Safety and Efficacy of Magnetic Resonance–Guided Vacuum-Assisted Large-Volume Breast Biopsy (MR-Guided VALB)

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Objective: Magnetic resonance (MR)-guided vacuum-biopsy is technically demanding and may fail depending on target-lesion size or breast size, and location of lesions within the breast. We developed an MR-guided vacuum-assisted biopsy protocol that collects larger amounts of tissue, aiming at an at least partial or complete ablation of the target-lesion, just as it is intended during surgical (excisional) biopsy. Rationale is to avoid biopsy failures (false-negative results due to undersampling) by collecting larger amounts of tissue. We report on our experience with MR-guided vacuum-assisted large-volume breast biopsy (VALB) (MR-guided VALB) with regard to clinical success and complication rates.

Materials: Institutional review board–approved analysis of 865 patients with 1414 MR imaging (MRI)-only breast lesions who underwent tissue sampling under MRI guidance. Magnetic resonance–guided VALB was performed on a 1.5 T-system with a 9G system. Per target lesion, we collected at least 24 samples, with the biopsy notch directed toward the position of the target until on postbiopsy control imaging the target lesion appeared completely or at least greatly removed. The standard-of-reference was established by at least 24-months follow-up (for benign biopsy results), or results of surgical histology (for malignant or borderline results). We investigated the technical success rates as a function of factors that usually interfere with MR-guided vacuum biopsy.

Results: Target lesions were located in the central versus peripheral parts of the breast in 66.6% (941/1414) versus 33.6% (473/1414), occurred in large, intermediate, or small breasts in 22.7% (321/1414), 56.4% (797/1414), or 20.9% (296/1414), corresponded to nonmass enhancement (NME) versus mass enhancement (ME) in 64.0% (905/1414) vs. 36.0% (509/1414), with an average size of 23 mm for NME versus 9 mm for ME, respectively. Primary technical failures, that is, inability to reach the target lesion occurred in 0.2% of patients (2/865) and 0.1% of target lesions (2/1414). Successful biopsy, that is, an MR-guided VALB diagnosis matching with the standard of reference, was achieved in 99.5% (859/863) of patients and 99.7% (1408/1412) target lesions that had been amenable to MR-guided VALB. In 0.5% of patients (4/863) and 0.3% of target lesions (4/1412), a radiologic-pathologic mismatch suggested a false-negative biopsy, confirmed by secondary excisional biopsy. The likelihood of failure was independent of the lesion's location in the breast, breast size, target lesion size, or target lesion type (NME vs ME). None of the patients with benign MR-guided VALB diagnoses developed breast cancer at the biopsy site during follow-up of 2 years. None of the patients developed major complications.

Conclusion: Magnetic resonance–guided VALB is a safe procedure that is associated with a high success rate (99.7%) that is independent of the size, type, or location of a target lesion, or the size of the breast, and is associated with a very low complication rate.

Key Words: breast MRI, breast intervention, MR-guided vacuum biopsy

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Vacuum-assisted biopsy (VAB) under mammographic guidance was introduced in the late 1990s.[1–3] Only a couple of years later, the first experiences with magnetic resonance (MR)-guided VAB were reported.[4–7] Since then, both mammography-guided and MRI-guided VAB has gained broad clinical acceptance.[8–13]

M agnetic resonance–guided VAB is a safe and accurate technique for histological clarification of suspicious or equivocal lesions visible by MRI alone. However, some challenges do exist. Vacuum-assisted biopsy, irrespective of type of guidance, may be technically demanding in patients with very small or very large breasts, or in target lesions that are located in specific locations such as the immediate retroareolar, superficial subcutaneous, deep prepectoral, or far medial or far lateral parts of the breast.[14–16]

Compared to mammography, or ultrasound-guided VAB, for VAB conducted under MRI guidance, there exist some additional challenges. One important additional challenge is the fact that the spatial resolution with which the needle can be placed during MR-guided breast interventions is usually limited, especially when using a grid compression device. This is because in most setups for MR-guided biopsy, sterile needle guides (bushings) are used that need to accommodate 8G needle sheaths, thus offer fixed access routes through the compression plates every 4 to 5 mm. This coarse spatial resolution of needle access routes implies that in many cases, the needle cannot be placed exactly into the desired position, but only within a couple of millimetres off the target position. If, in such a situation, the regular sampling process is conducted according to current guidelines, that is, in the usual clockwise fashion, lesion misses may be the consequence. This may contribute to the fact that even in more recent reports, the reports rate of false-negative results after MR-guided biopsy is relatively high.[11,12]

In our department, we compensate for the offset between needle placement and target lesion by directing the biopsy chamber toward the actual position of the target lesion, and by then collecting tissue mainly in this direction, that is, in the direction of the target lesion, and, finally, by using T2-weighted turbo spin echo (TSE) (T2w-TSE) images to document at least partial lesion removal.

The aim of this study was to report on our long-term experience with such vacuum-assisted large-volume biopsy (VALB) under MRI guidance (MR-guided VALB) of breast lesions visible by MRI alone in success rates as well as the rate of associated complications.

MATERIALS AND METHODS

This institutional review board–approved analysis was conducted on MR-guided VALB procedures performed between January 2009 and January 2013, followed by a follow-up period of at least 2 years. All data were entered prospectively into a dedicated database that was designed to prospectively record all variables analyzed in this study (Fig. 1). All procedures were performed after the risks and benefits were explained to the patients, and written informed consent was obtained.

