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Stereotactic Breast Core Needle Biopsy in a Tertiary Breast Center of Tehran University of Medical Sciences

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ABSTRACT

Background: The purpose of this study was to evaluate the results of stereotactic breast core needle biopsy in a tertiary breast center of Tehran University of Medical Sciences.

Methods: Patients who were candidates for mammography-guided stereotactic breast core biopsy from March 2011 to December 2013 were included in this study. Stereotactic biopsy was performed by a dedicated prone Hologic mammography unit employing an automatic biopsy device with a 14-gauge needle. Patients with malignant or premalignant biopsy results were followed up with surgical pathology reports and patients with benign core biopsy findings were followed up with mammograms.

Results: Among the 150 patients who were included in the final analyses, 30 had malignant findings on stereotactic biopsy and 10 patients had a premalignant pathology result on stereotactic biopsy. The remaining 110 patients had benign results on histopathology; however, in 30 patients, wire localization and surgery of the same area were performed due to either discordant mammography-pathology findings or clinical suspicion of malignancy and in two of them, advancing pathologic grade was witnessed. A total of 80 patients with benign histopathologic results had follow-up mammograms and the follow-up period was between 12 months to 3 years. The sensitivity and specificity of stereotactic breast core biopsy in this study were 94% and 96%, respectively.

Conclusions: Stereotactic breast core needle biopsy is an effective and safe method in evaluation of suspicious mammography-detected lesions but caution should be warranted when taking results into account, especially in mammography-pathology discordance and in patients with premalignant pathology reports.

Keywords: Stereotactic, breast biopsy, mammography

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Introduction

Breast cancer is a prevalent type of cancer worldwide and almost 50% of breast cancer cases and 58% of its related deaths happen in underdeveloped countries, where they have limited medical resources for confronting the disease.¹⁻⁴ For most



women suspicious of having breast cancer, biopsy is needed to determine if the lesion seen on imaging is benign or malignant and decide whether further work-up and management is needed or not.

Previous studies suggest that 2–4% of women undergoing screening mammography are referred for biopsy due to a mammographic abnormality.^{5, 6} Breast biopsies may be performed by open surgery (incisional or excisional biopsy) or by minimally invasive image-guided techniques, especially for non-palpable breast lesions. The majority of these patients have benign lesions. The cost and psychological effects of further manipulation of these abnormalities are considerable and most of this is caused by surgical biopsies. In comparison with surgery, stereotactic breast biopsy seems to be a less expensive and less invasive method to assess suspicious non-palpable breast lesions detected in mammography.⁷

In this study, we aimed to determine the accuracy of stereotactic biopsy in our center which includes sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of this biopsy technique.

Methods

This study was conducted at the radiology department of Cancer Institute affiliated to Tehran University of Medical Sciences from March 2011 to December 2013. Referred patients (n = 154) who were candidates for stereotactic breast biopsy in the department were included. All patients had prebiopsy mammograms that were taken via a direct full-field digital Hologic mammography unit and the images included craniocaudal (CC) and true lateral views. The mammograms were reviewed by experienced radiologists. The mammographic findings were categorized according to the American college of radiology breast imaging, reporting and data system (BI-RADS). Patients with BI-RADS IVa (low suspicion for malignancy) or IVb (intermediate suspicion for malignancy) or IVc (moderate suspicion for malignancy) or V (highly suggestive of malignancy) scores were included in our study. The biopsy was performed in patients with BI-RADS III mammograms in the following situations: 1) strong family history of breast cancer 2) history of malignancy in the contralateral breast 3) clinician's reluctance to wait for six months to obtain a follow-up mammogram due to the patient's anxiety 4) clinician was concerned that the patient would not attend follow-up mammography. All patients signed a written informed consent.

The biopsy was performed on a prone Hologic stereotactic breast biopsy table (MultiCare Platinum prone breast biopsy table, Hologic Inc., USA) and for this purpose an automated gun with a 14-gauge needle (Angiotech [PBN MEDICALS Denmark A/S], Stenløse, Denmark) was used. The best plane selected for biopsy was the one in which the needle passed the least distance in breast to get to the target. It was also important that Z distance of the target should be at least 5 mm more than breast compression thickness on that view. Suspicious lesions were targeted by the standard technique of stereo pair images (+15 and -15) and the X, Y and Z axes were determined by the radiologist. Consequently, the skin entrance area was disinfected and locally anesthetized. The needle's area of movement and insertion was located in the X-axis and parallel to the portion where images were received (Figure 1).

An incision was made with a scalpel blade number 11 parallel to the compression paddle. After needle insertion was complete, a pair of stereo (+15 and -15) views were obtained to confirm that whether



Figure 1. Five different microcalcification targets were selected by the radiologist on +15 and -15 stereo images.



