

Dedicated Breast PET

Experience Using the Elmammo Dedicated Breast PET System



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1. Clinic Overview

MI Clinic was opened in November 2005 in Toyonaka City, northern Osaka Prefecture. MI Clinic (Fig. 1) is a diagnostic imaging center that only accepts referred patients and is primarily focused on local health care. Located just three monorail stops from Osaka International (Itami) Airport, MI Clinic sees a significant number of foreigners and Japanese patients from other prefectures as well as Osaka residents.

The main diagnostic facilities at MI Clinic are a cyclotron, three PET/CT systems, two MRI systems, and three ultrasound systems (all from GE), plus a FUJIFILM mammography system and a Shimadzu dedicated breast PET system. Approx. 7,000 PET/CT examinations are performed each year, of which 75 % are provided under health insurance and 501 are performed by the Shimadzu Elmammo dedicated breast PET (hereafter “dbPET”) system (of which 88 % or 441 are screenings). At present, MI Clinic has 10 radiological technologists (6 men and 4 women) and all breast examinations are performed by female technologists.



Fig.1 External View of MI Clinic

2. Introduction

Despite increasing rates of morbidity and mortality for breast cancer, Japan has a low mammogram screening rate compared to other countries. This disparity is believed to be due to patients’ aversion to pain caused by breast compression and dislike of one’s breasts being handled. Mammograms also have difficulty showing tumors in dense breast tissue that is commonly present in young women.

Meanwhile, dbPET examinations cause almost no pain and require almost no handling of the breasts. Examinations are performed in a prone position with each breast placed alternatively in a single detector hole. This position reduces movement due to respiration and, because the breast hangs perpendicular from the body, allows visualization of a larger area of the breast. The detector is also equipped with high-resolution depth of interaction (DOI) technology that determines the depth of detected tumors. The close proximity of the breast and detector in the dbPET system improves both examination sensitivity and spatial resolution and allows the detection of even small breast cancers (Fig. 2). It has also been reported that lesions in high density breast tissue are clearly visualized by dbPET and utilizing dbPET in an ancillary role to mammographic screening could help in the detection of early breast cancers. In July 2013, dbPET was

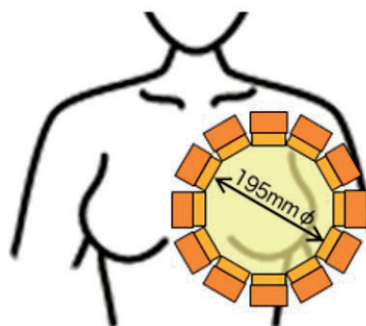


Fig.2 Detector Layout (Detector Diameter: 195 mm)

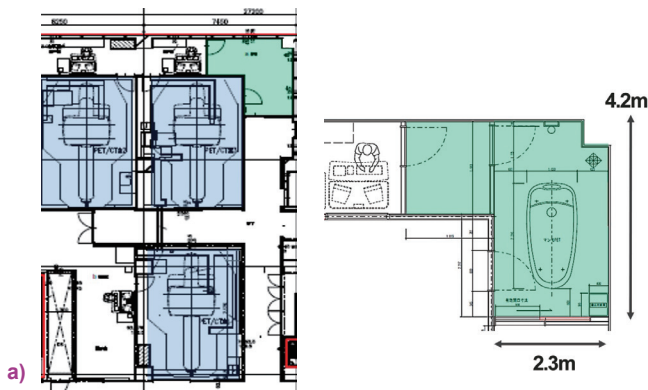


Fig.3 a) Refurbishment of Controlled Area (Changes only made to ■ area. Left: before changes, Right: after changes)
 The compact design of the Shimadzu dbPET system allowed installation in a confined area of 2.3 m × 4.2 m.
b) dbPET room



listed for health insurance coverage when performed in combination with whole-body PET/CT, and in 2015, MI Clinic procured a Shimadzu dbPET system.

