

Digital Breast Tomosynthesis–guided Vacuum-assisted Breast Biopsy: Initial Experiences and Comparison with Prone Stereotactic Vacuum-assisted Biopsy¹

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Purpose:

To use digital breast tomosynthesis (DBT)–guided vacuum-assisted biopsy (VAB) to sample target lesions identified at full-field digital screening mammography and compare clinical performance with that of prone stereotactic (PS) VAB.

Materials and Methods:

In this institutional review board–approved study, 205 patients with 216 mammographic findings suspicious for cancer were scheduled to undergo mammography-guided VAB. Written informed consent was obtained. PS VAB was performed in 159 patients with 165 target lesions. DBT VAB was performed in 46 consecutive patients with 51 target lesions. Tissue-sampling methods and materials (9-gauge needles) were the same with both systems. For calcifications, specimen radiographs were obtained, and for masses or architectural distortions, control mammography or DBT was performed to confirm adequate target lesion sampling. χ^2 and Student *t* tests were used to compare biopsy time, and the Fisher exact test was used to compare lesion type distribution for DBT versus PS VAB.

Results:

Technical success was achieved in 51 of 51 lesions (100%) with DBT VAB versus 154 of 165 lesions (93%) with PS VAB. In one of 11 lesions in which PS VAB failed, DBT VAB was performed successfully. Mean time to complete VAB was 13 minutes \pm 3.7 for DBT VAB versus 29 minutes \pm 10.1 for PS VAB ($P < .0001$). Reidentifying and targeting lesions during PS VAB took longer than it did during DBT VAB ($P < .0001$). Tissue sampling took about the same time for PS VAB and DBT VAB ($P = .067$). Significantly more “low-contrast” (ie, uncalcified) target lesions were biopsied with DBT VAB (13 of 51 lesions) versus PS VAB (nine of 165 lesions) ($P < .0002$). No major complications were observed with either system. One patient who underwent DBT VAB in the sitting position and one patient who underwent PS VAB developed self-limiting vasovagal reactions.

Conclusion:

Clinical performance of DBT VAB was significantly superior to PS VAB. Because DBT VAB allows use of the full detector size for imaging and provides immediate lesion depth information without requiring triangulation, it facilitates target lesion reidentification and sampling of even low-contrast targets, such as uncalcified masses.

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Digital breast tomosynthesis (DBT) allows improved visualization of masses and architectural distortions. There is evidence that DBT helps reduce recall rates for false-positive findings and leads to a higher breast

cancer detection rate compared with conventional full-field digital mammography (1–6).

Prone stereotactic (PS) vacuum-assisted biopsy (VAB) with the use of dedicated biopsy tables is a reliable and safe method for tissue sampling with mammographic guidance and has widely replaced surgical excision for histologic verification (7–11). However, findings based primarily on DBT results may not be visible at digital mammography performed during PS VAB. Although some of the lesions detected with DBT may be visible at second-look ultrasonography (US) (ie, targeted US in the area of the mammographic finding) and managed with US-guided biopsy, there is a need for methods that allow targeting of lesions that are identified with DBT alone.

Moreover, PS VAB per se is sometimes a demanding procedure. One reason is the fact that the imaging area corresponds to the small biopsy window and will therefore only cover a small fraction of the fibroglandular tissue. Therefore, for PS VAB, the breast must be positioned carefully so the area with the target lesion is covered by the biopsy window. Moreover, a one-view mammogram does not provide depth information along the z-axis. The concept of stereotactic biopsy is to reconstruct this information by means of triangulation—which can be a cumbersome and time-consuming procedure, especially for low-contrast lesions, such as uncalcified masses or architectural distortions.

By contrast, DBT provides depth information without triangulation and allows one to use the full detector size for imaging during the intervention. Accordingly, our hypothesis was that DBT can help prevent technical difficulties that can occur during PS VAB and may therefore facilitate mammographic breast biopsy, irrespective of whether a lesion is visible at DBT alone or also at conventional two-dimensional (2D) mammography.

Accordingly, in this study, we report our experience with using DBT VAB to sample target lesions identified at full-field digital screening mammography and compare its clinical performance with that of PS VAB.

Advances in Knowledge

- Digital breast tomosynthesis (DBT)–guided vacuum-assisted biopsy (VAB) allows one to use the full detector field for imaging during stereotactic biopsy or to use the full detector field for imaging during DBT-guided VAB; this prevents difficulties associated with the restricted imaging capabilities through the small biopsy window of conventional prone stereotactic (PS) biopsy systems.
- DBT-guided VAB provides tissue depth information by allowing one to obtain insertion depth of biopsy needles along the z-axis; this prevents difficulties associated with the process of triangulation that is required to provide this information for conventional PS breast biopsy.
- Both effects led to the fact that DBT-guided breast biopsy required significantly less biopsy planning time (mean, 4 minutes vs 15 minutes, respectively) and significantly less time to complete the procedure (mean, 13 minutes vs 29 minutes, respectively) than conventional PS breast biopsy ($P < .0001$).
- DBT improves depiction of low-contrast lesions; this, together with the fact that DBT-guided biopsy depicts the breast fibroglandular tissue in its entirety, leads to more low-contrast target lesions (low-contrast calcifications, uncalcified masses) being biopsied successfully by using DBT-guided biopsy compared with PS breast biopsy (25% [13 of 51 lesions] for DBT VAB vs 5% [nine of 165 lesions] for PS VAB; $P < .0002$).