Before MR-guided biopsy was done, all patients had undergone diagnostic breast MRI according to a standardized protocol published previously.[17] To be eligible for MR-guided VALB, women had to undergo a thorough diagnostic workup of the respective suspicious lesion to investigate whether the lesion was, in retrospect, visible on conventional mammography or on second-look breast ultrasound. Only if the workup did not show a clear correlate of the suspicious MRI lesion, women underwent MR-guided VALB.

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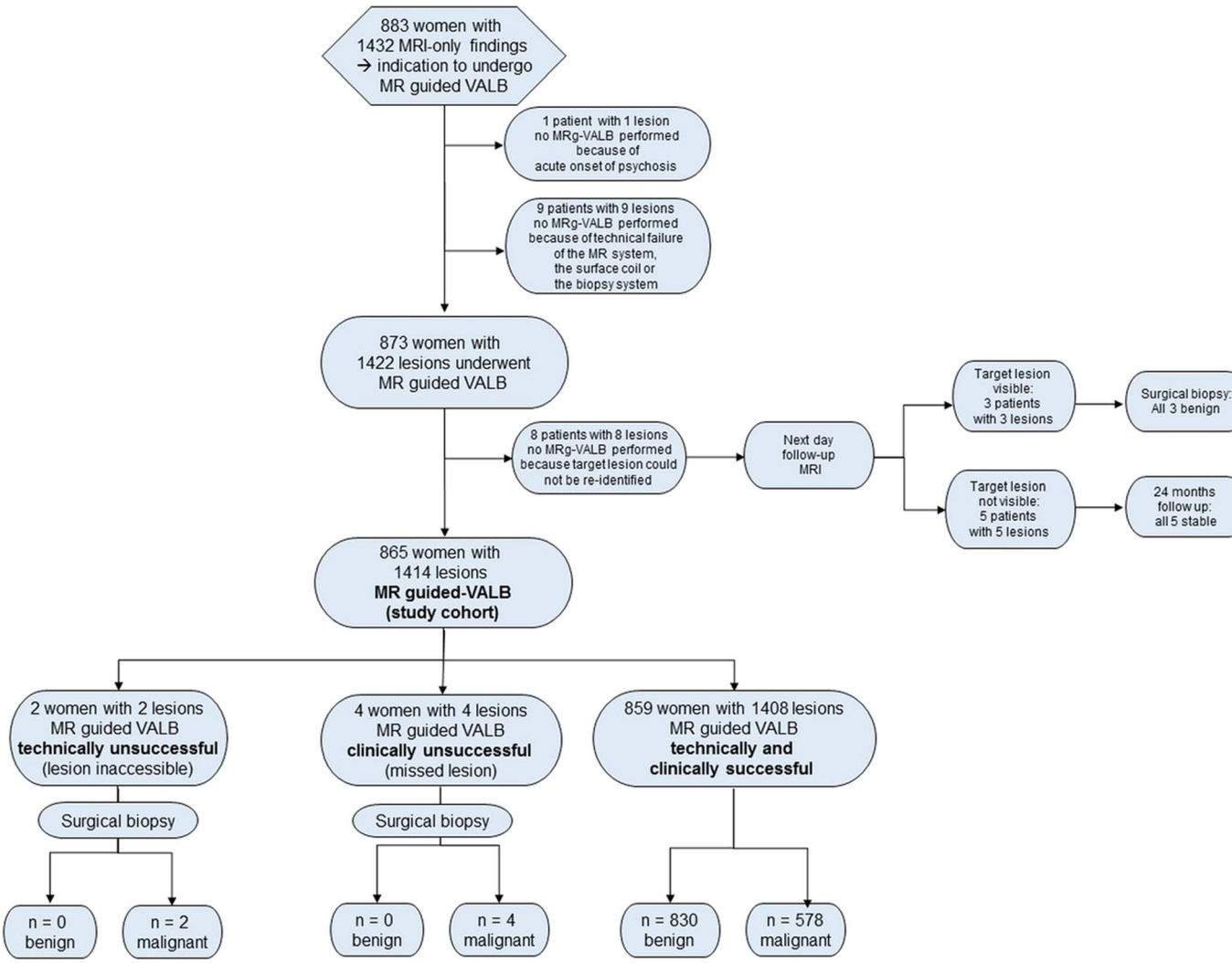

FIGURE 1. Flow chart of study cohort. Figure 1 can be viewed online in color at www.investigativeradiology.com.

VALB Procedure

All MR-guided VALBs were performed at a 1.5 T MR System (Philips Intera Achieva, Best, the Netherlands) equipped with a dedicated surface coil (Open Breast Array Coil, Invivo). Magnetic resonance–guided biopsies were done with a 9-gauge VAB device (Suros, ATEC, Hologic). The biopsy system and the coil used do allow only a lateral approach to the breast; a medial or craniocaudal access is not feasible with our setup.

Biopsies were performed by 8 different breast radiologists who had between 2 and 18 years of experience in performing breast interventions.

All patients underwent appropriate coagulation tests before MR-guided VALB. Patients were asked to discontinue medications that would interfere with coagulation or clotting function for at least 1 week before biopsy.

The patient was positioned prone. One or both breasts (in case of bilateral biopsy) were immobilized by 2 compression plates that allow a lateral-only access to the breast through a grid localization system. To re-identify the target lesion, an abridged version of the diagnostic breast MRI study was performed as previously described.[17] A high-resolution (noninterpolated 0.5-mm inplane) T2w-TSE pulse sequence without fat suppression was acquired with exactly matching anatomic parameters as the actual T1-weighted dynamic series. The target lesion was re-identified on the subtracted images of the dynamic series; then, the nonsubtracted precontrast and postcontrast images were carefully compared with the T2w-TSE non–fat-suppressed images to relocate the target lesion on the respective T2w-TSE images. Fat signal was not suppressed to use the architectural information it provides to re-identify anatomical landmarks and the target lesion.

