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A Patient Safety Approach for Imaging-Guided Breast Interventions: Red Rules for Prevention of Hematoma

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Abstract: It was aimed to present the safety program and red rules we use to prevent hematoma complications in imaging-guided breast interventions. Patients who underwent breast intervention between January 2011 and January 2013 were included in the study. Based on the patient records, procedure-related features and hematoma complications were investigated retrospectively. A total of 173 patients had breast intervention. In the records, it was understood that hematoma developed in 3 cases, these were approximately 1-1.5 cm in diameter, and 2 of them developed after a core biopsy and one the vacuum biopsy. A successful interventional procedure not only provides proper diagnosis but also prevents possible complications. The most important complication in breast interventions is the hematoma. For the prevention, some points to be applied before, during, and after the procedure may be useful. Before the procedure, bleeding diathesis, drugs should be questioned, and INR and platelet levels should be checked. During the procedure, the biopsy region should be evaluated with Doppler ultrasonography. Interventions should be performed in a non-traumatic manner. The needle should be entered by holding itself, not the handle of the needle. Among the samples, compression can be made to the biopsy region with an ultrasound probe. After the procedures, the patient should be turned into the prone position, and passive compression should be performed on the biopsy site with her body weight for 10 minutes. In mammography, after the intervention, active compression should be made for 10 minutes with the compression plate of the device, and passive compression should be continued as in ultrasonography. A pressure bandage can be applied while closing the biopsy site. As a result, red lines in breast interventions can be determined as the investigation of the patient's bleeding diathesis, evaluation of the vascularity of the biopsy region, and compression.

Keywords: Patient safety, Breast interventions, Compression.

1. Introduction

Recently, safety (error prevention) programs have been a successful tool for minimizing the error in the industry (1).

This program includes error prevention training, determination of the “red rules,” an applied safety coaching program, and an element to include patients and families in safety.

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Red rules, when not obeyed, have the most severe results or pose the highest risk to safety (1).
The breast interventions must be applied in a safety program to prevent errors. We tried to describe our safety program in terms of the formation of red rules for providing hemostasis in imaging-guided breast biopsies.

2. Patient and Methods

Between January 2011 and January 2013, the patients who underwent breast intervention by one radiologist (IDS) were included in the study by a retrospective viewpoint. The local ethical committee confirmed the study and informed consent was waived. Information on lesion laterality, lesion location, type of the intervention, and thickness of the needle, number of sampling and complication of hematoma were obtained from records.

3. Results

Between January 2011 and January 2013 one hundred and seventy-three patients who underwent breast intervention in our tertiary center were included in the study. Except for one man, the rest 172 patients were women. The patients were between 19–87 years (Mean±Standard Deviation of 48±14 years).
Of the lesions, 98 (56.6%) were at the left breast, and 74 (42.8%) right. One patient had bilateral lesions (0.6%). Seventy lesions (40.5%) were at the upper outer quadrant, 35 (20.2%) at the upper inner quadrant, 28 (16.2%) at the subareolar region, 17 (9.8%) at the lower outer quadrant and 16 (9.2%) at the lower inner quadrant. The location of the seven lesions had not been recorded.
Breast needle biopsies are carried out under image guidance with either ultrasound or using a prone stereotactic mammography table. Of the 173 breast interventions, 141 (81.5%) were core biopsy, 13 (7.5%) fine-needle aspiration (FNA), 12 (6.9%) hook wire insertion and 7 (4%) vacuum biopsy.
During core biopsy, 16 and 18 gauge needles were used respectively for 137 (79.2) and 4 (2.3%) procedures. Fine needles were 21, 24, and 27-gauge (respectively 2, 10, and 1 procedure). Marking hook wires were 20-gauge (12 patients, 6.9%). Vacuum biopsies were performed by 11-gauge needles (7 patients, 4%).
Of the patients, 88 had 2 number of sampling during the intervention (50.9%). 28 (16.2) had one, 28 (16.2%) had 3, 17 (9.8%) had 4, 5 (2.9%) had 5 and 7 (4%) had 12 number of sampling. Twelve-samplings were performed during vacuum biopsies.
All of the methods except FNAs were performed under local anesthesia in the outpatient setting. During FNA local anesthesia was not applied.
The monitorization of hematoma formation has been done both during and after the procedure by sonography. It was learned from the records that 3 patients had been determined to have a hematoma (1.7%). All of them resorbed at about 3-4 weeks after the intervention. One patient underwent a vacuum and 2 patients' core biopsies. All three hematomas were approximately 1-1,5-cm. Additionally, the patient was informed about the admission to the hospital if her breast swelled significantly and became red. There was no applicant with such a complaint.