Implications for Patient Care

- DBT is not only useful to allow biopsy of lesions that are visible at DBT alone; if substantiated in further studies, it may replace PS VAB for routine use in patients with abnormalities on regular two-dimensional digital mammograms, as well.
- DBT-guided biopsy is likely to help expand the number of mammographic lesions that are considered amenable to mammographic VAB.

Materials and Methods

Study Setup and Patients

A retrospective analysis, approved by the authors' institutional review board, was conducted to compare the clinical performance of DBT-guided VAB with that of PS breast biopsy. Informed consent was obtained from all women.

Between March 2012 and June 2014, 205 women (mean age, 55.6 years \pm 10.2; range, 36–81 years) with 216

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Abbreviations:

CI = confidence interval

DBT = digital breast tomosynthesis

DCIS = ductal carcinoma in situ

PS = prone stereotactic

VAB = vacuum-assisted biopsy

Author contributions:

Guarantors of integrity of entire study, S.S., M.D., C.K.K.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; agrees to ensure any questions related to the work are appropriately resolved, all authors; literature research, S.S., C.K.K.; clinical studies, S.S., M.D., T.D., L.B., K.S., C.K.K.; experimental studies, C.K.K.; statistical analysis, S.S., M.D., S.D., L.B., K.S., C.K.K.; and manuscript editing, S.S., M.D., S.D., C.K.K.

Conflicts of interest are listed at the end of this article.

mammographic findings were scheduled for mammography-guided VAB. Between March 2012 and November 2013, all mammography-guided VABs were performed by using a dedicated digital prone breast biopsy table. Since December 2013, a three-dimensional DBT-guided biopsy system was installed and was used for mammography-guided VAB at the discretion of the radiologist. This resulted in an abrupt change of practice with conversion to the DBT method of biopsy.

All interventions were performed after risks and benefits were explained to the patients and written informed consent was obtained. Mammography-guided VAB was performed in accordance with national and European guidelines. All target lesions were nonpalpable and classified as Breast Imaging Reporting and Data System grade 4 or 5. Before the mammography-guided VAB, all women underwent targeted US of the area that included the mammographic finding to find out whether a correlate would be visible that would allow US-guided biopsy. Patients only underwent mammography-guided VAB if US did not demonstrate an unambiguous correlate for the mammographic abnormality.

Pre- and postbiopsy patient care was standardized and followed written institutional guidelines.

Biopsy Technique

Biopsies were performed by one of three dedicated breast radiologists (S.S., M.D., T.D.), with 4–9 years of experience in performing breast interventional procedures. Both PS VAB and DBT VAB were performed with a 9-gauge vacuum biopsy device (Eviva; Hologic, Bedford, Mass). In all patients, at least 24 biopsy specimens were obtained in two biopsy rounds, with 12 specimens acquired in each in a clockwise manner.

Performance of PS VAB

PS VAB was performed with a dedicated system (Lorad Multicare Platinum; Hologic) with the patient in prone position by using a standard technique described previously (11,12). In short, after positioning the patient, breast compression was applied in the

direction that allowed the shortest access to the target lesion. The breast was carefully positioned to center the lesion under the 5×5 -cm biopsy window. If the lesion was located off center or if stroke margins were too short, the breast was repositioned. Position of the target lesion within the biopsy window was controlled by acquiring a digital scout mammogram. Stereotactic coordinates were calculated on the basis of $+15^\circ$ and -15° stereotactic images and appropriate triangulation. After skin disinfection, subcutaneous and deep local anesthesia along the expected track of the needle with 10 mL of lidocaine (Scandicain; AstraZeneca, London, United Kingdom) was induced until the puncture was entirely painless. After inserting the biopsy needle into the calculated coordinates, another pair of stereotactic images was obtained to document the needle in the prefire position. If necessary, the needle position was corrected. Postfire stereotactic images were obtained to document needle position. Postbiopsy stereotactic images were obtained after two clockwise biopsy rotations were completed to check for adequate removal of the target lesion.

Performance of DBT VAB

DBT VAB was performed by using a full-field digital mammography system equipped with a three-dimensional tomosynthesis platform (Selenia Dimensions 3D; Hologic). For breast biopsy, a dedicated guidance system (Affirm; Hologic) was installed as an add-on. This system can be used for “conventional,” two-dimensional mammography-guided stereotactic breast biopsy or can be used in DBT mode for DBT-guided biopsy. During the study period, only the DBT mode was used. During two- or three-dimensional DBT-guided biopsy procedures, the full detector (18×24 cm) was used for imaging. The size of the biopsy area depends on the type of paddle that is used for compression; during the study period, the paddle with a 74×62 -mm biopsy window was used (Fig 1). The patient was positioned in a lateral decubitus or sitting position on a dedicated

armchair. The biopsy approach (lateral or decubitus) was chosen on the basis of the lesion location. In general, the shortest access to the target lesion was chosen. If the lesion was in the center of the breast, a lateral approach was favored. The breast was fixated with a special compression paddle, and DBT was performed to reidentify the target lesion. The biopsy coordinates, including z-axis location, were determined directly from the DBT images by identifying the DBT section that yielded the sharpest depiction of the target. Coordinates were automatically determined by the biopsy software system after the operator indicated the position of the target with a cursor.