3. Course of Events up to Clinical Use

3.1 Process

dbPET systems are subject to regulations on the use of unsealed radiation sources, hence MI Clinic sent a notification of use to the Nuclear Regulation Authority, and in July 2015, submitted a written application for permission for partial change to a public health center. In August, work began on converting a storage room into a dbPET examination room and control room (Fig. 3a). After consulting with female staff, the room interior was decorated to resemble the relaxing atmosphere of a salon with indirect lighting, tasteful curtains, and calming music (Fig. 3b). The system was installed and phantom imaging and volunteer imaging were performed in September, and in October private practice and health insurance treatment began. In private practice cases, MI Clinic explains that the dbPET system is specifically for breast cancer screening and must be combined with other examinations, and performs examinations once the patient is satisfied.

3.2 Investigations

(1) Waiting Time

At MI Clinic, the normal waiting time from FDG administration to whole-body PET/CT is 60 minutes, and assuming the time needed for dbPET is 15 minutes and for whole-body PET/CT is 25 minutes, dbPET examinations were performed in a healthy volunteer 40, 90, and 120 minutes after FDG administration (Fig. 4). Comparing these images showed a waiting time of 40 minutes resulted in

inadequate FDG uptake with uneven uptake by normal mammary gland tissue. Based on this finding and also to reduce X-ray dose levels received by radiological technologists during examination tasks, a waiting time of 90 ± 5 minutes was selected.

(2) Scanning Time

Data was acquired for 10 minutes and images were reconstructed based on data acquired after scanning times between 3 and 10 minutes (Fig. 5). Extending the imaging time reduced noise and

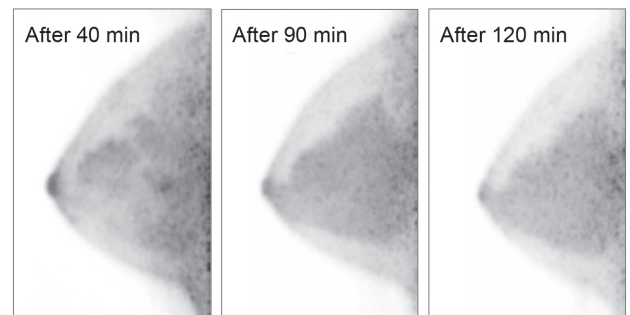


Fig.4 dbPET Images of a Healthy Volunteer

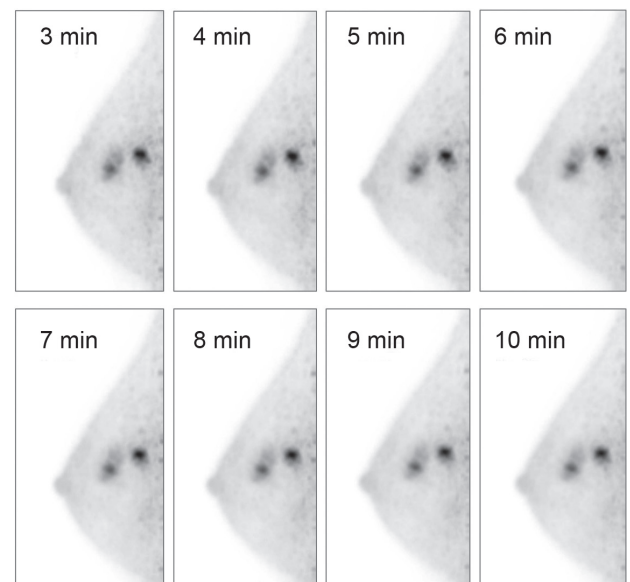


Fig.5 Comparing Images at Different Data Acquisition Times

improved image quality, but also the reconstruction time become longer for about the same amount and negatively affected throughput. Subjects also complained of discomfort after bending the neck for an extended period in the prone position, hence the normal imaging time was set to 5 minutes per side. For delayed phase imaging, a waiting time of 120 minutes and an scanning time of 7 minutes per breast were selected with an imaging start time of up to ± 5 minutes.