The stereotactic coordinates and an appropriate needle trajectory were calculated by use of a dedicated software system (DynaCAD, Invivo). Subcutaneous and deep local anesthesia with 10- to 20-mL lidocaine (Scandicain, AstraZeneca) was given until the puncture was entirely painless. Then, the puncture was done with a trocar through a sheath. After puncture, the trocar was removed and an MRI-visible obturator was inserted in the sheath, and the T2w-TSE pulse sequence was repeated to check the position of the obturator (i.e., the needle) with regard to the target lesion, especially to identify a possible offset of the needle.

Vacuum biopsy was then performed. In all patients, at least 24 biopsy specimens were obtained per target lesion. Only in cases where the biopsy needle was placed in the center of the lesion were biopsies taken in a clockwise direction ("biopsy round"). If the needle had to be placed in the periphery or only in the proximity of a target lesion, the biopsy chamber was turned toward the direction of the target, and samples were taken mainly or only in this direction.

After cores were taken, the biopsy cavity was thoroughly flushed with saline solution. The success of biopsy was controlled by repeating the T2w-TSE pulse sequence. Images were carefully compared with the T2w-TSE images obtained before biopsy to check whether the fluid-filled biopsy cavity would include the area of the target lesion (Figs. 2 and 3). If any doubt persisted, further biopsies were taken in the fashion previously mentioned (Fig. 3).

Once T2w-TSE images suggested a satisfactory biopsy, the biopsy site was marked by a clip (Trimark for ATEC, Hologic). A postinterventional mammogram was obtained in at least 2 views to document the clip position (Fig. 3).

After completion of biopsy, fluid collections within the biopsy cavity were aspirated through the sheath before it was removed. Any possible residual fluid collections were evacuated by manually massaging the actual biopsy site toward the percutaneous puncture site. Care was taken not to compress the puncture tract during this procedure to let wound fluids exit through the puncture-site. Thereafter, the biopsy site was compressed manually by a radiologist for at least 15 minutes beyond complete hemostasis. Sterile adhesives were then placed on the puncture site, followed by a circular compression dressing which was left in place for 12 hours. All women were seen clinically the day after the procedure for a clinical examination, wound control, and discussion of the histologic results.

Radiologic-Pathologic Correlation

Histologic processing included hematoxylin and eosin staining and immunohistochemical staining at the discretion of the breast pathologist. Specimens were embedded completely and sliced according to a standardized protocol. A careful radiologic/pathologic correlation was performed for each biopsy site of every patient. If discordance between the MRI finding and the pathologic result was suspected, the patient was recalled for another diagnostic MRI to check whether the target had been successfully biopsied or not. In accordance with current guidelines, women with an MR-guided VALB diagnosis of borderline or high-risk lesions underwent subsequent excisional (surgical) biopsy.[18,19]

Data Collection and Analysis

The following data were entered prospectively into a dedicated database: The respective clinical indications for diagnostic breast MRI preceding the biopsy, patient's age and demographic data, imaging findings including lesion size and lesion type (mass (ME) versus nonmass lesion (NME)); breast thickness under lateral compression as measured on axial T2-weighted images; overall breast density (amount of breast tissue), location of the lesion within the breast by quadrant, distance to skin, to nipple and chest wall, and width of the possible offset between the target lesion and the needle tip in mm.

We distinguished between central and peripheral parts of a quadrant, with peripheral part representing the region between the skin, the nipple, or the pectoral muscle until a depth of 15 to 20 mm (i.e., width of the biopsy chamber). Accordingly, this includes the immediate retroareolar, prepectoral, far medial, and axillar region. All other parts were considered central parts. A breast was considered small when the maximal diameter of the compressed breast was within the lower quartile of the distribution of breast sizes of the cohort, and large for the upper quartile. All remaining breast sizes were considered average.

The standard of reference was established by surgical pathology results for all women who underwent surgery or excisional biopsy after MR-guided VALB, or by radiological and MR imaging follow-up of at least 24 months. Moreover, we report on upgrades, that is, a difference of histology with implications with regard to patient's prognosis, but not with regard to immediate patient management, for example, atypical ductal hyperplasie (ADH) to ductal carcinoma in situ (DCIS).

All minor and major complications were recorded. Major complication were defined as a complication resulting in an unplanned increase in level of care, prolonged hospitalization, permanent adverse sequelae, or death (e.g., severe bleeding or infections, which need medical or surgical treatment). Minor complications were defined as complications resulting in no sequelae and requiring only nominal therapy or observation (e.g., pain, conservatively treated hematoma, syncope).

During the follow-up period, patients were seen in our breast clinics and underwent physical examination to assess any clinical changes of the breast after vacuum biopsy, especially visible scar formation, persistent bruising, or cosmetic changes/change of breast contour.