The actual biopsy DBT VAB procedure was identical to the procedure performed by using the PS biopsy table. Pre- and postfire control images were usually obtained by using a pair of stereotactic full-field digital mammographic images, because the inserted needle would lead to artifacts at DBT. After the biopsy, postbiopsy control was performed by using DBT.

Postbiopsy Procedure

A clip (Securmark for Eviva; Hologic) was placed in all patients with uncalsified target lesions or in whom no or only a few residual calcifications were present after PS or DBT VAB. Immediately after placing the clip, postclip placement DBT for DBT VAB and scout mammography for PS VAB were performed to prove that the clip was deployed at the biopsy site.

Per institutional guidelines, on the day after the biopsy, patients underwent repeat two-view full-field digital mammography or two-view DBT to document target lesion removal and/or position of the clip. All patients were seen clinically to identify possible complications and were interviewed about discomfort or pain experienced during or after the biopsy procedure. Any pain the patient experienced during or after the biopsy procedure and any complications (infection, vasovagal reaction, larger hematoma, and bleeding) were recorded. This information was then included in the standardized procedure report.

Figure 1

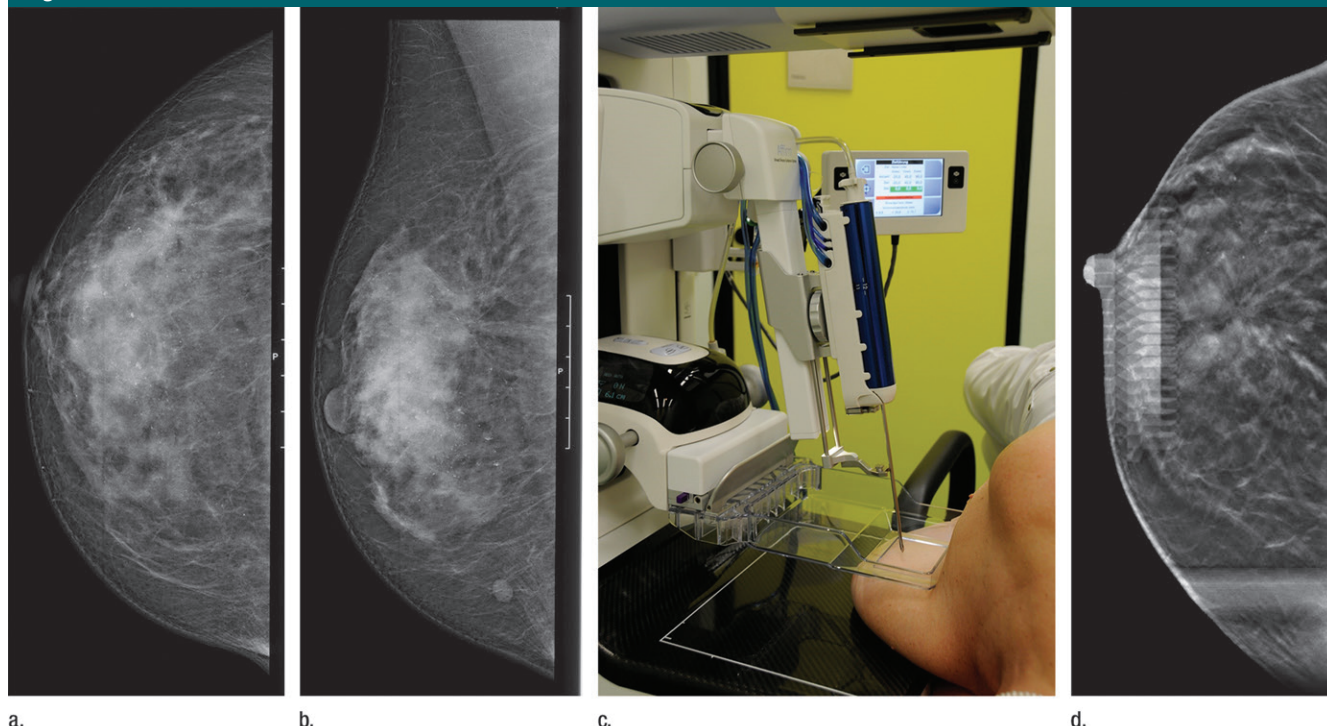
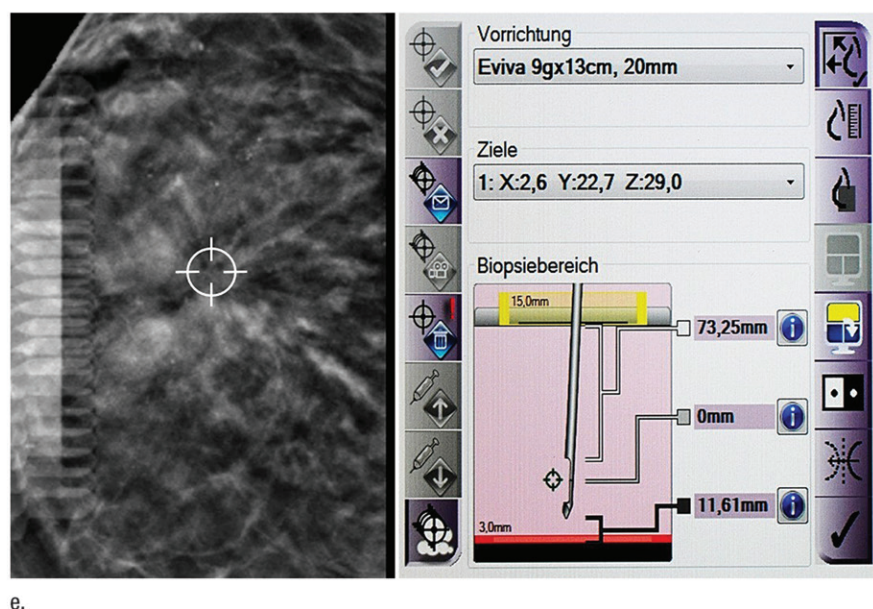