(3) Positioning

It is said that the patient positioning is simple because the dbPET system reconstructs two directions in real time then can be simply displayed on a monitor, but the blind area of chest wall is a weak point. In our clinic, a towel is placed in the lower abdomen of the breast on the examination side to minimize the blind area and to provide a wider view of the area with the most mammary glands (Fig. 6a), and the radiologist gently presses against the shoulder blade to prevent a gap between the size of the image and the type of mammary gland. These measures help position the breast deeper in the detector hole (Fig. 6b).

(4) Display and Outputs

Because dbPET systems produce high-resolution three-dimensional tomographic images, MI Clinic

follows the 2019 clinical practice guideline for high-resolution breast PET that recommend, “concerning images similar to mammographic images, prepare ML and CC-MIP images, and prepare tomographic images in three directions (transverse, sagittal, and coronal images).” When saving images, images are first verified on a monitor at a fixed maximum standardized uptake value (SUV), after which density is adjusted based on background mammary glands. In patients with past examination history, past images are used as reference (SUV value) and, when saving images, images are prepared at the appropriate density for each patient.

4. Case Study

4.1 Case 1: 43 Years Old, Histology: Phyllodes Tumor (Fig. 7)

This case presented with dense breast tissue. A tumor that was not clearly identified by mammography but was revealed by dbPET as clear FDG uptake (SUVmax: 5.5) in the upper inner/upper outer quadrants of the right breast. In this case, the tumor was found only because dbPET produces high-contrast images that are less affected by background mammary glands.

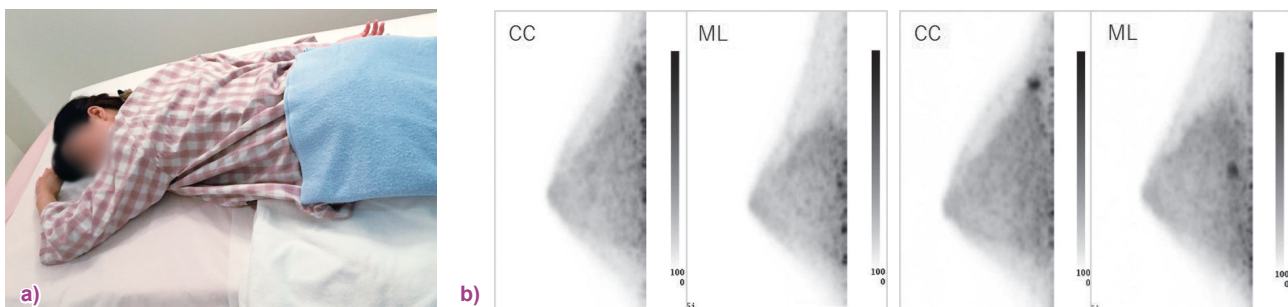


Fig.6 a) Towel Placed on Unexamined Side during Positioning
b) Images that Show the Importance of Positioning. Left: Poor Positioning, Right: Amended Positioning