Figure 2. Sample mammography. Some samples show retrieved microcalcifications.

the needle was in a pre-fire correct position or not, with the needle tip aiming at the target. After confirming the needle was in correct location and alarming the patient, firing was done. To be assured, post-firing stereo images were also taken.

At least six and on average nine biopsies were taken. Radiography of all removed specimens was performed to confirm that the sample contained the targeted suspicious microcalcifications or parenchymal density or mass (Figure 2).

A decrease in the number of calcifications, between the radiographs obtained before and after biopsy, was also helpful for reassurance. Sampling of masses, architectural distortion or focal asymmetry was checked by ghost tracks of air density in the lesions on post-biopsy radiographs.

Surgery was recommended in patients with malignant or premalignant results, or with mammographic-pathologic discordance. Comparison was made between the pathology results of core and excisional tissues. Complications including infection, vasovagal reactions and hematomas were documented.

The age of the patient, type of mammographic abnormality (microcalcifications, architectural distortion, mass, focal asymmetry), BI-RADS scores, histopathological reports and type of further management were recorded. Sensitivity, specificity, positive predictive value and negative predictive value of stereotactic core biopsy were calculated.

Results

One hundred and fifty four women were included for stereotactic core biopsy during the study period. Patients age ranged from 30 to 70 years with an average of 45 years. In 150 patients, the biopsy was successfully performed and they were included in further analysis. Indications for biopsy were suspicious microcalcifications in 130 patients (86.6%), mass in 6 patients (4%), focal asymmetry in

Table 1. Histopathological results of stereotactic
biopsy among the study population

	N (%)
Benign FCC and hyperplasia	110 (73.33%)
Atypical ductal hyperplasia	7 (4.6%)
Atypical ductal and lobular hyperplasia	2 (1.3%)
Papillary lesion	1 (0.6%)
LCIS	1 (0.6%)
DCIS	15 (10%)
Invasive ductal carcinoma	13 (8.97%)
Invasive lobular carcinoma	1 (0.6%)

Abbreviation: FCC: fibrocystic changes; LCIS: lobular carcinoma in situ; DCIS: ductal carcinoma in situ

6 patients (4%), architectural distortion in 3.3% of patients (n = 5) and masses with calcifications in 2% of patients (n = 3).

Pre-biopsy mammograms were categorized as BI-RADS III in 12% (n = 18), BI-RADS IVa in 50% (n = 75), BI-RADS IVb in 22.66% (n = 34), BIRADS IVc in 5.33% (n = 8) and BIRADS V in 10% (n=15) of cases.

Among the patients who underwent biopsy, 30 had malignant findings and 10 patients had premalignant biopsy results. The remaining 110 patients had benign results on histopathology (Table 1).

One case of 13 invasive ductal carcinoma was found to be *in situ* at surgery. Three cases of 15 ductal carcinoma *in situ* [DCIS] advanced to infiltrating ductal carcinoma. Two cases of 15 DCIS turned out to be benign on surgical pathology (one atypical ductal hyperplasia case and one fibrocystic change case). One case of papillomatosis was identified initially at core biopsy, as well as it was at surgical excision. Seven cases of atypical ductal hyperplasia were detected after stereotactic biopsy, of which three advanced to DCIS and four turned to fibrocystic change after surgery (Figure 3).

Two cases of mixed atypical ductal hyperplasia and atypical lobular hyperplasia were identified as DCIS and lobular carcinoma *in situ* (LCIS) on surgical pathology.

Thirty patients (20%) had benign results but needle localization of the same area (lesion) due to either suspicious mammographic findings or clinical suspicion of malignancy was done for them; twenty eight were proven to be histopathologically benign on open surgical biopsy and in two (6.6%) pathologic results had advanced.

Eighty patients (53.33%) with benign results underwent follow-up mammograms. Follow up mammography after one year revealed no latent lesions. In summary, stereotactic core biopsy discordance rate was 11.33% (Figure 3).



Figure 3. Discordant results between stereotactic biopsy and final surgical pathology reports at follow up

The sensitivity and specificity was 94 % and 96%, respectively. Positive and negative predictive values were 82% and 98%, respectively. Complications that were encountered included vasovagal reaction (1.3%), hematoma (1%), vomiting (1%) and technical failure (2.6%). We did not have any major complications in this study.

The procedure was unsuccessful in three of the cases because their core specimen radiographs did not show calcifications. They preferred to perform follow-up with imaging rather than re-biopsy or surgery, in which calcifications were shown to be stable. In addition, the biopsy was not performed on one obese patient due to lumbar discal herniation and consequent inability to be immobilized during the procedure. This patient was also followed up with imaging and the calcifications were stable afterwards.