Figure 1: (a) Craniocaudal and (b) mediolateral screening digital mammograms of the right breast in a 51-year-old asymptomatic woman demonstrate an architectural distortion in the right upper outer quadrant. (c) Photograph shows the patient undergoing DBT VAB in the lateral decubitus position and use of a compression paddle with a 74 × 62-mm biopsy window. (d) Craniocaudal DBT image was obtained for planning the DBT VAB. (e) The architectural distortion was reidentified on the DBT image, and the coordinates were automatically determined by the biopsy software after indicating the position of the target with a cursor. (Fig 1 continues)

Validation of Biopsy Results

If the target lesion contained calcifications, specimen radiographs were obtained with the breast still under compression to confirm the adequate sampling of microcalcifications. If specimen radiographs did not include calcifications, an additional biopsy round was performed. Follow-up images acquired the day after the procedure were used to determine whether representative biopsy of the target lesion could be assumed. In every patient, pathology



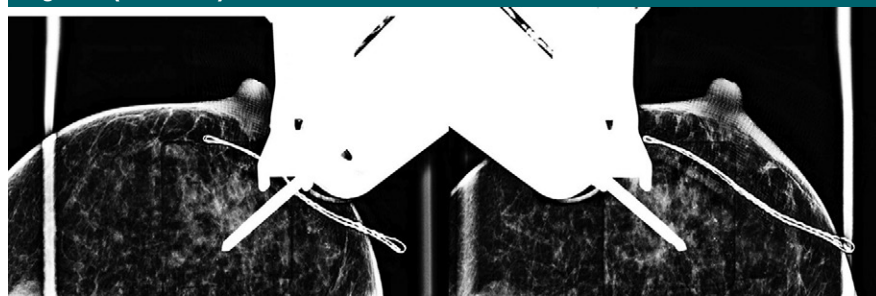
results were carefully correlated with mammographic or DBT findings.

Data Collection and Analysis

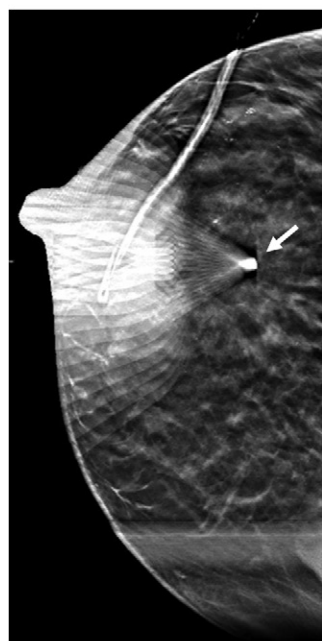
Distribution of target lesion types, classified as “high-contrast” lesions, which included microcalcifications with or

without accompanying mass, or “low-contrast” lesions, which consisted of masses without calcifications and architectural distortions; target lesion size; time needed for the entire intervention (defined as time between patient positioning and clip placement); time

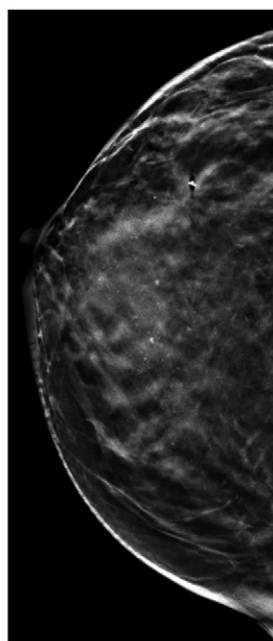
Figure 1 (continued)



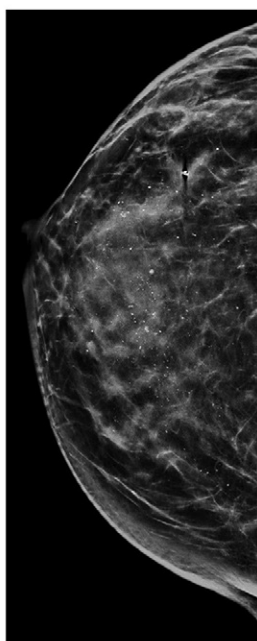
f.



g.



h.



i.

