Subsequent Marking under Ultrasound Guidance of Vacuum-Assisted Breast Biopsy Areas after Receipt of Histology: A Feasibility Study of a New Technique

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Keywords

Breast cancer · Diagnostic markers · Stereotactic vacuum biopsy · Ultrasound

Abstract

Purpose: The aim of this study was to evaluate the feasibility and the accuracy of a secondary, metachronous ultrasound (US)-guided marking of the stereotactic vacuum-assisted breast biopsy (ST-VABB) area. **Materials and Methods:** The institutional ethics committee approved the study. The retrospective study included 98 patients. In ST-VABB of 45 women, no tissue markers were deployed at the biopsy site, even if no residual calcifications remained. After histology proved the necessity for a subsequent operation, the biopsy site was marked under US guidance using a coil marker. All interventions were technically successful. No complications occurred. Mammography was done to visualize the coil deployment. The distances from the center of the lesion and the biopsy cavity to the coil location were measured in both planes to evaluate the accuracy of the marking procedure. **Results:** In 24 of the 46 cases, the whole lesion was biopsied without residual elements. The mean time between ST-VABB and sonographic marking of the lesion was 9.7 days (median 6.5). The biopsy cavity could be detected in 40 (87%) cases and thus marked exactly. The mean time of US-guided mark-

ing was 12.5 min. The mean distance between the coil and the target lesion was 0.6 ± 1.5 cm in the craniocaudal (cc) view and 0.5 ± 1.5 cm in the mediolateral (ml) view for all markings. The mean delta value from the distance nipple–original lesion and from the distance nipple–coil was 0.85 ± 1.2 cm (median 0.5) in the cc view and 0.88 ± 1.2 cm (median 0.6) in the ml view for all cases. Clip migration was not observed. **Conclusion:** Our study demonstrates the feasibility and the technical success of secondary metachronous coil marking of the biopsy site under US guidance after receipt of histology. This approach seems to be a cost-effective alternative to the standard procedure of the primary coil marking especially in all completely removed lesions. It may offer advantages for allergic patients.

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Introduction

Coil or clip marking of a breast lesion after percutaneous biopsy has been reported for over 20 years [1, 2]. Breast tissue markers are supposed to facilitate correlation across imaging methods, preoperative planning, and oncological surveillance [3]. After percutaneous stereotactic vacuum-assisted breast biopsy (ST-VABB), a clip or coil is usually inserted into the biopsy site to guarantee

Table 1. Inclusion and exclusion criteria

Initial database	Selection criteria	Exclusion criteria	Final database
From 2009 to 2011, 98 consecutive patients who received a metachronous coil marking were documented	patients undergoing an ST-VABB received a metachronously inserted marker coil if there was no residual radiologic finding left at the biopsy site and the histology warranted a further operation (B3–B5 lesions)	Lost to follow-up, patient did not receive an ST-VABB, patient left the hospital, patient received an MR-guided biopsy	45 patients, 46 lesions

identification of the area if the patient requires a subsequent operation. Marking is especially necessary if the lesion is completely removed by needle biopsy and the histology warrants further excision [4]. There are a variety of commercially available clips and coils [5]. The position of breast tissue markers may differ substantially from the location of the biopsy site [6]. Studies of the precision of clip placement show that 2–28% of clips [7] are more than 1 cm from the target [1, 2, 8–10]. Migration of the clip following ST-VABB is an accepted risk of the procedure [8, 11–20]. The accurate placement of a tissue marker is of utmost importance for patients requiring neoadjuvant chemotherapy and undergoing complete tumor remission [21]. Another aspect is the additional cost of tissue markers [3, 12, 22, 23]. It is assumed that about two-thirds of all cases with coil marking could be avoided (in case of a negative biopsy) [24]. Also, the fact of getting a foreign body implanted with potential localization error, migration, and re-intervention or allergic reaction is of importance. If no surgery is needed, it is supposed to remain in the breast for a whole lifetime. In the concept of metachronous marker placement, the implantation of a foreign body is only performed if an operative excision is planned after receipt of histology [3]. In this case, it becomes a temporary and urgently needed step of intervention. As an advantage, clip migration could be avoided and reduced by using the method of the metachronous marking after receipt of the histology. To our knowledge, no study has proven this approach yet.

