Evaluation of diagnostic underestimation and incidence in nodules BI-RADS 3, 4 and 5, studied by ultrasound-guided core biopsy

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INTRODUCTION

Percutaneous large-core breast biopsy may be performed with either stereotactic or ultrasonographic (US) guidance, as an alternative to open-breast biopsy. US-guided 14-gauge core-needle breast biopsy (CNB) has been well researched. It is performed in real time, and direct needle visualization allows accurate tissue sampling. The procedure does not deform the breast and causes no scarring on subsequent mammograms. It is fast, minimally invasive for the patient and less expensive than radio-surgical biopsy (1,2).
OBJECTIVES

To retrospectively determine the false negatives rate and the extent of underestimation of ultrasound-guided core biopsy of palpable or non-palpable breast nodules. A comparison is made with surgical findings and/or clinical and imaging follow-up.

To determine the incidence of the various lesions presenting as breast nodules by US-guided core-needle biopsy.

MATERIALS AND METHODS

We retrospectively studied the results of US-guided core biopsies of breast nodules from January 2000 to September 2010.

Biopsy technique: patients were placed on the dorsal decubitus position; the skin was cleansed with iodine alcohol solution and local anesthesia was performed with Lidocaine. Core biopsy was performed using a 14-gauge, 10-cm long needle.

Firing was performed using an automated needle device (Manan/E) with a 25-mm-throw biopsy gun. A minimum of 2 core specimens per lesion were obtained, which were placed in bottles with 10% formalin for transport to the pathology department. Core biopsies were performed by a radiologist with over 10 years’ experience.

For ultrasound guidance, Phillips/E ATL-4000 and HDI-11 ultrasound machines with high resolution 5-12 MHZ linear transducers were used. Lesion size was measured according to the maximum lesion diameter. Core biopsies were performed with direct visualization of the needle tip, before and after firing. Longitudinal and orthogonal images were obtained to ensure that the needle was within the lesion (Fig. 1).

Patients: we studied patients with symptomatic lesions and patients in whom a lesion was found in routine breast screening. All images were reviewed by...
two radiologists who specialized in breast imaging to determine the pre-biopsy level of suspicion according to the BI-RADS classification.

Suspicious lesions (BR 4) and lesions highly suggestive of malignancy (BR 5) were biopsied. Some of the probably benign lesions (BR 3) were histologically assessed only in explicit cases according to the referring physician’s preference. The studied nodules were 5 to 45 mm in size.

In patients with malignant findings at biopsy, surgery was performed and in other patients with benign lesions surgical removal was also performed (by the patient’s and/or her treating physician’s decision). In all cases, biopsy histologic findings were correlated with surgical excision histologic findings in each lesion. Patients with benign biopsy findings who did not undergo surgery had a clinical follow-up of 1 to 10 years. At the end of follow-up, none of these patients had a malignant lesion, and were therefore considered as true negative.

Statistical analysis: tables for appraising the diagnostic ability of a diagnostic test were used to determine the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPP) of US-guided biopsy. Comparisons were made with surgical findings and/or the clinical follow-up of the lesion.

RESULTS

A total of 190 biopsies of palpable and non-palpable breast nodules were performed. Patients were 18 to 86 years old (mean age: 51 years).

The classification was: BR 3 in 52 (27%), BR 4 in 74 (39%) and BR 5 in 64 (34%) (Chart 1).

Histologic biopsy findings were: fibroadipose tissue (n = 20; 11%), interstitial fibrosis (n = 31; 16%), fibrocystic disease (n = 18; 9%), infiltrating ductal carcinoma (n = 77; 41%), epithelial hyperplasia (n = 8; 4%), infiltrating lobular carcinoma (n = 4; 2%), sclerosing adenosis (n = 3; 2%), mucus-secreting carcinoma (n = 2; 1%), metastatic leiomyosarcoma (n = 1; 0.1%). There were 3 non-conclusive biopsies (2%) (Chart 2).

Of the 190 patients, 82 (43%) were not operated on and underwent a 1- to 10-year clinical follow-up because the core needle biopsy was negative for malignancy. No malignancy was revealed during follow-up in any of these patients (Chart 3).

Of the total of patients, 108 (57%) were operated on. Surgical excision histologic findings were: fibroadipose tissue (n = 1; 0.1%), fibrocystic disease (n = 7; 4%), infiltrating ductal carcinoma (n = 82; 43%), fibroadenoma (n = 9; 5%); epithelial hyperplasia (n = 2; 1%), infiltrating lobular carcinoma (n = 4; 2%), mucus-
Ultrasound-guided core biopsy

secretion carcinoma (n = 2; 0.8%) and chronic mastitis (n = 1; 0.7%). (Chart 4).

Of the lesions that were surgically excised and proved to be malignant, 3 were classified as BR 3 (5%), 26 as BR 4 (35%) and 59 as BR 5 (60%).

Of all nodules that were operated on, there was agreement with histologic biopsy findings in 83 malignant lesions and in 18 benign lesions (these are considered as true positive).

In histologic biopsy findings, 82 lesions were found to be benign, and therefore these results were not correlated with surgical findings. Even if these patients were not operated on, they underwent a 1- to 10-year clinical follow-up. No malignancy was revealed in any of these patients and these cases were considered as true negative.

Based on the above findings, we found 94% agreement between biopsies and final results, with a false-negative rate of 3%. This implies 95% sensitivity and 100% specificity for core needle breast biopsy, with PPV 100% and NPV 94% (Table 1).

DISCUSSION

The results of our study confirm that core needle biopsy is a valid alternative to surgical biopsy, as diagnostic strategy, both in palpable and impalpable breast lesions. This is because this procedure is faster, less invasive and less expensive than surgical biopsy.

The radiologist performing the core needle biopsy must be aware of any technical difficulties that might result in inaccurate sampling. These difficulties include poor lesion or needle visualization, lesion mobility, deep lesions, central lesions in a large breast, dense fibrotic tissue resistant to needle traversing, patient movement, etc.

The core needle biopsy finding of atypical ductal hyperplasia (ADH) is less reliable owing to the probable underestimation of malignancy, as it may then result in ductal carcinoma in situ or invasive ductal carcinoma. According to Youk et al, the rate of underestimation is approximately 45%. Therefore, there is a consensus on the need for surgical excision when ADH is diagnosed at CNB, given its association with ductal carcinoma in situ (DCIS) or invasive ductal carcinoma.

Consequently, our data support the recommendation from prior studies, that surgical excision is necessary in all cases in which the histologic findings do not explain the imaging features.

Documentation of the biopsy procedure is crucially important to prevent missed breast cancers. At our institution, a minimum of 2 core biopsy specimens per lesion are obtained, although other reports suggest that at least 5 specimens should be obtained. This will depend on the size of each lesion (8,11,14,15).

It should be noted that this procedure may result in some complications. Even if complications are very rare, the most frequent is hematoma at the biopsy site (occurring in approximately 1% of cases). Other potential complications include extreme pain and vasovagal reactions, which may occur in 1-7% of cases, respectively, according to Helvie et al.

CONCLUSIONS

This study indicates that ultrasound-guided core biopsy is a valid method for the diagnosis of both malignant and benign breast nodules. It has a high degree of accuracy and a low rate of false negatives and underestimation, confirmed by surgical excision and/or clinical and imaging follow-up of different lesions.

References

Table 1: Assessment of the predictive ability of a diagnostic test: core needle biopsy.

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<th>Surgery (Gold Standard)</th>
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The authors declare no conflict of interests.