Figure 1 (continued): (f) A pair of stereotactic images was used to maintain postfire control. (g) DBT images were used to achieve postfire control. The arrow marks the tip of the needle. (h) Postprocedure DBT image with (i) reconstructed two-dimensional digital mammogram (C-view) obtained after clip placement suggests successful biopsy of the target lesion. Histologic findings demonstrated a complex sclerosing lesion (a “radial scar”). Per current guidelines for the management of high-risk lesions, surgical excision was performed, which confirmed a complex sclerosing lesion without evidence of malignancy. The time needed to perform the entire intervention was 12 minutes; 4 minutes were needed to target the lesion and obtain the needle trajectories, and 8 minutes were needed to perform the tissue sampling.

needed for target lesion reidentification (defined as the time between acquisition of the first scout image and completion of acquisition of stereotactic images for PS VAB and as the time between acquisition of the first DBT image and acquisition of the DBT images used for calculation of the target coordinates for DBT VAB); time needed for the actual tissue sampling (defined as the time between completion of acquisition

of prefire stereotactic images and the postbiopsy images or DBT images for clip placement control); and number of exposures (image pairs) obtained to complete the procedure. In patients in whom more than one target was biopsied during one intervention, the time needed for the different time steps and the time needed for the entire biopsy were determined for each biopsy separately. The start of a new biopsy was

defined as the beginning of repositioning the patient. Patient tolerance and complications that occurred after the biopsy with the two different systems were compared.

The final surgical pathology result was compared with the results obtained from VAB to find out about the rates of upgrades (ie, high-risk lesions upgraded to ductal carcinoma in situ [DCIS] and DCIS upgraded to invasive cancer).

Statistical Analysis

The χ^2 test and a Student *t* test were used to compare patient demographics, the rate of vasovagal reactions, and the time needed for the entire biopsy, as well as the different time steps of the intervention by using both biopsy systems. The Fisher exact test was used to compare the distribution of lesion types that undergo DBT versus PS VAB, with lesion type dichotomized into calcified (high-contrast) versus uncalcified (low-contrast) targets. SPSS software version 20.0 (IBM, Chicago, Ill) was used for statistical analysis. A *P* value of .05 was considered to indicate a statistically significant difference. For both systems, 95% confidence intervals (CIs) were calculated for the rate of vasovagal reactions.

Results

Patients and Target Lesions

Of the 205 women with 216 lesions scheduled to undergo mammography-guided VAB, 159 patients (mean age, 56.3 years \pm 11.7) with 165 lesions underwent PS VAB, and 46 patients (mean age, 53.0 years \pm 7.5) with 51 lesions underwent DBT VAB. Target lesion characteristics are given in Table 1. No statistically significant differences were found between the two groups with respect to patient age, lesion size, or distribution of benign versus high-risk changes versus DCIS and invasive cancer (*P* > .05) (Table 1).

The rate of calcified (high-contrast) versus uncalcified (low-contrast) targets was 74% (38 of 51 lesions) versus 25% (13 of 51 lesions) for DBT VAB, as opposed to 94% (156 of 165 lesions)

Table 1

Target Lesion Characteristics

Parameter	DBT VAB (n = 51)	PS VAB (n = 165)	PValue
Lesion type (%)			<.0002
High-contrast lesions	74 (38/51)	94 (156/165)	
Low-contrast lesions	25 (13/51)	5 (9/165)	
Median size (mm)*			
High-contrast lesions	8 (4–38)	9 (4–55)	.258
Low-contrast lesions	13 (5–34)	15 (5–36)	...
Histologic results (%)			.848
Benign changes	51 (26/51)	55 (85/154)	
High risk	12 (6/51)	10 (15/154)	
Malignant	37 (19/51)	35 (54/154)	
DCIS	74 (14/19)	74 (40/54)	
Invasive breast cancer	26 (5/19)	26 (14/54)	

Note.—Numbers in parentheses are the data used to calculate the percentages, unless indicated otherwise. “High-contrast” lesions were calcifications with or without an accompanying mass. “Low-contrast” lesions were masses without calcifications or architectural distortions.

* Numbers in parentheses are ranges.

versus 5% (nine of 165 lesions) for PS VAB ($P < .0002$).

Technical Success Rate

Targeting and sampling of the lesions with DBT VAB were successful in all 51 lesions (100%) with one biopsy attempt. None of the biopsy procedures had to be cancelled because of inability to visualize or reach the target lesions. Postprocedural imaging (DBT or two-view mammography) demonstrated that all of the 51 target lesions had been sufficiently sampled. No radiologic-pathologic discordance was observed. No upgrading of DBT VAB pathology results was observed in the final surgical pathologic specimen.

