoma (Table 1). One study found 95% of all breast cancers were invasive ductal carcinomas, and more than half of the patients had grade III tumors, which correlate with this study (12).

This research revealed that 35.3% of patients exhibited TNBC, a subtype of malignancy that was previously observed in another study where 40% of cases were identified as TNBC (11).

This study divided the study population into responder and non-responder groups by the response of the primary tumor from PERCIST 1.0 stated that 13 (76.5%) patients were in responder and four (23.5%) patients were in non-responder according to the decrease or increase in

metabolic activity, respectively. The responder group had 13 patients who had seven (41.1%) complete metabolic and six (35.3%) partial metabolic responses. The non-responder group had four patients with two (11.8%) stable metabolic disease and two (11.8%) progressive metabolic disease (Table 2). One study also demonstrated that 16 (69.6%) patients were responders and seven (30.4%) were non-responders of PET-CT in pathological response to NAC of BC, which is almost similar to the current study (13).

The distribution of the study population into responder and non-responder groups by the response of the primary tumor from RECIST 1.1 stated that 10 (58.8%) patients were in the responder group and seven (41.2%) patients were in the non-responder group. The responder group had 10 patients who had one (5.9%) complete and nine (52.9%) partial responses. The non-responder group had a total of seven patients, with six (35.2%) having stable disease and one (5.8%) having progressive disease (Table 3).

The study population was divided into responder and non-responder groups according to overall pathological response after surgery. The responder group had 12 (70.6%) patients, and the non-responder group had five (29.4%) patients. In a different study, a total of 33 patients underwent NAC and conducted both PET-CT and MRI scans after NAC. Like the present study, they also divided the total study population into 17 pathological responders and 16 non-responders (7).

In this study, when comparing treatment response assessments between pathological response and either RECIST 1.1 or PERCIST 1.0, almost perfect agreement was found between pathological response and PERCIST 1.0 (Kappa = 0.850, $p = 0.002$), indicating strong concordance. However, the agreement between pathological response and RECIST 1.1 was slightly lower but still substantial (Kappa = 0.746, $p = 0.003$), indicating moderate concordance. PERCIST 1.0 showed higher agreement with pathological response compared to RECIST 1.1 (Table 4).

The Kappa values indicate moderate to strong agreement between different assessment methods and pathological response. Among the methods compared, PERCIST 1.0 showed the highest agreement with pathological response

in comparison to RECIST 1.1. Therefore, PERCIST 1.0 appears to be a more reliable method for assessing treatment response compared to RECIST 1.1.

In the comparison between PERCIST 1.0 and RECIST 1.1, there was moderate agreement (Kappa = 0.611, $p = 0.015$) between PET-CT response (PERCIST 1.0) and MRI response (RECIST 1.1) in the current study. PERCIST 1.0 demonstrated a higher agreement with pathological response compared to RECIST 1.1 (Table 5). Another study showed about 21.9% concordance between the RECIST 1.1 and PERCIST 1.0 response classifications, whereas 78.1% showed discordance. For response classification, there was a significant variation between RECIST 1.1 and PERCIST 1.0 ($k=0.103$, $p<0.0001$) (14).

Sensitivity of PET-CT with pathological response was 80%, followed by specificity 100%, PPV 100%, and NPV 92.31%. The accuracy level was 94.12% (Table 6). When comparing the histology of 16 responders, two were false positives and 14 were true positives, according to Kumar et al. (2009). Six of the seven non-responder patients were true negatives, while one was a false negative. They noticed, nearly identical to the current study, that 18F-FDG PET-CT may distinguish between responders and non-responders with high accuracy following two cycles of neoadjuvant treatment (13).

The sensitivity of MRI with pathological response to NAC of the study population was 100%, followed by specificity of 83.33%, PPV of 71.43%, and NPV of 100% (Table 6). The accuracy level was 88.24%. The current study's validity test revealed that the sensitivity of PET-CT (80%) with the pathological response to NAC of the study population was lower than that of MRI (100%), followed by higher specificity (100% vs. 83.33%), higher PPV (100% vs. 71.43%), lower NPV (92.31% vs. 100%), and higher accuracy (94.12% vs. 88.24%) (Table-6). Though sensitivity was more in MRI scans, the accuracy compared to RECIST 1.1; PERCIST 1.0 was more accurate in predicting pathological response to NAC of BC patients (94.12% vs. 88.24%). A meta-analysis was conducted to see the comparison between the utility of PET-CT and breast MRI to detect pathological response to NAC in BC patients. There were eleven trials that

included 527 patients. PET-CT was found to be more sensitive and specific than MRI if the follow-up scan was done after 3 cycles of NAC (15). One additional study also evaluated intra-NAC response evaluations using these techniques in a study of 142 breast cancer patients; FDG PET-CT and dynamic contrast-enhanced MRI scans were analyzed for predicting pathological complete response. In this regard, RECIST 1.1 showed values of 45.5% for sensitivity, 85.5% for specificity, and 82.4% for accuracy, whereas PERCIST 1.0 showed values of 70.4%, 95.7%, and 90.8%, respectively (16).

Several studies have been conducted related to comparing the RECIST 1.1 and PERCIST 1.0 to detect tumor response to NAC in BC patients. Although no significant difference was observed between PET-CT and MRI results, PET-CT exhibited higher sensitivity but lower specificity and accuracy compared to MRI scans (7).

Overall, both imaging tests were about equally accurate in assessing response to NAC treatment. However, PET-CT was better at detecting whether or not lymph nodes near the breast tumor were responding to treatment. The study also looked at different criteria for predicting how well patients would do after surgery. The findings of both Sobhi et al. and the present investigations are almost the same (17).

The parameters of both 18F-FDG PET-CT and MRI exhibited predictive potential in distinguishing between pathological responders and non-responders. The application of PET-CT may facilitate a more informed decision regarding the types of surgery. PET-CT was anticipated to be a more precise technique for NAC response to BC patients compared to MRI.

CONCLUSION

PET-CT showed higher specificity in predicting pathological response in BC patients following NAC in the primary breast mass or ALNs. PET-CT had better accuracy than MRI in identifying the pathological responses of tumors to NAC. Based on preoperative imaging response, unnecessary surgical intervention and chemoradiation burden can be avoided. These findings of the study will play a potential role in treatment guidelines for BC patients of Bangladesh.

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