Discussion

Screening mammography has proved to be effective in detecting non-palpable breast lesions and has reduced the mortality rate of breast cancer.⁸⁻¹⁰ Accordingly, there is a higher need for techniques that can accurately discriminate between benign and malignant tumors.¹¹

Surgical biopsy used to be the most widely accepted source of diagnosis, but it has some drawbacks including its high cost, invasiveness and resulting scars and the latter can distort future radiologic examinations. Additionally, in most cases the final pathology report reveals a benign lesion for which surgical intervention would not be necessary. For instance, data from National Health Service of UK showed that in 2616 open surgical biopsies which were performed in 2008–2009, 69% of the results were benign and 31% of them were malignant.¹²

For years, researchers have sought different

techniques to minimize unnecessary surgery. The biopsy method must be minimally invasive, accurate and cost-effective. For years researchers have sought different techniques to minimize unnecessary surgery. The biopsy method must be minimally invasive, accurate and cost-effective. Any suspicious lesion identified on mammography and visible on ultrasound is usually biopsied under ultrasound guidance. Ultrasound-guided biopsy is generally more comfortable for the patient, does not expose the patient or breast to additional radiation, is less costly and is often more readily accessible.¹³ The nonpalpable lesions detected on mammography which are not visible on ultrasonography, such as microcalcifications, need to be biopsied under mammographic guidance.

Until recently, most studies reported a high rate of inconclusive results of stereotactic fine needle aspiration (FNA) due to inadequate diagnostic tissue sampling of non-palpable lesions. Of note, false negative rate has been reported up to 31% and false positive rate comprises 1% of the biopsy results. Moreover, in many cases it is impossible to reach a definitive diagnosis or to differentiate between carcinoma *in situ* and invasive carcinoma.¹⁴⁻¹⁸

Stereotactic breast core needle biopsy has been introduced as an alternative diagnostic method in order to improve the evaluation of suspicious lesions detected on mammography which are not visible on ultrasound.⁵ During the preceding 40 years, the general improvement of diagnostic techniques has allowed this method to assess both palpable and non-palpable lesions in both screening and symptomatic settings.¹⁹ The previously reported concordance rate for surgical and stereotactic biopsy was 87–96%.^{20,21}

In terms of stereotactic breast biopsy results, in our study 73.3% of patients had benign lesions. This finding was rather similar to its counterpart in one of the largest studies in terms of patient population. In that study, 506 stereotactic core needle biopsies of mammographic lesions were performed on 492 patients. Their histologic results were as follows: 113 (22.3%) pathology samples were malignant, 369 (72.9%) benign and 24 (4.7%) atypical. Of the 113 malignant lesions identified on stereotactic core needle biopsy, 111 were confirmed to be malignant and 2 were denoted as benign on surgical pathology.²² In our study, 28 out of 30 malignant lesions detected on stereotactic biopsy remained malignant in the final pathology reports.

Regarding complications, five (1.0%) cases of vasovagal shock and four (0.8%) cases of bleeding as results of stereotactic breast core biopsy have been reported in scientific literature.²² In our series, 1.3% of patients experienced a vasovagal shock and 1% had a bleeding-related complication such as hematoma.

Our results showed that the sensitivity, specificity, PPV and NPV of stereotactic breast core needle biopsy in our institute were 94, 96, 82 and 98 percent, respectively. In a study conducted by Kirshenbaum *et al.*, the corresponding figures were 98.3%, 93.0%, 86.0% and 99.2%, respectively. They concluded that biopsy with an add-on unit is safe, reliable, accurate and cost-effective.²²

Our specificity was rather similar to the reported specificity in the COBRA study (99%), in which all patients underwent stereotactic core needle biopsy. Subsequently, open surgical biopsy was performed, if the results of stereotactic core needle biopsy were benign and therapeutic surgery was chosen, if the results of stereotactic core needle biopsy were malignant.²³ In our study, PPV of 82 % and NPV of 98% were obtained. The stereotactic breast biopsies did not require hospital admission and the entire procedure was completed in one hour. Also, it was associated with no clinical or radiological scarring and patients could resume their daily activities immediately after the procedure.

Some other authors declared their use of vacuumassisted biopsy instead of core (14-gauge) needle biopsy and compared these two methods. Philpotts *et al.* showed that the 11-gauge vacuum-assisted biopsy method significantly decreases the necessity for re-biopsy after stereotactic biopsy, especially in case of calcifications, but in some cases the need for re-biopsy after stereotactic biopsy still prevails. However, vacuum-assisted biopsy has some pitfalls when compared to stereotactic core needle biopsy including being less available in developing countries, more expensive and more commonly associated with complications.^{24,25}

In conclusion, stereotactic breast core needle biopsy is an effective and safe method with acceptable sensitivity, specificity, PPV and NPV to assess mammographically suspicious lesions. Nevertheless, it is recommended that patients with pre-malignant stereotactic biopsy results be considered for further evaluation or close follow-up.

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