Among the 159 patients with 165 target lesions that underwent PS VAB, sampling was successful in 148 of 159 patients (93.1%) and in 154 of 165 lesions (93.3%) with one biopsy attempt. In 11 patients with 11 lesions, biopsy was not successful because of failure to access or visualize the target. In nine of these 11 patients, PS VAB had to be canceled because the target lesion was inaccessible. This was because of a prepectoral location in two patients, inadequate breast thickness under compression in another two patients, and inability to visualize the

lesion during the biopsy in five lesions in five patients. The latter was the case for low-contrast or diffuse microcalcifications in three of five cases and uncanceled masses within dense breast tissue in two of five cases. Three of these five patients finally underwent surgical biopsy after mammographic needle localization; one patient with microcalcifications opted against surgery and underwent follow-up instead. In the last patient, a 52-year-old woman with a cluster of fine calcifications, DBT VAB was attempted after unsuccessful PS VAB and was completed successfully. In the remaining two of 11 patients, both with microcalcifications, the target appeared accessible, but sampling of the calcifications failed, as proven by postbiopsy mammographic findings and specimen radiographs, even after obtaining 48 specimens (four complete rounds of biopsy, respectively). Both patients ultimately underwent surgical biopsy.

No radiologic-pathologic discordance was observed. Subsequent surgical biopsy findings demonstrated an upgrade of one case of atypical ductal hyperplasia and flat epithelial atypia each to low-grade DCIS in two patients and an upgrade of DCIS to invasive cancer in another two patients.

Time Needed to Perform Biopsy

Biopsies performed with DBT guidance were completed within significantly shorter time intervals than PS VAB, with a mean total procedure time of 13 minutes (range, 8–32 minutes) for DBT versus 29 minutes (range, 12–65 minutes) for PS VAB (Table 2, Table E1 [online], Fig 2).

The significantly shorter procedure time for DBT VAB was largely due to the fact that target lesion reidentification was easier and therefore significantly faster with DBT VAB compared with PS VAB.

The mean time needed to accurately identify and target the lesion was 4 minutes (range, 2–12 minutes) for DBT VAB versus 15 minutes (range, 2–34 minutes) for PS VAB ($P < .0001$). Time needed to perform the actual tissue sampling differed only slightly, with less time needed for DBT VAB than for PS VAB ($P > .06$) (Fig 2).

Number of Exposures Acquired during the Procedure

Significantly fewer exposures were acquired during DBT VAB compared with PS VAB (Table 2), again mainly with regard to exposures needed for targeting.

Patient Tolerance and Complications

Of the 51 lesions in which DBT VAB was performed, 63% (32 of 51 lesions) were biopsied with the patient in the lateral decubitus position; 37% (19 of 51 lesions) were biopsied in the upright position (with the patient sitting).

No major complications were observed during the biopsies with either of the systems. None of the biopsies had to be interrupted because of complications. None of the patients reported severe pain. None of the patients developed hematoma or wound infection that required treatment.

One patient who had undergone DBT VAB in the sitting position (one of all 46 patients who underwent DBT VAB, 2% [95% CI: 0.01%, 12.38%]; and one of the 19 patients who underwent DBT VAB in the sitting position, 5% [95% CI: <0.01%, 26.48%]) and one patient (one of 156, 0.6%; 95% CI: <0.01%, 3.90%) who underwent

Table 2

Time Needed and Number of Images Acquired for the Total Intervention, Lesion Targeting, and Performance of the Actual Biopsy Procedure (tissue sampling) per Target Lesion

Parameter	DBT VAB (<i>n</i> = 51)	PS VAB (<i>n</i> = 165)	<i>P</i> Value
Time (min)			
Total intervention			<.0001
Mean*	12.9 ± 3.7	29.1 ± 10.1	
Median	13 (8–32)	28 (12–65)	
Lesion targeting			<.0001
Mean*	4.1 ± 1.8	15.0 ± 9.3	
Median	4 (2–12)	12 (2–34)	
Tissue sampling			.067
Mean*	8.3 ± 2.6	10.3 ± 4.5	
Median	8 (4–21)	9 (5–31)	
No. of images acquired			
Median for total intervention	5 (4–8)	8 (5–13)	.024
Median for lesion targeting	1 (1–3)	3 (1–7)	.009
Median for tissue sampling	4 (3–6)	4 (4–8)	.786

Note.—Numbers in parentheses are ranges.

* Data are means ± standard deviations.

PS VAB developed self-limiting vasovagal reactions. The rate of vasovagal reactions in patients who underwent DBT VAB versus those who underwent PS VAB was not significantly different ($P = .44$); also, the rate of vasovagal reactions among women who underwent biopsy in the sitting position versus patients who underwent PS VAB was not different ($P = .199$).

Discussion

Although we are reporting our first experiences with DBT VAB, we found that this technique outperformed standard PS VAB in every aspect. DBT VAB proved to be completed within half the time needed for PS VAB and proved to allow successful tissue sampling of even low-contrast lesions that are known to be difficult to sample with PS VAB.

PS VAB is considered to represent the reference standard for tissue sampling with mammographic guidance. PS VAB, especially if performed with contemporary large-core (8–10-gauge) vacuum biopsy needles, offers a high diagnostic accuracy that ranges between 93% and 100% (7–12), even for diagnosis of high-risk lesions and preinvasive

cancers. Compared with add-on upright systems, PS VAB allows the patient to rest in a stable, relatively comfortable position and helps prevent the patient from facing the biopsy area (13,14).

