Peer Review File

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Reviewer Comments

Comment 1: This study is originally enrolled 1070 patients from pathological record. After the selection by the inclusion criteria and exclusion criteria, only 77 patients were enrolled to this study. As a result, 93% of the initially enrolled patients were excluded and this is very unusual in the clinical research. The authors need to clarify the reason why majority of the patients were excluded and need to prove there is no selection bias to enroll patients.

Reply 1: Yes, I agree with you. I have modified the flowchart of patient selection. **Changes in the text:** The sentence "Breast surgery was performed without neoadjuvant chemotherapy." was added (see Page 3, line 108-109).

Comment 2: Although major fundamental method to predict lymph node metastasis is based on radiomics assessment, detailed information about radiomics analysis is not provided. In radiomics assessment, many radiomics features are generated. Also, several radiomics features are commonly selected for prediction of lymph node metastasis. Please provide detailed information of the radiomics features which is used in this assessment to predict lymph node metastasis.

Reply 2: The radiomics features that selected frequently in the FFDM and SM model via cross-validation method are added in Table 3.

Changes in the text: Radiomic features subsection was added in the RESULTS section. (see Page 8, line 172-175).

Comment 3: What kinds of software and platform are used for radiomics assessment, self-made program or commercially-available software? (I believe 3D Slicer is only for segmentation, and not for radiomics assessment software.)

Reply 3: Image segmentation and radiomics extraction were performed using PyRadiomics extension in 3D slicer. Radiomics assessment was performed using self-made program (Python version 3.7).

Changes in the text: The sentense "(Python Version 3.7, Python Software Foundation)" was added in "Model Development and Evaluation of Predictive Model" paragraph (see Page 7, line 149).

Comment 4: In this research, two-dimensional synthetic mammography (SM) which is generated from thin-sliced DBT image is used. SM is just an alternative imaging for FFDM and the image quality to delineate morphological features is degraded through synthetic process. I wonder why the authors used degraded synthetic image rather than use original thin-sliced DBT image with higher quality of morphological information.

Reply 4: The combination of FFDM and DBT improves diagnostic accuracy. However, the radiation dose increases with the use of both FFDM and DBT. SM synthesised from DBT is worthy of omitting additional radiation dose in predicting lymph node status.

Changes in the text: (see Page 4, line 87-90)

Comment 5: The authors concluded that radiomic feature of primary breast tumor using SM of DBT provided satisfactory performance to predict lymph node metastasis. I agree that they showed performances of radiomic models between FFDM and SM of DBT is identical. But AUC, sensitivity, and specificity are 0.742, 0.783, 0.630. I am afraid that I do not agree that these performances are satisfactory. Please provide performance of lymph node prediction by other traditional clinical method, such as lymph node assessment by ultrasound, preoperative lymph node biopsy, and so on.

Reply 5: As you mentioned, these results may not be entirely satisfactory. However, we believe that by combining this method with others, we can achieve complementary outcomes. I have included the accuracy of predicting lymph node metastasis using non-invasive imaging methods such as ultrasound, MRI, and ¹⁸F-FDG-PET/CT.

Changes in the text: (see Page 11, line 233-242)