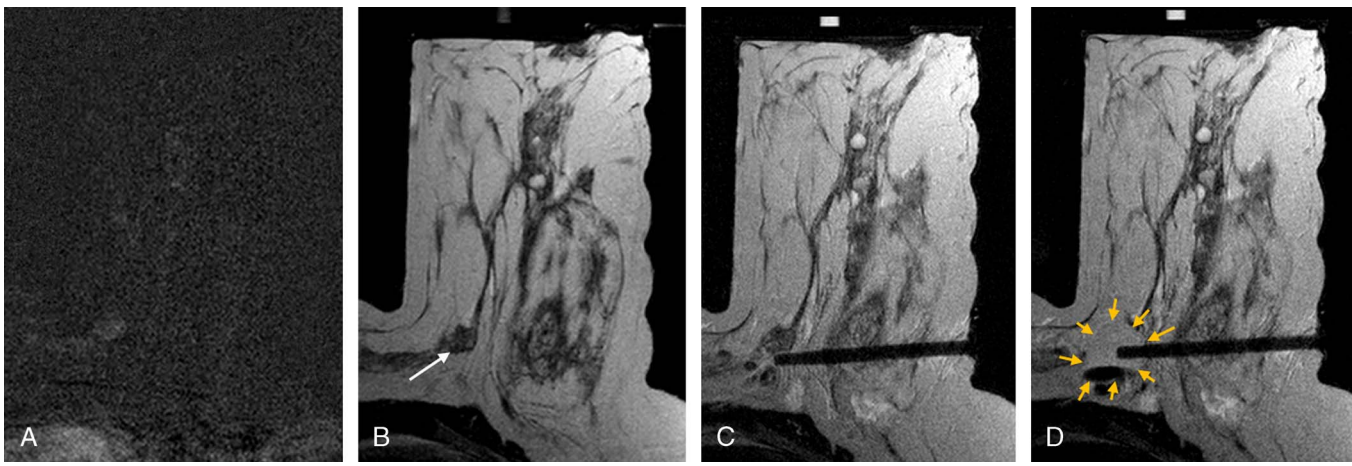

FIGURE 2. A 52-year-old woman at average risk of breast cancer. The patient underwent dynamic contrast-enhanced MRI that revealed a 9-mm suspicious mass in upper inner quadrant of the left breast. Mammographic and second-look ultrasound images did not reveal a correlate for MRI finding. The patient underwent MR-guided VALB (A–D). Magnetic resonance–guided VALB revealed invasive ductal cancer (pT1b, pN0, G3). A–D, Magnetic resonance -guided VALB. Magnetic resonance–guided VALB of the mass in the upper inner quadrant of the left breast (*arrow*). First postcontrast subtracted image (A); prebiopsy T2-weighted TSE sequence prior (B) and after placing an introducer sheath with the obturator in place (C). The obturator was placed posterior to the target lesion. Therefore, the biopsy chamber of the biopsy needle was turned toward the nipple and the biopsy was strictly performed in this direction (C). Postbiopsy T2-weighted TSE sequence (D) obtained after MR-guided VALB and flush of the biopsy cavity with isotonic sodium chloride solution shows that because of fresh saline solution and evacuation of the developing hematoma, the biopsy cavity (*arrows*) can be accurately delineated on T2- weighted TSE sequence. Figure 2 can be viewed online in color at www.investigativeradiology.com.