And, yet, PS VAB can be a challenging procedure. In clinical practice, the main difficulty is reidentification of the target lesion within the small 5 × 5-cm biopsy window that can be used for imaging during the procedure. Moreover, calculating the needle position along the z-axis—that is, calculating needle penetration depth—requires that one identify the target lesion on both stereotactic images and use triangulation to calculate needle penetration depth. This may be challenging in cases with low-contrast targets, such as uncalsified masses or architectural distortions.

The DBT guidance system is an add-on for the regular digital mammography and tomosynthesis system. It can be used for “conventional” stereotactic targeting of breast biopsies, or, in DBT mode, for actual “DBT-guided” VAB—which was the mode used in our study. If the system is used in the “stereotactic biopsy mode,” the tomosynthesis arm is used to generate the angulated stereotactic images. These scout images

are obtained with the full 18 × 24-cm detector as full-field digital mammograms that depict the same amount of breast tissue and in the same position as in the corresponding diagnostic full-field digital mammogram. This already greatly facilitates lesion reidentification and targeting compared with the situation PS VAB, with its small 5-cm biopsy window. If the system is used in DBT mode for the actual DBT-guided biopsy, another advantage is that immediate depth information is available. In DBT mode, no stereotactic images are obtained, but a set of DBT images; depth of the target lesion along the z-axis is readily determined by selecting the DBT image that best visualizes the target lesion. The system software then automatically calculates needle insertion depth, as well as stroke margins and distance to skin. This replaces the entire process of triangulation.

Another advantage of DBT VAB over PS VAB becomes apparent during the actual biopsy procedure. With PS VAB, it is not possible to directly visualize the position of the needle with respect to the position of the lesion. In DBT VAB, the lesion and the needle tip can be directly visualized, which allows one to directly measure the distance between the target lesion and the needle tip or the biopsy notch—and thus allows subtle corrections of needle insertion depth.

The ease with which target lesions were located and biopsy coordinates calculated, including lesion depth, as well as the fact that DBT imaging allows one to directly control the position of the needle versus the target, contributed to a significantly reduced overall procedure time for DBT VAB versus PS VAB (13 vs 29 minutes).

The technical and clinical success rate of DBT VAB in this small group of patients was high (100%). For the group scheduled to undergo PS VAB, in 11 of 165 lesions (7%), PS VAB failed because the lesion could not be reidentified, accessed, or sampled. This is in good agreement with the rate reported in the literature (15–18). In one patient with a cluster of fine, low-contrast calcifications in whom PS VAB had failed, successful DBT VAB was performed.