Thus, our purpose was to evaluate the feasibility and the accuracy of a subsequent marking of biopsy areas under ultrasound (US) guidance after receipt of histology of the ST-VABB of microcalcifications or mammographic masses which have not been detected by US.

Materials and Methods

The institutional ethics committee approved the study and granted a waiver of informed consent.

Patients and Lesions

All interventional procedures and examinations were performed at the institution of the senior author. Between 2009 and

2011, patients undergoing a ST-VABB received a metachronously inserted marker coil if there was no representative lesion left at the biopsy site and the histology warranted a further operation (B3–B5 lesions). In 2011, a nationwide quality agreement was brought into action that recommended a synchronous marker placement in these cases. In the patient documentation system (Orbis, Agfa Healthcare, Mortsel, Belgium), 98 consecutive patients who received a coil marking were documented. The interventional procedures were performed by the senior author with >15 years of experience in breast imaging and interventions. Due to the following reasons, 52 patients were not included in our retrospective analysis: lost to follow-up, patient did not receive a ST-VABB, patient left the hospital, or patient received a magnetic resonance (MR)-guided biopsy. For reasons of data homogeneity, we focused on 45 women who received a ST-VABB procedure with a subsequent US-guided coil placement of 46 lesions/biopsy areas (Table 1).

All mammograms were performed using a phosphor storage digital mammography system (DMR+, General Electric, Boston, MA, USA; FCR PROPECT CS, FUJIFILM Corporation, Tokyo, Japan).

Vacuum-Assisted Stereotactic Biopsy

All biopsies were performed using a dedicated prone biopsy unit with digital imaging (Senovision, General Electric) and a vacuum-assisted biopsy system with a 10-gauge biopsy probe (Vacora, Bard Medical Division, Covington, GA, USA). Specimen radiography was done of all obtained probes. No tissue markers were deployed at the biopsy site. All specimens were sent to the in-house pathology in a usual 10% formalin solution.

Coil Placement under Sonographic Guidance

A Logic 9 sonographic unit (GE Healthcare, Boston, MA, USA) with 10- and 13-MHz linear transducers was used. Coil placement was done using a 4-mm MR-compatible metallic coil marker (MReye®, Cook Medical, Bloomington, IN, USA) (Fig. 1). After preparation of the intervention area, the coil introducer (19.5 G) was placed directly into the center of the biopsy cavity using US real-time guidance with a freehand technique and sterile US gel. During the procedure, the transducer was always placed at a minimum distance of 1 cm to the needle insertion site. The coil is about 2 cm long and acquires a spiral configuration with 4 mm diameter when placed. Subsequently, two-view mammograms were obtained to confirm deployment of the coil and to assess the accuracy of its location.

Radiologic Evaluation and Statistical Analysis

The direct method of measurement [6, 25, 26] was used to define the distance from the center of the lesion and the biopsy cavity to the clip in both planes. Statistical analysis was performed using dedicated software (BiAS version 11.0, Epsilon Verlag, Germany). The distances from the original lesion/the coil to the nipple were measured. The delta values from the distance nipple–original

Fig. 1. Coil MReye®, Cook Medical, Bloomington, IN, USA. **a** Two-part needle. **b** Stylet with the preloaded coil. **c** Pusher.

lesion and from the distance nipple–coil were determined. All measurements were made with a precision under 1 mm, using the measuring tool which is available with the standard software package in AGFA IMPAX (AGFA HealthCare, Mortsel, Belgium). The Wilcoxon-Mann-Whitney test was used to test for any influence of the time interval between the ST-VABB and the coil placement under US guidance on the precision of the marker deployment. A p value ≤ 0.05 was considered as statistically significant.

