Clinical benefits of tomosynthesis-guided vacuum assisted breast biopsy: A comparison with stereotactic vacuum assisted biopsy

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Research Article

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Abstract

Background

Tomosynthesis-guided vacuum assisted breast biopsy (3D-VAB) has been used increasingly and it is now replacing stereotactic vacuum assisted biopsy (2D-VAB). The aim of our study is to compare the clinical effectiveness of 3D-VAB and 2D-VAB on the number of tissue cores containing targeted calcifications and on the procedure time.

Methods

Consecutive 87 women who underwent biopsy at our hospital from April 2020 to March 2022 for calcifications mammographically suspicious of malignancy were included in this study: 57 patients with 3D-VAB and 30 patients with 2D-VAB. The procedure time was defined as the time between scout tomosynthesis for 3D-VAB and scout stereo images for 2D-VAB as a start and confirmation of targeted calcifications by specimen radiography as an end.

Results

Grouped or clustered calcified lesions were found in 39 and 21 patients among the 3D-VAB group and the 2D-VAB group, respectively. A mean long diameter and a mean area of the grouped or clustered calcified lesions of 39 patients were 9 mm and 50 mm$^2$ from a MLO view. With the 21 cases of the 2D-VAB group, the corresponding figures were 10 mm and 78 mm$^2$ from a MLO view. The mean number of tissue cores per biopsy containing targeted calcifications from the grouped or clustered calcified lesions was 3 and 2.3 specimens for 39 patients of the 3D-VAB group and for 21 patients of the 2D-VAB group, respectively. The mean procedure time for grouped or clustered calcifications was significantly shorter in the 3D-VAB group than in the 2D-VAB group (16.5 min vs. 27.4 min, $P<0.01$). For all 87 patients, the mean procedure time was 18.1 minutes for 57 3D-VAB patients and 27.7 minutes for 30 2D-VAB patients, thus being significantly shorter with 3D-VAB than 2D-VAB ($P<0.01$).

Conclusion

Our study demonstrated that the clinical performance of 3D-VAB is superior to that of 2D-VAB and that the significant reduction in examination time with 3D-VAB compared with 2D-VAB is expected to benefit patients.

Introduction

Since 2000 mammography examinations have been performed for breast cancer screening in Japan, and as a result the detection rate of breast cancer has increased dramatically (1, 2). With the spread of mammography screening, the detection rate of calcified lesions that cannot be confirmed by palpation or ultrasound examination is also increasing. All calcified lesions detected are normally classified according
to the mammography guidelines (3). With this practice, however, suspicious calcifications are required to proceed to subsequent examination.

In the United States in 1990 stereotactic vacuum assisted breast biopsy (2D-VAB) was introduced for histologic verification of indeterminate or suspicious lesions detected only on mammography (4). In Japan the first 2D-VAB was performed in 1994, and thereafter 2D-VAB has been used widely (5). Recently digital breast tomosynthesis (so called 3D mammography) was introduced into clinical practice and has been reported as useful in detecting low-contrast masses and distortions (6). Since its feature allows positioning of information, including the depth of the target findings in breast, with a single tomosynthesis imaging, the use of tomosynthesis-guided vacuum assisted breast biopsy (3D-VAB) is increasing as an alternative to conventional 2D-VAB for nonpalpable lesions in breast (7, 8).

At our hospital we have been using 3D-VAB for calcified lesions since April 2021. We have studied the clinical effectiveness of 2D-VAB and 3D-VAB for the calcified lesions, considering the morphology and distribution of calcifications. The aim of our study is to compare the clinical performance of 3D-VAB and 2D-VAB, focusing on the number of tissue cores containing targeted calcifications and on the procedure time.

**Materials and methods**

We included in this study consecutive 87 women with calcifications mammographically suspicious of malignancy. They were referred to our hospital for biopsy between April 2020 and March 2022. Of these 87 patients, 30 underwent 2D-VAB from April 2020 to the end of March 2021 (the 2D-VAB group). We transitioned from 2D-VAB to 3D-VAB at the beginning of April 2021, and therefore 3D-VAB was performed with the remaining 57 patients (the 3D-VAB group). Written informed consent was obtained from all patients in this study.

We performed 2D-VAB using full-field digital mammography, SIEMENS MAMMOMAT 3000®. The procedure of 2D-VAB was the same as described in other studies (9, 10). 3D-VAB was performed with digital breast tomosynthesis, FUJIFILM AMULET Innovality. Briefly, patients were positioned in the lateral decubitus or upright position at the time of targeting to allow the shortest skin-to-target approach, and the breast was compressed. Digital breast tomosynthesis exposure was obtained in order to identify the targeting calcification, and the area of targeting calcification was marked to determine \(x\)-\(y\)-\(z\) coordinates. These coordinates were transferred to the biopsy device, which moved to the targeted \(x\)-\(y\) coordinates, and then one of us adjusted the biopsy device manually to the required \(z\) depth. Tissue sampling methods were the same for 2D-VAB and 3D-VAB, using Mammotome Revolve system (Devicor Medical products Japan) with a 10-gauge needle to obtain 12 pieces in each case. A specimen radiography was performed to confirm the presence of calcifications within tissue cores in all cases.