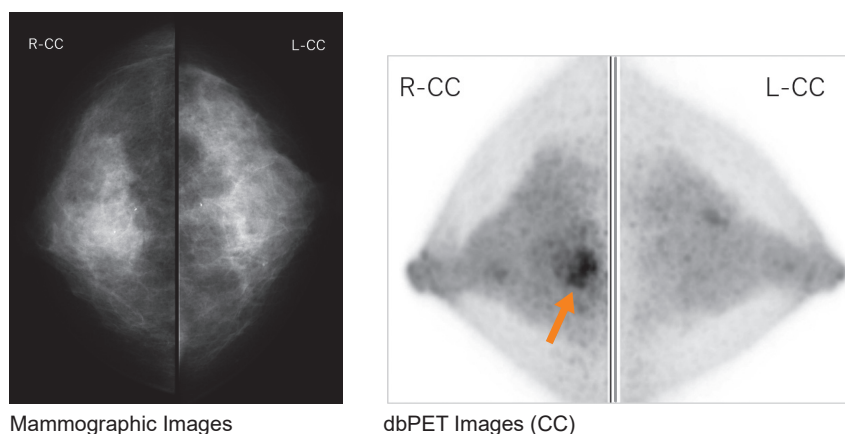


Fig.7 Tumor Discovered in Patient with Dense Breast

4.2 Case 2: 77 Years Old, Histology: Mucinous Carcinoma (Fig. 8)

Whole-body PET/CT and dbPET were performed after contrast-enhanced breast MRI revealed a 25-mm tumor (→) near the upper inner/upper outer quadrants and central portion of the left breast and a 10-mm daughter nodule (↔) on the boundary between the upper inner and upper outer quadrants. Examination of the 25-mm tumor (→) by whole-body PET/CT revealed strong FDG uptake throughout the entire mass while contrast-enhanced MRI and dbPET revealed the tumor was ring-shaped. The daughter nodule (↔) was also found in the same position by MRI and dbPET, which indicates the diagnostic performance of dbPET is equivalent to that of contrast-enhanced MRI. Accordingly, dbPET is an effective substitute when MRI is contraindicated due to an allergy to contrast medium or implanted metal.

4.3 Case 3: 47 Years Old, Histology: Intraductal Papilloma (Fig. 9)

dbPET revealed abnormal uptake (SUVmax: 4.5) in the upper outer quadrant of the right breast and biopsy revealed intraductal papilloma. As shown in this case, because FDG can also be metabolized by

benign tumors, it is important to make a comprehensive judgment with other modalities.

4.4 Case 4: 71 Years Old, Histology: Invasive Ductal Carcinoma (Fig. 10)

Breast ultrasonography revealed a 17-mm diameter hypoechoic region in the upper outer quadrant of the right breast that was diagnosed as invasive ductal carcinoma (triple negative type) after core needle biopsy and was subject to further preoperative examinations. Whole-body PET/CT revealed a non-significant level of FDG uptake (SUVmax: 1.5), but dbPET revealed FDG uptake (SUVmax: 3.4→2.4) in the upper outer quadrant of the right breast. Since FDG uptake sometimes does not increase during delayed phase imaging of breast cancer, this difference in FDG uptake was attributed to histology in this case, and further investigations such as subtyping are considered necessary.

4.5 Case 5: 54 Years Old, Histology: Invasive Ductal Carcinoma (Fig. 11)

After 6 months of neo-adjuvant chemotherapy for left breast cancer (cT2N1M0, luminal B), whole-body PET/CT and dbPET were performed to determine the response. Whole-body PET/CT had revealed