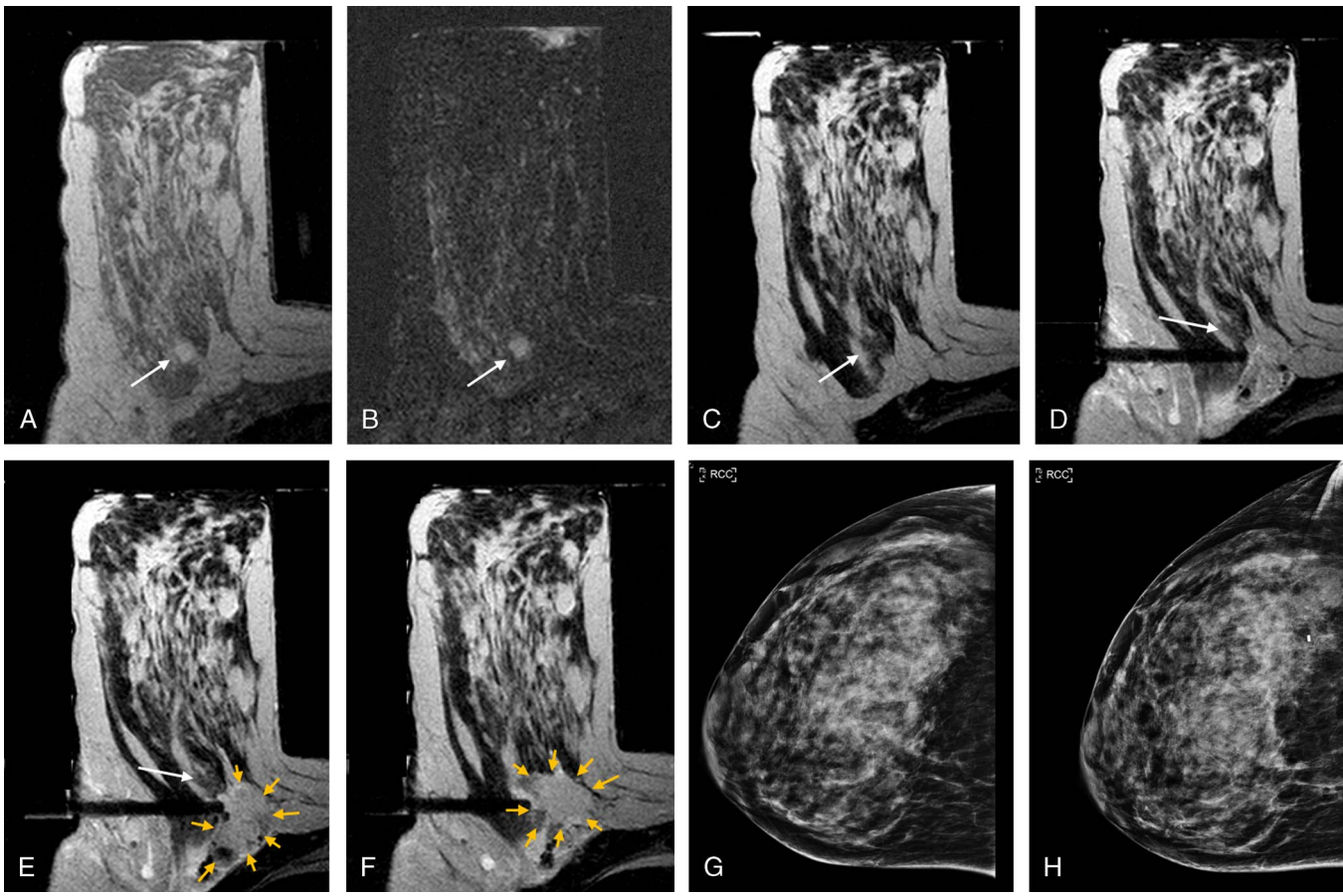

FIGURE 3. A 50-year-old patient who had undergone breast MRI for screening and who had shown an 8-mm suspicious mass in the prepectoral region of the upper outer quadrant of the right breast. Mammographic work up and second-look ultrasound did not reveal a correlate. Accordingly, the patient underwent MR-guided VALB. After puncture, the needle tip rested with an offset of 6 mm dorsal to the target lesion as visualized by the T2-w TSE control images. During the first round of biopsy, 28 cores were collected with the biopsy notch directed strictly toward the position of the target lesion. However, control imaging suggested that the target lesion had not been sampled. A second biopsy round was initiated; another 24 cores were retrieved and collected in a separate sampling vial. Histologic analysis of the specimen in the first vial revealed only normal breast tissue, whereas the specimen in the second vial did contain the suspected invasive cancer (pT1b, pN0, G2). The diagnosis was confirmed by surgical pathology. A–F, Magnetic resonance–guided VALB. Magnetic resonance–guided VALB of the mass in the upper outer quadrant of the right breast (*arrow*). A–B, Axial T1-weighted 2D gradient-echo. First contrast-enhanced (A) with subtracted image (B). C, T2-weighted TSE image before biopsy. Note that the target lesion is re-identified on T2-weighted images by close comparison of the site, size, and shape of enhancement. D, T2-weighted TSE image after puncture, with the introducer sheath and obturator in place. The needle position is 6 mm off (dorsal) the position of the target lesion (arrow). Note that the position of the target lesion and its offset to the needle (obturator) is visible on the T2-weighted image. Therefore, the biopsy chamber was turned to open toward the target lesion, and biopsies were taken strictly in this direction. E, Postbiopsy T2-weighted TSE images obtained after first round of vacuum biopsies, with 28 cores taken, and after flushing the biopsy cavity with saline solution. The biopsy cavity (*yellow arrows*) is clearly visible. However, the biopsy cavity does not include the target lesion, which is still visible, with identical size and morphology as before biopsy (white arrow). Note that the target as well as the biopsy cavity is clearly delineated on T2-weighted TSE images. The assumption was that the target lesion had not yet been successful sampled, and a second round of biopsy was initiated and performed in the same fashion, with biopsy notch facing the target lesion. F, Repeat postbiopsy T2-weighted TSE image obtained after the second round of vacuum biopsies, with 24 cores taken. The biopsy cavity now does include the target lesion (*yellow arrows*), suggesting that the lesion had been successfully sampled. G–H, Digital full field mammography before and after MR-guided VALB of the right breast. Craniocaudal view (cc) before (G) and 24 hours after MR-guided VALB (H). Mammography did not show any correlate for the MRI finding in the right breast (G). In the postbiopsy mammography (H) the clip, which was performed after MR-guided VALB, is visible in the right upper outer part of the right breast. Note absence of hematoma or other sequelae. Figure 3 can be viewed online in color at www.investigativeradiology.com.

For further analysis, 95% confidence intervals were calculated by Clopper Pearson statistics.

RESULTS

A total 883 consecutive patients (mean age, 53.5 years) with 1.432 MRI-only visible findings were scheduled for MR-guided VALB during the study period. In 10 women, the MR-guided VALB could not be performed for different technical reasons or, in one patient, because of an acute onset of a so-far undiagnosed psychosis (Fig. 1). Accordingly, a total of 873 consecutive patients (mean age, 53.1 years) with 1,422 MRI-only visible findings underwent MR-guided VALB during the study period.

In 8 patients with 8 target lesions, the target lesion could not be identified on the prebiopsy MR images, so that MR-guided VALB was not performed. A repeat MRI 1 day after the biopsy was performed in all patients. Five of these 8 target lesions remained invisible also on the repeat MRI as well as on MRI follow-up after 6 and 12 months and were therefore finally categorized as benign. Three target lesions in 3 patients were visible on a repeat MRI. Patients opted to undergo MRI

follow-up instead of a second try to biopsy. All 3 lesions were stable on MRI for a median of 24 months and therefore finally categorized as benign.

The final cohort therefore consists of 865 patients, with 1414 MR-only visible lesions who underwent MR-guided VALB. Their demographic details are listed in Table 1. Target lesion characteristics are given in Table 2.