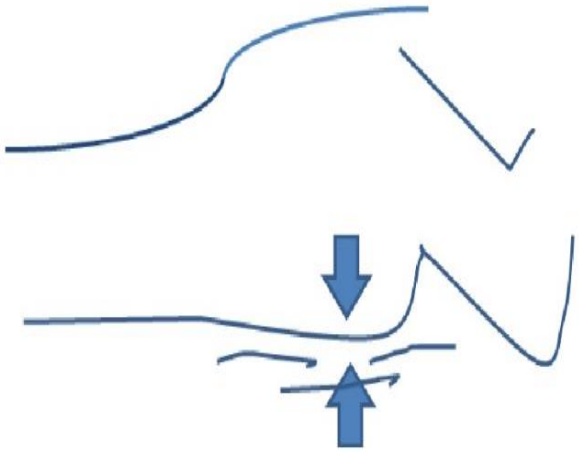

Figure 1: In the prone position; a passive breast compression is applied.

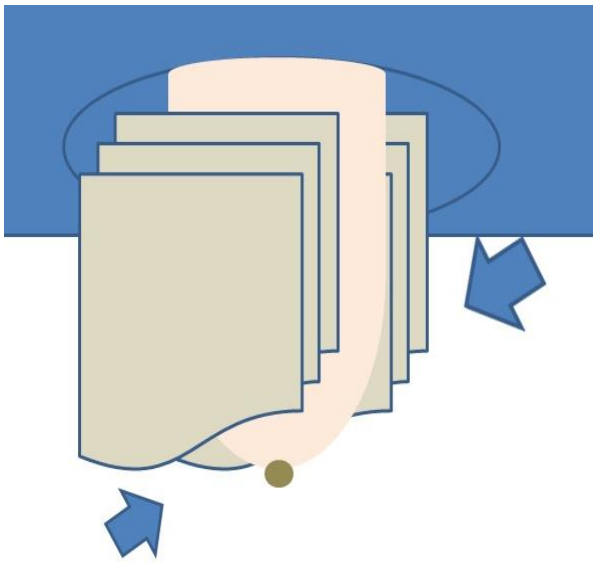

Figure 2: Mammography plates of prone table can be used for active compression, immediately after the intervention.

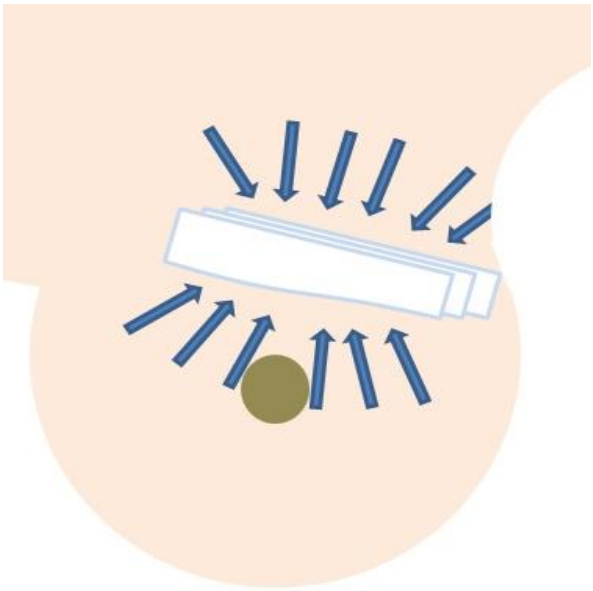

Figure 3: After the procedure, pressure bandage is being applied.