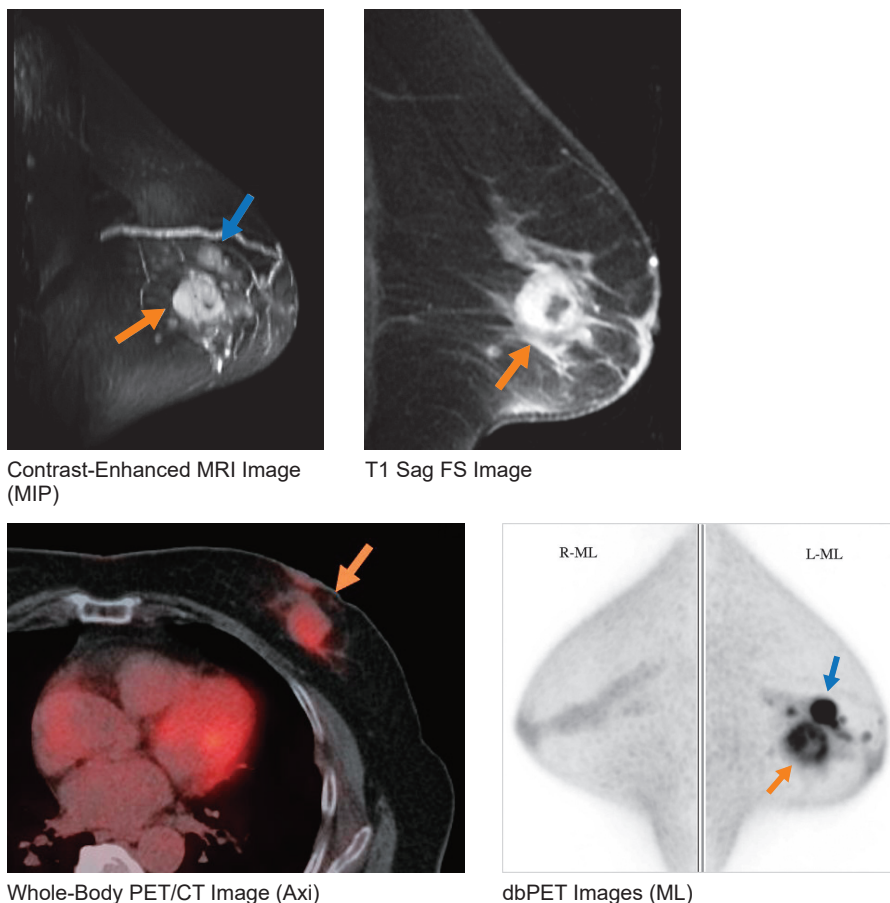
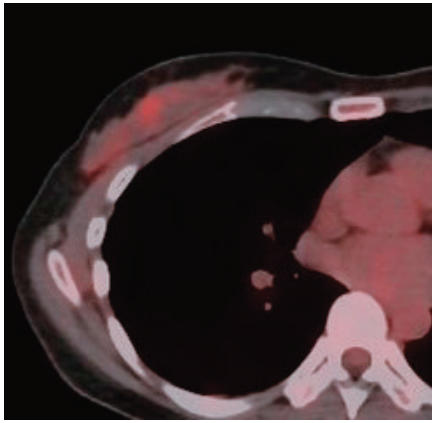
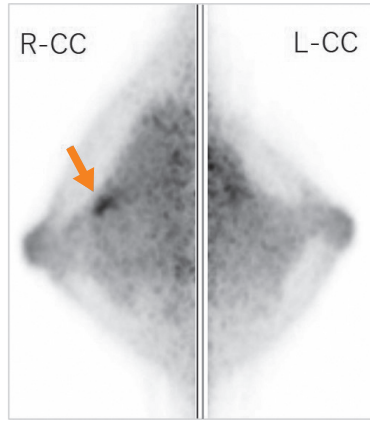


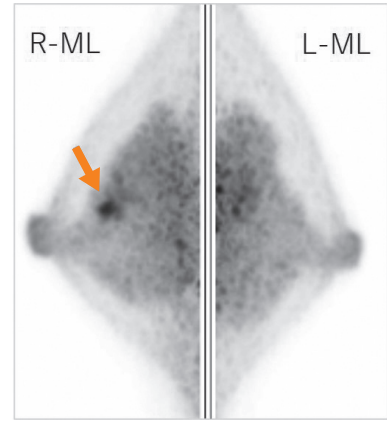
Fig.8 dbPET Helpful in Diagnosis of Cancer Extent



Whole-Body PET/CT Image (Axi)

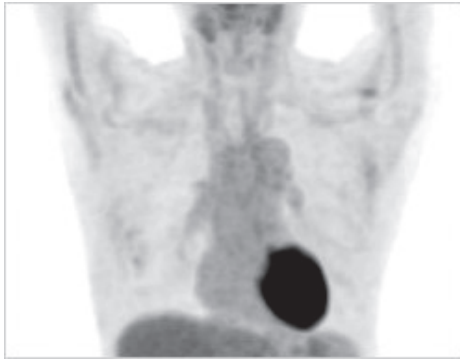


dbPET Images (CC)