The mean size of the compressed breast was 3.6 cm; range, 1.5 to 5.8 cm. The distribution of target lesions was representative of the distribution of lesions seen in breast MRI in our clinical practice, suggesting that lesions were not selected based on a preferable location. One third of target lesions [473 of 1414 (33.6%) (13.3–36.0%)] were located in the peripheral part of a quadrant, another 255 [18.0% (16.1%–20.1%)] target lesions were located either in the immediate retroareolar or prepectoral area, that is, in locations considered as "difficult" according to previous publications on MR-guided breast biopsy. Approximately 43.6% [41.1%–46.2%; 617/1414] of women had very small or very large breasts.

In more than one third of target lesions [491/1414; 34.7% (32.2–37.3%)], there was an offset between the target lesion and the biopsy needle that measured between 1 and 8 mm (median, 3 mm). This offset was more frequently present in biopsies done for enhancing masses [312/509; 61.3% (56.9–65.6%)], especially small masses below 10 mm, and less frequently for biopsy of NME [179/905; 19.8% (17.2–22.5%)], mainly because target lesions with NME tended to be significantly larger than enhancing masses.

Magnetic resonance–guided VALB failed technically in 2 patients [2/865; 0.23% (95% confidence interval [CI]), 0.03%–0.08%] with 2 target lesions [2/1414; 0.14% (95% CI, 0.02%–0.5%)] located in a far medial and posterior location because the target lesion was not accessible from a lateral approach.

TABLE 1. Demographics and Indications of Diagnostic Breast MRI in Patients Scheduled for MR-Guided VALB

	All Women (n = 865)		
Age, years			
Mean ± SD	53.1 ± 10.8	—	—
Median/range	54/28–79	—	—
	n	**%**	**95% CI**
Menopausal Status			
Premenopausal	511	59.1	55.7–62.4
Postmenopausal	354	40.9	37.6–44.3
Familial breast cancer risk			
No	452	52.3	48.9–55.6
Moderate	280	32.4	29.3–35.6
High	133	15.4	13.0–18.0
Indication for diagnostic MRI			
Preoperative staging	343	39.7	36.4–43.0
Screening	239	27.6	24.7–30.7
Follow-up after breast cancer	161	18.6	16.1–21.4
Diagnostic assessment of conventional imaging findings	106	12.3	10.1–14.6
Carcinoma of unknown primary	16	1.9	1.1–3.0
Number of target lesions per patient			
1	460	53.2	49.8–56.6
2	285	33.0	29.8–36.2
≥3	120	13.9	11.6–16.4

95% CI indicates 95% confidence intervals; MRI, magnetic resonance imaging; SD, standard deviation.

TABLE 2. Target Lesion and Breast Characteristics in Women Undergoing MR-Guided VALB

	MR-Guided VALB n = 1414		
Lesion type	n	%	95% CI
Masses (ME)	509	36.0	33.5–38.6
Nonmass (NME)	905	64.0	61.4–66.5
Lesion size, mean ± SD, mm			
Masses (ME)	9 ± 4.2		8.8–9.3
Nonmass (NME)	23 ± 13.2		22.3–23.7
Lesion localization	n	%	95% CI
Quadrant			
Upper outer	480	34.0	31.5–36.5
Upper inner	226	16.0	14.1–18.0
Lower outer	325	23.0	20.8–25.3
Lower inner	171	12.1	10.4–13.9
Central	212	15.0	13.2–17.0
Location in the center of a quadrant	941	66.6	64.0–86.7
Location in the periphery of a quadrant	473	33.5	13.3–36.0
Immediate retroareolar	107	22.6	18.9–26.7
Dorsal-prepectoral	148	31.3	27.1–35.7
Medial subcutaneous	96	20.3	16.8–24.2
Lateral subcutaneous	122	25.8	21.9–30.0
Breast thickness under compression, cm			
small (<2.5)	296	20.9	18.8–23.2
average (2.5–5)	797	56.4	53.8–58.9
large (>5)	321	22.7	20.5–25.0
Number of biopsy specimens per lesion			
Median/range	39/24–60		36.4–42.5

ME indicates mass enhancement; NME, nonmass enhancement.

Accordingly, 863 patients (863/865; 99.8%) with 1412 target lesions (1412/1.414; 99.9%) finally underwent technically successful MR-guided VALB.

In 15 patients with 15 target lesions [15/1412; 1.1% (95% CI, 0.06%–1.8%) of target lesions; 15/863; 1.6% (95% CI, 0.9%–2.9%) of patients], a radiologic-pathologic mismatch was suspected. A repeat MRI, which was performed within 1 week after the MR-guided VALB in these patients showed that in 5 of 15 patients, the respective target lesions had been removed or largely ablated by MR-guided VALB, suggesting that tissue sampling had indeed been representative; long-term follow-up documented stability or regression of the residual lesion suggesting their benign nature in these women. In the remaining 10 patients with 10 target lesions, major parts or the target lesions were still present, such that a nonrepresentative biopsy could not be excluded. These 10 women underwent surgery after MR-guided needle localization. Surgical pathology was concordant with the MR-guided VALB histology in 6 of these 10 patients, suggesting that the lesion had indeed not been missed.