4. Discussion

In this study, breast interventions, those carried out in a 2-year-period by a single radiologist at a tertiary center, were reviewed and hematoma complication rates were evaluated. The hematoma was a rare complication in this group.

Recently many hospitals and health care organizations have recognized the importance of prevention of medical errors resulting from behavior-based events and started to apply patient safety programs (2). A manifestation of this consciousness during medical school training is "primum non-nocere" with the common expression.

All women with breast abnormalities are assessed using the triple diagnostic method. Clinical and imaging assessment should be carried out prior to needle biopsy. Therefore, interventional methods of the breast are relatively frequent. This relatively frequent procedure requires a safety program. We tried to call attention to this fact.

Red rules are rules about critical actions. Red rules, when broken, have the most severe consequences or pose the highest risk to safety. When a red rule is broken the process has to be stopped in every condition in every hand (1). The red rules should be a few in number, clear, and unforgettable (3). Red rules for breast interventions are discussed in this paper.

Imaging-guided needle biopsy is a skilled technique and requires diagnostic, interventional, and ultrasound skills (4). The success of the intervention is not only measured by obtaining a specimen, large enough to provide an adequate pathological assessment. Also, factors related to patient safety, and no procedure related-complication may be a criterion. Before any invasive procedures, some information should be taken from the patient. Bleeding diathesis should be questioned; use of drugs, such as acetylsalicylic acid or warfarin, should be queried. If so with the consultation of a related physician the drug is discontinued before the intervention. Duration of discontinuation is one week for aspirin and 3 days for warfarin. Also before the intervention INR (international normalized ratio) level and platelet count should be checked.

Informed consent is required for any procedure, but written consent is not essential for diagnostic breast needle sampling procedures. It is up to the policy of the hospital. The main risks associated with breast biopsy are bleeding and hematoma formation, post-procedure pain, or discomfort (5). The core biopsy of the breast is a commonly performed procedure. Serious complications are rare. The most common problem is bleeding, which is usually easy to control at the time of the procedure. The bleeding rate has been reported as 1-3.9% for vacuum-assisted biopsies. Rarer complications include infection and abscess formation, pneumothorax, milk fistula formation, cosmetic deformity, and seeding of the tumor along the biopsy tract (6-7).

During the procedure, firstly the vascular assessment of the region of interest is done. This control process may be performed by color Doppler sonography. At mammography, a prominent vasculature must not be seen in the region of interest, too. Passes have to be made in a non-traumatic manner as much as possible. The entrance has to be performed by keeping the needle itself not the stem. After the acquisition of each core sample, the needle has to be re-inserted for further samples. During these subsequent passes specimens composed of blood are experienced due to the destruction of the breast and focal minimal hemorrhage (8). Between each of the sampling, we offer compression by the ultrasound probe.

According to our clinical ceremony, after a sonography-guided intervention, the patient is turned around herself and in the prone position; a passive breast compression is applied for about 10 minutes (Figure 1). In mammography, immediately after the intervention, the biopsy site is compressed against the compression plate of the device (active compression) for about 10 minutes (Figure 2) and then passive compression in the prone position is applied for 5 minutes to provide hemostasis, too.

After the procedure, pressure bandage can be applied if required (Figure 3). Although unconditionally abide by the rules, we encountered a 1.7% rate of bleeding. None of them did require surgery and at follow-up they all resorbed.

5. Conclusions

As a result, for hemostasis during breast interventions, questioning of the patients in terms of bleeding diathesis and drug usage, evaluation of the vascularity of the region before the process, and compression are the red rules. In our opinion, with adherence to these red rules, reasonable complication rates may be seen.

Conflict of interest statement
The author(s) declare(s) that there is no conflict of interests regarding the publication of this article.

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