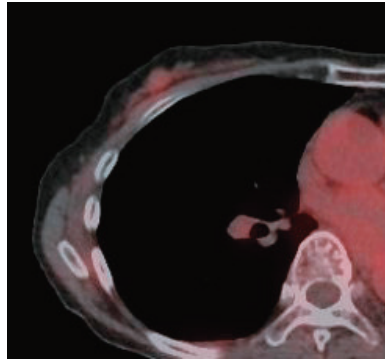


dbPET Images (ML)

Fig.9 False-Positive Case



Whole-Body PET MIP Image



Whole-Body PET/CT Image (Axi)



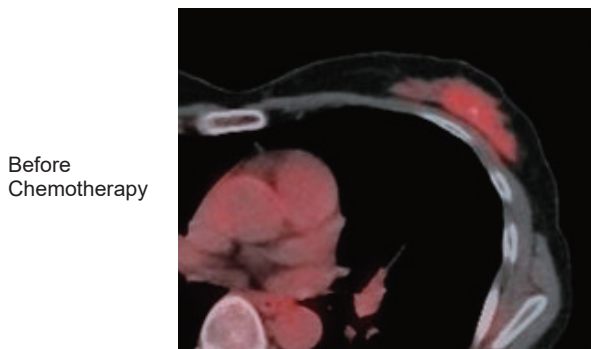
Delayed Phase



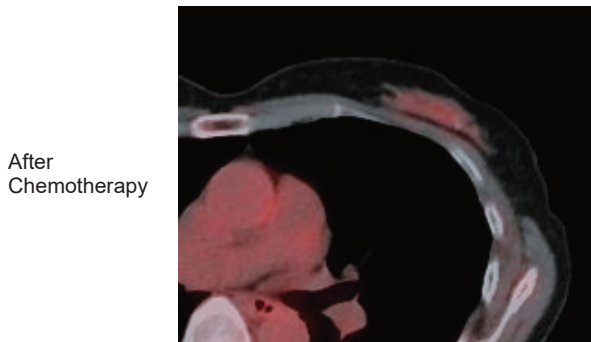
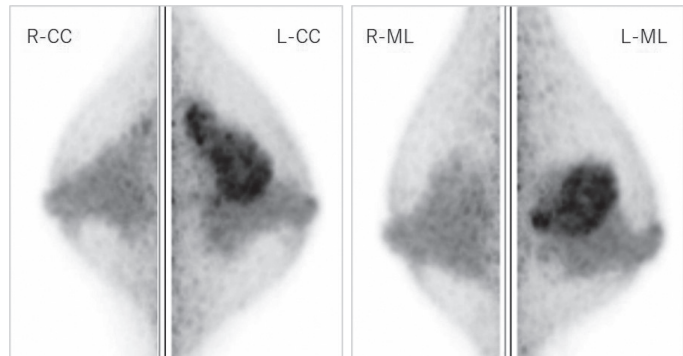
Early Phase

dbPET Images of Right Breast (CC)

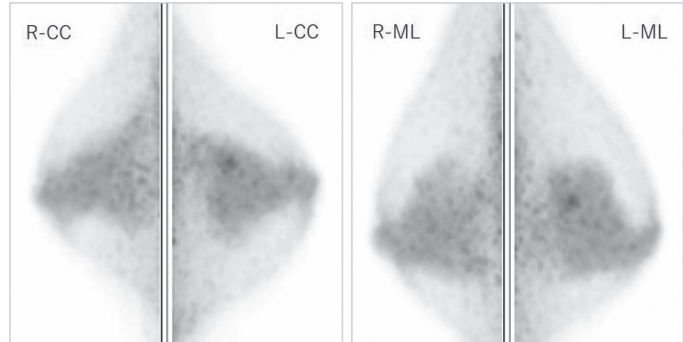
Fig.10 False Negative Case (Breast Cancer with Reduced FDG Uptake in Late Phase)