The long diameter and the area of calcified lesions were measured on the images from mediolateral-oblique (MLO) and craniocaudal (CC) views, using image analysis software (VuePACS®, Carestream Health, inc., Japan) as shown in Fig. 1. The total procedure time was calculated as the time needed for
actual tissue sampling (defined as the time between scout tomosynthesis for 3D-VAB and scout stereo images for 2D-VAB as a start and confirmation of targeted calcifications by specimen radiography as an end).

Student t-test was used to compare the following variables between 2D-VAB and 3D-VAB groups: long diameter and area of calcified lesion, number of specimens containing targeted calcifications, and procedure time. Statistical analysis was performed with a static software (EZR). P values less than .05 were considered to indicate a statistically significant difference.

**Results**

We evaluated 87 patients whether their calcifications were benign or malignant according to the categories specified in the mammography guidelines (3). The calcification categories of 57 patients who underwent 3D-VAB were as follows: category 2, 5 patients (9%); category 3, 34 patients (59%); category 4, 13 patients (23%); and category 5, 5 patients (9%). In terms of calcification morphology, small round type and amorphous or indistinct type were seen in 21 patients (37%) and in 20 patients (35%), respectively, followed by pleomorphic type in 13 (23%) and fine linear in 2 patients (4%). In terms of calcification distribution, grouped or clustered lesions were observed in 39 cases (68%), segmental lesions in 11 cases (19%), and linear lesions in 3 cases (5%). Assessment of the calcification categories of the 30 patients in the 2D-VAB group showed that categories 2, 3, 4, and 5 were 5 (17%), 14 (47%), 10 (33%), and 1 (3%), respectively. In terms of calcification distribution, 21 cases (70%) had grouped or clustered, 5 (17%) had regional, 3 (10%) segmental, and 1 (3%) linear.

As shown in Table 1, for the 39 patients in the 3D-VAB group the mean long diameter of grouped or clustered calcified lesions was 9 mm from both MLO view and CC view. The mean areas were 50 mm$^2$ (5-170 mm$^2$) from the MLO view and 55 mm$^2$ (11–156 mm$^2$) for the CC view, respectively. The mean areas of linear or segmental calcified lesions of 14 patients were 342 mm$^2$ (14–915 mm$^2$) from the MLO view and 305 mm$^2$ (89–929 mm$^2$) from the CC view, respectively. With regards to 21 patients with the grouped or clustered calcifications among the 2D-VAB group, the mean long diameter of calcified lesions was 10 mm for both the MLO and CC views. The mean areas of such lesions were 78 mm$^2$ (16–197 mm$^2$) from the MLO view and 78 mm$^2$ (15–279 mm$^2$) from the CC view, respectively. There was no significant difference in the long diameter and area of the grouped or clustered calcified lesions between the 3D-VAB and 2D-VAB groups.

Whenever possible, 12 core tissues were taken per biopsy. When this was not possible, 10 or 11 specimens were taken. A specimen radiography was performed to confirm the presence of targeted calcifications in core tissues. The mean number of specimens in which calcifications were identified per category in the 3D-VAB group was as follows: 2.7 specimens in category 3 calcifications, 4.2 specimens in category 4, and 5.2 specimens in category 5. The number of specimens containing the targeted calcifications increased as the calcification category progressed, but there was no significant correlation between the number of specimens and the calcification category (Table 2). Based on the distribution of
calcifications in the 3D-VAB group, the mean number of specimens containing the targeted calcifications was 3 pieces for 39 patients with grouped or clustered calcifications and 4.4 pieces for 14 patients with linear and segmental calcifications, respectively. Among the 21 2D-VAB patients with grouped or clustered calcifications the mean number of specimens containing the targeted calcifications was 2.3 pieces. With respect to the mean number of specimens biopsied from the grouped or clustered calcifications lesions, 3D-VAB tended to obtain more tissue cores containing the targeted calcifications than 2D-VAB.