Results

The average age of the patients was 59.2 years (median 58, min. 45 and max. 87). The laterality distribution was as follows: 22 (47.8%) of the 46 lesions were right-

sided and 24 (52.2%) were left-sided. The mammographic presentation was a mass in 6 (13%) and microcalcifications in 40 (87%) cases. Altogether, 56.5% of all lesions were classified as BI-RADS® category 4a, 21.7% as 4b, 19.6% as 4c, and 2.2% as 5 according to the classification of the American College of Radiology (BI-RADS 4th ed.). The distance of the lesion from the nipple ranged from 2.4 to 11.9 cm (mean 6.6 ± 2.3 ; median 6) in the craniocaudal (cc) view and from 2.3 to 10.9 cm (mean 6.5 ± 2.2 ; median 6) in the mediolateral (ml) view. The size of the lesions ranged from 0.5 to 2.5 cm. In 37 of 46 (80.4%) biopsies, 12 specimens were taken, in 7 (15.2%) biopsies 18 specimens, and in 2 (4.4%) biopsies 6 specimens. The postbiopsy/preoperative histo-

Fig. 2. Marking precision versus time interval from biopsy to marking.

Table 2. Inexact US-guided markings

	Distance from coil to biopsy cavity, cm	95% CI
Craniocaudal view	Range: 2.1–7.1 Mean: 3.9 ± 2.3 Median: 2.7	1.5–6.3
Mediolateral view	Range: 1.5–7.1 Mean: 3.6 ± 2.4 Median: 2.3	1.0–6.1

Table 3. Distances from coil to biopsy cavity and from nipple to original lesion versus coil

	Distance from coil to biopsy cavity, cm	Δ distance nipple–original lesion/ nipple–coil, cm
Craniocaudal view	Mean: 0.04 ± 0.2 Range: 0–1.2	Mean: 0.85 ± 1.2 Median: 0.5
Mediolateral view	Mean: 0.04 ± 0.2 Range: 0–1.0	Mean: 0.88 ± 1.2 Median: 0.6

logical diagnoses comprised of 11 (23.9%) B-3 lesions (4 cases with papillary findings, 2 with ADH, 3 with FEA, 1 with LN, and 1 with radial scar complex), 23 (50%) B-5a lesions (ductal carcinoma in situ), and 12 (26.1%) B-5b lesions (invasive ductal carcinoma/invasive carcinoma of no special type).

The mean time between ST-VABB and sonographic marking was 9.7 ± 9.2 days (median 6.5 [range 2–52]). The mean time for the not instantly exact markings was 9.8 ± 3.9 days (median 11 [range 5–14]). The Wilcoxon-Mann-Whitney test showed no statistical difference

($p = 0.46$) between the 2 groups (Fig. 2). The biopsy cavity could be detected by the interventionalist under US guidance in 40 (87%) of the 46 cases. A coil marker was used for every patient. The mean imaging time of the marking procedure was 12.5 min. The mammography after marking showed an exact placement of the coil in 40 cases.

Of the 46 US-guided markings, 6 were not precise (13%, 95% CI 5–26). Concerning the inexact markings, please see the data for the distances in Table 2. In all 6 initially inexact markings, the biopsy site could be successfully marked in the second attempt.

The mean distance between the nipple and the coil was 6.9 ± 2.3 cm in the cc view and 6.7 ± 2.3 cm in the ml view for all cases. The mean distance between the coil and the target lesion was 0.6 ± 1.5 cm in the cc view and 0.5 ± 1.5 cm in the ml view for all lesions. For the instantly exact markings, the mean distance between the coil and the target lesion was 0.04 ± 0.2 cm (range 0–1.2) in the cc view and 0.04 ± 0.2 cm (range 0–1) in the ml view. The mean delta value from the distance nipple–original lesion and from the distance nipple–coil was 0.85 ± 1.2 cm (median 0.5) in the cc view and 0.88 ± 1.2 cm (median 0.6) in the ml view for all cases (Table 3).

All interventions were technically successful and no complications occurred (Fig. 3, 4). In 87% of the 45 women who were biopsied due to suspect microcalcifications, 52.2% of the calcifications were removed completely and 47.8% incompletely. Solid masses (in 6 of 45 women) were removed completely in 60% and incompletely in 40%. All postoperative findings were in concordance with the preoperative histologies.