Before
Chemotherapy



After
Chemotherapy



Whole-Body PET/CT Images (Axi)

dbPET Images

Fig.11 Before and after Neo-Adjuvant Chemotherapy

FDG uptake (SUVmax: 3.1) in the upper outer quadrant of the left breast but images acquired after chemotherapy showed no FDG uptake and a complete response (CR) was determined based on diagnostic imaging. By contrast, dbPET revealed FDG uptake (SUVmax: 2.1) in the upper outer quadrant of the left breast even after chemotherapy, and residual tumor activity was deemed a possibility based on diagnostic imaging. This case was identified thanks to the superior sensitivity and spatial resolution of dbPET compared to whole-body PET/CT.

4.6 Case 6: 47 Years Old, Histology: Invasive Ductal Carcinoma (Fig. 12)

Examinations were performed to search for distant metastasis before administering neo-adjuvant

chemotherapy for stage IIIb left breast cancer (T4bN1M0). Whole-body PET/CT and dbPET both revealed nodular FDG uptake (➔) in the left breast, but only dbPET revealed punctiform FDG uptake in the upper outer quadrant of the right breast. Further investigation of the right breast revealed stage 0 breast cancer (TisN0M0). This case shows that dbPET can identify unexpected lesions and have a major effect on treatment strategy.

4.7 Case 7: 42 Years Old, Histology: Flat Epithelial Atypia (FEA) (Fig. 13)

Screening was performed by breast ultrasonography, whole-body PET/CT, and dbPET. Ultrasonography and whole-body PET/CT failed to identify any anomalies, but dbPET revealed FDG uptake (SUVmax: 5.7) in the central portion of the right