We measured the procedure time for the 3D-VAB and 2D-VAB groups (Table 3). It took 18.7 minutes for the cases of Category 3 calcification in the 3D-VAB group. For the cases of Category 4 and 5 calcifications, the mean procedure time was 17.6 minutes and 16.6 minutes, respectively. Looking at the difference by the distribution of calcifications within 3D-VAB group, the mean procedure time was significantly shorter for grouped or clustered calcifications than for linear and segmental calcifications (16.5 versus 22.8 minutes, \( P < 0.01 \)). When comparing the procedure time for grouped or clustered calcifications between the 3D-VAB and 2D-VAB groups, the mean time to complete biopsy was significantly shorter in the 3D-VAB than in the 2D-VAB (16.5 min vs. 27.4 min, \( P < 0.01 \)). In addition, comparison of the mean procedure time by the type of calcification morphology also proved that the 3D-VAB group took significantly less time than the 2D-VAB group, as shown in Table 3. For all patients, the mean procedure time was 18.1 minutes (10–47 minutes) for 3D-VAB group and 27.7 minutes for 2D-VAB (19–53 minutes). Thus, the mean procedure time was significantly shorter for 3D-VAB than for 2D-VAB (\( P < 0.01 \), Fig. 2).

**Discussion**

In the past decade, a new technique for breast biopsy was developed using digital breast tomosynthesis (7, 11, 12). Its introduction to our hospital in April 2021 allowed us to perform digital breast tomosynthesis biopsy (3D-VAB) instead of stereotactic biopsy (2D-VAB) for patients with highly suspicious malignancy of calcifications. One advantage of tomosynthesis is that it enables to eliminate the overlap of mammary tissues. For this reason, the boundaries and margins of a mass can be observed in detail and differentiating benign and malignant masses becomes easier (13). An application of tomosynthesis on calcified lesions is regarded somewhat less useful than on mass and architectural distortion, but it makes identifying the location and distribution of calcified lesions easier (14). Our study showed that with 3D-VAB tissue cores containing calcifications could be collected from calcified lesions as small as 3 mm in size and 5 mm\(^2\) in area. This indicates that 3D-VAB is more effective in sampling from the calcified lesions distributed over a narrower range than 2D-VAB, despite the study’s limitations that the subjects were not identical between the 3D-VAB and the 2D-VAB groups and that the total number of subjects was small.

Grouped or clustered calcifications can be caused due to benign or malignant processes. In many cases of grouped or clustered calcifications, biopsies are necessary to distinguish breast cancer from benign conditions such as epithelial hyperplasia or sclerosing adenosis. Pathological diagnoses on these biopsies are expected to become easier when sample numbers are large. We collected 12 cores per
biopsy with both 2D-VAB and 3D-VAB with a few exceptions and counted the number of specimens containing the targeted microcalcifications. Although there was no statistically significant difference, 3D-VAB tended to obtain more specimens containing calcifications than 2D-VAB. Similarly, one previous study showed that more tissue cores could be obtained with 3D-VAB than with 2D-VAB (15). The use of three dimensional tomosynthesis is considered to facilitate the understanding of the density at which multiple calcifications are distributed.

Several studies have demonstrated that 3D-VAB has a higher success rate, shorter completion time, and fewer radiation exposures than 2D-VAB (8, 16–21). One of these studies examined the procedure time based on morphology and distribution of calcifications (21). They made phantom samples that consisted of small round, amorphous, and pleomorphic clustered calcifications, and examined the targeting time for calcifications in 2D-VAB and 3D-VAB. They found that 3D-VAB could shorten the targeting time compared to 2D-VAB and the type of calcifications did not make any significant difference. The present study investigated the time required for biopsy of calcified lesions in terms of morphology, distribution, and category of calcifications. For all patients who underwent 3D-VAB the mean procedure time was 18.1 minutes, a figure similar to the findings of the above studies (8, 16). The result proved that, regardless of morphology, distribution, and category of calcifications, the mean procedure time was shorter with 3D-VAB than with 2D-VAB. In contrast to determining the position of calcification from stereo images in 2D-VAB, the digital breast tomosynthesis images enable direct confirmation of the biopsy coordinates, including the z-axis, which significantly reduce the 3D-VAB procedure time compared to 2D-VAB.

In conclusion, even when the targeted lesions were grouped or clustered calcifications which included more than five calcifications in a small area (< 2 cm³), 3D-VAB could accurately acquire tissue cores containing the targeted calcifications. The procedure time was also significantly reduced. Although there is a limitation that the number of patients investigated was small, the present study successfully demonstrated that the clinical performance of 3D-VAB is superior to that of 2D-VAB. The accuracy and time reduction with 3D-VAB compared to 2D-VAB is expected to bring benefits to future patients.

**Declarations**

**Conflict of interest**

There are no conflicts of interest. This research did not receive any specific grant from funding agencies in the public, commercial or not-for profit sectors.

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**References**


Tables

Tables are available in Supplementary Files section.

Figures
Fig. 1

Left: Long diameter of calcified lesions
Right: Area of calcified lesions

Figure 1

See image above for figure legend

Fig. 2

Mean procedure time (min)
Figure 2

Comparison of procedure time between 3D-VAB and 2D-VAB groups

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.xlsx
- Table2.xlsx
- Table3.xlsx