Figure 2

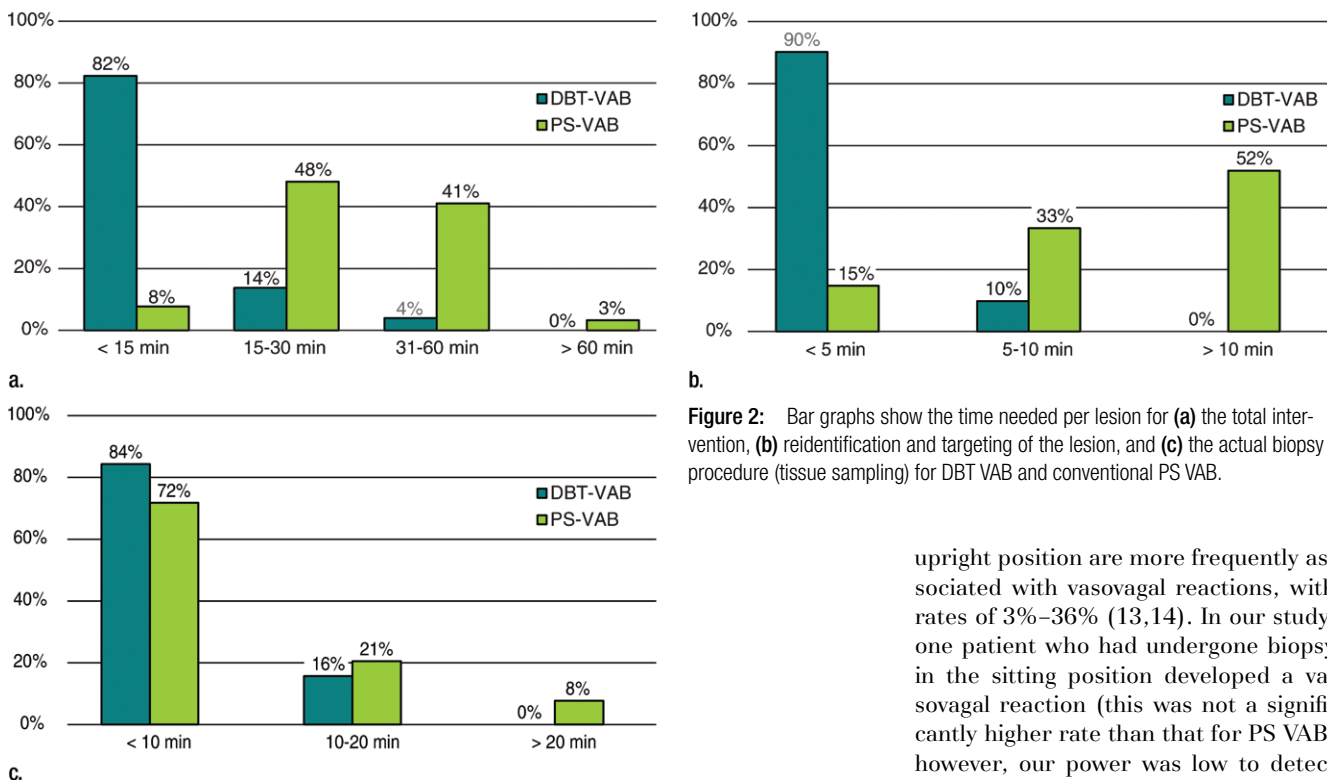


Figure 2: Bar graphs show the time needed per lesion for (a) the total intervention, (b) reidentification and targeting of the lesion, and (c) the actual biopsy procedure (tissue sampling) for DBT VAB and conventional PS VAB.

So beyond procedure duration, DBT VAB appears to offer further clinical advantages over PS VAB. To the best of our knowledge, available data on the success rates of PS VAB include only women who eventually did undergo PS VAB; we did not find a publication that included an “intention-to-treat” (in this context, “intention-to-biopsy”) analysis—that is, an analysis that also included the number of women whose mammographic findings did warrant biopsy but who did not proceed to PS VAB in the first place because the respective mammographic findings were deemed not amenable to PS VAB. Although such data are lacking, the practicing breast radiologist will probably agree that PS VAB of low-contrast lesions, such as uncalcified masses, is difficult. We believe that even in experienced breast centers, a substantial (although yet unreported) number of women with mammographic findings suspicious for cancer do not undergo stereotactic biopsy because of these

difficulties. In our department, this changed with the availability of DBT VAB. With the full-field digital mammogram or DBT image that was used to guide the intervention, it was possible to delineate and, thus, reliably target and perform VAB in even uncalcified, low-contrast masses.

This perspective change of clinical practice was already perceivable in this small cohort: Only 5% of lesions (nine of 165) that underwent PS VAB corresponded to uncalcified masses or uncalcified architectural distortions, whereas in the women undergoing DBT VAB, 25% of the lesions (13 of 51) had already undergone DBT VAB for uncalcified masses or architectural distortions ($P < .0002$). So, we expect that DBT VAB will increase the overall number of patients that are amenable to mammography-guided breast biopsy in general.

A possible disadvantage associated with DBT-guided VAB is patient comfort. It has been reported that vacuum biopsies with the patient sitting in an

upright position are more frequently associated with vasovagal reactions, with rates of 3%–36% (13,14). In our study, one patient who had undergone biopsy in the sitting position developed a vasovagal reaction (this was not a significantly higher rate than that for PS VAB; however, our power was low to detect a difference). We believe that the short overall intervention time compensated for some of the reduced patient comfort associated with the sitting or lateral decubitus position during DBT VAB. Another disadvantage of DBT VAB is the fact that the radiation dose increases as compared with plain 2D digital mammography; in addition, the “full-field approach” increases the amount of breast tissue that does receive radiation compared with the small biopsy window during PS VAB. However, the additional glandular dose administered during DBT-guided VAB will, at least in part, be compensated for by the fact that substantially fewer exposures or control images were acquired for DBT-guided VAB versus PS VAB.

A limitation of our study is the small number of patients who underwent DBT VAB, which limits the validity of our conclusions. Also, since the follow-up period of patients with benign DBT biopsy results is still short, we cannot report on the false-negative rate of DBT VAB. However, care of women after receiving benign VAB findings is unaffected by the

method of biopsy guidance (DBT versus stereotactic) and was conducted in accordance with international practice guidelines. Accordingly, in patients with a benign histologic result, careful attention was paid to make sure that specimen radiographs confirmed that the target had been adequately sampled, that a representative removal of the target was visible on the control mammogram after biopsy, and that radiologic-pathologic correlation demonstrated a histologic finding that was plausible and explained the respective imaging finding. Follow-up data and more data on DBT VAB will still be needed to confirm our initial results. Our procedure time was also not directly comparable to that expected from other sites, since our standard procedure is to acquire two rounds of 9-gauge biopsy cores, with 24 samples for each lesion always acquired, and this is not generalized practice elsewhere. Another limitation is that our comparison groups were not randomized but were rather divided by time.

In conclusion, our initial experiences with DBT VAB demonstrate that the system seems to outperform PS VAB with regard to the ease with which target lesions are reidentified and biopsy coordinates calculated. This led to a significant reduction of procedure time and a significant increase in the rate of women who underwent mammography-guided VAB for low-contrast lesions, such as uncalcified masses or architectural distortions. We anticipate, therefore, that DBT VAB will increase the number of mammographic findings that are deemed amenable to VAB. DBT VAB is useful not only to allow biopsy of lesions that are visible on DBT images alone; if our results are confirmed in other centers, it is likely to replace PS VAB for routine use in patients with abnormalities demonstrated on regular 2D digital mammograms, as well.

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