In the remaining 4 patients, malignant lesions were found in the surgical excision. Accordingly, the false-negative rate was 4 of 1422, or 0.3% (95% CI, 0.1 %–0.7 %): 2 patients with DCIS and 2 with invasive cancer (one pT1a, pN0, M0, G3 and one pT1b, pN0, M0, G2). These 4 lesions were small, 2 were enhancing masses of 6 mm and 8 mm in size, and 2 were NME, and 9 mm and 12 mm in size. The 4 lesions were located in the central part of the breast and occurred in women with an average-size breast. In all of these patients, MR-guided VALB had been performed according to the protocol, and no difficulties had been encountered during or after the biopsy.

Upgrades were observed in 5 patients with 5 target lesions, (5/1414; 0.4%). Two patients had a diagnosis of ADH, where subsequent

TABLE 3. Final Diagnosis of Target Lesions (Standard of Reference)

	N = 1412	
	n	**%**
Based on MR-guided VALB followed by surgical histology		
Malignant	582	41.2
Invasive	306	52.6
Type		
No specific type (NOS)	188	61.4
Lobular	75	24.5
Ductal-lobular	27	8.8
Other	16	5.2
Grading		
Low grade	60	16.3
Intermediate grade	108	35.3
High grade	148	48.4
DCIS	276	47.4
Grading		
Low grade	36	13.0
Intermediate grade	105	38.0
High grade	135	48.9
Nonmalignant		
High-risk lesion	244	17.3
Based on MR-guided VALB and follow-up		
Benign lesion	586	41.5

surgical excision confirmed the (low-grade) DCIS that had been suspected to be present based on diagnostic breast MRI, and 3 had a diagnosis of DCIS at MR-guided VALB, where subsequent surgical excision revealed an upgrade to (micro)-invasive breast cancer.

Final Diagnoses and Results of Follow Up

A total 582 target lesions [41.2% (16.7–43.8%)] proved malignant; these women underwent surgical treatment (resection). A total 830 (58.8% [56.2–83.3%]) target lesions yielded benign changes (Table 3). Surgical biopsy in 202 benign target lesions, or MRI follow-up of at least 24 months (median, follow- up, 28 months; range, 24–51 months) in 336 women with 628 benign target lesions, is available to confirm absence of breast cancer in these women.

In one woman with NME in the upper outer quadrant suspicious of DCIS, MR-guided VALB yielded LIN1, confirmed by subsequent excisional biopsy. She was put on intensified surveillance including annual MRI follow-up. On the second follow-up MRI 28 months later, she developed a new enhancing mass in another quadrant (upper-inner quadrant), occult on mammography or second-look ultrasound. Magnetic resonance–guided vacuum biopsy yielded a pT1b, G2, N0 lobular-invasive cancer.

On long-term clinical follow-up, none of the patients who underwent MR-guided VALB alone (i.e., without additional surgical procedure) developed clinically visible or palpable scars or fat necrosis.

Complications

No major complications were observed, especially no hematoma formation that required treatment, no abscess formation, or mastitis occurred. Three patients developed a minor complication, a vasovagal reaction, managed by simply reassuring the patient. Biopsy-related fluid collections or hematomas subsided spontaneously in all patients that were seen on follow-up after benign breast biopsy.

DISCUSSION

Magnetic resonance–guided VALB implies the use of contemporary vacuum biopsy methods to collect larger amounts of tissue with the intention to remove, at least in part, the target lesion, and to use imaging to control the success of biopsy.

In this cohort of 865 women with 1414 MRI-only visible lesions, such MR-guided VALB was highly efficient, that is, helped establish a correct tissue diagnosis that was congruent with the standard of reference in 99.5% of patients and 99.7% of target lesions. No major complications occurred, especially no hematoma requiring treatment, and the rate of even minor complications was negligible.

Current guidelines do not specify the number of cores to be retrieved during MR-guided vacuum biopsy. In 2009, a consensus paper was published that recommended "… acquisition of >24 cores (11G) should be routinely attempted", or an "equivalent (smaller) volume should be retrieved if a larger probe is used."[20] However, as a matter of fact, published evidence on MR-guided vacuum biopsy reveals that this recommendation is not put to practice. Although the actual number of retrieved cores varies between publications, an analysis of practice patterns (Table 4) reveals that most operators retrieve between 6 and 12, and up to 20 cores with 9G needles, substantially less tissue than that retrieved routinely in our cohort, where a minimum of 24, a median 39, and up to 60 9G cores were retrieved per target lesion. The relatively small number of cores that is apparently retrieved during MR-guided vacuum-assisted biopsy procedures may contribute to the fact that recently published results on MR-guided vacuum-assisted breast biopsy report on failure rates ranging between 4% and 12%.[24,26,29]

In contrast, in this study, none of the reported limitations were observed. Target lesions were successfully sampled irrespective of their location within the breast and irrespective of the size of the breast.

TABLE 4. Overview on Published Practice Patterns Regarding MR-Guided Vacuum Biopsy

Author	Journal, Publication Year	No. Target Lesions	Needle Size	No. Cores Taken	Setting
Liberman et al[9]	*AJR Am J Roentgenol* 2005	98	9G	Up to 12	Single center
Perlet et al[8]	*Cancer* 2006	538	11G	At least 20	Multicenter (5 sites)
Liberman et al[21]	*AJR Am J Roentgenol* 2007	237	9G	Median, 9; range, 8–18	Single center
Hauth et al[22]	*Eur Radiol* 2008	34	10G	Mean, 14.5: range, 2–25	Single center
Meeuwis et al[23]	*Eur Radiol* 2012	155	9G	Up to 12	Single center
Rauch et al[24]	*AJR Am J Roentgenol* 2012	218	9G	6–12	Single center
Mahoney et al[25]	*JMRI* 2013	55	10G	12	Single center
Spick et al[26]	*Eur Radiol* 2016	487	8G–10G	12–24	Single center
Ferre et al[27]	*Breast J* 2016	259	10G	6–18	Single center
Verheyden et al[28]	*Radiology* 2016	1509	7–10G	Mean, 12; range, 12–14	Multi center (9 sites)
This study		**1414**	**9G**	**Mean, 39; range, 24–60**	**Single center**