Discussion

The use of tissue markers is one of the keys for optimal patient management and allows the multidisciplinary team to synthesize the information gained from the different procedures [5]. According to Thomassin-Naggara et al. [3], breast tissue markers should even be deployed after each percutaneous intervention. Efforts have been made to reduce costs with regard to clip marking [25] in a climate of increasingly restrictive reimbursement. As one drawback of marker placement, immediate and delayed migration of marker clips has been reported, though [16, 27]. A couple of attempts have been made to avoid clip migration and to improve the visibility of the tissue marker. Collagen-plug marking devices were developed to ensure that the marker is placed exactly into the biopsy cavity and “the accordion effect” is avoided [28]. In the literature, some attempts to explain clip migration, for example, as a part of radiographer technique can be found, especially with large breasts [2, 12]. The question

Fig. 3. A 70-year-old patient with ductal carcinoma in situ G3, left breast. **a** Suspicious calcifications in cc-view mammography. **b** ST-VABB setting in post-fire position. **c** Coil artefact after US-guided marking. **d** cc view showing the coil in the exact place.

which remains is to which extent clip migration has to be tolerated as an unavoidable and unpredictable event and which breast features foster clip migration. So far, there are no guidelines on how to manage clip displacement [5].

A study from Uematsu et al. [23] reports that breast thickness may play a role in clip migration, however, with thin breasts exhibiting a greater clip movement. Another group experienced that clip migration occurred in predominantly fatty breasts [8].

The coil we used provides a good visibility in all breast imaging modalities. It consists of a nickel-titanium alloy, which is well tolerated. Once the coil is released, it attaches to the wall of the biopsy site. Through secondary clip marking, migration of a clip by decompression could be avoided. In this study, we could not investigate if slow migration occurred, since every patient was operated.

Hematoma-directed ultrasound-guided lumpectomy was introduced in a publication by Arentz et al. [29]. The hematoma which was created during the initial biopsy was used to localize the lesion either pre- or intraoperatively for excision. Since a hematoma is supposed to be absorbed after 2–5 weeks, this technique has its disadvantages in patients with neoadjuvant chemotherapy. Hence, our approach to mark the hematoma/biopsy cavity a short time after proof of a relevant histology seems to be more reliable.

The same coil that was used in our study was placed by Sever et al. [30] under US guidance into the tumor of patients prior to neoadjuvant chemotherapy. Speck et al. [31] showed a stable localization of the coil after 1–9 months. In a study by Viehweg et al. [32], US-guided clip marking was accomplished in patients with proven breast cancer under neoadjuvant chemotherapy, if there was a marked response under therapy.

Fig. 4. A 62-year-old patient with ductal carcinoma in situ G2, right breast. **a** Suspicious calcifications in ml-view mammography. **b** ST-VABB setting in post-fire position. **c** US-guided marking of the biopsy cavity. **d** Coil artefact after US-guided marking. **e** ml view showing the coil in the exact place.

There are only a few case reports which deal with allergic reactions to breast tissue markers. One noteworthy publication is that by Tamai et al. [33]. A patient with a history of atopic dermatitis was marked with titanium clips and experienced a severe exacerbation. Such allergic reactions might be very rare, but in the context of a potentially avoidable foreign body implantation relevant to mention.

Our study has several limitations. We did not involve a comparison group; the number of patients studied was relatively small; and this was a retrospective single-center study. A prospective 2-armed multi-institutional study comparing synchronous with metachronous marking of the biopsy site could overcome these drawbacks. By avoiding synchronous marking after every complete or incomplete resection of a lesion during an ST-VABB procedure, unnecessary clip marking could be avoided and reduced.

In conclusion, our study demonstrates the feasibility of metachronous coil marking of the stereotactic vacuum biopsy site under US guidance. The accuracy of the lesion localization proved to be high. No marker migration was seen using metachronous coil marking. This approach

seems to be a cost-effective alternative to the standard procedure of primary coil marking in all completely removed lesions, particularly in allergic patients.

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Statement of Ethics

The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. The authors state that subjects (or their parents or guardians) have given their written informed consent. The study protocol was approved by the institute's committee on human research.

Disclosure Statement

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Author Contributions

C.P., D.L., B.K., T.J.V.: manuscript writing, statistical analysis. F.C., M.M.-S.: executors of the study, performers of the interventions. V.M., P.H., K.E., S.F.: literature research, critical analysis of the manuscript.

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