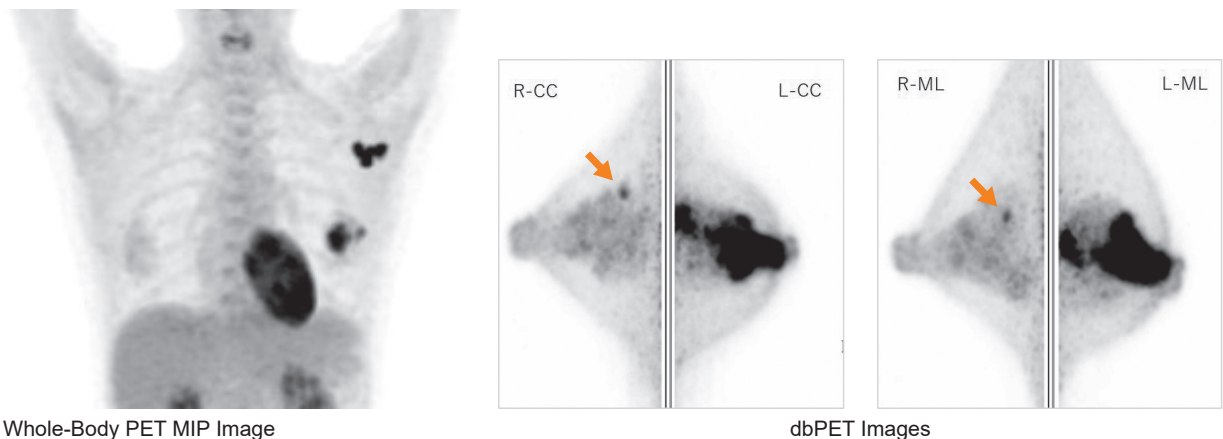


Fig.12 Accidental Discovery of Contralateral Breast Cancer

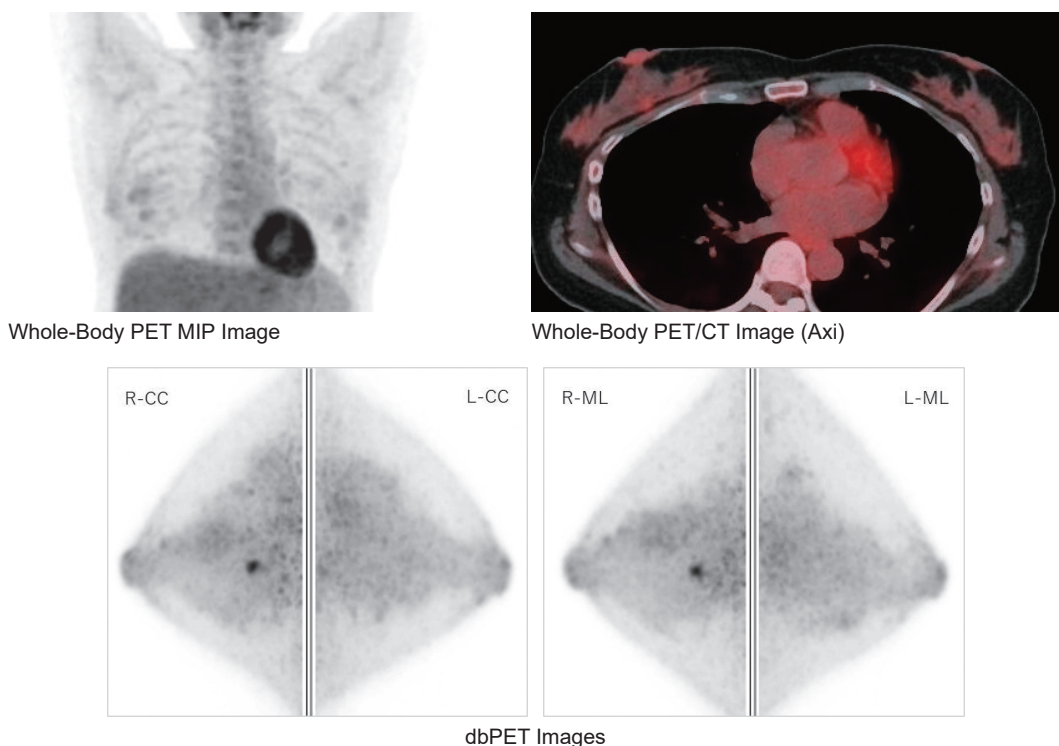


Fig.13 Lesion Detected at Very Early Stage

breast. In these situations, the finding is reported to the technologist responsible for ultrasonography and another ultrasound (second-look ultrasonography) is performed if required. In this case, even second-look ultrasonography failed to identify the tumor. Contrast-enhanced ultrasonography performed by a referral institution revealed a 5-mm tumor in the central portion of the right breast and biopsy revealed FEA (the earliest histological sign or a precursor lesion of low grade DCIS). In this case, dbPET was deemed exceptional as the only modality that discovered the tumor at a very early stage.

5. Conclusion

Since MI Clinic procured a dbPET system and commenced screening for all types of breast cancer, the number of women examined in 2019 has doubled compared to 2014 before procurement, and the rate of repeat clients is 40 %. This increase is thanks to a dbPET system that accommodates

patient wishes for painless breast cancer screening. Using dbPET in combination with whole-body PET/CT also offers the advantage of revealing unexpected diseases outside the breasts. The diagnostic performance of dbPET is similar to that of contrast-enhanced MRI, and given that MRI has been listed for health insurance coverage in April 2020 in cases of hereditary breast and ovarian cancer (HBOC) syndrome, clinical research is expected to commence into using dbPET for the same condition. If dbPET is shown to be effective for HBOC, it promises to play an increasingly useful role in the growth of breast cancer screening. MI Clinic is also committed to working with other facilities towards this goal.

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