Indeed, one third of the target lesions were located in areas considered to be "difficult". In only 2 patients with 2 target lesions located in an almost presternal location (0.1% of all target lesions), the biopsy needle could be placed not even close to the target, such that no biopsy was performed. In another 4 patients (0.5%) with 4 target lesions (0.3%), the biopsy needle was placed and tissue removed, but the target lesion was obviously missed, resulting in a false-negative biopsy result. However, these misses became immediately evident through postinterventional radiologic-pathologic correlation that suggested a mismatch. In 5 target lesions (0.4%), final surgical pathology revealed an upgrade of pathology from ADH to low-grade DCIS, or from DCIS to invasive breast cancer, respectively. Since ADH as well as DCIS or invasive cancer requires surgical excision, patient management was unchanged in these cases. We conclude that in 99.5% of patients (859/863) and 99.7% of target lesions (1408/1412), the MR-guided VALB procedure allowed the successful sampling of sufficient tissue to correctly guide subsequent patient management.

The rationale to retrieve larger tissue volumes during MR-guided biopsy procedures is not only meant to avoid undersampling of heterogeneous targets or of small lesions, but is also driven by a specific problem inherent to MR-guided vacuum biopsy procedures which does not exist for mammography- or ultrasound-guided vacuum biopsy procedures: The spatial resolution with which current grid-based vacuum biopsy systems for use under MRI guidance offer access to the breast is limited. Owing to the use of so-called sterile bushings, the needle can be placed only every 3 to 4 mm. Accordingly, during MR-guided biopsy especially for smaller target lesions, it is a frequent situation that the biopsy needle cannot be placed within the center of the target but only in the periphery or even only the proximity of the target. If a lesion is located in a "difficult" location, the offset between the needle and the target lesion may be even larger. It is unknown to us whether so called "post and pillar" based vacuum biopsy systems allow a more targeted needle placement and could thus help avoid such offsets. For the grid-based system used by us, we solved the problem by collecting additional tissue in the direction of the target as described herein. In our cohort, an offset of up to 9 mm between the needle tip and the target lesion was present in more than one third (35.1%) of cases, and more likely occurred during biopsy of (small) enhancing masses than in targets with NME—probably because areas of NME were significantly larger than the small enhancing masses that are typically subjected to biopsy under MRI guidance.

In our cohort, this offset was successfully compensated for by the fact that (*a*) we turned the biopsy chamber toward the direction of the target, and sampled in this direction only, instead of turning the biopsy notch in a clockwise fashion as is usual practice, and by (*b*) collecting additional tissue until (*c*) the target lesion had been (at least in part) removed, as controlled by T2-weighted imaging (Figs. 1 and 2).

It may seem counter-intuitive to use T2- instead of T1-weighted imaging for biopsy control. However, due to the progressive enhancement of the normal fibroglandular tissue, and the loss of enhancement due to washout, particularly in malignant lesions in the late postcontrast phase, the contrast between cancer and normal tissue is poor. Accordingly, we preferred T2-weighted, non–fat-suppressed TSE imaging to control the success of biopsy. This was done because on T2-weighted images, the image contrast remains constant, irrespective of the postcontrast phase. On non–fat-suppressed T2-weighted images, we found the architectural information provided by the fat tissue helpful to re-identify the target lesion and to identify the fluid-filled biopsy cavity. Whatever pulse sequence one chooses, the main aspect is to indeed use postbiopsy control imaging to carefully check whether the biopsy cavity does include the target lesion.

One may argue that harvesting such larger amounts of tissue is not needed to establish most of the histopathological diagnoses. However, even with 36 or more samples, the removed tissue volume is small compared with an average excisional biopsy. One reason for this is that with the equipment we used, biopsy cores are usually fractionated. Moreover, complication rates in our patients were at the lower end of the spectrum of reported complication rates for conventional, "low-volume" vacuum-assisted biopsy. It should be well understood, however, that we used specific measures to avoid hematoma formation, for example, by evacuation of postinterventional fluids from the biopsy cavity, by manual compression of the biopsy for at least 15 minutes by a radiologist, and by application of a circular compression dressing that was left in place for 12 hours. Moreover, the false-negative rate observed with MR-guided VALB in this large cohort of patients was exceedingly low (0.3%; 4/1412). This helps effectively avoid secondary surgeries that are frequently needed after equivocal results based on regular vacuum biopsy procedures.

Yet, despite of the low false-negative rate of MR-VALB, our results do underscore the need for careful radiologic-pathologic correlation to help avoid late diagnoses of cancer.

A limitation of our study is that we did not investigate the influence of operator experience on the clinical results; however, procedures were done by several breast radiologists and even residents with variable degrees of practical experience in doing MR-guided vacuum procedures. This is a single-center study, and most of the patients were taken from our own clinical breast MRI service, which will influence the rate of positive biopsies.

In conclusion, MR-guided VALB is a safe, efficient, and reliable procedure that helps avoid previously reported shortcomings and technical difficulties of MR-guided vacuum biopsy, without causing additional minor or major complications.

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